UnitedHealthcare West HMO SignatureValue Prior Authorization Guidelines for Non-Specialty Pharmacy Drugs

GL-32556 5-Aminosalicylates ........................................................................................................... 7
GL-33280 5HT-1 Receptor Agonists (Triptans) ................................................................................... 11
GL-49485 Abilify MyCite (aripiprazole tablet with sensor) - PA/Med Nec ........................................... 16
GL-47550 Absorica (isotretinoin) - PA/Med Nec ............................................................................. 21
GL-51941 Addyi (flibanserin) - PA/Med Nec ..................................................................................... 25
GL-51942 Afrezza (insulin human) - PA/Med Nec ........................................................................... 32
GL-51290 Amitiza (lubiprostone) - PA/Med Nec .............................................................................. 37
GL-33136 Angiotensin Receptor Blockers .......................................................................................... 45
GL-49920 Anthelmintics - PA/Med Nec ............................................................................................ 49
GL-51002 Anticonvulsants - Banzel (rufinamide), Diacomit (stiripentol), Onfi (clobazam), Sabril (vigabatrin), Sympazan (clobazam) .................................................................................... 59
GL-49278 Anticonvulsants - Single Source Brand - PA/Med Nec ......................................................... 65
GL-56310 Anticonvulsants - Step Therapy ......................................................................................... 70
GL-51671 Antiemetics Quantity Limit Overrides .................................................................................. 75
GL-53093 AntiGout Agents .............................................................................................................. 84
GL-6427 Anti-Influenza Agents ......................................................................................................... 87
GL-15893 Antipsoriatic Agents ........................................................................................................... 106
GL-5873 Apidra (insulin glulisine) ..................................................................................................... 116
GL-30083 Atelvia (risedronate delayed-release) ................................................................................. 122
GL-56155 Azole Antifungals ............................................................................................................. 126
GL-49066 Basaglar (insulin glargine) ST ............................................................................................ 134
GL-54779 Belbuca (buprenorphine hydrochloride film) and Butrans (buprenorphine patch, extended-release) - PA/Med Nec ......................................................................................... 137
GL-49190 Benznidazole .................................................................................................................... 146
GL-49253 Blood Glucose Test Strips .................................................................................................. 149
| GL-54946 | Bonjesta (doxylamine/pyridoxine extended-release), Diclegis (doxylamine/pyridoxine) - PA/Med Nec | 155 |
| GL-47947 | BPH Agents | 158 |
| GL-13198 | Caduet (amlodipine/atorvastatin) | 160 |
| GL-45234 | Cetraxal (ciprofloxacin otic suspension) | 164 |
| GL-51432 | CGRP Antagonists - PA/Med Nec | 166 |
| GL-55882 | CNS Stimulants | 177 |
| GL-47549 | Compounds and Bulk Powders | 188 |
| GL-50671 | Contraceptives | 198 |
| GL-47417 | Corlanor (ivabradine) | 210 |
| GL-8033 | Coverage of Drugs for Off-Label or Non-FDA Approved Indications (OR, WA, TX) | 214 |
| GL-8031 | Coverage of Drugs for Off-Label or Non-FDA Approved Indications (UHC of CA) | 217 |
| GL-8032 | Coverage of Drugs for Off-Label or Non-FDA Approved Indications (UHC of OK) | 220 |
| GL-39486 | Daliresp (roflumilast) | 227 |
| GL-54239 | DAW Override | 230 |
| GL-53961 | Devices | 234 |
| GL-42455 | Dihydroergotamine nasal spray (Migranal), Ergomar (ergotamine) | 239 |
| GL-49219 | Dihydroergotamine nasal spray (Migranal), Ergomar (ergotamine) - PA/Med Nec | 243 |
| GL-33493 | Dipeptidyl Peptidase-4 Inhibitors - UHC Core | 248 |
| GL-47571 | Doxepin Cream | 253 |
| GL-49577 | Dry Eye Disease – PA/Med Nec | 256 |
| GL-55513 | Duopa (carbidopa/levodopa) - PA/Med Nec | 260 |
| GL-56172 | Elidel (pimecrolimus), Protopic (tacrolimus) - Step Therapy | 263 |
| GL-48532 | Endari (L-glutamine Powder for Solution) - PA/Med Nec | 267 |
| GL-48533 | Entresto (valsartan-sacubitril) - PA/Med Nec | 271 |
| GL-32699 | Erectile Dysfunction Agents | 276 |
| GL-49902 | Erleada (apalutamide) | 282 |
| GL-51420 | Eucrisa (crisaborole) - Step Therapy | 286 |
GL-50427 Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer) - PA/Med Nec .... 403
GL-45393 Long-Acting Bronchodilator Combinations ......................................................... 407
GL-47804 Long-Acting Bronchodilators ............................................................................... 410
GL-50388 Long-Acting Opioids ............................................................................................. 414
GL-46107 Lotronex (alostron) ............................................................................................. 429
GL-57060 Lotronex (alostron) - Notification .......................................................................... 433
GL-47276 Lucemyra (lofexidine) - PA/Med Nec .................................................................... 437
GL-55336 Lyrica (pregabalin) - Step Therapy ................................................................. 440
GL-50514 MEDcDUR - Opioid Overutilization Cumulative Drug Utilization Review Criteria
(including individual long-acting opioid supply limits) ................................................. 444
GL-10604 Meglitinides and Meglitinide Combination Agents ........................................... 454
GL-37644 Mesalamine Delayed-Release ST .................................................................. 456
GL-47763 Migraine Quantity Limit .................................................................................. 458
GL-49258 Minocycline extended-release tablet (generic Solodyn), Minolira (minocycline
extended-release tablet), Solodyn (minocycline extended-release tablet), Ximino (minocycline
extended-release capsule) ........................................................................................... 465
GL-50477 Motegrity (prucalopride) - PA/Med Nec ........................................................... 470
GL-51427 Movantik (naloxegol) - PA/Med Nec ................................................................. 474
GL-46033 Mulpleta (lusutrombopag) ................................................................................ 478
GL-50649 Multaq (dronedarone) ...................................................................................... 481
GL-49284 Multisource Brand Anticonvulsants ................................................................ 485
GL-49289 Noctiva (desmopressin acetate), Nocdurna (desmopressin acetate) - PA/Med Nec
........................................................................................................................................ 490
GL-30078 Non-Benzodiazepine Sedatives ..................................................................... 496
GL-36177 Non-Formulary Exceptions Process - UHC ....................................................... 501
GL-55878 Non-Solid Oral Dosage Forms ...................................................................... 504
GL-37299 Non-steroidal Anti-Inflammatory Agents .......................................................... 509
GL-32590 Nucynta (tapentadol), Tramadol-containing Products .................................. 514
GL-47423 Nuedexta (dextromethorphan/quinidine) ......................................................... 521
GL-53639 Nuplazid (pimavanserin tartrate) ................................................................. 524
GL-43781 Omega-3-Acid derivatives ...................................................................... 527
GL-35989 Ophthalmic Anti-Allergic Agents ......................................................... 531
GL-5934 Ophthalmic Corticosteroids (Alrex, Lotemax, Vexol) .............................. 537
GL-53034 Opioid Dependence .............................................................................. 546
GL-56174 Opioid-containing cough medicines (including: Flowtuss, Hycofenix, Obredon, Tuzistra XR, Tussionex, Tussicaps, Tuxarin ER, Zutripo, codeine/phenylephrine/promethazine, codeine/promethazine, hydrocodone/homatropine, hydrocodone bitartrate/guaifenesin) - PA/Med Nec .................................................................................................................. 549
GL-37220 Oral Antidepressants ............................................................................ 552
GL-47130 Orilissa (elagolix) - PA/ Med Nec .......................................................... 556
GL-50424 Osphena (ospemifene) ....................................................................... 562
GL-31907 Overactive Bladder Agents .................................................................. 566
GL-55324 Oxistat (oxiconazole) cream - PA/Med Nec ........................................ 568
GL-53435 Pancreatic Enzyme Products ................................................................. 571
GL-53673 Pancreatic Enzyme Products (PEPs) - Step Therapy .......................... 574
GL-5991 Premenstrual Dysphoric Disorder Agents (Sarafem, Selfemra) ............ 577
GL-40869 Prevpac (lansoprazole, amoxicillin and clarithromycin) ...................... 580
GL-54242 Prior Authorization Administrative Guideline ......................................... 583
GL-11546 Progesterone Products ......................................................................... 586
GL-43294 Proton Pump Inhibitors ....................................................................... 592
GL-47572 Provigil (modafinil) and Nuvigil (armodafinil) ..................................... 603
GL-54862 Quantity Limit General ........................................................................ 607
GL-53588 Regranex (becaplermin gel) ................................................................. 611
GL-50479 Rexulti (brexpiprazole) - PA/Med Nec .................................................. 614
GL-51443 Rhofade (oxymetazoline) - PA/Med Nec .............................................. 620
GL-53338 Savella (milnacipran) ........................................................................... 624
GL-53612 Sensipar (cinacalcet) - PA/Med Nec ....................................................... 627
GL-56618 SGLT2 Inhibitors .................................................................................. 631
| GL-49323 | Short-Acting Bronchodilators | 637 |
| GL-48056 | Short-Acting Opioid Review Criteria for opioid naïve members | 640 |
| GL-6092 | Silenor (doxepin) | 649 |
| GL-51450 | Solaraze (diclofenac 3% gel) | 652 |
| GL-49227 | Solosec (secnidazole) - Step Therapy | 655 |
| GL-49791 | Statins - NonFormulary and Step Therapy | 658 |
| GL-49545 | Sublingual Immunotherapy (SLIT) - PA/Med Nec | 661 |
| GL-16468 | Symlin (pramlintide acetate injection) | 673 |
| GL-45575 | Temodar (temozolomide) | 676 |
| GL-49285 | Topical Androgens | 687 |
| GL-49635 | Topical Antifungals - PA/Med Nec | 698 |
| GL-48749 | Topical Retinoid Products | 702 |
| GL-13347 | Toujeo (insulin glargine injection) | 709 |
| GL-14614 | Tresiba (insulin degludec) | 711 |
| GL-49550 | Trulance (plecanatide) - PA/Med Nec | 713 |
| GL-53044 | Uloric (febuxostat) - Step Therapy | 717 |
| GL-48575 | Ultravate (halobetasol propionate) lotion - PA/Med Nec | 720 |
| GL-49191 | Viberzi (eluxadoline) - PA/Med Nec | 723 |
| GL-49642 | Xifaxan (rifaximin) - PA/Med Nec | 727 |
| GL-50242 | Zyflo (zileuton), Zyflo CR (zileuton extended-release) - Step Therapy | 735 |
1. Indications

**Drug Name: Asacol HD (mesalamine delayed-release), generic mesalamine tablet**

**Indications**

*Ulcerative colitis* Indicated for the treatment of moderately active ulcerative colitis in adults. Safety and effectiveness of Asacol HD beyond 6 weeks have not been established.

**Drug Name: Delzicol (mesalamine delayed-release)**

**Indications**
Treatment of mildly-moderately active ulcerative colitis Indicated for the treatment of mildly to moderately active ulcerative colitis in patients 12 years of age and older.

Maintenance of remission of ulcerative colitis Indicated for the maintenance of remission of ulcerative colitis in adults. The safety and effectiveness of Delzicol for the maintenance of remission of ulcerative colitis in pediatric patients have not been established.

Drug Name: Dipentum (olsalazine)

Indications

Ulcerative colitis Indicated for the maintenance of remission of ulcerative colitis in patients who are intolerant of sulfasalazine.

Drug Name: Giazo (balsalazide)

Indications

Ulcerative colitis Indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older. Limitations of Use: Effectiveness of Giazo in the treatment of female patients was not demonstrated in clinical trials. Safety and effectiveness of Giazo therapy beyond 8 weeks have not been established.

Drug Name: Pentasa (mesalamine)

Indications

Ulcerative colitis Indicated for the induction of remission and for the treatment of patients with mildly to moderately active ulcerative colitis.

2. Criteria

Product Name: Dipentum, Giazo, Pentasa

| Guideline Type | Non Formulary |
Approval Criteria

1 Diagnosis of ulcerative colitis

AND

2 History of failure, contraindication, or intolerance to two of the following formulary alternatives:

- Azulfidine (sulfasalazine) or Azulfidine EN (sulfasalazine delayed-release)
- Colazal (balsalazide)
- Lialda (mesalamine delayed-release)
- Apriso (mesalamine delayed-release)

Product Name: Asacol HD, Delzicol, generic mesalamine tablet

Guideline Type | Step Therapy
---|---

Approval Criteria

1 History of both Lialda and Apriso

3. References

8. Pentasa Prescribing Information. Shire, August 2015.
Prior Authorization Guideline

GL-33280 5HT-1 Receptor Agonists (Triptans)

Formulary UHC Core

Formulary Note

Approval Date 2/23/2017

Revision Date 2/23/2017

Technician Note:

P&T Approval Date: 2/13/1998; P&T Revision Date: 5/19/2016

1. Indications

Drug Name: Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan), Relpax (eletriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan orally disintegrating tablets)

Indications

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness have not been established for cluster headache, which is present in an older, predominantly male population.
### Drug Name: Axert (almotriptan)

#### Indications

**Migraine Headaches for adults** Indicated for the acute treatment of migraine with or without aura in adults.

**Migraine Headaches for adolescents** Indicated for adolescents, age 12 to 17 years, for the acute treatment of migraine headache pain in patients with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

### Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan orally disintegrating tablets)

#### Indications

**Migraine headaches** Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine and is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

### Drug Name: Treximet (sumatriptan/naproxen)

#### Indications

**Migraine Headaches** Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is
administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

**Drug Name: Zecuity (sumatriptan succinate, extended-release patch)**

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zecuity reconsider the diagnosis of migraine before Zecuity is administered to treat any subsequent attacks. Zecuity is not intended for the prevention of migraine attacks.

**Drug Name: Zomig Nasal Spray (zolmitriptan)**

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment

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### 2. Criteria

**Product Name**: Generic almotriptan, Brand Amerge, Brand Axert, Frova, Generic naratriptan, or Relpax

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Non Formulary</th>
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</table>

**Approval Criteria**

1. Diagnosis of migraine headaches with or without aura
2 History of failure, contraindication or intolerance to three formulary 5-HT1 receptor agonist (triptan) alternatives [e.g., Imitrex (sumatriptan), Maxalt/Maxalt-MLT (rizatriptan), Zomig/Zomig-ZMT (zolmitriptan)]

**Product Name:** Onzetra, Treximet, Zecuity

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
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</table>

**Approval Criteria**

1 History of one of the following:

- Rizatriptan/rizatriptan ODT
- Sumatriptan tablets/nasal spray
- Zolmitriptan/zolmitriptan ODT

**3. Background**

**Benefit/Coverage/Program Information**

**Quantity Limit**

These products are subject to an OptumRx standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.
4. References

Prior Authorization Guideline

GL-49485 Abilify MyCite (aripiprazole tablet with sensor) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 5/10/2019

Revision Date 5/10/2019

Technician Note :

P&T Approval Date: 1/16/2019, 04/17/2019; **Effective Date: 7/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Abilify MyCite (aripiprazole tablet with sensor)</th>
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<tr>
<td><strong>Indications</strong></td>
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<tr>
<td>Schizophrenia, Bipolar I disorder, Major depressive disorder</td>
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2. Criteria

**Product Name:** Abilify MyCite*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</table>

**Approval Criteria**

1. Diagnosis of one of the following:
   - schizophrenia
   - bipolar I disorder
   - major depressive disorder
   - autistic disorder
   - Tourette’s disorder

2. Submission of medical records documenting the patient is currently prescribed aripiprazole and tolerates the medication.

3. Submission of medical records documenting the patient’s adherence to aripiprazole is less than 80% 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).
4 All of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success:

- 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

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.

AND

6 History of failure, contraindication, or intolerance to one long-acting injectable antipsychotic (e.g. Abilify Maintena, Risperdal Consta, Invega Trinza)

AND

7 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

8 Prescriber agrees to track and document adherence of Abilify MyCite through software
provided by the manufacturer.

| Notes | *Abilify MyCite is typically excluded from coverage. |

**Product Name:** Abilify MyCite*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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**Approval Criteria**

1. Documentation that patient is clinically stable on Abilify MyCite.

   AND

2. Submission of medical records documenting that the use of Abilify MyCite has increased adherence to 80% or more.

   AND

3. Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent.

| Notes | *Abilify MyCite is typically excluded from coverage. |
3. Background

Benefit/Coverage/Program Information

Background:

Abilify MyCite (aripiprazole tablet with sensor)* is a drug-device combination product comprised of aripiprazole tablets embedded with a sensor intended to track drug ingestion. Abilify MyCite is indicated for the treatment of schizophrenia, bipolar I disorder, and as adjunctive treatment for major depressive disorder. Abilify MyCite has not been shown to improve patient adherence and should not be used to track real-time ingestion during an emergency as the detection may be delayed or may not occur.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

*Abilify MyCite is typically excluded from coverage.

4. References

Prior Authorization Guideline

GL-47550 Absorica (isotretinoin) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 1/28/2019

Revision Date 1/28/2019

Technician Note:

P&T Approval Date: 12/19/2019; **Effective Date: 3/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Absorica (isotretinoin)</th>
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</table>

**Indications**

**Acne** Indicated for the treatment of severe recalcitrant nodular acne.

2. Criteria
**Product Name:** Absorica* (isotretinoin)

<table>
<thead>
<tr>
<th>Approval Length</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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**Approval Criteria**

1 Submission of medical records documenting one of the following:

1.1 Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

   OR

1.2 Diagnosis of treatment resistant acne

   AND

2 History of failure, contraindication, or intolerance to an adequate trial of two of the following conventional therapy regimens

2.1 Topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin),]

   OR

2.2 Oral antibiotic [e.g., Ery-Tab (erythromycin), Minocin (minocycline)]

   OR

2.3 Topical antibiotic with or without benzoyl peroxide [e.g, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]
3 History of failure, contraindication, or intolerance to an adequate trial on two oral isotretinoin formulations (document duration of trial):

- Claravis
- Myorisan
- Zenatane
- Amnesteem

Notes | *May be excluded from benefit coverage

**Product Name:** Absorica* (isotretinoin)

<table>
<thead>
<tr>
<th>Approval Length</th>
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</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
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<tr>
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<td>Prior Authorization</td>
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</tbody>
</table>

**Approval Criteria**

1 Will be approved for continuation of therapy based on submission of medical records documenting one of the following criterion:

1.1 After greater than or equal to 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present.

**OR**

1.2 Total cumulative dose for total duration of therapy is less than 150 mg/kg (will be approved up to a total up 150 mg/kg)

Notes | *May be excluded from benefit coverage
3. Background

Benefit/Coverage/Program Information

Background:

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or more. “Severe,” by definition, means “many” as opposed to “few or several” nodules. Isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. Due to its teratogenicity, isotretinoin is not indicated in females who are or may become pregnant.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it is recommended to wait at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References

1. Indications

**Drug Name: Addyi (flibanserin)**

**Indications**

**Generalized hypoactive sexual desire disorder (HSDD)** Indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance. Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD...
refers to HSDD that occurs regardless of the type of stimulation, situation or partner. Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men and is not indicated to enhance sexual performance.

2. Criteria

Product Name: Addyi

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month(s)</th>
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</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</table>

Approval Criteria

1 Diagnosis of one of the following:

1.1 Acquired, generalized hypoactive sexual desire disorder (HSDD)

OR

1.2 Female sexual interest/arousal disorder

AND

2 Symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months

AND
3 Low sexual desire is NOT due to any of the following:

- A co-existing medical or psychiatric condition
- Problems within the relationship
- The effects of a medication or other drug substance

AND

4 Patient was female at birth

AND

5 Patient is premenopausal

AND

6 Prescriber must be certified/enrolled in the Addyi REMS Program

AND

7 One of the following:

7.1 Patient has no known history of alcohol abuse

OR

7.2 For a patient with a known history of alcohol abuse, patient has abstained from alcohol
abuse for the past 6 months

AND

8 Patient will abstain from alcohol use during treatment with Addyi

AND

9 Patient does not have hepatic impairment (e.g., a Child-Pugh score of 6 points or greater)

AND

10 Patient is not concomitantly on moderate or strong CYP3A4 inhibitors (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)

AND

11 Prescriber attests to all of the following:

- The potential benefits of Addyi therapy outweigh the risks
- Both the prescriber and patient have completed the Addyi REMS Program Patient-Provider Agreement Form
- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Product Name: Addyi

<p>| Approval Length | 12 Month(s) |</p>
<table>
<thead>
<tr>
<th>Therapy Stage</th>
<th>Reauthorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to Addyi therapy

AND

2. Patient continues to be premenopausal

AND

3. Patient continues to abstain from alcohol use during treatment with Addyi

AND

4. Patient does not have hepatic impairment (e.g., a Child-Pugh score of 6 points or greater)

AND

5. Patient is not concomitantly on moderate or strong CYP3A4 inhibitors (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)
3. Background

Benefit/Coverage/Program Information

Background:

Addyi is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance. Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner. Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men and is not indicated to enhance sexual performance.

Additional Clinical Rules:

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

4. References


GL-51942 Afrezza (insulin human) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 8/21/2019

Revision Date 8/21/2019

Technician Note:

P&T Approval Date: 7/14/2015; P&T Revision Date: 4/26/2017, 5/18/2018, 6/19/2019;
**Guideline Effective Date: 9/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Afrezza (insulin human)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
</tbody>
</table>

**Diabetes Mellitus** Indicated to improve glycemic control in adult patients with diabetes mellitus.
2. Criteria

**Product Name:** Afrezza*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### 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 [2])

   **AND**
3 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:

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

Notes

*Typically excluded from coverage

Product Name: Afrezza*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in FEV1

AND

2 Patient continues to be unable to self-inject short-acting insulin 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 [2])

AND

3 Patient continues to not smoke cigarettes

<table>
<thead>
<tr>
<th>Notes</th>
<th>*Typically excluded from coverage</th>
</tr>
</thead>
</table>

3. Background

Benefit/Coverage/Program Information

Background:

Coverage criteria outlined below are for patients unable to self-inject short-acting insulin.

Additional Clinical Rules:

• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
• Supply limits may be in place

4. References
Prior Authorization Guideline

GL-51290 Amitiza (lubiprostone) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 8/8/2019

Revision Date 8/8/2019

Technician Note :

P&T Approval Date: 2/18/2014; P&T Revision Date: 7/26/2017, 11/17/2017, 7/18/2018.
7/17/2019 **Effective Date: 10/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Amitiza (lubiprostone)</th>
</tr>
</thead>
</table>

Indications

Chronic Idiopathic Constipation Indicated for the treatment of chronic idiopathic constipation.

Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain Indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
Irritable Bowel Syndrome with Constipation Indicated for the treatment of irritable bowel syndrome with constipation in women aged 18 years and older.

2. Criteria

Product Name: Amitiza[a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Opioid-induced constipation in an adult with chronic, non-cancer pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following criteria:

1.1 Diagnosis of opioid-induced constipation in an adult with chronic, non-cancer pain

OR

1.2 Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 History of failure, contraindication or intolerance to both of the following:

- OTC medication used for the treatment of constipation (document name and date tried)
• Symproic (document date of trial)

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Amitiza[a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Opioid-induced constipation in an adult with chronic, non-cancer pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Documentation of positive clinical response to Amitiza therapy

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Amitiza[a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic idiopathic constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria
1 Diagnosis of chronic idiopathic constipation

AND

2 History of failure, contraindication or intolerance to one OTC medication used for the treatment of constipation (document name and date tried).

AND

3 One of the following criteria:

3.1 History of failure, contraindication, or intolerance to Linzess

OR

3.2 Age less than or equal to 17

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** Amitiza[a]

| Diagnosis | Chronic idiopathic constipation |
| Approval Length | 12 |
| Therapy Stage | Reauthorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**
1 Documentation of positive clinical response to Amitiza therapy

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**Product Name:** Amitiza[a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Irritable bowel syndrome with constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of irritable bowel syndrome with constipation

AND

2 Patient was female at birth

AND

3 History of failure, contraindication or intolerance to one OTC medication used for the treatment of constipation (document name and date tried).

AND
4 One of the following criteria:

4.1 History of failure, contraindication, or intolerance to Linzess

OR

4.2 Age less than or equal to 17

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Amitiza[a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Irritable bowel syndrome with constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Documentation of positive clinical response to Amitiza therapy

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. Background

**Benefit/Coverage/Program Information**

**Background:**

Amitiza (lubiprostone) is indicated for the treatment of chronic idiopathic constipation (CIC) in adults, the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation, and the treatment of irritable bowel syndrome with constipation (IBS-C) in women at least 18 years old. Linzess (linaclotide) is indicated in adults for the treatment of IBS-C and CIC. Linzess has a black box warning regarding the risk of serious dehydration in pediatric patients less than 17 years of age, and use of Linzess should be avoided in pediatric patients. Symproic (naldemedine) is indicated for OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Physicians and patients should periodically assess the need for continued treatment with Amitiza, Symproic or Linzess.

This prior authorization program is intended to encourage the use of lower cost alternatives. This program requires a member to try an over-the-counter medication (OTC) for constipation and either Linzess (linaclotide) for CIC or cIBS-C or Symproic for OIC before providing coverage for Amitiza (lubiprostone).

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Notification/Prior Authorization may be in place
- Step Therapy may be in place

4. References

Prior Authorization Guideline

GL-33136 Angiotensin Receptor Blockers

Formulary UHC Core

Formulary Note

Approval Date 3/14/2017

Revision Date 3/14/2017

Technician Note:

P&T Approval Date: 5/17/2005; P&T Revision Date: 1/25/2017. **Effective 7/1/2017**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Azor (amlodipine/olmesartan)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td><strong>Hypertension</strong> Indicated for the treatment of hypertension, alone or with other antihypertensive agents, and as initial therapy in patients likely to need multiple antihypertensive agents to achieve their blood pressure goals.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Edarbi (azilsartan)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Indications

**Hypertension** Indicated for the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction.

**Drug Name:** Edarbyclor (azilsartan/ chlorthalidone)

**Indications**

**Hypertension** Indicated for the treatment of hypertension. Edarbyclor is also indicated for initial therapy of hypertension in patients who are likely to need multiple drugs to achieve their blood pressure goals.

**Drug Name:** Tekturna (aliskiren)

**Indications**

**Hypertension** Indicated for the treatment of hypertension, to lower blood pressure.

**Drug Name:** Tekturna HCT (aliskiren and hydrochlorothiazide)

**Indications**

**Hypertension** Indicated for the treatment of hypertension, to lower blood pressure. Tekturna HCT may be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

**Drug Name:** Tribenzor (olmesartan/ amlodipine/ hydrochlorothiazide)

**Indications**

**Hypertension** Indicated for the treatment of hypertension, to lower blood pressure. These fixed dose combinations are not indicated for the initial therapy of hypertension.

### 2. Criteria
**Product Name:** Brand Azor, Edarbi, Edarbyclor, Tekturna, Tekturna HCT, Brand Tribenzor

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

**Approval Criteria**

1. Trial and failure or intolerance to one of the following:

- benazepril
- captopril
- enalapril
- fosinopril
- lisinopril
- moexipril
- perindopril
- quinapril
- ramipril
- benazepril-HCTZ
- captopril-HCTZ
- enalapril-HCTZ
- fosinopril-HCTZ
- lisinopril-HCTZ
- moexipril-HCTZ
- quinapril-HCTZ
- amlodipine-benazepril
- trandolapril-verapamil
- losartan
- losartan-HCTZ
- candesartan
- irbesartan
- irbesartan-HCTZ
- telmisartan
- telmisartan-HCTZ
- olmesartan
- olmesartan-HCTZ
3. References

2. Edarbi Prescribing Information. Takeda Pharmaceuticals. May 2014.
1. Indications

**Drug Name: Albenza (albendazole)**

**Indications**

**Parenchymal neurocysticercosis** Indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.

**Cystic hydatid disease** Indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.
Drug Name: Emverm (mebendazole)

Indications

Pinworm, whipworm, common roundworm, common hookworm, American hookworm
Indicated for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), and Necator americanus (American hookworm) in single or mixed infections.

Drug Name: Vermox (mebendazole)

Indications

Gastrointestinal infections Indicated for the treatment of patients one year of age and older with gastrointestinal infections caused by Trichuris trichiura (whipworm), and Ascaris lumbricoides (roundworm).

2. Criteria

Product Name: [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Enterobius vermicularis (pinworm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of Enterobius vermicularis (pinworm)

AND
### History of failure, contraindication or intolerance to over-the-counter pyrantel pamoate

<table>
<thead>
<tr>
<th>Notes</th>
<th>[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</th>
</tr>
</thead>
</table>

**Product Name:** Albenza [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Taenia solium (Neurocysticercosis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

#### Approval Criteria

1. **Diagnosis of Neurocysticercosis**

<table>
<thead>
<tr>
<th>Notes</th>
<th>[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</th>
</tr>
</thead>
</table>

**Product Name:** [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Echinococcosis (Tapeworm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

#### Approval Criteria

1. **Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]**
### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Ancylostoma/Necatoriasis (Hookworm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Ascariasis (Roundworm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Diagnosis of Ascariasis (Roundworm)

### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
### Product Name: [Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Mansonella perstans (Filariasis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

#### Approval Criteria

1. Diagnosis of Mansonella perstans (Filariasis)

#### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Toxocariasis (Roundworm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

#### Approval Criteria

1. Diagnosis of Toxocariasis (Roundworm)

#### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Trichinellosis</th>
</tr>
</thead>
</table>
### Approval Criteria

1 Diagnosis of Trichinellosis

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

- **Product Name:** [Albenza, Emverm or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Trichuriasis (Whipworm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1 Diagnosis of Trichuriasis (Whipworm)

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

- **Product Name:** [Albenza, Emverm, or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Capillariasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
### Approval Criteria

1 Diagnosis of Capillariosis

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** [Albenza, Emverm, or Vermox] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Baylisascaris</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1 Diagnosis of Baylisascaris

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** Albenza [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Clonorchiasis (Liver flukes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</tbody>
</table>

### Approval Criteria

1 Diagnosis of Clonorchiasis
### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: Albenza [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Gnathostomiasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</tbody>
</table>

#### Approval Criteria

1. Diagnosis of Gnathostomiasis

### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: Albenza [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Strongyloidiasis</th>
</tr>
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<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</tbody>
</table>

#### Approval Criteria

1. Diagnosis of Strongyloidiasis

### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. Background

**Benefit/Coverage/Program Information**

**Background:**

Albenza is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium. Albenza is also indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.

Emverm is indicated for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm) and Necator americanus (American hookworm) in single or mixed infections.

Vermox is indicated for the treatment of patients one year of age and older with gastrointestinal infections caused by Trichuris trichiura (whipworm) and Ascaris lumbricoides (roundworm).

CDC guidelines recommend use in several other parasitic infections.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
4. References

Prior Authorization Guideline

GL-51002 Anticonvulsants - Banzel (rufinamide), Diacomit (stiripentol), Onfi (clobazam), Sabril (vigabatrin), Sympazan (clobazam)

Formulary UHC Core

Formulary Note

Approval Date 7/31/2019

Revision Date 7/31/2019

Technician Note:

P&T Approval Date: 7/18/2018; P&T Revision Date: 5/17/2019 **Effective Date: 8/1/2019**

1. Indications

| Drug Name: Banzel (rufinamide), Onfi (clobazam), and Sympazan (clobazam)* |
| Indications |

| Drug Name: Diacomit (stiripentol) |
**Indications**

**Seizures associated with Dravet syndrome** Indicated for seizures associated with Dravet syndrome in patients taking clobazam.

**Drug Name:** Sabril (vigabatrin)

**Indications**

**Refractory complex partial seizures** Indicated as adjunctive therapy for refractory complex partial seizures in patients who have inadequately responded to several alternative treatments and for infantile spasms for whom the potential benefits outweigh the risk of vision loss.

---

2. **Criteria**

**Product Name:** Banzel

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 One of the following:

1.1 All of the following:

- Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

OR
1.2 For continuation of prior therapy for a seizure disorder

**Product Name:** Onfi or Sympazan*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 One of the following:

1.1 All of the following:

1.1.1 One of the following:

- Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
- Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

    AND

1.1.2 Both of the following:

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

    OR

1.2 For continuation of prior therapy for a seizure disorder

**Product Name:** Sabril

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
</tbody>
</table>
Guideline Type | Prior Authorization
---|---

**Approval Criteria**

1 One of the following:

1.1 All of the following:

- Diagnosis of partial-onset seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment
- Patient has had inadequate response to several (at least three) alternative anticonvulsants

OR

1.2 Diagnosis of infantile spasms

OR

1.3 For continuation of prior therapy for a seizure disorder

**Product Name:** Diacomit

**Approval Length** | 12 Month(s)
---|---
**Therapy Stage** | Initial Authorization
**Guideline Type** | Prior Authorization

**Approval Criteria**

1 One of the following:

1.1 Diagnosis of Dravet syndrome and currently taking clobazam
OR

1.2 For continuation of prior therapy for a seizure disorder

Product Name: Banzel, Diacomit, Onfi, Sabril, or Sympazan*

<table>
<thead>
<tr>
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<th>12 Month(s)</th>
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<tbody>
<tr>
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<td>Reauthorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
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</table>

Approval Criteria

1. Documentation of positive clinical response to therapy

3. Background

Benefit/Coverage/Program Information

Background:

Banzel (rufinamide), Onfi (clobazam), and Sympazan (clobazam)* are indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). There is some clinical evidence to support the use of clobazam for refractory partial onset seizures.

Diacomit (stiripentol) is indicated for seizures associated with Dravet syndrome in patients taking clobazam.

Sabril (vigabatrin) is indicated as adjunctive therapy for refractory complex partial seizures in patients who have inadequately responded to several alternative treatments and for infantile spasms for whom the potential benefits outweigh the risk of vision loss.

Adjunctive therapy is defined as treatment administered in addition to another therapy. Coverage will not be provided for Banzel as primary treatment.
Additional Clinical Programs:

- *Typically excluded from coverage.
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References

Prior Authorization Guideline

GL-49278 Anticonvulsants - Single Source Brand - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 4/30/2019

Revision Date 4/30/2019

Technician Note:

P&T Approval Date: 2/18/2014; P&T Revision Date: 6/28/2017, 9/19/2018, 11/16/2018;
**Effective Date: 2/1/2019**

1. Criteria

Product Name: [Aptiom, Briviact, Fycompa or Vimpat] [a]

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<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria
1 One of the following:

1.1 All of the following:

1.1.1 One of the following:

- For Aptiom, Briviact or Vimpat: diagnosis of partial-onset seizures
- For Fycompa: diagnosis of partial-onset or primary generalized tonic-clonic seizures

    AND

1.1.2 History of greater than or equal to 8 week trial [b] of at least two of the following (any release formulation qualifies):

- Carbamazepine
- Divalproex
- Gabapentin
- Lamotrigine
- Levetiracetam
- Oxcarbazepine
- Phenytoin
- Pregabalin
- Topiramate
- Valproic acid
- Zonisamide

    AND

1.1.3 One of the following:

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

    OR

1.1.3.2 Both of the following:
• Documentation of failure due to intolerable side effects
• Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes  [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Connecticut and Kentucky business, only a 30 day trial will be required.

Product Name: Epidiolex [a]

<table>
<thead>
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<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of seizures associated with Dravet syndrome

OR

2 All of the following :

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2.2 History of greater than or equal to 8 week trial [b], contraindication or intolerance of at least two of the following (any release formulation qualifies):
• Divalproex
• Lamotrigine
• Topiramate
• Valproic acid

AND

2.3 One of the following:

2.3.1 Both of the following:

• Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
• Lack of compliance as a reason for treatment failure has been ruled out

OR

2.3.2 Both of the following:

• Documentation of failure due to intolerable side effects.
• Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

3 For continuation of prior therapy for a seizure disorder

Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] Connecticut and Kentucky business, only a 30 day trial will be required.
2. Background

**Benefit/Coverage/Program Information**

**Background:**

This program requires a member to try at least two antiepileptic medications prior to receiving coverage for Aptiom, Briviact, Fycompa, Vimpat or Epidiolex when it is used for seizures associated with Lennox-Gastaut syndrome. Epidiolex for seizures associated with Dravet syndrome does not require a trial of alternative antiepileptic medications.

**Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

3. References

Prior Authorization Guideline

GL-56310 Anticonvulsants - Step Therapy

Formulary  UHC Core

Formulary Note

Guideline Note:

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<th>Effective Date:</th>
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<td>2/15/2019</td>
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<tr>
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<td>9/18/2019</td>
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</tbody>
</table>

Technician Note:

P&T Approval Date: 2/15/2019; P&T Revision Date: 9/18/2019. **Guideline Effective Date: 11/1/2019**

1. Criteria
**Product Name: Lyrica**

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following criteria:

1.1 Both of the following:

1.1.1 History of greater than or equal to a 2 week trial of pregabalin

AND

1.1.2 History of an inadequate response to pregabalin

OR

1.2 History of intolerance to generic pregabalin formulations

OR

1.3 Patient is receiving Lyrica for the treatment of a seizure disorder

---

**Product Name: Oxtellar XR**

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following criteria:
1.1 Both of the following:

1.1.1 History of greater than or equal to a 2 week trial of generic oxcarbazepine

AND

1.1.2 History of an inadequate response to generic oxcarbazepine

OR

1.2 History of intolerance to generic oxcarbazepine

OR

1.3 Patient is receiving Oxtellar XR for the treatment of a seizure disorder

Product Name: Qudexy XR (brand and authorized generic), Trokendi XR

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - One of the following criteria:

1.1 Both of the following:

1.1.1 History of greater than or equal to a 2 week trial of one generic topiramate immediate-release (IR) product

AND

1.1.2 History of an inadequate response to one generic topiramate immediate-release (IR) product
OR

1.2 History of intolerance to one generic topiramate immediate-release (IR) product

OR

1.3 Patient is receiving Trokendi XR or Qudexy XR (brand and authorized generic) for the treatment of a seizure disorder

2. Background

**Benefit/Coverage/Program Information**

**Background:**

Step Therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes.

This program requires a member to try one generic topiramate immediate-release product prior to coverage of Qudexy XR (brand and authorized generic) or Trokendi XR, generic pregabalin prior to coverage of Lyrica, and generic oxcarbazepine prior to coverage of Oxtellar XR. There will be exceptions for members with a documented diagnosis of a seizure disorder.

**Additional Clinical Rules:**

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References
4. Revision History

<table>
<thead>
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<th>Date</th>
<th>Notes</th>
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</table>
Prior Authorization Guideline

GL-51671 Antiemetics Quantity Limit Overrides

Formulary UHC Core

Formulary Note

Approval Date 8/19/2019

Revision Date 8/19/2019

Technician Note:

P&T Approval Date: 2/25/2016; P&T Revision Date: 9/28/2016, 3/21/2018, 8/16/2018, 8/15/2019.**Effective Date: 10/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Akynzeo (netupitant/palonosetron)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>Chemotherapy-induced nausea and vomiting Indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Akynzeo is an oral fixed combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.</td>
</tr>
</tbody>
</table>
Drug Name: Anzemet (dolasetron)

Indications

Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older.

Off Label Uses

Radiotherapy-induced nausea and vomiting Used for the prevention and treatment of nausea and vomiting induced by radiation therapy. [11, 12]

Postoperative nausea and vomiting Used orally for the prevention of postoperative nausea and vomiting. [13]

Drug Name: Cesamet (nabilone)

Indications

Chemotherapy-induced Nausea and Vomiting Indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. This restriction is required because a substantial proportion of any group of patients treated with Cesamet can be expected to experience disturbing psychotomimetic reactions not observed with other antiemetic agents. Because of its potential to alter the mental state, Cesamet is intended for use under circumstances that permit close supervision of the patient by a responsible individual particularly during initial use of Cesamet and during dose adjustments. Cesamet contains nabilone, which is controlled in Schedule II of the Controlled Substances Act. Schedule II substances have a high potential for abuse. Prescriptions for Cesamet should be limited to the amount necessary for a single cycle of chemotherapy (i.e., a few days). Cesamet capsules are not intended to be used on an as needed basis or as a first antiemetic product prescribed for a patient. As with all controlled drugs, prescribers should monitor patients receiving nabilone for signs of excessive use, abuse and misuse. Patients who may be at increased risk for substance abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse) or mental illness.

Drug Name: Emend (aprepitant)

Indications
**Chemotherapy-induced nausea and vomiting** Indicated, in combination with other antiemetic agents, in patients 6 months of age and older for oral suspension, or 12 years of age and older for the capsules, for the prevention of: (1) acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; (2) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

**Postoperative Nausea and Vomiting - capsules only** Indicated in adults for the prevention of postoperative nausea and vomiting. Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

**Drug Name: Granisetron**

**Indications**

**Chemotherapy-induced nausea vomiting** Indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.

**Radiation-induced nausea and vomiting** Indicated for the prevention of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

**Off Label Uses**

**Postoperative nausea and vomiting** Used for the prevention of postoperative nausea and vomiting. [14, 15]

**Drug Name: Marinol (dronabinol)**

**Indications**

**Chemotherapy-induced nausea and vomiting** Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

**Anorexia in patients with AIDS** Indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS.
<table>
<thead>
<tr>
<th>Drug Name: Sancuso (granisetron transdermal system)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Chemotherapy-induced nausea and vomiting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Sustol (granisetron injection)</th>
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</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Chemotherapy-induced nausea and vomiting</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Drug Name: Varubi (rolapitant)</th>
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</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Chemotherapy-induced nausea and vomiting</td>
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</table>

<table>
<thead>
<tr>
<th>Drug Name: Zofran (ondansetron), Zuplenz (ondansetron oral soluble film)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Chemotherapy-induced nausea and vomiting</td>
</tr>
<tr>
<td>Radiotherapy-induced nausea and vomiting</td>
</tr>
</tbody>
</table>
**Postoperative nausea and vomiting** Indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran ODT Orally Disintegrating Tablets, Zofran Oral Solution, and Zuplenz are recommended even where the incidence of postoperative nausea and/or vomiting is low.

**Off Label Uses**

_Hyperemesis gravidarum_ Used in the management of hyperemesis gravidarum. [10, 16]

---

### 2. Criteria

**Product Name:** Akynzeo, Anzemet, Cesamet, Generic dronabinol, Brand Emend, Generic aprepitant, granisetron, Brand Marinol, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Sancuso, Sustol, Varubi, Brand Zofran oral solution, Brand Zofran ODT, or Zuplenz

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chemotherapy-induced nausea and vomiting</th>
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<tbody>
<tr>
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<td>6 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Quantity Limit</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of chemotherapy-induced nausea and vomiting

    AND

2 Patient is receiving moderately to highly emetogenic chemotherapy

    AND
3 Patient has had at least a partial response to therapy at a dose within the quantity limit

**Product Name:** Anzemet, granisetron, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Brand Zofran oral solution, Brand Zofran ODT, or Zuplenz

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Radiotherapy-induced nausea and vomiting</th>
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<tbody>
<tr>
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<td>6 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Quantity Limit</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of radiotherapy-induced nausea and vomiting

AND

2 Patient is receiving radiotherapy consisting of total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen

AND

3 Patient has had at least a partial response to therapy at a dose within the quantity limit

**Product Name:** Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Brand Zofran oral solution, Brand Zofran ODT, or Zuplenz

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Hyperemesis gravidarum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
</tbody>
</table>
Guideline Type | Quantity Limit
---|---

Approval Criteria

1 Diagnosis of nausea and vomiting due to pregnancy (i.e., hyperemesis gravidarum) [10, 16]

   AND

2 History of failure, contraindication, or intolerance to at least one of the following: [A]

   - doxylamine
   - metoclopramide (Reglan)
   - prochlorperazine (Compazine)
   - promethazine (Phenergan)
   - pyridoxine (Vitamin B6)

   AND

3 Patient has had at least a partial response to therapy at a dose within the quantity limit

3. Background

Benefit/Coverage/Program Information

Quantity Limit

These products are subject to a standard quantity limit. The quantity limit may vary from the
4 . Endnotes

A. Treatment of nausea and vomiting of pregnancy with vitamin B6 or vitamin B6 plus doxylamine is safe and effective and should be considered first-line pharmacotherapy (Level A Evidence). Treatment of nausea and vomiting of pregnancy with ginger has shown beneficial effects and can be considered as a nonpharmacologic option (Level B Evidence). Several types of dopamine antagonists can be used for the treatment of nausea and vomiting of pregnancy such as promethazine, prochlorperazine, and metoclopramide. Antihistamines (such as dimenhydrinate and diphenhydramine) have been shown to be effective in controlling nausea and vomiting symptoms of pregnancy and are frequently used. Evidence is limited on the safety or efficacy of the 5-HT3 inhibitors (e.g. ondansetron) for nausea and vomiting of pregnancy. The ACOG recommends discussing the available data with patients as well as weighing the risks and benefits in women less than 10 weeks of gestation. Because of their limited data, they should not be advocated for first-line use until agents with established safety and efficacy have been tried and have failed. Treatment of severe nausea and vomiting of pregnancy or hyperemesis gravidarum with methylprednisolone may be efficacious in refractory cases; however, the risk profile of methylprednisolone suggests it should be a treatment of last resort (Level B Evidence). [16]

5 . References

Prior Authorization Guideline

GL-53093 AntiGout Agents

Formulary  UHC Core

Formulary Note

Guideline Note:

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<tr>
<td>P&amp;T Revision Date:</td>
<td>10/16/2019</td>
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</table>

Technician Note:

**Effective 12/01/2019**

1. Indications
**Drug Name: Uloric (febuxostat)**

**Gout** A xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

**Drug Name: Zurampic (lesinurad)**

**Gout** Indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. Zurampic is not recommended for the treatment of asymptomatic hyperuricemia. Zurampic should not be used as monotherapy.

**Drug Name: Duzallo (lesinurad/allopurinol)**

**Gout** Indicated for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone. Limitations of use: Duzallo is not recommended for the treatment of asymptomatic hyperuricemia.

---

**2. Criteria**

<table>
<thead>
<tr>
<th>Product Name: generic febuxostat, Duzalo, Uloric, Zurampic*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length: 12 Month(s)</td>
</tr>
<tr>
<td>Guideline Type: Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. History of an inadequate response, intolerance or contraindication to generic allopurinol

   **OR**

2. Patient is not a candidate for generic allopurinol therapy

**Notes**: *Product may be excluded depending on the plan.*
3 . References


4 . Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/3/2019</td>
<td>Annual review - updated reference no changes to clinical criteria</td>
</tr>
</tbody>
</table>
1. Indications

**Drug Name: Relenza (zanamivir) Inhalation Powder [1, 2]**

**Indications**

**Uncomplicated acute illness due to influenza A and B virus**

Relenza is indicated for treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years and older who have been symptomatic for no more than 2 days. Relenza is indicated for prophylaxis of influenza in adults and pediatric patients 5 years of age and older.
Drug Name: Tamiflu (oseltamivir) [1, 2]

**Indications**

**Uncomplicated acute illness due to influenza A and B virus**

Tamiflu is indicated for the treatment of uncomplicated acute illness due to influenza infection in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. Tamiflu is indicated for the prophylaxis of influenza in patients 1 year and older.

---

2. **Criteria**

**Product Name:** Relenza

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>5 Day</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. For the treatment of influenza virus [1, 10]

    **AND**

2. Patient age greater than or equal to 7 years [1, 10]

**Notes**

NOTE TO PRESCRIBER: Relenza is not recommended for patients with underlying respiratory disease (eg, asthma, chronic obstructive pulmonary disease) or heart disease. [1, 10]
<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>10 days for chemoprophylaxis in the household setting (quantity of 20 blisters per 180 days), or 28 days in the community setting (quantity of 56 blisters per 180 days) [1, B]</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. For the prophylaxis of influenza virus [1, 10]  

   AND

2. Patient age greater than or equal to 5 years [1, 10]

**Notes**

NOTE TO PRESCRIBER: Relenza is not recommended for patients with underlying respiratory disease (eg, asthma, chronic obstructive pulmonary disease) or heart disease. [1, 10]

**Product Name:** Tamiflu

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>5 Day</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. For the treatment of influenza virus [2, 10]  

   AND
2 Patient age greater than or equal to 2 weeks [2, 10]

**Product Name:** Tamiflu

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>10 days (30 mg: 20 capsules per 180 days, 45 and 75 mg: 10 capsules per 180 days, 6 mg/mL oral suspension: 180 mL per month) [C]; authorization may be issued for up to 6 weeks of therapy (for a total quantity of 42 capsules) for residents of nursing homes or long-term care facilities or during a community outbreak [D]</td>
</tr>
</tbody>
</table>

| Guideline Type | Non Formulary |

**Approval Criteria**

1. For the prophylaxis of influenza virus [2, 10]

   AND

2. Patient age greater than or equal to 1 year [2, 10]

**Product Name:** Relenza

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>5 days (additional quantity of 20 blisters)</td>
</tr>
</tbody>
</table>

| Guideline Type | Quantity Limit |

**Quantity Limit Table**

<table>
<thead>
<tr>
<th>DrugName</th>
<th>Strength</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>Relenza</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td>NOTE TO PRESCRIBER: Relenza is not recommended for patients with underlying respiratory disease (eg, asthma, chronic obstructive pulmonary disease) or heart disease. [1, 10]</td>
<td></td>
</tr>
</tbody>
</table>

| Relenza | 5 mg | 20 blisters per 180 days |

**Approval Criteria**

1. For the treatment of influenza virus [1, 10]

   **AND**

2. Patient age greater than or equal to 7 years [1, 10]

   **AND**

3. One of the following:

   3.1 Dose per day (mg/day) is supported in the dosage and administration section of the manufacturer's prescribing information

   **OR**

   3.2 Dose per day (mg/day) is supported by one of following compendia:

   - American Hospital Formulary Service Drug Information
   - Micromedex DRUGDEX System
<table>
<thead>
<tr>
<th>DrugName</th>
<th>Strength</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relenza</td>
<td>5 mg</td>
<td>20 blisters per 180 days</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. In persons who are at high priority for chemoprophylaxis defined by one of the following: [10, 11]

1.1 Both of the following:

1.1.1 One of the following:

1.1.1.1 High-risk persons [A] during the 2 weeks after vaccination before an adequate immune response to the influenza vaccine develops

    OR

1.1.1.2 All of the following:

    - High-risk children during the 6 weeks after vaccination before an adequate immune response to the influenza vaccine develops
    - Child was not previously vaccinated
    - Child requires 2 doses of vaccine

    AND

1.1.2 Influenza viruses are circulating in the community

    OR

1.2 Both of the following:

1.2.1 Adults and children who are at high risk [A]
AND

1.2.2 One of the following:

1.2.2.1 Influenza vaccination is contraindicated

OR

1.2.2.2 Influenza vaccination is unavailable (eg, due to shortage)

OR

1.2.2.3 Influenza vaccination is expected to have low effectiveness (eg, persons who are significantly immunocompromised)

OR

1.2.2.4 Situations in which there is documented low influenza vaccine clinical effectiveness due to circulation of influenza virus strains that are antigenically distant from the vaccine strains (ie, substantial increase in vaccine failure is anticipated) as determined by federal, state, and local public health institutions

OR

1.2.2.5 Both of the following:

- Patient has not yet received influenza vaccine
- Influenza activity has already been detected in the community

OR

1.3 Unvaccinated persons who are in close contact with persons at high risk [A] during periods of influenza activity

OR

1.4 Both of the following:
• All residents in institutions (eg, nursing homes, long-term care facilities)
• Institution is experiencing influenza outbreaks

AND

2 Patient age greater than or equal to 5 years [1, 10]

AND

3 One of the following:

3.1 Dose per day (mg/day) is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Dose per day (mg/day) is supported by one of following compendia:

• American Hospital Formulary Service Drug Information
• Micromedex DRUGDEX System

Notes
NOTE TO PRESCRIBER: Relenza is not recommended for patients with underlying respiratory disease (eg, asthma, chronic obstructive pulmonary disease) or heart disease. [1, 10]

Product Name: Tamiflu

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>5 days (additional quantities of: 20 capsules for 30 mg; 10 capsules for 45 mg, 75 mg; 180 mL for 6 mg/mL oral suspension)</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Quantity Limit</td>
</tr>
</tbody>
</table>

Quantity Limit Table
Approval Criteria

1 For the treatment of influenza virus [2, 10]

    AND

2 Patient age greater than or equal to 2 weeks [2, 10]

    AND

3 One of the following:

3.1 Dose per day (mg/day) is supported in the dosage and administration section of the manufacturer's prescribing information

    OR

3.2 Dose per day (mg/day) is supported by one of following compendia:

    - American Hospital Formulary Service Drug Information
    - Micromedex DRUGDEX System

Product Name: Tamiflu
Diagnosis | Prophylaxis
--- | ---
Guideline Type | Quantity Limit

### Quantity Limit Table

<table>
<thead>
<tr>
<th>DrugName</th>
<th>Strength</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamiflu</td>
<td>30 mg</td>
<td>20 capsules per 180 days</td>
</tr>
<tr>
<td>Tamiflu</td>
<td>45, 75 mg</td>
<td>10 capsules per 180 days</td>
</tr>
<tr>
<td>Tamiflu</td>
<td>6 mg/mL oral suspension</td>
<td>180 mL per month</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. In persons who are at high priority for chemoprophylaxis defined by one of the following: [10, 11]

1.1 Both of the following:

1.1.1 One of the following:

1.1.1.1 High-risk persons [A] during the 2 weeks after vaccination before an adequate immune response to the influenza vaccine develops

OR

1.1.1.2 All of the following:

- High-risk children during the 6 weeks after vaccination before an adequate immune response to the influenza vaccine develops
- Child was not previously vaccinated
- Child requires 2 doses of vaccine

AND

1.1.2 Influenza viruses are circulating in the community
1.2 Both of the following:

1.2.1 Adults and children who are at high risk [A]

AND

1.2.2 One of the following:

1.2.2.1 Influenza vaccination is contraindicated

OR

1.2.2.2 Influenza vaccination is unavailable (eg, due to shortage)

OR

1.2.2.3 Influenza vaccination is expected to have low effectiveness (eg, persons who are significantly immunocompromised)

OR

1.2.2.4 Situations in which there is documented low influenza vaccine clinical effectiveness due to circulation of influenza virus strains that are antigenically distant from the vaccine strains (ie, substantial increase in vaccine failure is anticipated) as determined by federal, state, and local public health institutions

OR

1.2.2.5 Both of the following:

- Patient has not yet received influenza vaccine
- Influenza activity has already been detected in the community

OR

1.3 Unvaccinated persons who are in close contact with persons at high risk [A] during periods of influenza activity
1.4 Both of the following:

- All residents in institutions (eg, nursing homes, long-term care facilities)
- Institution is experiencing influenza outbreaks

AND

2 Patient age greater than or equal to 1 year [2, 10]

AND

3 One of the following:

3.1 Dose per day (mg/day) is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Dose per day (mg/day) is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3. Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relenza - Treatment of influenza</td>
<td>2 inhalations (one 5 mg blister per inhalation for a total dose)</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Description</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Relenza [1]</td>
<td>One Diskhaler plus five Rotadisk containing 4 blisters (5 mg/blister) of zanamivir</td>
</tr>
<tr>
<td>Tamiflu [2]</td>
<td>30 mg, 45 mg, and 75 mg capsules; 6 mg/mL oral suspension</td>
</tr>
</tbody>
</table>
5. Background

Clinical Practice Guidelines

Centers for Disease Control and Prevention (2012-2013) [10]

Influenza antiviral prescription drugs can be used to treat influenza or to prevent influenza. The two FDA-approved influenza antiviral medications are recommended for use in the United States during the 2012-2013 influenza season: oseltamivir (Tamiflu) and zanamivir (Relenza). Oseltamivir and zanamivir are chemically related antiviral medications known as neuraminidase inhibitors that have activity against both influenza A and B viruses.

Treatment

Clinical trials and observational data show that early antiviral treatment can shorten the duration of fever and illness symptoms, and reduce the risk of complications from influenza (e.g., otitis media in young children, pneumonia, respiratory failure, and death) and shorten the duration of hospitalization. Clinical benefit is greatest when antiviral treatment is administered early, especially within 48 hours of influenza illness onset. Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who is hospitalized, has severe, complicated, or progressive illness, or is at higher risk for influenza complications.

Persons at higher risk for influenza complications recommended for antiviral treatment include:

- Children aged < 2 years
- Adults aged greater than or equal to 65 years
- Persons with chronic pulmonary (including asthma), cardiovascular (except hypertension alone), renal, hepatic, hematological (including sickle cell disease), metabolic disorders (including diabetes mellitus), or neurologic and neurodevelopment conditions (including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy [seizure disorders], stroke, intellectual disability [mental retardation], moderate to severe developmental
delay, muscular dystrophy, or spinal cord injury)

- Persons with immunosuppression, including that caused by medications or by HIV infection
- Women who are pregnant or postpartum (within 2 weeks after delivery)
- Persons aged <19 years who are receiving long-term aspirin therapy
- American Indians/Alaska Natives
- Persons who are morbidly obese (i.e., body-mass index greater than or equal to 40)
- Residents of nursing homes and other chronic-care facilities

Clinical judgment, on the basis of the patient’s disease severity and progression, age, underlying medical conditions, likelihood of influenza, and time since onset of symptoms, is important when making antiviral treatment decisions for high-risk outpatients. When indicated, antiviral treatment should be started as soon as possible after illness onset, ideally within 48 hours of symptom onset. However, antiviral treatment might still be beneficial in patients with severe, complicated or progressive illness and in hospitalized patients when started after 48 hours of illness onset as indicated by observational studies. Treatment should not wait for laboratory confirmation of influenza.

**Chemoprophylaxis**

Annual influenza vaccination is the best way to prevent influenza because vaccination can be given well before influenza virus exposures occur, and can provide safe and effective immunity throughout the influenza season. Antiviral medications are 70% to 90% effective in preventing influenza and are useful adjuncts to vaccination.

CDC does not recommend widespread or routine use of antiviral medications for chemoprophylaxis so as to limit the possibilities that antiviral resistant viruses could emerge. Indiscriminate use of chemoprophylaxis might promote resistance to antiviral medications, or reduce antiviral medication availability for treatment of persons at higher risk for influenza complications or those who are severely ill. An emphasis on close monitoring and early initiation of antiviral treatment is an alternative to chemoprophylaxis after a suspected exposure for some persons.

To be effective as chemoprophylaxis, an antiviral medication must be taken each day for the duration of potential exposure to a person with influenza and continued for 7 days
after the last known exposure. For persons taking antiviral chemoprophylaxis after inactivated influenza vaccination, the recommended duration is until immunity after vaccination develops (antibody development after vaccination takes about two weeks in adults and can take longer in children depending on age and vaccination history). Antiviral chemoprophylaxis generally is not recommended if more than 48 hours have elapsed since the last exposure to an infectious person. Patients receiving antiviral chemoprophylaxis should be encouraged to seek medical evaluation as soon as they develop a febrile respiratory illness that might indicate influenza.

Chemoprophylactic use of antiviral medications to control outbreaks among high risk persons in institutional settings is recommended. For example, when influenza is identified as a cause of respiratory outbreak among nursing home residents, use of antiviral chemoprophylaxis for all exposed or at-risk residents and for unvaccinated health care personnel is recommended. For vaccinated staff, antiviral chemoprophylaxis can be administered up to 2 weeks following influenza vaccination. For more information on the control of institutional outbreaks, please see the IDSA guidelines.

The following are examples of how antiviral medications can be considered for chemoprophylaxis to prevent influenza:

- Prevention of influenza in persons at high risk of influenza complications during the first two weeks following vaccination after exposure to an infectious person.

- Prevention for people with severe immune deficiencies or others who might not respond to influenza vaccination, such as persons receiving immunosuppressive medications, after exposure to an infectious person.

- Prevention for people at high risk for complications from influenza who cannot receive influenza vaccine due to a contraindication after exposure to an infectious person.

- Prevention of influenza among residents of institutions, such as long-term care facilities, during influenza outbreaks in the institution.


Treatment

Neuraminidase inhibitors (oseltamivir and zanamivir) have activity against both
influenza A and B viruses. Both zanamivir and the adamantanes are active against oseltamivir-resistant A influenza (H1N1) viruses. Rimantadine is preferred over amantadine because of its more favorable adverse effect profile. Ongoing surveillance for antiviral resistance is occurring in laboratories worldwide. Clinicians who treat patients with influenza should be aware of local public health data, when available, on the type and subtypes of influenza circulating in their area.

**Chemoprophylaxis**

Influenza vaccination is the primary tool to prevent influenza and antiviral chemoprophylaxis is not a substitute for influenza vaccination. When influenza viruses are circulating in the community, chemoprophylaxis can be considered for:

- High-risk persons during the 2 weeks after vaccination before an adequate immune response to inactivated vaccine develops (6 weeks for children who were not previously vaccinated and who require 2 doses of vaccine).

- Adults and children aged greater than or equal to 1 year who are at high risk of developing complications from influenza for whom influenza vaccination is contraindicated, unavailable, or expected to have low effectiveness (e.g., persons who are significantly immunocompromised). Contraindications to vaccination include anaphylactic hypersensitivity to eggs or other vaccine components, moderate-to-severe febrile illness, and as a precaution, a history of Guillain-Barre’s syndrome within 6 weeks after receipt of a prior influenza vaccination.

- Adults and children aged greater than or equal to 1 year who are at high risk of developing complications from influenza virus infection and have not yet received influenza vaccine when influenza activity has already been detected in the community. Whenever possible, influenza vaccine should be administered, and vaccination should continue for recommended persons until influenza is no longer in community circulation.

- Unvaccinated adults, including health care workers, and for children aged greater than or equal to 1 year who are in close contact with persons at high risk of developing influenza complications during periods of influenza activity. Whenever possible, influenza vaccine should be administered; 2 weeks after administration, chemoprophylaxis may be discontinued (6 weeks for children who were not previously vaccinated and who require 2 doses of vaccine).

- All residents (vaccinated and unvaccinated) in institutions, such as nursing homes and long-term care facilities, that are experiencing influenza
outbreaks.

- Persons at the highest risk of influenza-associated complications. The risk of influenza associated complications is not identical among all high-risk persons, and antiviral chemoprophylaxis is likely to have the greatest benefit among those at highest risk of influenza complications and death, such as recipients of hematopoietic stem cell transplants.

- Persons at high-risk of developing complications from influenza if influenza vaccine is not available due to shortage. If vaccine is available, it should be administered to these persons.

- High-risk persons in situations in which there is documented low influenza vaccine clinical effectiveness because of the circulation of influenza virus strains that are antigenically distant from the vaccine strains, such that a substantial increase in vaccine failures is anticipated, as determined by federal, state, and local public health authorities.

6. Endnotes

A. Persons at high risk of complications from influenza who should be considered for antiviral therapy: [10, 11] (1) Unvaccinated infants aged 12-24 months (2) Persons with asthma or other chronic pulmonary diseases, such as cystic fibrosis in children or chronic obstructive pulmonary disease in adults (3) Persons with hemodynamically significant cardiac disease (4) Persons who have immunosuppressive disorders or who are receiving immunosuppressive therapy (5) HIV-infected persons (6) Persons with sickle cell anemia and other hemoglobinopathies (7) Persons with diseases that require long-term aspirin therapy, such as rheumatoid arthritis or Kawasaki disease (8) Persons with chronic renal dysfunction (9) Persons with cancer (10) Persons with chronic metabolic disease, such as diabetes mellitus (11) Persons with neuromuscular disorders, seizure disorders, or cognitive dysfunction that may compromise the handling of respiratory secretions (12) Adults aged > 65 years (13) Residents of any age of nursing homes or other long-term care institutions

B. The safety and effectiveness of prophylaxis with Relenza have not been established for longer than 28 days duration. [1]

C. Tamiflu has been studied for the prophylaxis of influenza in close contacts. These studies have demonstrated the protective efficacy of Tamiflu and included prophylactic regimens that lasted 7 to 10 days. [2, 4, 8]
D. The prophylaxis studies conducted in healthy unvaccinated adults during a community outbreak and in elderly residents of skilled nursing homes (as described in the Tamiflu prescribing information) lasted for 42 days (6 weeks). [2]

7. References

1. Indications

**Drug Name:** 8-MOP (methoxsalen)

**Indications**

**Psoriasis**

Photochemotherapy (methoxsalen with long wave ultraviolet light) is indicated for the symptomatic control of severe, recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and when the diagnosis has been supported by biopsy. Methoxsalen is intended to be administered only in conjunction with a schedule of controlled doses of long wave ultraviolet radiation.
Vitiligo

Indicated for photochemotherapy (methoxsalen with long wave ultraviolet light) for the repigmentation of idiopathic vitiligo.

Cutaneous T-cell Lymphoma

Indicated for photopheresis (methoxsalen with long wave ultraviolet radiation of white blood cells) for use with UVAR System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) in persons who have not been responsive to other forms of treatment. While this dosage form of methoxsalen has been approved for use in combination with photopheresis, Oxsoralen Ultra capsules have not been approved for that use.

Drug Name: Calcitrene (calcipotriene) ointment

Indications

Psoriasis


Drug Name: Oxsoralen (methoxsalen) lotion

Indications

Vitiligo

Used as topical repigmenting agent in conjunction with controlled doses of ultraviolet A (320-400 nm) or sunlight.

Off Label Uses

Psoriasis

Used in the treatment of psoriasis when combined with UVA. [1]

Drug Name: Oxsoralen Ultra (methoxsalen) capsules

Indications

Psoriasis
Photochemotherapy (methoxsalen with long wave ultraviolet light) is indicated for the symptomatic control of severe, recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and when the diagnosis has been supported by biopsy. Methoxsalen is intended to be administered only in conjunction with a schedule of controlled doses of long wave ultraviolet radiation.

**Off Label Uses**

**Vitiligo**

Several studies have indicated the efficacy of PUVA therapy with methoxsalen in the treatment of vitiligo. [1,7,8] Oral methoxsalen is usually administered for repigmentation of idiopathic vitiligo prior to UVA light. [1]

**Cutaneous T-cell Lymphoma**

Methoxsalen in combination with photopheresis is indicated in the palliative treatment of skin manifestations of cutaneous T-cell lymphoma in patients unresponsive to other treatments. [1]

---

<table>
<thead>
<tr>
<th>Drug Name: Sorilux (calcipotriene) foam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td><strong>Psoriasis</strong></td>
</tr>
<tr>
<td>Indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 18 years and older.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Taclonex (calcipotriene/betamethasone) ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td><strong>Psoriasis</strong></td>
</tr>
<tr>
<td>Indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Taclonex (calcipotriene/betamethasone) suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td><strong>Psoriasis</strong></td>
</tr>
<tr>
<td>Indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 18 years</td>
</tr>
</tbody>
</table>
and older, and for the topical treatment of the scalp in patients age 12 to 17 years.

**Drug Name:** Enstilar (calcipotriene and betamethasone dipropionate) foam

**Indications**

**Plaque psoriasis**

Indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.

---

### 2. Criteria

**Product Name:** Generic calcipotriene ointment, Generic calcipotriene/betamethasone, Brand Calcitrene, Sorilux foam, Brand Taclonex ointment, or Taclonex suspension

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Psoriasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of psoriasis

2. History of failure, contraindication, or intolerance to two medium to high potency corticosteroid topical treatments (See Table 1 in Background section)

   AND

   AND
3 History of failure, contraindication, or intolerance to generic calcipotriene cream or solution

**Product Name:** Oxsoralen lotion

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Psoriasis or Vitiligo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following diagnoses:
   - Psoriasis (off-label) [1]
   - Vitiligo

   AND

2. Used in conjunction with PUVA therapy

   AND

3. Prescribed by a dermatologist

   AND

4. History of failure, contraindication, or intolerance to two medium to high potency corticosteroid topical treatments (See Table 1 in Background section)
**Product Name:** 8-MOP, Generic methoxsalen, or Brand Oxsoralen Ultra

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Psoriasis or Vitiligo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following diagnoses:
   - Psoriasis
   - Vitiligo \[1,7,8\]
   
   **AND**

2. Used in conjunction with PUVA therapy

   **AND**

3. History of failure, contraindication, or intolerance to three medium to high potency corticosteroid topical treatments (See Table 1 in Background section)

**Product Name:** 8-MOP, Generic methoxsalen (off-label), or Brand Oxsoralen Ultra (off-label)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Cutaneous T-cell lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>
Approval Criteria

1 Diagnosis of cutaneous T-cell lymphoma [1]

Product Name: Enstilar

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of psoriasis vulgaris/plaque psoriasis

AND

2 History of failure or intolerance to both of the following USED CONCURRENTLY:

- A medium to high potency topical steroid (See Table 1 in Background section)
- A Vitamin D analog

Product Name: Enstilar

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Patient has responded to therapy (e.g., symptoms have improved)
3. Background

Clinical Practice Guidelines

Table 1. Relative Potency of Selected Topical Corticosteroid Products

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage Form</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very High Potency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Augmented betamethasone dipropionate (Diprolene)*</td>
<td>Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td>Clobetasol propionate (Temovate)*</td>
<td>Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td>Diflorasone diacetate (Psorcon)</td>
<td>Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td>Halobetasol propionate (ultravate)</td>
<td>Cream, Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td><strong>High Potency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amcinonide (Cyclocort)</td>
<td>Cream, Lotion, Ointment</td>
<td>0.1%</td>
</tr>
<tr>
<td>Augmented betamethasone dipropionate (Diprolene, Diprolene AF)*</td>
<td>Cream</td>
<td>0.05%</td>
</tr>
<tr>
<td>Betamethasone dipropionate (Diprosone)*</td>
<td>Cream, Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td>Betamethasone valerate (Valisone)*</td>
<td>Ointment</td>
<td>0.1%</td>
</tr>
<tr>
<td>Desoximetasone (Topicort)*</td>
<td>Cream, Ointment</td>
<td>0.25%</td>
</tr>
<tr>
<td></td>
<td>Gel</td>
<td>0.05%</td>
</tr>
<tr>
<td>Diflorasone diacetate (Florone, Maxiflor)</td>
<td>Cream, Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td>Fluocinolone acetonide (Synalar)*</td>
<td>Cream</td>
<td>0.2%</td>
</tr>
<tr>
<td>Fluocinonide (Lidex)*</td>
<td>Cream, Ointment, Gel</td>
<td>0.05%</td>
</tr>
<tr>
<td>Halcinonide (Halog)</td>
<td>Cream, Ointment</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>Medium Potency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betamethasone dipropionate (Diprosone)*</td>
<td>Lotion</td>
<td>0.05%</td>
</tr>
</tbody>
</table>
Betamethasone valerate (Valisone)* Cream 0.1%
Betamethasone valerate (Luxiq) Foam 0.12%
Clocortolone pivalate (Cloderm) Cream 0.1%
Desoximetasone (Topicort)* Cream 0.05%
Flucinolone acetonide (Synalar)* Cream, Ointment 0.025%
Flurandrenolide (Cordran) Cream, Ointment 0.025%
Flurandrenolide (Cordran) Cream, Ointment, Lotion 0.05%
Fluticasone propionate (Cutivate)* Cream 0.05%
Fluticasone propionate (Cutivate)* Ointment 0.005%
Hydrocortisone butyrate (Locoid)* Ointment, Solution 0.1%
Hydrocortisone butyrate (Aristocort, Kenalog)* Cream, Ointment 0.2%
Hydrocortisone butyrate (Aristocort, Kenalog)* Cream, Ointment, Lotion 0.1%
Hydrocortisone butyrate (Westcort)* Cream, Ointment 0.2%
Mometasone furoate (Elocon)* Cream, Ointment, Lotion 0.1%
Triamcinolone acetonide (Aristocort, Kenalog)* Cream, Ointment, Lotion 0.025%
Triamcinolone acetonide (Aristocort, Kenalog)* Cream, Ointment, Lotion 0.1%


* Formulary Topical corticosteroids

4. References

13. Taclonex Topical Suspension Prescribing Information. Leo Pharma, September 2014.
GL-5873 Apidra (insulin glulisine)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 3/21/2013

Technician Note:

CPS Approval Date: 8/2/2004; CPS Revision Date: 8/21/2012 According to Texas State Law, all diabetic medications used for the treatment of diabetes shall be covered.

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Apidra (insulin glulisine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>Diabetes Mellitus [1]</td>
</tr>
</tbody>
</table>

Is indicated to improve glycemic control in adults and children with diabetes mellitus.
2 . Criteria

Product Name: Apidra or, if covered, Apidra SoloStar*

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1 History of one of the following:

- Humalog (insulin lispro)†
- Novolog (insulin aspart)†

Notes

*For plans that provide coverage for insulin vials only, see separate “Insulin Delivery Systems” administrative guideline for criteria. †Per the American Geriatric Society 2012 Beers Criteria Update, sliding-scale insulin (eg, insulin dose based on pre-defined blood glucose ranges) should be avoided in patients greater than or equal to 65 years of age. [a]

3 . Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apidra - Recommended Dosing [1]</td>
<td>Should be given within 15 minutes before a meal or within 20 minutes after starting a meal. The dosage of Apidra should be individualized.</td>
</tr>
</tbody>
</table>

4 . Availability
5. Background

Clinical Practice Guidelines

American Diabetes Association (2012) [5, 8, 9]

Overall key points

- Glycemic targets and glucose-lowering therapies must be individualized.

- Diet, exercise and education remain the foundation of any T2DM regimen program.

- Unless there are prevalent contraindications, metformin is the optimal first-line drug.

- After metformin, there are limited data for guidance. Combination therapy with additional 1-2 oral or injectable agents is reasonable, aiming to minimize side effects where possible.

- Ultimately, many patients will require insulin therapy alone or in combination with other agents to maintain glucose control.

- All treatment decisions, where possible, should be made in conjunction with the patient, focusing on his/her preferences, needs and values.

- Comprehensive CV risk reduction must be a major focus of therapy.

Initial drug therapy

- Specific patient preferences, characteristics, susceptibilities to side effects, potential for weight gain, and hypoglycemia should play a major role in drug selection.
• Metformin is the preferred and most cost-effective agent.

• If metformin cannot be used, another oral agent could be chosen, such as a SFU/glinide, pioglitazone, or a DPP-4 inhibitor. In occasional cases where weight loss is an essential aspect of therapy, initial treatment with a GLP-1 receptor agonist might be useful.

• Less commonly used drugs (ie, AGIs, coleselam, bromocriptine) might be considered in selected patients, but their modest glycemic effects and side-effect profiles make them less attractive candidates.

Advancing to dual combination therapy

• If monotherapy alone does not achieve or maintain an A1C target over ~3 months, then next step would be to add a second oral agent, a GLP-1 receptor agonist, or basal insulin.

• On average any second agent is typically associated with an approximate further reduction in A1C of ~1%. If no clinically meaningful reduction (ie, non-responder) is demonstrated, then, adherence having been investigated, that agent should be discontinued, and another agent with a different mechanism of action substituted.

• With a distinct paucity of long-term comparative effectiveness trials available, uniform recommendations or the best agent combined with metformin cannot be made. Thus the advantages and disadvantages of specific drugs for each patient should be considered.

Advancing to triple combination therapy

• The essential consideration is to use agents with complementary mechanisms of action.

• Some studies have shown advantages of adding a third noninsulin agent to a two-drug combination that is not yet or no longer achieving the glycemic target. However, at this juncture, the most robust response will usually be with insulin.

American Association of Clinical Endocrinologists/American College of Endocrinology (2009) [7,10]

The AACE/ACE recommends achieving an A1C of less than or equal to 6.5%, with an
emphasis on minimizing the risk of hypoglycemia and weight gain. The AACE/ACE algorithm is stratified by the patient’s current A1C level and, as with the ADA, positions lifestyle modifications and metformin as first-line therapy.

In patients with an A1C of 7.5% or lower, initial monotherapy with metformin or, alternatively, a DPP-4 inhibitor, GLP-1 receptor agonist, TZD, or AGI, is recommended. If monotherapy fails to achieve the A1C goal of less than or equal to 6.5%, then dual therapy should be started by adding one of the following agents in this preferential order based on hypoglycemia risk: GLP-1 receptor agonist, DDP-4 inhibitor, TZD, glinide, or SU. When metformin is contraindicated or not tolerated, a TZD with either a GLP-1 receptor agonist or DPP-4 inhibitor may be used. Two additional second-line therapy options included in the algorithm for this A1C group only are colesevelam and AGI. These agents are included because of their minimal risk of hypoglycemia and the ability of colesevelam to lower the LDL cholesterol levels. If dual therapy fails, then triple therapy or insulin therapy should be started.

In patients with an A1C between 7.6% and 9.0%, one should begin with dual therapy because monotherapy is unlikely to be successful in this group. Metformin is again the foundation of therapy with either a GLP-1 agonist or a DPP-4 inhibitor as the preferred second component due to their low risk of hypoglycemia, efficacy in reducing postprandial glucose excursions, and beneficial or neutral effect on weight. Alternatively, a TZD, SU, or glinide may be used in this preferential order as second components of the dual therapy when the incretin-based therapies would not be appropriate. If dual therapy does not achieve the A1C goal, then triple therapy or insulin therapy should be started.

In patients with an A1C > 9.0%, therapy is recommended based on the patient’s prior treatment history and whether or not symptoms are present. If the patient is asymptomatic, particularly with a relatively recent onset of diabetes, a good probability exists for preservation of some endogenous beta cell function, implying that dual therapy or triple therapy may be sufficient. In contrast, if the patient is symptomatic with polydipsia, polyuria, and weight loss, or if the patient has already been receiving treatment and regimens similar to the aforementioned ones have failed, then it is appropriate to initiate insulin therapy without delay.
6. Endnotes

A. Sliding-scale insulin is included in the 2012 American Geriatrics Society Beers Criteria list of inappropriate medications in older adults (greater than or equal to 65 years old). [11]

7. References

Prior Authorization Guideline

GL-30083 Atelvia (risedronate delayed-release)

Formulary UHC Core

Formulary Note

Approval Date 6/24/2016

Revision Date 6/24/2016

Technician Note:

P&T Approval Date: 11/20/1998; P&T Revision Date: 6/22/2016. **Effective 7/1/2016**

1. Indications

Drug Name: Atelvia (risedronate delayed-release tablets)

Indications

Postmenopausal osteoporosis Indicated for the treatment of osteoporosis in postmenopausal women. In postmenopausal women, risedronate sodium reduces the incidence of vertebral fractures and a composite endpoint of nonvertebral osteoporosis-related fractures. Important Limitations of Use: The optimal duration of use has not been determined. The safety and effectiveness of Atelvia for the treatment of osteoporosis are based on clinical data of one year duration. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug
discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.

2 . Criteria

**Product Name:** Brand Atelvia, Generic risedronate delayed-release

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1 History of alendronate or alendronate solution

3 . Background

**Benefit/Coverage/Program Information**

**Quantity Limit**

This product is subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . References


Prior Authorization Guideline

GL-56155 Azole Antifungals

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<tr>
<th>Effective Date:</th>
<th>1/1/2020</th>
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</thead>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>10/20/1998</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>11/14/2019</td>
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</table>

Technician Note:

P&T Approval Date: 10/20/1998; P&T Revision Date: 2/25/2016, 12/20/2017, 8/16/2018, 11/15/2018, 2/14/2019. **Effective Date: 3/1/2019**

1. Indications
### Drug Name: Sporanox (itraconazole) capsules

**Blastomycosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary

**Histoplasmosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis

**Aspergillosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy

**Onychomycosis of the toenail** Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (Tinea unguium)

**Onychomycosis of the fingernail** Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

### Drug Name: Sporanox Pulse Pak (itraconazole)

**Onychomycosis of the fingernail** Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)

### Drug Name: Sporanox (itraconazole) oral solution

**Oropharyngeal and esophageal candidiasis** Indicated for the treatment of oropharyngeal and esophageal candidiasis.

### Drug Name: Onmel (itraconazole)

**Onychomycosis of the toenail** Indicated for the treatment of onychomycosis of the toenail due to Trichophyton rubrum or T. Mentagrophytes in non-immunocompromised patients. Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis.

### Drug Name: Tolsura (itraconazole) capsules

**Blastomycosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary.

**Histoplasmosis** Indicated for the treatment of the following fungal infection in
immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis.

**Aspergillosis** Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy.

## 2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Brand Sporanox capsules or generic itraconazole capsules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
</tr>
<tr>
<td><strong>Approval Length</strong></td>
</tr>
<tr>
<td><strong>Guideline Type</strong></td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis)

    **OR**

2 - All of the following:

2.1 One of the following diagnoses:

- Tinea corporis (ring worm)
- Tinea cruris (jock itch)
- Tinea pedis (athlete's foot)
- Tinea capitis (scalp ringworm)
- Pityriasus versicolor

    **AND**

2.2 One of the following:

2.2.1 The tinea infection is resistant to topical antifungal treatment
2.2.2 Trial and failure, contraindication, or intolerance to oral terbinafine [3]

<table>
<thead>
<tr>
<th>Product Name: Brand Sporanox capsules, generic itraconazole capsules, or Sporanox Pulse Pak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Diagnosis of fingernail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

**AND**

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, wearing shoes, or appropriately manicuring nails) [4]

**AND**

3 - Trial and failure, contraindication, or intolerance to oral terbinafine

<table>
<thead>
<tr>
<th>Product Name: Brand Sporanox capsules or generic itraconazole capsules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>
Approval Criteria

1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient’s condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure, contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox oral solution or generic itraconazole oral solution

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Candidiasis (esophageal or oropharyngeal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 month [E, F]</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - One of the following:

1.1 Diagnosis of esophageal candidiasis

OR

1.2 Diagnosis of oropharyngeal candidiasis
AND

2 - Candidiasis is refractory to treatment with fluconazole

Product Name: Onmel

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Onychomycosis - Toenails</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 months [13]</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient’s condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure, contraindication, or intolerance to oral terbinafine

Product Name: Tolsura

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 months [5, 10-12, B-D]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
Approval Criteria

1 - Diagnosis of one of the following fungal infections:
   - Blastomycosis
   - Histoplasmosis
   - Aspergillosis

   **AND**

2 - Trial and failure or intolerance to generic itraconazole capsules

3. Endnotes

   A. Fingernail infections are usually reevaluated 18 weeks or longer after completion of therapy. Toenail infections are usually reevaluated 6-9 months after completion of therapy. [5] Indeed, considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [6] Reports of long-term follow-up of treated patients have recently been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [8]

   B. The optimal duration of therapy for aspergillosis has not been defined. Most clinicians treat infections (pulmonary) until resolution or stabilization of clinical and radiographic manifestations. The IDSA recommends a minimal treatment period of 6 – 12 weeks in immunocompetent patients for invasive conditions. [11]

   C. According to the IDSA guidelines for aspergillosis, duration of therapy for most conditions for aspergillosis has not been optimally defined. Most experts attempt to treat pulmonary infection until resolution or stabilization of all clinical and radiographic manifestations. Other factors include site of infection (e.g., osteomyelitis), level of immunosuppression, and extent of disease. Reversal of immunosuppression, if feasible, is important for a favorable outcome for invasive aspergillosis.” [11]

   D. According to the IDSA guidelines for the treatment of aspergillosis, both Amphotericin B and itraconazole are listed as second line treatment options for the treatment of invasive disease. [11]

   E. For fluconazole-refractory OPC, either itraconazole or posaconazole for up to 28 days is recommended. [3]

   F. Patients may be expected to relapse shortly after discontinuing therapy with Sporanox oral solution. Limited data on the safety of long-term use (> 6 months) of Sporanox Oral Solution are available at this time. [2]
4. References

15. Tolsura Prescribing Information. Merz Pharmaceuticals, LLC.; Greensboro, NC. December 2018.

5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>10/28/2019</td>
<td>Updated criteria for Nov 2019 P&amp;T - SL - 10.28.19</td>
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</table>
Prior Authorization Guideline

GL-49066 Basaglar (insulin glargine) ST

Formulary UHC Core

Formulary Note

Approval Date 4/18/2019

Revision Date 4/18/2019

Technician Note :

P&T Review Date: 8/18/16; P&T Revision Date: 12/20/2017, 9/19/2018. **Effective 01/01/2019**

1. Indications

Drug Name: Basaglar (insulin glargine)

Indications

Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Limitations of use: Not recommended for the treatment of diabetic ketoacidosis.
2. Criteria

Product Name: Basaglar

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Diabetes mellitus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Trial of two of the following:

- Lantus (insulin glargine)
- Levemir (insulin detemir)
- Toujeo (insulin glargine) [A]
- Tresiba (insulin degludec)

3. Endnotes

A. Newer basal insulin formulations (glargine U300, degludec U100 and U200) have more prolonged and stable pharmacokinetic and pharmacodynamic characteristics than glargine U100 and detemir [2]. Randomized control trials have reported equivalent glycemic control and lower rates of severe or confirmed hypoglycemia, particularly nocturnal hypoglycemia.

4. References
1. Basaglar Prescribing Information. Lilly USA, LLC. Indianapolis, IN. September 2018.
Prior Authorization Guideline

GL-54779 Belbuca (buprenorphine hydrochloride film) and Butrans (buprenorphine patch, extended-release) - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

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<tr>
<th>Effective Date:</th>
<th>10/10/2019</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>8/19/2016</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>11/15/2019</td>
</tr>
</tbody>
</table>

1. Indications

Drug Name: Belbuca (buprenorphine) buccal film, Butrans (buprenorphine) transdermal patch
Pain Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.

2. Criteria

Product Name: Belbuca [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Cancer or End of Life (defined as a &lt; 2 year life expectancy) related pain [c]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>24 Month(s)</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - The patient is being treated for cancer related pain or pain associated with end of life (defined as less than 2 years life expectancy) (Document diagnosis and date of diagnosis)

AND

2 - Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] In Connecticut, trial must be a generic product. [c] Coverage of medications used to treat stage four advanced metastatic cancer or associated conditions (e.g., cancer pain) may be approved based on state mandates.

Product Name: Butrans^ [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Cancer or End of Life (defined as a &lt; 2 year life expectancy) related pain [c]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>24 Month(s)</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</table>
Approval Criteria

1 - Patient is being treated for cancer related pain or pain associated with end of life. (defined as less than 2 years life expectancy). (Document diagnosis and date of diagnosis).

AND

2 - The patient has a history of failure, contraindication or intolerance to a trial of Belbuca [b] (Document duration of trial)

AND

3 - Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] In Connecticut, trial must be a generic product. [c] Coverage of medications used to treat stage four advanced metastatic cancer or associated conditions (e.g., cancer pain) may be approved based on state mandates. ^ Butrans is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

Product Name: Belbuca [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-cancer pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month(s)</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment
2 - Prescriber attests to all of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Medication is not being used for opioid dependence
- Dose does not exceed the maximum recommended dose per product label. (See Table 1)

3 - The patient is not receiving other long-acting opioids concurrently

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] In Connecticut, trial must be a generic product. |

<table>
<thead>
<tr>
<th>Product Name: Butrans^ [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment

AND
2 - Prescriber attests to all of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Medication is not being used for opioid dependence
- Dose does not exceed the maximum recommended dose per product label. (See Table 1)

AND

3 - The patient is not receiving other long-acting opioids concurrently

AND

4 - The patient has a history of failure, contraindication or intolerance to a trial BOTH of the following (Document duration of trial) [b]

- Belbuca
- tramadol (e.g. Ultram ER)

Notes

^Butrans is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] In Connecticut, trial must be a generic product.
Approval Criteria

1 - All of the following

1.1 Prescriber attests to ALL of the following:

- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- 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 information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

AND

1.2 Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

1.3 Identify rationale for not tapering and discontinuing opioid. (Document rationale).

AND

2 - Dose does not exceed maximum dose recommended by product label (see Table 1). (Document total daily dose).

Notes

^Butrans is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management
3. Background

Clinical Practice Guidelines

CDC and the American Academy of Neurology

The CDC and the American Academy of Neurology recommend the following best practices in the prescription of long-acting opioids:

- Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy, treatment goals should be established with patients that include realistic goals for pain and function and should consider how therapy will be discontinued if benefits do not outweigh risks. Track pain and function at every visit (at least every 3 months) using a brief, validated instrument. Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids.
- Document the daily morphine equivalent dose (MME) in mg/day from all sources of opioids. Access the state prescription drug monitoring program (PDMP) data at treatment initiation and periodically during treatment. Currently all states except for Missouri have a PDMP.
- To avoid increased risk of respiratory depression, long-acting opioids should not be prescribed concurrently with benzodiazepines.
- Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.
- Use random urine drug screening prior to initiation and periodically during treatment with a frequency according to risk.
- Use a patient treatment agreement, signed by both the patient and prescriber, that addresses risks of use and responsibilities of the patient.
- Methadone should not be the first choice for a long-acting opioid. Only clinicians who are familiar with methadone’s unique risk profile and who are prepared to educate and closely monitor their patients should consider prescribing methadone for pain.
- Avoid escalating doses above 50-90 mg/day MME unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist.
- Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, opioids should be tapered and discontinued. Evaluation should include assessment of substance use disorder/opioid dependence. Validated scales (such as the DAST-10) are available at www.drugabuse.gov.

Benefit/Coverage/Program Information

Additional Clinical Rules:
• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
• Supply limits and/or Step may be in place.

^ Butrans is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

Background

Buprenorphine is a partial opioid agonist. Belbuca and Butrans^ are buprenorphine products indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. Similar to other long-acting opioids, the use of Butrans^ and Belbuca should be reserved for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or inadequate to provide sufficient management of pain. Belbuca and Butrans^ are not indicated for as-needed (prn) analgesics.

Table 1. Maximum Recommended Dose Per Product Label

<table>
<thead>
<tr>
<th>Brand</th>
<th>Active Ingredient</th>
<th>Max Dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belbuca</td>
<td>Buprenorphine (buccal film)</td>
<td>1800 mcg (900 mcg every 12 hours)</td>
</tr>
<tr>
<td>Butrans^</td>
<td>Buprenorphine (patch)</td>
<td>20 mcg/hour patch every 7 days</td>
</tr>
</tbody>
</table>

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/10/2019</td>
<td>Added a note for stage four advanced metastatic cancer and state mandates</td>
</tr>
</tbody>
</table>
Prior Authorization Guideline

GL-49190 Benznidazole

Formulary UHC Core

Formulary Note

Approval Date 4/25/2019

Revision Date 4/25/2019

Technician Note:

P&T Approval Date: 3/21/2018; P&T Revision Date: 3/20/2019; **Guideline Effective Date: 6/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Benznidazole</th>
</tr>
</thead>
</table>

**Indications**

**Chagas disease (American trypanosomiasis)** Indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by Trypanosoma cruzi. [1]
2. Criteria

Product Name: Benznidazole

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chagas disease (American trypanosomiasis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>60 Day</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of Chagas disease (American trypanosomiasis) due to Trypanosoma cruzi

3. Background

Benefit/Coverage/Program Information

Background

Benznidazole, a nitroimidazole antimicrobial, is indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by Trypanosoma cruzi.¹

Antiparasitic treatment is indicated for all cases of acute or reactivated Chagas disease and for chronic Trypanosoma cruzi (T. cruzi) infection in children up to 18 years old. Congenital infections are considered acute disease. Treatment is strongly recommended for adults up to 50 years old with chronic infection who do not already have advanced Chagas cardiomyopathy. For adults older than 50 years with chronic T. cruzi infection, the decision to treat with antiparasitic drugs should be individualized, weighing the potential benefits and risks for the patient. Physicians should consider factors such as the patient’s age, clinical status, preference, and overall health.²
Additional clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-
  authorization based solely on previous claim/medication history, diagnosis codes (ICD-
  10) and/or claim logic. Use of automated approval and re-approval processes varies by
  program and/or therapeutic class.

4. References

   2017.
2. CDC Guidelines. Parasites – American Trypanosomiasis (also known as Chagas
Prior Authorization Guideline

GL-49253 Blood Glucose Test Strips

Formulary UHC Core

Formulary Note

Approval Date 4/29/2019

Revision Date 4/29/2019

Technician Note:

P&T Approval Date: 4/18/2018; P&T Revision Date: 6/20/2018, 2/15/2019 **Effective Date: 5/1/2019**

1. Criteria

Product Name: Abbott Diabetic Test Strips [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria
1 One of the following:

1.1 All of the following:

- Patient is currently using an OmniPod Insulin Pump
- Patient is requesting only FreeStyle test strips
- Patient is not requesting FreeStyle Insulinx, FreeStyle Lite, FreeStyle Precision Neo or Precision Xtra test strips

OR

1.2 All of the following:

- Patient is currently using a FreeStyle Libre Flash Glucose Monitoring System
- Patient is requesting only FreeStyle Precision Neo test strips
- Patient is not requesting FreeStyle, FreeStyle Insulinx, FreeStyle Lite, or Precision Xtra

OR

1.3 Submission of medical records documenting a physical or mental limitation that makes utilization of one of the following Lifescan diabetic meter/test strip products unsafe, inaccurate, or otherwise not feasible (e.g. manual dexterity)

- OneTouch UltraMini Meter (OneTouch Ultra Test Strips)
- OneTouch Ultra 2 Meter (OneTouch Ultra Test Strips)
- OneTouch Verio Meter (OneTouch Verio Test Strips)
- OneTouch Verio IQ Meter (OneTouch Verio Test Strips)
- OneTouch Verio Sync Meter (OneTouch Verio Test Strips)

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**Product Name:** Ascensia Diabetic Test Strips (excluding Contour Next**) [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
Approval Criteria

1 Submission of medical records documenting a physical or mental limitation that makes utilization of one of the following Lifescan diabetic meter/test strip products unsafe, inaccurate or otherwise not feasible (e.g., manual dexterity):

- OneTouch UltraMini Meter (OneTouch Ultra Test Strips)
- OneTouch Ultra 2 Meter (OneTouch Ultra Test Strips)
- OneTouch Verio Meter (OneTouch Verio Test Strips)
- OneTouch Verio IQ Meter (OneTouch Verio Test Strips)
- OneTouch Verio Sync Meter (OneTouch Verio Test Strips)

Notes

**Contour Next test strips are covered without prior authorization review. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Roche Diabetic Test Strips [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following:

1.1 All of the following:

- Patient is currently utilizing an Accu-Chek Combo Insulin Pump
- Patient is requesting only Accu-Chek Aviva Plus test strips
- Patient is not requesting Accu-Chek Compact, Accu-Chek Compact Plus, or Accu-Chek Smartview test strips

OR

1.2 Submission of medical records documenting a physical or mental limitation that makes utilization of one of the following Lifescan diabetic meters/test strips product unsafe, inaccurate
or otherwise not feasible (e.g. manual dexterity):

- OneTouch UltraMini Meter (OneTouch Ultra Test Strips)
- OneTouch Ultra 2 Meter (OneTouch Ultra Test Strips)
- OneTouch Verio Meter (OneTouch Verio Test Strips)
- OneTouch Verio IQ Meter (OneTouch Verio Test Strips)
- OneTouch Verio Sync Meter (OneTouch Verio Test Strips)

<table>
<thead>
<tr>
<th>Notes</th>
<th>[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</th>
</tr>
</thead>
</table>

**Product Name:** Other non-preferred test strip products [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 One of the following:

1.1 Submission of medical records documenting a physical or mental limitation that makes utilization of one of the following Lifescan diabetic meter/test strip products unsafe, inaccurate, or otherwise not feasible (e.g. manual dexterity)

- OneTouch UltraMini Meter (OneTouch Ultra Test Strips)
- OneTouch Ultra 2 Meter (OneTouch Ultra Test Strips)
- OneTouch Verio Meter (OneTouch Verio Test Strips)
- OneTouch Verio IQ Meter (OneTouch Verio Test Strips)
- OneTouch Verio Sync Meter (OneTouch Verio Test Strips)

**OR**

1.2 Patient is currently on an insulin pump that requires a specific glucometer/test strip

<table>
<thead>
<tr>
<th>Notes</th>
<th>[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</th>
</tr>
</thead>
</table>
Product Name: Preferred or non-preferred test strip products [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Quantity Limit</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Physician confirmation that the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)*

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Self-monitoring of blood-glucose should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. For patients using less frequent insulin injections, non-insulin therapies, or medical nutrition therapy alone, self-monitoring of blood glucose may be useful as a guide to management. [1]

2. Background

Benefit/Coverage/Program Information

Background:

The American Diabetes Association (ADA) recommends routine blood glucose monitoring in patients using insulin therapy. The ADA also notes that blood glucose monitoring may be helpful to guide treatment decisions for patients using noninsulin therapies. The ADA does not differentiate between brands of diabetic meters or test strips in their recommendation.
This program allows members utilizing an insulin pump to continue on their current diabetic meter/test strip if it the diabetic meter/strip is part of the system and interfaces directly with the insulin pump. Members not utilizing an insulin pump must have documentation demonstrating why utilization of a Lifescan diabetic meter/test strip is unsafe, inaccurate or not feasible before coverage will be provided for Abbott, Ascensia, or Roche diabetic test strips.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References

Prior Authorization Guideline

GL-54946 Bonjesta (doxylamine/pyridoxine extended-release), Diclegis (doxylamine/pyridoxine) - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<tr>
<th>Effective Date:</th>
<th>12/1/2019</th>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>4/18/2014</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>9/18/2019</td>
</tr>
</tbody>
</table>

1. Indications

Drug Name: Bonjesta (doxylamine/pyridoxine extended-release), Diclegis (doxylamine/pyridoxine)
# Nausea and vomiting of pregnancy

Approved by the Food and Drug Administration (FDA) for the treatment of nausea and vomiting of pregnancy in women who have not responded to conservative management.

## 2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Bonjesta* or Diclegis* [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**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. Documented trial and failure or contraindication 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).

**Notes**

*Bonjesta and Diclegis (as of 1/1/2019) are typically excluded from coverage. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.*

## 3. Background
Benefit/Coverage/Program Information

Background:

Bonjesta and Diclegis are fixed dose combinations of doxylamine and pyridoxine approved by the Food and Drug Administration (FDA) for the treatment of nausea and vomiting of pregnancy in women who have not responded to conservative management.

Additional Clinical Rules:

Bonjesta and Diclegis (as of 1/1/2019) are typically excluded from coverage.

• Supply limitations may be in place.
• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4 . References


5 . Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/11/2019</td>
<td>Annual review. Updated references, added automation language, and clarified trial/failure language with separate dosage forms.</td>
</tr>
</tbody>
</table>
1. Indications

Drug Name: Cardura XL (doxazosin mesylate extended-release)

Indications

Benign prostatic hyperplasia (BPH) Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Cardura XL is NOT indicated for the treatment of hypertension.
2. Criteria

Product Name: Cardura XL

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Trial and failure, contraindication, or intolerance to any TWO of the following generics: [2]

- alfuzosin
- doxazosin
- tamsulosin
- terazosin
- silodosin

3. References

1. Indications

**Drug Name: Caduet (amlodipine/atorvastatin)**

**Indications**

**General**

Indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate. Limitations of use: The antidyslipidemic component of Caduet has not been studied in conditions where the major lipoprotein abnormality is elevation of chylomicrons (Fredrickson Types I and V).
Drug Name: Amlodipine

**Indications**

**Hypertension**

Indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

**Coronary Artery Disease (CAD) - Chronic Stable Angina**

Indicated for the treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal or antihypertensive agents.

**CAD - Vasospastic Angina (Prinzmetal’s or Variant Angina)**

Indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy or in combination with other antianginal drugs.

**Angiographically Documented CAD**

In patients with recently documented CAD by angiography and without heart failure or an ejection fraction < 40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.

---

Drug Name: Atorvastatin

**Indications**

**General**

Therapy with HMG CoA-reductase inhibitors (lipid-altering agents) should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease from hypercholesterolemia. Drug therapy is recommended as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with CHD or multiple risk factors for CHD, atorvastatin can be started simultaneously with diet restriction.

**Prevention of Cardiovascular Disease**

In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and
angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk for revascularization procedures • Reduce the risk of hospitalization for CHF • Reduce the risk of angina

Hyperlipidemia

Indicated: • As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb) • As an adjunct to diet for the treatment of patients with elevated serum TG levels (Fredrickson Type IV); • For the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet • To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable • As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: 1. LDL-C remains greater than or equal to 190 mg/dL or 2. LDL-C remains greater than or equal to 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient

2. Criteria

Product Name: Brand Caduet or Generic amlodipine/atorvastatin

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1. History of amlodipine

AND
2 History of one of the following:

- One formulary statin (eg, lovastatin, simvastatin, pravastatin, atorvastatin, or Crestor)
- Vytorin

3. References

1. Indications

**Drug Name: Cetraxal (ciprofloxacin otic solution)**

**Indications**

**Acute otitis externa** Indicated for the treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus.
2. Criteria

Product Name: Brand Cetraxal, Generic ciprofloxacin otic solution

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Trial and failure, contraindication, or intolerance to ofloxacin otic solution

3. References

1. Indications

**Drug Name: Aimovig, Ajovy*, and Emgality 120mg**

**Indications**

**Migraine** Indicated for the preventive treatment of migraine in adults.

**Drug Name: Emgality 100mg**

**Indications**

2. Criteria

Product Name: Aimovig or Emgality 120mg [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Episodic Migraines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 Month(s)</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of episodic migraines with both of the following:

- Less than 15 headache days per month
- Patient has 4 to 14 migraine days per month

AND

2 Trial and failure (after a trial of at least two months [b]), contraindication, or intolerance to two of the following prophylactic therapies from the list below:

- Amitriptyline (Elavil)
- One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- Divalproex sodium (Depakote/Depakote ER)
- Topiramate (Topamax)
- Venlafaxine (Effexor/Effexor XR)
AND

3 Medication will not be used in combination with another CGRP antagonist or inhibitor

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required. |

**Product Name: Ajovy® [a]**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Episodic Migraines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 Month(s)</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of episodic migraines with both of the following:

- Less than 15 headache days per month
- Patient has 4 to 14 migraine days per month

AND

2 Trial and failure (after a trial of at least two months [b]), contraindication, or intolerance to two of the following prophylactic therapies from the list below:

- Amitriptyline (Elavil)
- One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
- Divalproex sodium (Depakote/Depakote ER)
• Topiramate (Topamax)
• Venlafaxine (Effexor/Effexor XR)

AND

3 Trial and failure (after a trial of at least three months [b]), contraindication, or intolerance to both of the following:

• Aimovig
• Emgality 120mg

AND

4 Medication will not be used in combination with another CGRP antagonist or inhibitor

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required. * Ajovy is typically excluded from benefit coverage.

Product Name: Aimovig, Ajovy* or Emgality 120mg [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Episodic Migraines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month(s)</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

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 antagonist or inhibitor

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Ajovy is typically excluded from benefit coverage |

**Product Name:** Aimovig or Emgality 120mg [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic Migraines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 Month(s)</td>
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<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of chronic migraines with both of the following:

- Greater than or equal to 15 headache days per month
- Greater than or equal to 8 migraine days per month

AND

2 Trial and failure (after a trial of at least two months [b]), contraindication, or intolerance to two of the following prophylactic therapies from the list below:

- Amitriptyline (Elavil)
- One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
• Divalproex sodium (Depakote/Depakote ER)
• OnabotulinumtoxinA (Botox)
• Topiramate (Topamax)
• Venlafaxine (Effexor/Effexor XR)

AND

3 Medication will not be used in combination with another CGRP antagonist or inhibitor

Notes
[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required.

Product Name: Ajovy* [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
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<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of chronic migraines with both of the following:

• Greater than or equal to 15 headache days per month
• Greater than or equal to 8 migraine days per month

AND

2 Trial and failure (after a trial of at least two months [b]), contraindication, or intolerance to two of the following prophylactic therapies from the list below:
• Amitriptyline (Elavil)
• One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
• Divalproex sodium (Depakote/Depakote ER)
• OnabotulinumtoxinA (Botox)
• Topiramate (Topamax)
• Venlafaxine (Effexor/Effexor XR)

AND

3 Trial and failure (after a trial of at least three months [b]), contraindication, or intolerance to both of the following:

• Aimovig
• Emgality 120mg

AND

4 Medication will not be used in combination with another CGRP antagonist or inhibitor

Notes
[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required. * Ajovy is typically excluded from benefit coverage

Product Name: Aimovig, Ajovy* or Emgality 120mg [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic Migraines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
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<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

172
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 antagonist or inhibitor

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Ajovy is typically excluded from benefit coverage

Product Name: Emgality 100mg [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Episodic Cluster Headache</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 Month(s)</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of episodic cluster headache

   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
3 Medication will not be used in combination with another CGRP antagonist or inhibitor

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** Emgality 100mg [a]

| 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 antagonist or inhibitor

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |
3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References

1. Indications
Drug Name: CNS stimulants

Attention Deficit Hyperactivity Disorder (ADHD) FDA approved indication for Attention Deficit Hyperactivity Disorder (ADHD)

Attention Deficit Disorder (ADD) FDA approved indication for Attention Deficit Disorder (ADD)

Narcolepsy FDA approved indication for narcolepsy

Off Label Uses: Idiopathic hypersomnolence There is evidence for off label use for idiopathic hypersomnolence.

Fatigue associated with multiple sclerosis There is evidence for off label use for fatigue associated with multiple sclerosis.

Mental fatigue secondary to traumatic brain injury There is evidence for off label use for mental fatigue secondary to traumatic brain injury.

Depression There is evidence for off label use for depression.

Weight Loss (Not Covered) The potential use of these agents for weight loss is not a covered benefit.

Drug Name: Vyvanse (lisdexamfetamine)

Binge Eating Disorder Indicated for Moderate to Severe Binge Eating Disorder (BED).

2. Criteria

Product Name: Brand Adderall XR, generic amphetamine-dextroamphetamine mixed salts (generic Adderall), generic dexamphetamine (generic Focalin), generic dexamphetamine extended-release (generic Focalin XR), generic dextroamphetamine (generic Dexedrine, generic Zenzedi), generic dextroamphetamine extended-release (generic Dexedrine Spansule), generic methylphenidate (generic Ritalin), generic methylphenidate extended-release (generic Metadate CD, Ritalin LA)

| Approval Length | 12 Month(s) |
| Guideline Type | Prior Authorization |
Approval Criteria

1 - One of the following:

1.1 The patient is less than 19 years of age

OR

1.2 Both of the following:

1.2.1 The patient is 19 years of age or older

AND

1.2.2 The patient has one of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care.
- Fatigue associated with multiple sclerosis

Product Name: Brand Adderall, Adhansia XR, Adzenys ER, Adzenys XR-ODT, Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Desoxyn, brand Dexedrine, brand Dexedrine Spansule, Dyanavel XR, Evekeo, Evekeo ODT, brand Focalin, brand Focalin XR, Jornay PM, brand Metadate CD, Metadate ER, Methylin, Methylin ER, Mydayis, Procentra, QuilliChew ER, Quillivant XR, brand Ritalin, Ritalin SR, brand Ritalín LA, and brand Zenzedi

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
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</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non-Formulary or Prior Authorization or Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - One of the following:

1.1 Both of the following:
1.1.1 The patient is less than 19 years of age

AND

1.1.2 History of two of the following generics or preferred brands:

- amphetamine-dextroamphetamine IR
- dexmethylphenidate IR
- dextroamphetamine IR or SR
- methylphenidate IR or ER
- Vyvanse
- Adderall XR

OR

1.2 All of the following:

1.2.1 The patient is 19 years of age or older

AND

1.2.2 The patient has one of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care.
- Fatigue associated with multiple sclerosis

AND

1.2.3 History of two of the following generics or preferred brands:

- amphetamine-dextroamphetamine IR
- dexmethylphenidate IR
- dextroamphetamine IR or SR
- methylphenidate IR or ER
- Vyvanse
- Adderall XR

<table>
<thead>
<tr>
<th>Product Name: Generic amphetamine-dextroamphetamine mixed salts extended-release (generic Adderall XR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following:

1.1 Both of the following:

1.1.1 The patient is less than 19 years of age

AND

1.1.2 History of failure or intolerance to Brand Adderall XR

OR

1.2 All of the following:

1.2.1 The patient is 19 years of age or older

AND

1.2.2 The patient has one of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care.
- Fatigue associated with multiple sclerosis

**AND**

1.2.3 History of failure or intolerance to Brand Adderall XR

<table>
<thead>
<tr>
<th>Product Name: Vyvanse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following:

1.1 The patient is less than 19 years of age

**OR**

1.2 Both of the following:

1.2.1 The patient is 19 years of age or older

**AND**

1.2.2 The patient has one of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care.
• Fatigue associated with multiple sclerosis

OR

1.3 All of the following:

1.3.1 The patient is 19 years of age or older

AND

1.3.2 The patient has Moderate to Severe Binge Eating Disorder (BED)

AND

1.3.3 The patient meets both of the following:

• Patient has had binge eating disorder for 3 months or longer
• Patient has between 4 and 13 binge-eating episodes per week

AND

1.3.4 The patient meets three (3) or more of the following:

• Patient eats much more rapidly than normal
• Patients eats until feeling uncomfortably full
• Patient eats large amounts of food when not feeling physically hungry
• Patient eats alone because of feeling embarrassed by how much one is eating
• Patient feels disgusted with oneself, depressed, or very guilty after binge-eating

Product Name: Vyvanse

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
Approval Criteria

1 - One of the following:

1.1 The patient is less than 19 years of age

OR

1.2 Both of the following:

1.2.1 The patient is 19 years of age or older

AND

1.2.2 The patient has one of the following diagnoses:

- Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
- Depression
- Narcolepsy
- Other hypersomnia of central origin
- Autism Spectrum Disorder
- Mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)
- Fatigue associated with medical illness in patients in palliative or end of life care
- Fatigue associated with multiple sclerosis

OR

1.3 All of the following:

1.3.1 The patient is 19 years of age or older

AND

1.3.2 The patient has Moderate to Severe Binge Eating Disorder (BED)
1.3.3 Documentation of positive clinical response (e.g., meaningful reduction in the number of binge eating episodes or binge days per week from baseline, improvement in the signs and symptoms of binge eating disorder) to Vyvanse therapy.

3. Background

Benefit/Coverage/Program Information

Additional Clinical Programs:
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may also be in place.

Background:
This program will allow coverage for diagnoses supported by FDA labeling and clinical evidence. The CNS stimulants have a variety of FDA approved labeled indications, such as Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD), and narcolepsy. In addition, Vyvanse is indicated for Moderate to Severe Binge Eating Disorder (BED). There is evidence for off label use for the stimulants in idiopathic hypersomnolence, fatigue associated with multiple sclerosis, mental fatigue secondary to traumatic brain injury, and depression. The potential use of these agents for weight loss is not a covered benefit. Because of the high abuse potential for this class of medications, their use should be closely monitored in certain age groups. In addition, if the member is less than 19 years of age, the prescription will automatically process without a coverage review.

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/23/2019</td>
<td>8/2019 - Added Adhansia XR and Evekeo ODT to criteria</td>
</tr>
</tbody>
</table>
1. Criteria

**Product Name:** Compounds and bulk powders [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
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</table>

**Approval Criteria**
1. The requested drug component is a covered medication

   AND

2. The requested drug component is to be administered for an FDA-approved indication

   AND

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

4. If the drug component is no longer available commercially it must not have been withdrawn for safety reasons

   AND

5. One of the following:

   5.1 A unique vehicle is required for topically administered compounds

   OR

   5.2 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.
5.3 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

AND

6 Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 Requested compound contains any of the following ingredients which are available as over-the-counter products:

- Cetyl Myristoleate
- Coenzyme Q10
- Methylcobalamin
- Hyaluronic Acid
- Nicotinamide
- Methyltetrahydrofolate
- Ibuprofen
- Lipoic acid
- Beta Glucan
- Ubiquinol
- Chrysin
- Glutathione
- Lactobacillus
- Vitamin E
- Ascorbic Acid
- Melatonin
- Pyridoxal-5-Phosphate (Vitamin B6)
- Loperamide
- Dextromethorphan
- Dehydroepiandrosterone
- Pregnenolone
- Biotin
- L-Glutamine
- Serotonin
- Aloe vera
- Sodium butyrate
- L-Isoleucine
- Vitamin D3
- Ginseng
• Phosphatidylserine
• Resveratrol
• Methionine
• Naproxen
• Carnosine L
• Arnica LG

OR

6.2 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), requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

• Ketamine
• Gabapentin
• Flurbiprofen (topical ophthalmic use not included)
• Ketoprofen
• Morphine
• Nabumetone
• Oxycodone
• Cyclobenzaprine
• Baclofen
• Tramadol
• Hydrocodone
• Meloxicam
• Amitriptyline
• Pentoxifylline
• Orphenadrine
• Piroxicam
• Levocetirizine
• Amantadine
• Oxytocin
• Sumatriptan
• Chorionic gonadotropin (human)
• Clomipramine
• Dexamethasone
• Hydromorphone
• Methadone
• Papaverine
• Mefenamic acid
• Promethazine
• Succimer DMSA
• Tizanidine
• Apomorphine
• Carbamazepine
• Ketorolac
• Dimercaptopropane-sulfonate
• Dimercaptosuccinic acid
- Duloxetine
- Fluoxetine
- Bromfenac (topical ophthalmic use not included)
- Nepafenac (topical ophthalmic use not included)

OR

6.3 Requested compound contains topical fluticasone. Topical fluticasone will NOT be approved unless:

6.3.1 Topical fluticasone is intended to treat a dermatologic condition. Scar treatments are considered cosmetic and will not be covered (refer to criteria "6.5" below).

AND

6.3.2 Patient has a contraindication to all commercially available topical fluticasone formulations

OR

6.4 Requested compound contains leuprolide when prescribed for off-label use (refer to leuprolide criteria)

OR

6.5 Requested compound contains any of the following ingredients when used for cosmetic purposes:

- Hydroquinone
- Acetyl hexapeptide-8
- Tocopheryl Acid Succinate
- PracaSil TM-Plus
- Chrysaderm Day Cream
- Chrysaderm Night Cream
- PCCA Spira-Wash
- Lipopen Ultra
- Versapro
- Fluticasone
- Mometasone
- Halobetasol
- Betamethasone
- Clobetasol
- Triamcinolone
- Minoxidil
• Tretinoin
• Dexamethasone
• Spironolactone
• Cycloserine
• Tamoxifen
• Sermorelin
• Mederma Cream
• PCCA Cosmetic HRT Base
• Sanare Scar Therapy Cream
• Scarcin Cream
• Apothederm
• Stera Cream
• Copasil
• Collagenase
• Arbutin Alpha
• Nourisil
• Freedom Cepapro
• Freedom Silomac Andydrous
• Retinaldehyde
• Apothederm

OR

6.6 Requested compound contains cholestyramine when prescribed for off-label use. (FDA labeled uses include: hypercholesterolemia, coronary artery atherosclerosis, and pruritus associated with biliary obstruction)

OR

6.7 Requested compound contains any of the following ingredients which are on the FDA's Do Not Compound List:

• 3,3',4',5-tetrachlorosalicylanilide
• Adenosine phosphate
• Adrenal cortex
• Alatrofloxacin mesylate
• Aminopyrine
• Astemizole
• Azaribine
• Benoxaprofen
• Bithionol
• Camphorated oil
• Carbetapentane citrate
• Casein, iodinated
• Cerivastatin sodium
• Chlormadinone acetate
• Chloroform
• Cisapride
Exfenfluramine hydrochloride
Diamthazole dihydrochloride
Dibromsalan
Dihydrostreptomycin sulfate
Dipyrene
Encainide hydrochloride
Etretinate
Fenfluramine hydrochloride
Flosequinan
Glycerol, iodinated
Grepafloxacin
Mepazine
Metabromsalan
Methaprilene
Methopholine
Methoxyflurane
Mibefradil dihydrochloride
Nomifensine maleate
Novobiocin sodium
Oxyphenisatin acetate
Oxyphenisatin
Pemoline
Pergolide mesylate
Phenacetin
Phenformin hydrochloride
Phenylpropanolamine
Pipamazine
Potassium arsenite
Propoxyphene
Rapacuronium bromide
Rofecoxib
Sibutramine hydrochloride
Sparteine sulfate
Sulfadimethoxine
Sweet spirits of nitre
Tegaserod maleate
Temafloxacin hydrochloride
Terfenadine
Ticrynafen
Tri bromosalan
Trichloroethane
Troglitazone
Trovafl oxacin mesylate
Urethane
Valdecoxib
Zomepirac sodium

Notes
[a] For Kentucky, requests for therapeutic food, formulas, supplements, low-protein modified food products, vitamins, nutritional supplements
and amino acid-based elemental medical formula for the treatment of inborn errors of metabolism, genetic conditions, mitochondrial disease, food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders, or short-bowel syndrome may be approved through review by UnitedHealthcare Pharmacy. Please note there is a plan year cap of twenty five thousand dollars ($25,000) for therapeutic foods, formulas and supplements, and a separate cap for each plan year of four thousand dollars ($4,000) on low-protein modified foods. Each cap shall be subject to annual inflation adjustments based on the consumer price index.

**Product Name:** [First-Lansoprazole or First-Omeprazole compounding kits]* [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. The requested drug component in the compounding kit is to be administered for an FDA-approved indication

   AND

2. One of the following:

   2.1 A unique dosage form is required for a covered commercially available product due to the patient’s age, weight or inability to take a solid dosage form

   OR

   2.2 A unique formulation is required for a covered commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

**Notes**

[a] For Kentucky, requests for therapeutic food, formulas, supplements, low-protein modified food products, vitamins, nutritional supplements and amino acid-based elemental medical formula for the treatment of
inborn errors of metabolism, genetic conditions, mitochondrial disease, food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders, or short-bowel syndrome may be approved through review by UnitedHealthcare Pharmacy. Please note there is a plan year cap of twenty five thousand dollars ($25,000) for therapeutic foods, formulas and supplements, and a separate cap for each plan year of four thousand dollars ($4,000) on low-protein modified foods. Each cap shall be subject to annual inflation adjustments based on the consumer price index. *First-Lansoprazole and First-Omeprazole are typically excluded from coverage.

2. Background

Benefit/Coverage/Program Information

Background:

Compounded medications can provide a unique route of delivery for certain patient-specific conditions and administration requirements. Compounded medications should be produced for a single individual and not produced on a large scale. In general, compounded medications should not be a covered pharmacy benefit if being provided as an equivalent alternative for a commercially available product. There may be exceptions if the commercially available product is an excluded drug. A dollar threshold may be used to identify compounds which require Notification and must meet the criteria below in order to be covered. Drugs included in the compound must be a covered product.

Additional Clinical Rules:

- First-Lansoprazole and First-Omeprazole are typically excluded from coverage.
- Supply limits, Step Therapy and/or Prior Authorization may be in place.
3. References

Prior Authorization Guideline

GL-50671 Contraceptives

Formulary UHC Core

Formulary Note

Approval Date 8/7/2019

Revision Date 8/7/2019

Technician Note:

P&T Approval Date: 12/6/2004; P&T Revision Date: 10/14/2014, 12/19/2018, 7/17/2019.

**Effective Date: 9/1/2019** **THIS GUIDELINE ONLY APPLIES TO PLANS THAT DO NOT HAVE FAMILY PLANNING BENEFITS.**

1. Criteria

Product Name: Formulary contraceptives

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<th>Approval Length</th>
<th>12 Month(s)</th>
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<tbody>
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<td>Guideline Type</td>
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Approval Criteria
**1 Patient is using the medication for non-contraception purposes***

| Notes | *Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner’s syndrome; (17) Uterine fibroids or adenomyosis. [1-7, 9-11] |

**Product Name:** Non-formulary contraceptives

| Approval Length | 12 Month(s) |
| Guideline Type | Administrative |

**Approval Criteria**

1. Patient is using the medication for non-contraception purposes*

   **AND**

2. History of failure, contraindication, or intolerance to three formulary contraceptives

| Notes | *Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner’s syndrome; (17) Uterine fibroids or adenomyosis. [1-7, 9-11] |
2. Background

Clinical Practice Guidelines

Table 1. Contraceptives [3, 8]
This information should not be considered comprehensive. Please refer to individual prescribing information for more details.

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**Product** | **Estrogen (MCG)** | **Progestin (MG)**
---|-------------------|-------------------
Azurette | 20 ethinyl estradiol x 21d, placebo x 2d, 10 x 5d | 0.15 desogestrel x 21d
Kariva     |                                               |                     
Mircette   |                                               |                     

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<td>Tri-Legest Fe</td>
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<td>Jencycla</td>
</tr>
<tr>
<td>Jolivette</td>
<td>Lyza</td>
<td>Nora-BE</td>
</tr>
<tr>
<td>Norethindrone</td>
<td>Norlyroc</td>
<td>Nor-QD</td>
</tr>
<tr>
<td>Ortho-Micronor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. References
1. Indications

**Drug Name: Corlanor (ivabradine)**

**Indications**

**Symptomatic chronic heart failure** Indicated to reduce the risk of hospitalization for worsening of heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.
2. Criteria

Product Name: Corlanor

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

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

2. Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

   AND

3. The patient is in sinus rhythm

   AND

4. Patient has a resting heart rate greater than or equal to 70 beats per minute
AND

5 One of the following:

5.1 Patient is on maximum tolerated doses of beta blockers (e.g., carvedilol, metoprolol succinate, bisoprolol)

OR

5.2 Patient has a contraindication or intolerance to beta-blocker therapy

Product Name: Corlanor

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Documentation of positive clinical response to Corlanor therapy

3. Background

Benefit/Coverage/Program Information
Background:

Corlanor (ivabradine) is a hyperpolarization-activated cycle nucleotide-gated channel blocker indicated to reduce the risk of hospitalization for worsening of heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

Additional Clinical Rules:

Supply Limits may be in place.

4. References

5. Colucci, W. Overview of the therapy of heart failure due to systolic dysfunction In: UpToDate, Gottlieb, SS (Ed). UpToDate, Waltham, MA, 2015.
Prior Authorization Guideline

GL-8033 Coverage of Drugs for Off-Label or Non-FDA Approved Indications (OR, WA, TX)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 7/22/2013

Technician Note:

CPS Approval Date: 10/2/2007

1. Criteria

Product Name: A drug used for an off-label indication or non-FDA approved indication

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Administrative</th>
</tr>
</thead>
</table>

Approval Criteria

1. Requests will be reviewed on a case-by-case basis by a clinical pharmacist
2 The drug is approved by the FDA

3 The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition or for a chronic and seriously debilitating condition

4 The drug is medically necessary to treat the condition

5 Documented history of failure, intolerance, or contraindication to standard, conventional therapies to treat or manage the disease or condition, where available

6 The drug has been recognized for treatment of that condition by one of the following:

6.1 Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal*
OR

6.2 The American Hospital Formulary Service (AHFS) Drug Information

OR

6.3 The United States Pharmacopoeia Dispensing Information (USPDI)†

OR

6.4 The American Medical Association Drug Evaluations†

<table>
<thead>
<tr>
<th>Notes</th>
<th>Authorization will be issued for length of therapy or indefinitely as appropriate. *May not apply to all benefit plans. †The American Medical Association Drug Evaluations and USPDI are currently not published.</th>
</tr>
</thead>
</table>
Prior Authorization Guideline

GL-8031 Coverage of Drugs for Off-Label or Non-FDA Approved Indications (UHC of CA)

Formulary UHC Core
Formulary Note
Approval Date 3/21/2013
Revision Date 7/22/2013

Technician Note:
CPS Approval Date: 11/18/2008; CPS Revision Date: 12/15/2009

1. Criteria

Product Name: A drug used for an off-label indication or non-FDA approved indication

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Administrative</th>
</tr>
</thead>
</table>

Approval Criteria

1 Requests will be reviewed on a case-by-case basis by a clinical pharmacist
2 The drug is approved by the FDA

AND

3 The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition or for a chronic and seriously debilitating condition

AND

4 The drug is medically necessary to treat the condition

AND

5 Documented history of failure, intolerance, or contraindication to standard, conventional therapies to treat or manage the disease or condition, where available.

AND

6 The drug has been recognized for treatment of that condition by one of the following:

6.1 The American Hospital Formulary Service (AHFS) Drug Information
OR

6.2 One of the following compendia as part of an anticancer chemotherapeutic regimen:

- The Elsevier Gold Standard’s Clinical Pharmacology
- The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- DRUGDEX System by Micromedex

OR

6.3 Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

<table>
<thead>
<tr>
<th>Notes</th>
<th>Authorization will be issued for length of therapy or indefinitely as appropriate</th>
</tr>
</thead>
</table>

2. References

Prior Authorization Guideline

GL-8032 Coverage of Drugs for Off-Label or Non-FDA Approved Indications (UHC of OK)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 7/22/2013

Technician Note:

CPS Approval Date: 10/2/2007; CPS Revision Date: 4/5/2011

1. Criteria

Product Name: A drug used for an off-label or non-FDA approved non-cancer indication

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Off-label non-cancer indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

Approval Criteria
1 Requests will be reviewed on a case-by-case basis by a clinical pharmacist

   AND

2 The drug is approved by the FDA

   AND

3 The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition or for a chronic and seriously debilitating condition

   AND

4 The drug is medically necessary to treat the condition

   AND

5 Documented history of failure, intolerance, or contraindication to standard, conventional therapies to treat or manage the disease or condition, where available

   AND

6 The drug has been recognized for treatment of that condition by one of the following:
6.1 The American Hospital Formulary Service (AHFS) Drug Information under the Therapeutic Uses section

OR

6.2 The United States Pharmacopoeia Dispensing Information (USPDI)†

OR

6.3 The American Medical Association Drug Evaluations†

OR

6.4 Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes
Authorization will be issued for length of therapy or indefinitely as appropriate. Off-label use may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available. †The American Medical Association Drug Evaluations and USPDI are currently not published.

Product Name: A drug used for an off-label or non-FDA approved cancer indication

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Off-label cancer indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

Approval Criteria

1 The drug has been recognized for treatment of that condition by one of the following:

1.1 The American Hospital Formulary Service (AHFS) Drug Information under the Therapeutic Uses section

OR
1.2 The Elsevier Gold Standard’s Clinical Pharmacology under the Indications section

OR

1.3 The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A or 2B (See Table 1 in the Background section)

OR

1.4 DRUGDEX System by Micromedex with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (See Table 2 in the Background section)

OR

1.5 Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there are clear and convincing contradictory evidence presented in a major peer-reviewed journal

| Notes | Authorization will be issued for length of therapy or indefinitely as appropriate. Off-label use of drugs for the treatment of cancer may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available. |

2. Background

Clinical Practice Guidelines

NCCN Categories of Evidence and Consensus

Table 1: NCCN Categories of Evidence and Consensus

<table>
<thead>
<tr>
<th>Category</th>
<th>Quality of Evidence</th>
<th>Level of Consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>High</td>
<td>Uniform</td>
</tr>
</tbody>
</table>
Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions.

Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent.

Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data.

<table>
<thead>
<tr>
<th></th>
<th>Lower</th>
<th>Uniform</th>
</tr>
</thead>
<tbody>
<tr>
<td>2A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2B</td>
<td></td>
<td>Non-uniform</td>
</tr>
<tr>
<td>3</td>
<td>Any</td>
<td>Major disagreement</td>
</tr>
</tbody>
</table>
**Category 3:** Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side’s results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy.

**DRUGDEX (Micromedex) Strength of Recommendation Ratings**

**Table 2: Strength of Recommendation**

<table>
<thead>
<tr>
<th>Class</th>
<th>Recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Recommended</td>
<td>The given test or treatment has been proven useful, and should be performed or administered.</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Recommended, In Most Cases</td>
<td>The given test or treatment is generally considered to be useful, and is indicated in most cases.</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Recommended, in Some Cases</td>
<td>The given test or treatment may be useful, and is indicated in some, but not most, cases.</td>
</tr>
<tr>
<td>Class III</td>
<td>Not Recommended</td>
<td>The given test or treatment is not useful, and should be avoided</td>
</tr>
<tr>
<td>Class Indeterminate</td>
<td>Evidence Inconclusive</td>
<td>-</td>
</tr>
</tbody>
</table>
3. References

1. Oklahoma Statute, Title 63, Article 26, Section 1-2604 - Coverage for Prescription Drugs for Cancer Treatment or Study of Oncology.
Prior Authorization Guideline

GL-39486 Daliresp (roflumilast)

Formulary UHC Core

Formulary Note
Approval Date 11/30/2017
Revision Date 11/30/2017

Technician Note:
P&T Approval Date: 11/1/2011; P&T Revision Date: 10/25/2017; Effective Date: 2/1/2018;
Oxford only: 2/1/2018

1. Indications

Drug Name: Daliresp (roflumilast)

Indications

Chronic obstructive pulmonary disease (COPD) Indicated for reducing the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.
2. Criteria

**Product Name:** Daliresp

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of severe to very severe COPD (i.e., FEV1 less than or equal to 50 percent of predicted)

   AND

2. COPD is associated with chronic bronchitis

   AND

3. History COPD exacerbation(s)

**Product Name:** Daliresp

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>
Approval Criteria

1. Documentation of positive clinical response to Daliresp therapy

3. Background

Benefit/Coverage/Program Information

Additional Clinical Programs:

Supply limits may be in place.

Background:

Daliresp (roflumilast) is a phosphodiesterase-4 inhibitor indicated for reducing the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

4. References

Prior Authorization Guideline

GL-54239 DAW Override

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>12/1/2019</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>12/19/2015</td>
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<tr>
<td>P&amp;T Revision Date:</td>
<td>10/16/2019</td>
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</table>

Technician Note:

P&T Revision Date: 4/26/2017, 12/19/2018. The intent of this policy is to serve as guidance for clients who would like to implement a dispense as written (DAW) override program. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available.
1. Criteria

<table>
<thead>
<tr>
<th>Product Name: Brand drugs with two or more generic equivalents available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - Patient has tried two generic equivalents of the requested drug from different manufacturers

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

3.1 Requested drug is FDA-approved for the condition being treated

OR

3.2 If requested for an off-label indication, the off-label guideline approval criteria have been met
Product Name: Brand drugs with only one generic equivalent available

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Patient has tried one generic equivalent of the requested drug from a different manufacturer

   AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

   OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

   AND

3 - One of the following:

3.1 Requested drug is FDA-approved for the condition being treated

   OR

3.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

---

2. **Endnotes**

A. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a
provider/patient requests for coverage of a brand medication when a generic is available. There must be a clinical reason why the patient cannot take the generic version of the medication. Acceptable clinical reasons include having an inadequate response, an allergic reaction, or intolerance to two generic manufacturers of the branded product (or one if only one generic equivalent is available). Intolerance of the generic version may occur due to excipients in the generic version of the product. In order to receive approval for the prescribed drug, the prescriber will document the clinical reason as to why the patient cannot use a generic version of the product.

3. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
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</table>
Prior Authorization Guideline

GL-53961 Devices

Formulary  UHC Core

Formulary Note

Guideline Note:

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<th>Effective Date:</th>
<th>10/1/2019</th>
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<td>4/17/2019</td>
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<td>P&amp;T Revision Date:</td>
<td>7/17/2019</td>
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</table>

Technician Note:

P&T Approval Date: 04/17/2019; P&T Revision Date: 7/17/2019. **Effective Date : 10/01/2019**

1. Criteria
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<tbody>
<tr>
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</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. All of the following:

1.1 Diagnosis of one of the following:
   - atopic dermatitis
   - allergic contact dermatitis
   - radiation dermatitis

   **AND**

1.2 History of trial and failure or contraindication to two OTC emollients (e.g. Aquaphor, Eucerin, Lubriderm, white petroleum; document name and duration of trial)

   **AND**

1.3 History of trial and failure or contraindication to two topical corticosteroids (document topical corticosteroid name and duration of trial)

**Notes**

*Devices are typically excluded from coverage.*

<table>
<thead>
<tr>
<th>Product Name: Aquoral*, NeutraSal* and SalivaMax*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:
1.1 Both of the following:

1.1.1 Diagnosis of xerostomia

AND

1.1.2 History of trial and failure or contraindication to both of the following:

1.1.2.1 Saliva stimulants (e.g. sugar-free hard candies or gum)

AND

1.1.2.2 Two OTC saliva substitutes (e.g. Biotene, Mouth Kote, Oasis, SalivaSure, Salivea; document name and duration of trial)

OR

1.2 Both of the following:

1.2.1 Diagnosis of oral mucositis

AND

1.2.2 History of trial and failure or contraindication to both of the following:

- topical lidocaine
- salt and sodium bicarbonate rinse

Notes

*Devices are typically excluded from coverage.

| Approval Length | 12 Month(s) |
| Therapy Stage    | Reauthorization |
Guideline Type | Non Formulary

Approval Criteria

1 - Documentation of a positive response to therapy.

Notes | *Devices are typically excluded from coverage.

2. Background

Benefit/Coverage/Program Information

Background:

The U.S. Food and Drug Administration (FDA) classifies devices as products that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease that do not achieve their purpose through chemical action and are not dependent on metabolism to achieve their purpose. Devices are typically benefit exclusions. This program only applies when devices are covered by the plan.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References


4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/30/2019</td>
<td>7/2019 - Aquoral added to program.</td>
</tr>
</tbody>
</table>
Prior Authorization Guideline

GL-42455 Dihydroergotamine nasal spray (Migranal), Ergomar (ergotamine)

Formulary UHC Core

Formulary Note

Approval Date 5/23/2018

Revision Date 5/23/2018

Technician Note :

P&T Approval Date: 3/21/2018; P&T Revision Date: 3/21/2018; **Guideline Effective Date: 6/1/2018**

1. Indications

| Drug Name: Migranal (dihydroergotamine) nasal spray |
| Indications |
| Migraine headaches | Indicated for the acute treatment of migraine headaches with or without aura. Migranal nasal spray is not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine. |

| Drug Name: Ergomar (ergotamine) |
**Indications**

**Vascular headache** Indicated to abort or prevent vascular headache, e.g., migraine, migraine variants or a so-called "histaminic cephalalgia". Ergomar should not be used for chronic daily administration.

---

**2 . Criteria**

**Product Name:** [Dihydroergotamine Nasal Spray (Migranal*)] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate to severe migraine headaches with or without aura.

   AND

2. History of failure, contraindication, or intolerance to one oral triptan (e.g., almotriptan [Axert], naratriptan [Amerge], sumatriptan [Imitrex]). Document medication(s) and date(s) of trial.

   AND

3. History of failure, contraindication, or intolerance to one nasal triptan (e.g., sumatriptan nasal spray [generic Imitrex]). Document medication(s) and date(s) of trial.

**Notes**

*Brand Migranal is typically excluded from coverage. [a] State mandates may apply. Any federal regulatory requirements and the
Product Name: Ergomar (ergotamine) [a]

Approval Length | 12 Month
---|---
Guideline Type | Prior Authorization

**Approval Criteria**

1. Diagnosis of moderate to severe migraine headaches with or without aura.

   **AND**

2. History of failure, contraindication, or intolerance to two oral triptans (e.g., almotriptan [Axert], naratriptan [Amerge], sumatriptan [Imitrex]). Document medication(s) and date(s) of trial.

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

---

3. Background

**Benefit/Coverage/Program Information**

**Background:**

The U.S. Headache Consortium guidelines offer a general strategy based on expert consensus.
Nonsteroidal anti-inflammatory drugs (NSAIDs) or caffeine-containing combination analgesics may be first-line treatment for mild to moderate migraine, or severe migraine that has previously responded to these agents. Triptans are considered first-line abortive treatment of moderate to severe migraine, or mild attacks that have not responded to nonprescription medicines. Ergotamine-containing compounds may also be reasonable in this situation.

This program requires a member to try one oral triptan and one nasal triptan prior to receiving coverage for brand or generic Migranal or two oral triptans prior to receiving coverage of Ergomar.

Additional Clinical Programs:

*Brand Migranal is typically excluded from coverage.

Supply limits may apply.

4. References

Prior Authorization Guideline

GL-49219 Dihydroergotamine nasal spray (Migranal), Ergomar (ergotamine) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 4/29/2019

Revision Date 4/29/2019

Technician Note :

**Guideline Effective Date: 6/1/2019**

1. Indications

Drug Name: Migranal (dihydroergotamine) nasal spray

**Indications**

**Migraine headaches** Indicated for the acute treatment of migraine headaches with or without aura. Migranal nasal spray is not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.
Drug Name: Ergomar (ergotamine)

Indications

Vascular headache Indicated to abort or prevent vascular headache, e.g., migraine, migraine variants or a so-called "histaminic cephalalgia". Ergomar should not be used for chronic daily administration.

2. Criteria

Product Name: [Dihydroergotamine Nasal Spray (Migranal*)] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of moderate to severe migraine headaches with or without aura.

   AND

2. History of failure, contraindication, or intolerance to one of the following oral triptans (Document duration of trial):

   - almotriptan (Axert)
   - eletriptan (Relpax)
   - frovatriptan (Frova)
   - naratriptan (Amerge)
   - rizatriptan (Maxalt/Maxalt MLT)
   - sumatriptan (Imitrex)
   - zolmitriptan (Zomig)

   AND
3 History of failure, contraindication, or intolerance to one of the following (Document duration of trial):

- sumatriptan nasal spray (generic Imitrex nasal spray)
- zolmitriptan nasal spray (Zomig Nasal Spray)

Notes
Brand Migranal is typically excluded from coverage. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Ergomar (ergotamine) [a]</th>
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<tbody>
<tr>
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<td>12 Month</td>
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<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of moderate to severe migraine headaches with or without aura.

AND

2 History of failure, contraindication, or intolerance to two of the following oral triptans (Document duration of trial):

- almotriptan (Axert)
- eletriptan (Relpax)
- frovatriptan (Frova)
- naratriptan (Amerge)
- rizatriptan (Maxalt/Maxalt MLT)
- sumatriptan (Imitrex)
- zolmitriptan (Zomig)
3. Background

Benefit/Coverage/Program Information

Background:

The U.S. Headache Consortium guidelines offer a general strategy based on expert consensus. Nonsteroidal anti-inflammatory drugs (NSAIDs) or caffeine-containing combination analgesics may be first-line treatment for mild to moderate migraine, or severe migraine that has previously responded to these agents. Triptans are considered first-line abortive treatment of moderate to severe migraine, or mild attacks that have not responded to nonprescription medicines. Ergotamine-containing compounds may also be reasonable in this situation.

This program requires a member to try one oral triptan and one nasal triptan prior to receiving coverage for brand or generic Migranal or two oral triptans prior to receiving coverage of Ergomar.

Additional Clinical Programs:

*Brand Migranal is typically excluded from coverage.

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply.
4. References

1. Indications

**Drug Name: Onglyza (saxagliptin)**

**Indications**

**Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Januvia, Onglyza, and Tradjenta should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. Januvia, Onglyza, and Tradjenta have not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Januvia,
Drug Name: Kombiglyze XR (saxagliptin/metformin extended-release)

**Indications**

**Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. Limitations of use: Kombiglyze XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Kombiglyze XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Kombiglyze XR.

Drug Name: Nesina (alogliptin)

**Indications**

**Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings. Limitation of use: Nesina should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Drug Name: Kazano (alogliptin/metformin)

**Indications**

**Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes in multiple clinical settings when treatment with both alogliptin and metformin is appropriate. Limitation of Use: Kazano should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Drug Name: Oseni (alogliptin/pioglitazone)

**Indications**

**Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes in multiple clinical settings when treatment with both alogliptin and pioglitazone is appropriate. Limitation of Use: Oseni should not be used in patients with type 1 diabetes.
diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. Use with caution in patients with liver disease.

2. Criteria

**Product Name:** Nesina**, Kazano**, Oseni**

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

**Approval Criteria**

1 History of one of the following:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

**AND**

2 History of one of the following:

- Januvia
- Janumet
- Janumet XR

**AND**

3 History of one of the following:
Product Name: Kombiglyze XR**, Onglyza**

Guideline Type | Step Therapy
---|---

**Approval Criteria**

1 History of one of the following:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

AND

2 One of the following:

2.1 Both of the following:

2.1.1 History of one of the following:

- Janumet
- Janumet XR
- Januvia

AND

2.1.2 History of one of the following:
• Jentadueto
• Jentadueto XR
• Tradjenta

OR

2.2 For continuation of prior therapy

<table>
<thead>
<tr>
<th>Notes</th>
<th>*These products may require step therapy or prior authorization. **Product may be excluded depending on the plan.</th>
</tr>
</thead>
</table>

3. References

GL-47571 Doxepin Cream

Formulary UHC Core

Formulary Note

Approval Date 1/29/2019

Revision Date 1/29/2019

Technician Note :

P&T Approval Date: 12/21/2016; P&T Revision Date: 12/20/2017, 12/19/2018; **Effective Date: 3/1/2019**

1. Indications

Drug Name: Prudoxin and Zonalon cream

Indications

Atopic dermatitis or lichen simplex chronicus Indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
### 2. Criteria

**Product Name:** Prudoxin or Zonalon

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>1 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate pruritus due to one of the following:

1.1 Atopic dermatitis

OR

1.2 Lichen simplex chronicus

**Product Name:** Prudoxin or Zonalon

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>1 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to doxepin therapy
3. Background

Benefit/Coverage/Program Information

Background:

Prudoxin and Zonalon cream are indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

4. References

Prior Authorization Guideline

GL-49577 Dry Eye Disease – PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 5/20/2019

Revision Date 5/20/2019

Technician Note :

P&T Approval Date: 3/1/2006; P&T Revision Date: 12/21/2016, 9/27/2017, 9/19/2018, 03/20/2019; **Effective Date: 06/01/2019**

1. Indications

Drug Name: Restasis and Restasis Multidose (cyclosporine ophthalmic emulsion 0.05%)

Indications

Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Drug Name: Xiidra (lifitegrast 5% ophthalmic solution)
Indications

Dry eye disease (DED) Indicated for the treatment of the signs and symptoms of dry eye disease (DED).

2. Criteria

Product Name: Cequa*, Restasis, Restasis MultiDose* or Xiidra

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Tear deficiency associated with ocular inflammation due to 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)

AND

3 History of failure to at least one OTC artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)
AND

4 Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Cequa and Restasis MultiDose are typically excluded from coverage. |

**Product Name:** Cequa*, Restasis, Restasis MultiDose* or Xiidra

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Patient has demonstrated clinically significant improvement with therapy

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Cequa and Restasis MultiDose are typically excluded from coverage. |
3. Background

Benefit/Coverage/Program Information

Background:

Cequa™ (cyclosporine 0.09% ophthalmic solution)*, Restasis® (cyclosporine 0.05% ophthalmic emulsion) and Restasis MultiDose (cyclosporine 0.05% ophthalmic emulsion)* are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Xiidra™ (lifitegrast 5% ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place
- Prior Authorization – Notification may be in place
- Compound and Bulk powder notification may be in place

4. References

Prior Authorization Guideline

GL-55513 Duopa (carbidopa/levodopa) - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

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<th>Effective Date:</th>
<th>12/1/2019</th>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>7/14/2015</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>9/18/2019</td>
</tr>
</tbody>
</table>

1. Indications

**Drug Name: Duopa (carbidopa/levodopa)**

**Advanced Parkinson's disease** Indicated for the treatment of motor fluctuations in patients
with advanced Parkinson's disease.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Duopa</th>
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<tbody>
<tr>
<td>Approval Length</td>
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<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
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</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Product Name: Duopa</th>
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<tbody>
<tr>
<td>Approval Length</td>
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<tr>
<td>Therapy Stage</td>
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<tr>
<td>Guideline Type</td>
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</tbody>
</table>

**Approval Criteria**

1 - Documentation of positive clinical response to Duopa therapy
3. Background

**Benefit/Coverage/Program Information**

**Background:**

Duopa (carbidopa/levodopa) enteral suspension is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.

Duopa should be administered continuously via an infusion pump over 16 hours through a procedurally-placed tube. Duopa may be administered through a naso-jejunal (NJ) tube for a short period of time until a gastrostomy tube can be placed.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>10/16/2019</td>
<td>Annual review. Updated references.</td>
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</table>
Prior Authorization Guideline

GL-56172 Elidel (pimecrolimus), Protopic (tacrolimus) - Step Therapy

Formulary UHC Core

Formulary Note

Guideline Note:

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<th>Effective Date:</th>
<th>11/1/2019</th>
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<td>P&amp;T Approval Date:</td>
<td>9/27/2017</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>8/16/2019</td>
</tr>
</tbody>
</table>

1. Indications

**Drug Name: Elidel (pimecrolimus)**

Mild to moderate atopic dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond
adequately to other topical prescription treatments, or when those treatments are not advisable.

Drugs Name: Protopic (tacrolimus)

**Moderate to severe atopic dermatitis** Indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Elidel[a], Protopic [a]</th>
</tr>
</thead>
</table>
| Approval Length                     | 12 Month(s) │
| Guideline Type                      | Step Therapy |

Approval Criteria

1 - One of the following:

1.1 History of failure, contraindication, or intolerance to one topical corticosteroid

OR

1.2 Drug is being prescribed for the facial or groin area

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

**Benefit/Coverage/Program Information**
**Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

**Background:**

Elidel (pimecrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable. Protopic (tacrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable.

Both Elidel and Protopic have demonstrated efficacy in the treatment of plaque psoriasis, and the American Academy of Dermatology recommend Elidel and Protopic for specific cases of facial and intertriginous psoriasis or situations where a topical corticosteroid may be associated with skin atrophy³.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. If a member has a prescription for a topical corticosteroid in claim’s history in the previous 365 days, the prescription for Elidel or Protopic will process automatically. Elidel or Protopic as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the below criteria.

---

**4. References**

## 5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
</table>
1. Indications

**Drug Name: Endari (L-glutamine Powder for Solution)**

**Indications**

**Acute complications of sickle cell disease** Indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.
2. Criteria

Product Name: Endari

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</table>

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

   AND

3 Patient has had 2 or more painful sickle cell crises within the past 12 months

   AND

4 History of failure to non-prescription L-glutamine supplementation
Product Name: Endari

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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</tbody>
</table>

Approval Criteria

1. Documentation of positive clinical response to Endari therapy

3. Background

Benefit/Coverage/Program Information

Background:

Endari (L-glutamine powder for solution) is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older. The recommended dose is 5 to 15 grams orally twice daily based on body weight.

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place
4. References

1. Indications

**Drug Name: Entresto (valsartan-sacubitril)**

**Indications**

**Chronic Heart Failure** Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure patients with chronic heart failure and reduced ejection fraction.
2. Criteria

Product Name: Entresto

<table>
<thead>
<tr>
<th>Approval Length</th>
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<tbody>
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<td>Therapy Stage</td>
<td>Initial Authorization</td>
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<td>Guideline Type</td>
<td>Prior Authorization</td>
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</table>

Approval Criteria

1 One of the following:

1.1 As continuation of therapy initiated during an inpatient stay

OR

1.2 All of the following:

1.2.1 Diagnosis of heart failure (with or without hypertension)

AND

1.2.2 Ejection fraction is less than or equal to 40 percent

AND

1.2.3 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

1.2.4 One of the following:
1.2.4.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following beta-blockers:

- bisoprolol
- carvedilol
- metoprolol

**OR**

1.2.4.2 Patient has a contraindication or intolerance to beta-blocker therapy

**AND**

1.2.5 Patient does not have a history of angioedema

**AND**

1.2.6 Patient will discontinue any use of concomitant ACE Inhibitor or ARB before initiating treatment with Entresto. ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto

**AND**

1.2.7 Patient is not concomitantly on aliskiren therapy

**AND**

1.2.8 Entresto is prescribed by, or in consultation with, a cardiologist

**Product Name:** Entresto

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<td>Reauthorization</td>
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<td>Guideline Type</td>
<td>Prior Authorization</td>
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</table>

**Approval Criteria**
1 The Entresto dose has been titrated to a dose of 97 mg/103 mg twice daily, or to a maximum dose as tolerated by the patient

AND

2 Documentation of positive clinical response to therapy

3 . Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

Background

Entresto (valsartan-sacubitril) is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure patients with chronic heart failure and reduced ejection fraction.

4 . References


1. Indications

**Drug Name**: Levitra (vardenafil), Muse (alprostadil), Staxyn (vardenafil), Stendra (avanafil), and Viagra (sildenafil)

**Indications**

**Erectile dysfunction** Indicated for the treatment of erectile dysfunction (ED).

**Drug Name**: Cialis (tadalafil)

**Indications**
Erectile Dysfunction Indicated for the treatment of erectile dysfunction (ED)

Benign Prostatic Hyperplasia Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Limitation of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

Erectile Dysfunction and Benign Prostatic Hyperplasia Indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH). Limitation of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

2. Criteria

Product Name: Cialis (2.5 mg, 5 mg, 10 mg, 20 mg), Levitra, Muse, Staxyn, Stendra, or Viagra

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Erectile Dysfunction</th>
</tr>
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<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non-Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Provided it is not a benefit exclusion

2. Diagnosis of organic erectile dysfunction as defined by one of the following:

2.1. Both of the following:
2.1.1 The patient has an underlying condition [e.g., atherosclerosis, cardiac disease (e.g., hypertension, peripheral arterial disease), diabetes, central nervous system disease, multiple sclerosis, renal disease, hypogonadism, history of cystectomy, prostate cancer, spinal injuries] [6-7]  

AND  

2.1.2 Physician confirmation that the underlying condition is causing the patient's ED [6,7]  

OR  

2.2 All of the following:  

2.2.1 The patient's ED is caused by one of the following drugs:  

- Cardiovascular drugs [eg, thiazide diuretics, Aldactone (spironolactone), Aldomet (methyldopa), Catapres (clonidine), Wytensin (guanabenz), Tenex (guanfacine), Tenormin (atenolol), Lopressor/Toprol XL (metoprolol), Visken (pindolol), Inderal (propranolol), Cardura (doxazosin), Minipress (prazosin), Hytrin (terazosin), Dibenzyline (phenoxybenzamine), Apresoline (hydralazine), Adalat/Procardia (nifedipine), Cardizem/Tiazac (diltiazem), Calan/Verelan (verapamil), Norpace (disopyramide)] [8]  
- Anticonvulsants [eg, Tegretol (carbamazepine), Dilantin (phenytoin)] [8]  
- Antidepressants [eg, TCAs, SSRIs, Desyrel (trazodone), MAO inhibitors] [7]  
- Antipsychotics [eg, phenothiazines] [7]  
- Anxiolytics [eg, short-acting barbiturates, benzodiazepines] [7]  
- Gastrointestinal drugs [eg, Tagamet (cimetidine), Zantac (ranitidine), Reglan (metoclopramide)] [7]  

AND  

2.2.2 Physician confirmation that the drug is causing the patient's ED [6,7]  

AND  

2.2.3 ED-causing drug cannot be discontinued or switched [6,7]  

Notes  

Cialis, Levitra, Staxyn, Stendra, and Viagra are NOT indicated for the treatment of pulmonary arterial hypertension (PAH). Adcirca and Revatio are the only PDE-5 inhibitors currently FDA-approved for the treatment of PAH. Adcirca and Revatio may require prior authorization.  

Product Name: Cialis 2.5 mg or Cialis 5 mg
Diagnosis  | Benign Prostatic Hyperplasia (BPH)  
---|---
Guideline Type  | Prior Authorization or Non-Formulary  

**Approval Criteria**

1. Diagnosis of benign prostatic hyperplasia (BPH)

    **AND**

2. History of failure, contraindication or intolerance to two alpha blockers [e.g., Flomax (tamsulosin), Rapaflo (silodosin), Uroxatral (alfuzosin)]

**Notes**  | Cialis is NOT indicated for the treatment of pulmonary arterial hypertension (PAH). Adcirca and Revatio are the only PDE-5 inhibitors currently FDA-approved for the treatment of PAH. Adcirca and Revatio may require prior authorization.

### 3. Definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organic erectile dysfunction</td>
<td>A consequence of chronic medical conditions that results in impaired arterial blood flow or nerve damage, mixed organic/psychogenic causes, or necessary use of medications that cannot be reduced or discontinued. [6-7]</td>
</tr>
</tbody>
</table>
4. References

GL-49902 Erleada (apalutamide)

Formulary UHC Core

Formulary Note

Approval Date 6/24/2019

Revision Date 6/24/2019

Technician Note:

P&T Approval: 5/18/2018; ** P&T Revision Date: 5/17/19; Guideline Effective Date: 8/1/2019**

1. Indications

Drug Name: Erleada (apalutamide)

Indications

Prostate cancer Indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.
2. Criteria

**Product Name:** Erleada

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Patients less than 19 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient is less than 19 years of age

**Product Name:** Erleada

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of prostate cancer

   AND

2. Disease is castration-resistant or recurrent

   AND
3 Disease is non-metastatic

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: Erleada

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Patient does not show evidence of progressive disease while on Erleada therapy
3. Background

### Benefit/Coverage/Program Information

#### Background

Erleada (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Erleada or should have had bilateral orchietomy.[1]

#### Coverage Information

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

#### Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References

1. Erleada [package insert]. Horsham, PA: Janssen Products LP. February 2018
1. Indications

**Drug Name: Eucrisa (crisaborole)**

**Indications**

**Mild to moderate atopic dermatitis** Indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.
2. Criteria

**Product Name:** Eucrisa* [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>All Diagnoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:

1.1 History of failure, contraindication, or intolerance to both of the following topical therapies:

- One topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

OR

1.2 Both of the following:

1.2.1 Patient is currently on Eucrisa therapy

AND

1.2.2 Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer sponsored Eucrisa 4 you program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Eucrisa*

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer sponsored Eucrisa 4 you program shall be required to meet initial
3. Background

**Benefit/Coverage/Program Information**

**Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one or more preferred topical products before providing coverage for Eucrisa (crisaborole).

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

The American Academy of Dermatology guidelines for the care and management of atopic dermatitis recommend topical corticosteroids for patients with atopic dermatitis who have failed to respond to standard nonpharmacologic therapy. They also recommend the use of topical calcineurin inhibitors (tacrolimus, pimecrolimus) in patients who have failed to respond to, or who are not candidates for topical corticosteroid treatment.

Elidel® (pimecrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
Protopic® (tacrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable.

Patients currently on Eucrisa therapy as documented in claims history will be allowed to continue on their current therapy. For patients with claims history documenting prior use of both topical corticosteroids and topical calcineurin inhibitors, a prescription for Eucrisa will automatically process.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References

Prior Authorization Guideline

GL-13119 Exforge (amlodipine/valsartan), Exforge HCT (amlodipine/valsartan/HCTZ)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 7/15/2015

Technician Note :

CPS Approval Date: 10/2/2007; CPS Revision Date: 7/14/2015

1. Indications

**Drug Name: Exforge (amlodipine and valsartan)**

**Indications**

**Hypertension**

Indicated for the treatment of hypertension, to lower blood pressure: (1) In patients not adequately controlled on monotherapy; (2) As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
Drug Name: Exforge HCT (amlodipine, valsartan, hydrochlorothiazide)

Indications

Hypertension

Indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes, and myocardial infarctions. Not indicated for initial therapy.

2. Criteria

Product Name: Brand Exforge, Generic amlodipine/valsartan, or Brand Exforge HCT

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1 History of one of the following:

- ACE Inhibitor
- ACE Inhibitor / HCTZ Combination
- ACE Inhibitor / Calcium Channel Blocker (CCB) Combination
- Candesartan
- Irbesartan or Irbesartan / HCTZ
- Losartan or Losartan / HCTZ
- Telmisartan

Notes | Exforge or Exforge HCT may be approved for patients who have tried an ARB or ARB combination.
3. References

Prior Authorization Guideline

GL-49776 Fanapt (iloperidone), Fanapt Pack (iloperidone), Vraylar (cariprazine) - Step Therapy

Formulary UHC Core

Formulary Note

Approval Date 5/28/2019

Revision Date 5/28/2019

Technician Note:

P&T Approval Date: 3/20/2019. **Guideline Effective Date: 6/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Fanapt (iloperidone)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Schizophrenia Indicated for the treatment of schizophrenia.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Vraylar (cariprazine)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
</tbody>
</table>
Schizophrenia  Indicated for the treatment of schizophrenia.

Bipolar I Disorder  Indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder.

2. Criteria

Product Name: [Fanapt, Fanapt Pak, or Vraylar] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
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</tbody>
</table>

Approval Criteria

1. One of the following:

1.1 History of failure, contraindication, or intolerance to at least two of the following (please document drug, date and duration of trial):

- aripiprazole
- olanzapine
- quetiapine immediate-release
- risperidone
- Saphris
- quetiapine extended-release
- ziprasidone

OR

1.2 Treatment with Fanapt, Fanapt Pack, or Vraylar was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

Notes  [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage.
3. Background

<table>
<thead>
<tr>
<th>Benefit/Coverage/Program Information</th>
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<tbody>
<tr>
<td>Background:</td>
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</tbody>
</table>

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Fanapt (iloperidone) is FDA approved for the treatment of schizophrenia. Vraylar (cariprazine) is FDA approved for the acute treatment of manic or mixed episodes associated with bipolar I disorder and for the treatment of schizophrenia.

For the treatment of schizophrenia, treatment guidelines recommend the use of any atypical antipsychotic (with the exception of clozapine) as first-line. For the acute treatment of bipolar I disorder (mania or mixed episodes), the American Psychiatric Association (APA) recommends treatment with lithium plus an antipsychotic or valproate plus an antipsychotic. For less ill patients, monotherapy with lithium, valproate, or an antipsychotic may be sufficient. Atypical antipsychotics are generally preferred over traditional antipsychotics.

This program requires a member to try two atypical antipsychotics (choices include aripiprazole, risperidone, olanzapine, ziprasidone, Saphris, quetiapine IR or quetiapine ER) before providing coverage for Fanapt or Fanapt Pack for schizophrenia or for Vraylar for schizophrenia or bipolar I disorder.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
Supply limits may also be in place.

4. References

1. Indications

**Drug Name:** Abstral, Actiq, Fentora, Lazanda, Subsys, and fentanyl citrate lozenges (generic Actiq)

**Indications**

**Breakthrough cancer pain** Indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain.

2. Criteria

**Product Name:** Fentanyl citrate lozenges (generic Actiq) [a]
Approval Length | 12 Month
---|---
Guideline Type | Prior Authorization

**Approval Criteria**

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records demonstrating use is for the management of pain associated with a cancer diagnosis (cancer diagnosis must be documented).

**AND**

1.1.2 Use is for the management of breakthrough cancer pain.

**AND**

1.1.3 Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids:

- 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
- 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
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

**AND**

1.1.4 The patient is currently taking a long-acting opioid around the clock for cancer pain.

**AND**

1.1.5 One of the following:
1.1.5.1 The patient is not concurrently receiving an alternative transmucosal fentanyl product.

OR

1.1.5.2 The patient is currently receiving an alternative transmucosal fentanyl product AND 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.

OR

1.2 The patient is currently taking fentanyl citrate lozenges (generic Actiq) and does not meet the notification criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

<table>
<thead>
<tr>
<th>Notes</th>
<th>[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</th>
</tr>
</thead>
</table>

**Product Name:** [Abstral*, Actiq* (brand only), Fentora*, Subsys*] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary or Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records demonstrating all of the following:

1.1.1.1 Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)
1.1.1.2 Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids:

- 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
- 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
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

1.1.1.3 The patient is currently taking a long-acting opioid around the clock for cancer pain

1.1.1.4 The patient has a history of failure, contraindication, or intolerance to fentanyl citrate lozenges (generic Actiq)

1.1.1.5 The patient has a history of failure, contraindication, or intolerance to Lazanda

1.1.1.6 One of the following:

1.1.1.6.1 The patient is not concurrently receiving an alternative transmucosal fentanyl product

OR

1.1.1.6.2 The patient is currently receiving an alternative transmucosal fentanyl product AND 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.

OR
1.2 The patient is currently taking Abstral*, Actiq*, Fentora*, or Subsys* and does not meet the notification criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

Notes

*Abstral, Actiq (Brand ONLY), fentanyl bulk powder, Subsys and Fentora are typically excluded from coverage. Please refer to plan specifics to determine coverage status. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Lazanda [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records demonstrating all of the following:

1.1.1.1 Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

1.1.1.2 Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids:

- 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
- 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
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or
equal to 20 mg/day)

AND

1.1.1.3 The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

1.1.1.4 One of the following:

1.1.1.4.1 The patient has a history of failure, contraindication, or intolerance to fentanyl citrate lozenges (generic Actiq)

OR

1.1.1.4.2 Medical records demonstrate that the patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting.

AND

1.1.1.5 One of the following:

1.1.1.5.1 The patient is not concurrently receiving an alternative transmucosal fentanyl product

OR

1.1.1.5.2 The patient is currently receiving an alternative transmucosal fentanyl product AND 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.

OR

1.2 The patient is currently taking Lazanda and does not meet the notification criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may
Product Name: [Fentanyl citrate bulk powder* or compounded fentanyl] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary or Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following criteria:

1.1 All of the following:

1.1.1 Submission of medical records demonstrating all of the following:

1.1.1.1 Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

1.1.1.2 Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids:

- 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
- 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
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

1.1.1.3 The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

1.1.1.4 A unique dosage form is required for a product that is not commercially available due to
patient’s age or weight

AND

1.1.1.5 One of the following:

1.1.1.5.1 The patient is not concurrently receiving an alternative transmucosal fentanyl product

OR

1.1.1.5.2 The patient is currently receiving an alternative transmucosal fentanyl product AND 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.

OR

1.2 The patient is currently taking a compounded fentanyl citrate product and does not meet the notification criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

Notes

*Abstral, Actiq (Brand ONLY), fentanyl bulk powder, Subsys and Fentora are typically excluded from coverage. Please refer to plan specifics to determine coverage status. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

Benefit/Coverage/Program Information

Background:
Abstral, Actiq, Fentora, Lazanda, Subsys, and fentanyl citrate lozenges (generic Actiq) are rapid-acting opioid analgesics indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg/hour of transdermal fentanyl, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg of oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids while taking a rapid-acting fentanyl product. Abstral, Actiq, Fentora, Lazanda, Subsys and fentanyl citrate lozenges (generic Actiq) must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not on a chronic regimen of opiates.

Dosage form differences provide alternatives for patients who are unable to swallow, have dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting.

Compounded fentanyl preparations may provide a unique delivery for certain patient-specific conditions and administration requirements. Compounded fentanyl preparations should be made for a single individual and not produced on a large scale. Compounded fentanyl preparations should not be covered if it is being prescribed as an alternative for a commercially available fentanyl product. Therefore, additional criteria will be provided for fentanyl citrate compounds.

**Additional Clinical Programs:**

Supply limits may be in place.

---

**4. References**

1. Indications

**Drug Name:** Fenofibrates (Fenoglide and Triglide)

**Indications**

**Primary Hypercholesterolemia and Mixed Dyslipidemia** Indicated as adjunctive therapy to diet to reduce elevated LDL-C, Total-C, triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

**Severe Hypertriglyceridemia** Indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia. Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually reduce fasting triglycerides and eliminate
chylomicronemia thereby obviating the need for pharmacologic intervention. Markedly elevated levels of serum triglycerides (eg, > 2000 mg/dL) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied.

2. Criteria

**Product Name:** Fenoglide, Brand Fenofibrate tablets (40 mg, 120 mg), or Brand Triglide

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approval Criteria</strong></td>
<td></td>
</tr>
</tbody>
</table>

1 History of both of the following:

1.1 One of the following generics:

- fenofibrate micronized capsule
- fenofibrate tablet (except 40 and 120 mg)
- fenofibric capsule
- fenofibric acid tablet

   and

1.2 Lipofen

3. References
2. Triglide Prescribing Information. Shionogi Pharma, April 2015.
1. Indications

Drug Name: Finacea (azelaic acid)

Indications

Rosacea indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.
## 2. Criteria

**Product Name:** Finacea

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Trial and failure, contraindication, or intolerance to Soolantra

## 3. References

GL-6004 Flurazepam

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 3/21/2013

Technician Note:

CPS Approval Date: 7/10/2012

1. Indications

Drug Name: Flurazepam [1]

Indications

Insomnia

Flurazepam is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakening. Flurazepam can be used effectively in patients with recurring insomnia or poor sleeping habits, and in acute or chronic medical situations requiring restful sleep. Sleep laboratory studies have objectively determined that flurazepam is effective for at least 28 consecutive nights of drug administration. Since insomnia is often transient and intermittent short-term use is usually sufficient. Prolonged use of hypnotics
is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

2. Criteria

**Product Name:** Flurazepam*

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Approval Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 Diagnosis of insomnia</td>
</tr>
</tbody>
</table>

**Notes:** * Flurazepam is only recommended for patients < 65 years old. [3-4, A]

3. Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flurazepam - Insomnia</td>
<td>30 mg before bedtime. In some patients, 15 mg may suffice.</td>
</tr>
</tbody>
</table>

4. Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flurazepam</td>
<td>15 mg, 30 mg capsules</td>
</tr>
</tbody>
</table>
5. Background

Clinical Practice Guidelines


Pharmacological Treatment

According to the American Academy of Sleep Medicine guideline for the management of chronic insomnia (2008), the choice of pharmacologic agent should be based on the following factors: symptom pattern, treatment goals, past treatment, patient preference, cost, availability of other treatments, comorbid conditions, contraindications, concurrent medication interactions, and AEs. The short/intermediate-acting benzodiazepine receptor agonists (BzRAs) (eg, zolpidem, eszopiclone, zaleplon, temazepam) or ramelteon are recommended as initial therapy. No specific agent within this group is considered preferable to the others, as each has been shown to have positive effects on sleep latency, total sleep time, and/or wake time after sleep onset (WASO) in placebo-controlled trials. However, individual patients may respond differently to these medications. For example, zaleplon and ramelteon have very short half-lives and consequently are likely to reduce sleep latency but have little effect on WASO; they are also unlikely to result in residual sedation. Eszopiclone and temazepam have relatively longer half-lives, are more likely to improve sleep maintenance, and are more likely to produce residual sedation. Triazolam has been associated with rebound anxiety and thus is not considered a first-line hypnotic. For patients who prefer not to use a DEA-scheduled drug and for patients with a history of substance use disorders, ramelteon may be an appropriate option. In the event that a patient does not respond well to the initial agent, a different agent within the same class is appropriate.

Selection of the alternative drug should be based on the patient’s response to the first. For instance, a patient who continues to complain of WASO might be prescribed a drug with a longer half-life or a patient who complains of residual sedation might be prescribed a shorter-acting drug. The choice of a specific BzRA may include longer-acting hypnotics, such as estazolam. Flurazepam is rarely prescribed because of its extended half-life. Benzodiazepines not specifically approved for insomnia (eg, lorazepam, clonazepam) might also be considered if the duration of action is appropriate for the patient’s presentation or if the patient has a comorbid condition that might benefit from these drugs. When accompanied with comorbid depression or in the case of other treatment failures, sedating low-dose antidepressants may next be considered. Examples of these drugs include trazodone, mirtazapine, doxepin, amitriptyline, and trimipramine. Although the guideline states that evidence for their efficacy when used alone is relatively weak and that no specific agent within this group is recommended as preferable to the others in this group, it should be noted that low-dose doxepin was not yet FDA-approved at the time these
recommendations were published. Chloral hydrate, barbiturates, and “non-barbiturate non-benzodiazepine” drugs such as meprobamate are not recommended for the treatment of insomnia, given their significant AEs, low therapeutic index, and likelihood of tolerance and dependence.

6. Endnotes

A. These drugs are included either on the 2012 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) or in the American Geriatrics Society 2012 Beers Criteria update. [3-4]

7. References

Prior Authorization Guideline

GL-55516 Fortamet (metformin extended-release, brand and generic), Glucophage XR (metformin extended-release, brand only) and Glumetza (metformin extended-release, brand and generic) - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

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<thead>
<tr>
<th>Effective Date:</th>
<th>12/1/2019</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>5/21/2014</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>9/18/2019</td>
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</table>

1. Criteria
<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - History of greater than or equal to 12 week trial \([b]\) of metformin extended-release (generic Glucophage XR)

   **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 following:
   
   - For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients 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)

   **AND**

3 - History of greater than or equal to 12 week trial \([b]\) of metformin immediate-release

   **AND**

4 - One of the following:

   4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release as evidenced by the following:
- For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

**OR**

4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

| Notes | *Typically excluded from coverage. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business only a 30 day trial will be required. |

Product Name: [Glumetza* or Fortamet (brand only)*] [a, b]

| Approval Length | 12 Month(s) |
| Guideline Type | Prior Authorization |

**Approval Criteria**

1 - 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**

2 - History of greater than or equal to 12 week trial[b] of metformin extended-release (generic Glucophage XR)

    **AND**

3 - One of the following:

3.1 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 following:
- For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

   OR

3.2 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

4 - History of greater than or equal to 12 week trial[b] of metformin extended-release (generic Fortamet).

   AND

5 - One of the following:

   5.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet) as evidenced by the following:

       • For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

        OR

   5.2 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

6 - History of greater than or equal to 12 week trial[b] of metformin immediate-release

   AND

7 - One of the following:
7.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release as evidenced by the following:

- For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

OR

7.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

Notes

Typically excluded from coverage. [a]State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply [b]For Connecticut and Kentucky business only a 30 day trial will be required.

2. Background

Benefit/Coverage/Program Information

Background:

According to the American Diabetes Association (ADA) metformin is the preferred initial pharmacological agent for type 2 diabetes if not contraindicated. Fortamet, Glucophage XR and Glumetza only differ in their extended-release formulation technology and excipient content. Treatment guidelines do not specify which metformin formulation should be selected for diabetes management.

This program requires a member to try metformin immediate-release (generic Glucophage) and metformin extended-release (generic Glucophage XR) prior to receiving coverage for Glucophage XR (brand only) and metformin extended-release (generic Fortamet)* and also requires an additional trial of metformin extended-release (generic Fortamet)* prior to receiving coverage for Glumetza * or Fortamet (brand only)*.

Additional Clinical Programs:

- Typically excluded from coverage.

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-
authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References

1. American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2019. Diabetes Care 2019: Jan; 42 (Supplement 1)

4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>10/16/2019</td>
<td>Annual review. References updated, added automation language.</td>
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</table>
Prior Authorization Guideline

GL-49784 Glaucoma Agents - Step Therapy

Formulary UHC Core

Formulary Note

Approval Date 5/28/2019

Revision Date 5/28/2019

Technician Note :

P&T Approval Date: 8/17/2018; P&T Revision Date: 3/20/2019; **Guideline Effective Date: 6/1/2019**

1. Indications

Drug Name: Vyzulta (latanoprostene)

Indications

Intraocular pressure Indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
2 . Criteria

Product Name: Vyzulta* [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1 History of failure, contraindication or intolerance to latanoprost (generic Xalatan)

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Vyzulta is typically excluded from coverage.

3 . Background

Benefit/Coverage/Program Information

Background:

Vyzulta (latanoprostene) is an ophthalmic agent indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try latanoprost (generic Xalatan) before providing coverage for Vyzulta.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
Supply limits may also be in place.

4. References

Prior Authorization Guideline

GL-56619 GLP-1 Agonists

Formulary UHC Core

Formulary Note

Guideline Note:

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<tr>
<td>P&amp;T Approval Date:</td>
<td>6/7/2005</td>
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<tr>
<td>P&amp;T Revision Date:</td>
<td>12/18/2019</td>
</tr>
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</table>

1. Indications

**Drug Name: Adlyxin (lixisenatide)**

**Type 2 Diabetes Mellitus** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other
antidiabetic therapies in patients with a history of pancreatitis. Adlyxin is not for treatment of
type 1 diabetes or diabetic ketoacidosis. Adlyxin has not been studied in combination with short
acting insulin. Adlyxin has not been studied in patients with gastroparesis and is not
recommended in patients with gastroparesis.

<table>
<thead>
<tr>
<th>Drug Name: Byetta (exenatide injection)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes Mellitus</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Byetta is not a substitute for insulin. Byetta should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. The concurrent use of Byetta with prandial insulin has not been studied and cannot be recommended. Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Bydureon/Bydureon BCise (exenatide extended-release)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes Mellitus</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: the medication is not recommended as first-line therapy for patients inadequately controlled on diet and exercise. The medication should not be used to treat type 1 diabetes or diabetic ketoacidosis. Use with insulin has not been studied and is not recommended. The medication is an extended-release formulation of exenatide. Do not coadminister with other exenatide containing products. The medication has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Ozempic (semaglutide)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes Mellitus</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus because of the uncertain relevance of rodent C-cell tumor findings to humans. Limitations of use: Ozempic is not recommended as first-line therapy for patients inadequately controlled on diet and exercise. Ozempic has not been studied in patients with a history of pancreatitis, consider another antidiabetic therapy. Ozempic is not a substitute for insulin. Ozempic is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Trulicity (dulaglutide)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes Mellitus</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Trulicity is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. Prescribe Trulicity only to patients for whom the potential benefits outweigh the potential risk. Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. Trulicity should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Trulicity is not a substitute for insulin. Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. The use of Trulicity is not recommended in patients with pre-existing severe gastrointestinal disease.</td>
</tr>
</tbody>
</table>
Drug Name: Victoza (liraglutide injection)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: Victoza is not a substitute for insulin. Victoza should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. The concurrent use of Victoza and prandial insulin has not been studied.

2. Criteria

Product Name: Byetta, Bydureon/Bydureon BCise, Ozempic, Trulicity, Victoza

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - Trial and failure, contraindication, or intolerance to one of the following generics:

- Metformin
- Metformin ER
- Glipizide-metformin
- Glyburide-metformin
- Pioglitazone-metformin

Product Name: Adlyxin

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - Trial and failure, contraindication, or intolerance to one of the following generics:
• Metformin
• Metformin ER
• Glipizide-metformin
• Glyburide-metformin
• Pioglitazone-metformin

AND

2 - Trial and failure or intolerance to one of the following preferred brands:

• Bydureon/Bydureon BCise
• Byetta

AND

3 - Trial and failure or intolerance to one of the following preferred brands:

• Ozempic
• Trulicity
• Victoza

Notes

*These products may require step therapy or prior authorization. **Product may be excluded depending on the plan.

3. References

## 4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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<tbody>
<tr>
<td>11/6/2019</td>
<td>no updates</td>
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</table>
Prior Authorization Guideline

GL-32318 Glucovance

Formulary UHC Core

Formulary Note

Approval Date 10/28/2016

Revision Date 10/28/2016

Technician Note:

CPS Approval Date: 3/16/2001; P&T Revision Date: 10/28/2016 According to Texas State Law, all diabetic medications used for the treatment of diabetes shall be covered.

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Glucovance (glyburide/metformin)</th>
</tr>
</thead>
</table>

**Indications**

**Type 2 Diabetes [1-4]** Indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
2. Criteria

Product Name: Glucovance

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1. History of one of the following: [1, 2]
   - metformin [eg, Glucophage (metformin), Glucophage XR (metformin extended release)]
   - sulfonylurea [eg, Diabeta, Micronase (glyburide), Glucotrol (glipizide)]

3. Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucovance - Initial therapy starting dose: [1, 2]</td>
<td>1.25/250 mg once or twice daily with meals. Dose should be individualized and titrated to therapeutic effect. 5/500 mg should not be used as initial therapy due to increased risk of hypoglycemia.</td>
</tr>
<tr>
<td>Glucovance - Dose in patients with inadequate glycemic control on a sulfonylurea and/or metformin: [1, 2]</td>
<td>2.5/500 mg or 5/500 mg twice daily with meals. Should not be started at a dose that exceeds the dose of glyburide (or equivalent dose of another sulfonylurea) or metformin already being taken.</td>
</tr>
<tr>
<td>Metaglip - Initial therapy starting dose: [1, 2]</td>
<td>2.5 mg/250 mg once a day with a meal.</td>
</tr>
<tr>
<td>Metaglip - Initial therapy starting dose for patients whose fasting plasma glucose is 280 mg/mL-320 mg/mL: [1, 2]</td>
<td>2.5 mg/500 mg twice a day should be considered.</td>
</tr>
<tr>
<td>Metaglip - Dose for patients not 2.5 mg/500 mg or 5 mg/500 mg twice daily with the morning</td>
<td></td>
</tr>
</tbody>
</table>
adequately controlled on either glipizide (or another sulfonylurea) or metformin alone: [1, 2] or evening meals.

4. Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucovance</td>
<td>Is available in: (1) 1.25 mg glyburide /250 mg metformin tablets; (2) 2.5 mg glyburide /500 mg metformin tablets; (3) 5 mg glyburide /500 mg metformin tablets</td>
</tr>
<tr>
<td>Metaglip</td>
<td>Is available as: (1) 2.5 mg glipizide /250 mg metformin tablets; (2) 2.5 mg glipizide /500 mg metformin tablets; (3) 5 mg glipizide /500 mg metformin tablets</td>
</tr>
</tbody>
</table>

5. Background

Clinical Practice Guidelines

American Diabetes Association (2011) [3, 6]

<table>
<thead>
<tr>
<th>Summary of antidiabetic interventions for type 2 diabetes [3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions</td>
</tr>
<tr>
<td>Tier 1: Well-validated Core Therapies</td>
</tr>
<tr>
<td>Step 1: initial therapy</td>
</tr>
<tr>
<td>Lifestyle to decrease weight and increase activity</td>
</tr>
<tr>
<td>Metformin</td>
</tr>
</tbody>
</table>
### Step 2: additional therapy

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Dose Range</th>
<th>Effect</th>
<th>Benefits/Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>1.5 – 3.5</td>
<td>No dose limit, rapidly effective, improved lipid profile</td>
<td>One to four injections daily, monitoring, hypoglycemia, weight gain, analogues are expensive</td>
</tr>
<tr>
<td>Sulfonlureas</td>
<td>1 – 2</td>
<td>Rapidly effective</td>
<td>Weight gain, hypoglycemia (especially with glibenclamide or chlorpropamide)</td>
</tr>
</tbody>
</table>

### Tier 2: Less Well-validated Therapies

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Dose Range</th>
<th>Effect</th>
<th>Benefits/Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>TZDs</td>
<td>0.5 – 1.4</td>
<td>Improved lipid profile</td>
<td>Fluid retention, CHF, weight gain, bone fractures, expensive, potential increase in MI (rosiglitazone)</td>
</tr>
<tr>
<td>GLP-1 agonist (exenatide)</td>
<td>0.5 – 1.0</td>
<td>Weight loss</td>
<td>Two injections daily, frequent GI side effects, long-term safety not established, expensive</td>
</tr>
</tbody>
</table>

### Other drugs

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Dose Range</th>
<th>Effect</th>
<th>Benefits/Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-Glucosidase inhibitors</td>
<td>0.5 – 0.8</td>
<td>Weight neutral</td>
<td>Frequent GI side effects, three times/ day dosing, expensive</td>
</tr>
<tr>
<td>Glinides (meglitinides)†</td>
<td>0.5 – 1.5†</td>
<td>Rapidly effective</td>
<td>Three times/day dosing, expensive, weight gain, hypoglycemia</td>
</tr>
<tr>
<td>Pramlintide (Symlin®)</td>
<td>0.5 – 1.0</td>
<td>Weight loss</td>
<td>Three injections daily, frequent GI side effects, expensive, long-term safety not established</td>
</tr>
<tr>
<td>DPP-4 inhibitor (sitagliptin)</td>
<td>0.5 – 0.8</td>
<td>Weight neutral</td>
<td>Long-term safety not established, expensive</td>
</tr>
</tbody>
</table>

†Repaglinide is more effective at lowering A1C than nateglinide.

GI, gastrointestinal; CHF, congestive heart failure; MI, myocardial infarction

TZD (glitizones): Actos, Avandia; Alpha-glucosidase inhibitors: Precose, Glyset;

Glinides (meglitinides): Prandin, Starlix
The AACE/ACE recommends achieving an A1C of less than or equal to 6.5%, with an emphasis on minimizing the risk of hypoglycemia and weight gain. The AACE/ACE algorithm is stratified by the patient’s current A1C level and, as with the ADA, positions lifestyle modifications and metformin as first-line therapy.

In patients with an A1C of 7.5% or lower, initial monotherapy with metformin or, alternatively, a DPP-4 inhibitor, GLP-1 receptor agonist, TZD, or AGI, is recommended. If monotherapy fails to achieve the A1C goal of less than or equal to 6.5%, then dual therapy should be started by adding one of the following agents in this preferential order based on hypoglycemia risk: GLP-1 receptor agonist, DDP-4 inhibitor, TZD, glinide, or SU. When metformin is contraindicated or not tolerated, a TZD with either a GLP-1 receptor agonist or DPP-4 inhibitor may be used. Two additional second-line therapy options included in the algorithm for this A1C group only are colesevelam and AGI. These agents are included because of their minimal risk of hypoglycemia and the ability of colesevelam to lower the LDL cholesterol levels. If dual therapy fails, then triple therapy or insulin therapy should be started.

In patients with an A1C between 7.6% and 9.0%, one should begin with dual therapy because monotherapy is unlikely to be successful in this group. Metformin is again the foundation of therapy with either a GLP-1 agonist or a DPP-4 inhibitor as the preferred second component due to their low risk of hypoglycemia, efficacy in reducing postprandial glucose excursions, and beneficial or neutral effect on weight. Alternatively, a TZD, SU, or glinide may be used in this preferential order as second components of the dual therapy when the incretin-based therapies would not be appropriate. If dual therapy does not achieve the A1C goal, then triple therapy or insulin therapy should be started.

In patients with an A1C >9.0%, therapy is recommended based on the patient’s prior treatment history and whether or not symptoms are present. If the patient is asymptomatic, particularly with a relatively recent onset of diabetes, a good probability exists for preservation of some endogenous beta cell function, implying that dual therapy or triple therapy may be sufficient. In contrast, if the patient is symptomatic with polydipsia, polyuria, and weight loss, or if the patient has already been receiving treatment and regimens similar to the aforementioned ones have failed, then it is appropriate to initiate insulin therapy without delay.
6. References

Prior Authorization Guideline

GL-49282 Gralise, Gralise Starter Pack - Step Therapy

Formulary UHC Core

Formulary Note

Approval Date 4/30/2019

Revision Date 4/30/2019

Technician Note:

P&T Approval Date: 2/15/2019 **Guideline Effective Date: 5/1/2019**

1. Criteria

Product Name: Gralise, Gralise Starter Pack

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria
2. Background

Benefit/Coverage/Program Information

Background:

Step Therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes.

This program requires a member to try gabapentin (generic Neurontin) prior to coverage of Gralise or Gralise Starter Pack.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References

Prior Authorization Guideline

GL-51272 Health Care Reform - Cardiovascular Disease Prevention Zero Cost Share

Formulary UHC Core

Formulary Note

Approval Date 8/7/2019

Revision Date 8/7/2019

Technician Note:

P&T Approval Date: 3/22/2017; P&T Revision Date: 3/21/2018, 3/20/2019; **Effective Date: 6/1/2019**

1. Criteria

Product Name: atorvastatin (generic Lipitor) 10 mg and 20 mg and simvastatin (generic Zocor) 5 mg, 10 mg, 20 mg, 40 mg

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Coverage at zero dollar cost share</th>
</tr>
</thead>
</table>

Guideline Type | Notification |
--- | --- |

| | |
Approval Criteria

1. Member is between the ages of 40 and 75

AND

2. Medication is being used for primary prevention of CVD (i.e., member has no history of cardiovascular events)

AND

3. Member has one or more risk factors for CVD (i.e., dyslipidemia, diabetes, hypertension, or smoking)

AND

4. Member has a calculated 10-year risk of a cardiovascular event of 10% or greater

Notes

Authorization will be issued for zero copay with deductible bypass for 24 months. If zero dollar cost share criteria is not met the requested drug will default to plan coverage requirements.

2. Background

Benefit/Coverage/Program Information
Background:

The U.S. Preventive Services Task Force (USPSTF) [1] recommends that clinicians engage in shared, informed decision making with patients who are at increased risk for cardiovascular disease (CVD).

The USPSTF recommends that adults without a history of cardiovascular disease (CVD) (ie, symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (ie, dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10% or greater. ([http://tools.acc.org/ASCVD-Risk-estimator/](http://tools.acc.org/ASCVD-Risk-estimator/))

This program is designed to evaluate whether or not members meet the primary prevention criteria for obtaining coverage of low to moderate dose lipid lowering therapy (statins) at zero dollar cost share.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References

Prior Authorization Guideline

GL-49793 Health Care Reform - Cardiovascular Disease Prevention Zero Cost
Share UCS Pharmacy Operations use only

Formulary UHC Core

Formulary Note

Approval Date 5/28/2019

Revision Date 5/28/2019

Technician Note:

P&T Approval Date: 3/22/2017; P&T Revision Date: 3/20/2019; **Guideline Effective Date: 6/1/2019**

1. Criteria

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Notification</th>
</tr>
</thead>
</table>

Approval Criteria
1 Coverage at zero dollar cost share will be approved based on all of the following criteria:

1.1 Member is between the ages of 40 and 75

AND

1.2 Low to moderate dose statin is being used for primary prevention of CVD (i.e., member has no history of cardiovascular events)

AND

1.3 Member has one or more risk factors for CVD (i.e., dyslipidemia, diabetes, hypertension, or smoking)

AND

1.4 Member has a calculated 10-year risk of a cardiovascular event of 10% or greater

AND

1.5 One of the following

1.5.1 If request is for pravastatin, fluvastatin, or rosuvastatin member has history of failure, contraindication or intolerance to one preferred zero cost share statin: atorvastatin (generic Lipitor) 10 mg and 20 mg, simvastatin (generic Zocor) 5 mg, 10 mg, 20 mg, 40 mg or lovastatin (generic Mevacor)

OR

1.5.2 If request is for any other statin criteria for other utilization management programs must be met and also history of failure, contraindication or intolerance to one preferred zero cost share statin: atorvastatin (generic Lipitor) 10 mg and 20 mg, simvastatin (generic Zocor) 5 mg, 10 mg, 20 mg, 40 mg or lovastatin (generic Mevacor)

Notes

Authorization will be issued for zero copay with deductible bypass for 12 months. If zero dollar cost share criteria is not met the requested drug will default to plan coverage requirements.
2. Background

Benefit/Coverage/Program Information

Background:

The U.S. Preventive Services Task Force (USPSTF) [1] recommends that clinicians engage in shared, informed decision making with patients who are at increased risk for cardiovascular disease (CVD).

The USPSTF recommends that adults without a history of cardiovascular disease (CVD) (ie, symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (ie, dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10% or greater. (http://tools.acc.org/ASCVD-Risk-estimator/)

This program is designed to evaluate whether or not members meet the primary prevention criteria for obtaining coverage of low to moderate dose lipid lowering therapy (statins) at zero dollar cost share.

Additional Clinical Rules

- Step therapy may be in place
- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References
   Accessed 2/2019
2. Stone NJ, Robinson JG, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH,
   blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the
   American College of Cardiology/ American Heart Association Task Force on Practice
Prior Authorization Guideline

GL-32965 Healthcare Reform (HCR) Exceptions

Formulary UHC Core

Formulary Note

Approval Date 1/11/2017

Revision Date 1/11/2017

Technician Note:

P&T Approval Date: 10/26/2016 The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1. Criteria

Product Name: Contraceptives [E]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
</table>


For medical necessity requests, requests to waive cost-sharing for a medication not included on a zero-cost-sharing coverage list must meet ALL of the following:

1.1 Patient is using the prescribed drug for contraception

AND

1.2 Requested product and quantity requested does not exceed the following quantities:

- OTC female contraceptive product (with prescription) including female condoms, spermicides, or sponges Max Day Supply = 30
- OTC emergency contraceptive (with prescription) or prescription emergency contraceptive drug (no quantity limit applies)
- Contraceptive patch (no quantity limit applies)
- Contraceptive ring - (no quantity limit applies)
- Injectable contraceptives (no quantity limit applies)
- Diaphragm or cervical caps 1 unit per year
- Contraceptive implant (eligible for inclusion only if the client chooses to cover through the pharmacy benefit)
- IUD (eligible for inclusion only if the client chooses to cover through the pharmacy benefit)
- Nonemergency oral contraceptives (no quantity limit applies)

AND

1.3 If the request is for a prescription product not on the HCR preventive drug list, there must be a clinical reason why the patient cannot take two products on the HCR preventative drug list (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Note: If a patient has an intolerance, allergic reaction, or an inadequate response to one of the products on the HCR preventive drug list, then the quantity limits will not apply for one time.
only per drug category (to allow for another product to be tried on the HCR preventive drug list). * Zero Cost Share contraceptive coverage lists are available at the Clinical Services Sharepoint (http://optumrx.optum.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUMCS%20Guidelines%2FHealthcare%20Reform%20Supporting%20Document). ** FDA Contraceptive Methods available at the Clinical Services SharePoint; also see Table in Background Section

**Product Name:** Tamoxifen (applies to 20mg tablets only), Soltamox (tamoxifen solution), Evista (raloxifene)

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>60 Months: Authorization will be issued for zero copay with deductible bypass for up to a total of 60 months (please determine if member has already received some length of therapy and if so subtract from total approval period).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Member is greater than or equal to 35 years of age

    **AND**

2 Member has no prior diagnosis of any of the following:

    - breast cancer
    - ductal carcinoma in situ (DCIS)
    - lobular carcinoma in situ (LCIS)

    **AND**

3 Member has no history of thromboembolic events (e.g.- deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)
4 Member has an estimated 5 year risk of breast cancer based on a breast cancer risk assessment tool of greater than or equal to 3% \[11\]

\[\text{AND}\]

5 One of the following:

5.1 Request is for Tamoxifen 20 mg once daily

\[\text{OR}\]

5.2 Both of the following:

5.2.1 Member is post-menopausal

\[\text{AND}\]

5.2.2 One of the following:

5.2.2.1 Request is for raloxifene 60 mg once daily

\[\text{OR}\]

5.2.2.2 Request is for Evista 60 mg once daily and member has had failure, contraindication or adverse reaction to raloxifene

\[\text{OR}\]

5.3 Both of the following:
**5.3.1** Request is for Soltamox 20 mg once daily

**AND**

**5.3.2** Member has had failure, contraindication or adverse reaction to tamoxifen tablets

| Notes | This program is designed to meet Health Care Reform requirements which require coverage of tamoxifen tablets, Soltamox (tamoxifen) solution, or Evista (raloxifene) at zero dollar cost share if being used for primary prevention of breast cancer and criteria are met. |

---

### 2. Background

**Clinical Practice Guidelines**

**Clinical Practice Guidelines **FDA Contraceptive Methods**

**FDA Contraceptives Methods**

| Items 6-18 pertain to the ORx standard Health Care Reform Benefit |
| 1 – Sterilization Surgery |
| 2 – Surgical Sterilization Implant for Women |
| 3 – Implantable Rod* |
| 4 – Copper IUD* |
| 5 – IUD with Progestin* |
| 6 – Shot/Injection |
| 7 – OC, Combined Pill |
| 8 – OC, Progestin Only |
Benefit/Coverage/Program Information

Program information

If the patient does not meet the above criteria, then the prescription will not be covered at zero cost-share.

3 . Endnotes

A. Important Risk Factors for Breast Cancer [5]: (1) Family history of breast or ovarian cancer (especially among first-degree relatives and onset before age 50 years); (2) History of atypical hyperplasia; (3) Non-malignant high-risk breast lesions; (4) Previous breast biopsy; (5) Extremely dense breast tissue; (6) Increasing age; (7) Race or ethnicity; (8) Age at menarche; (9) Age at first live childbirth; (10) Ductal carcinoma in situ (DCIS); (11) Lobular carcinoma in situ (LCIS); (12) Body mass index; (13)
Menopause status or age; (14) Estrogen and progestin use; (15) Smoking; (16) Alcohol use; (17) Physical activity; (18) Diet.

B. The Affordable Care Act (ACA) requires private insurers to cover certain preventive services without any patient cost-sharing (i.e., copayments) when they are delivered by a network provider. The Department of Health and Human Services (HHS) has recognized several recommending bodies (e.g., United States Preventive Services Task Force [USPSTF], Advisory Committee on Immunization Practices [ACIP] http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html, Health Resources and Services Administration [HRSA]) who have identified several medication categories that fall within the preventive health mandate.

C. OptumRx has developed a Healthcare Reform Preventative Drug List posted at: http://optumrx.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare Reform Supporting Document that identifies which products are eligible for coverage without patient copayment. Some products may be excluded (such as brand oral contraceptives) unless the patient meets the criteria in this exceptions policy.

D. Oral Contraceptives: In order to receive an oral contraceptive at zero cost-share, a woman must be of childbearing potential and must be requesting an oral contraceptive for contraception (and not for another use) (as well as meeting the other criteria noted at the beginning of the policy). In addition, the 21 or 28 day oral contraceptive packs should not be approved for continuous use because there are continuous use products already on the Healthcare Reform Preventative Drug List posted at: http://optumrx.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare Reform Supporting Document.

E. Breast Cancer Prevention: The USPSTF recommends that clinicians engage in shared, informed decision-making with women who are at increased risk for breast cancer about medications to reduce their risk. [5] For women who are at an increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction of primary breast cancer in women who are not at increased risk for breast cancer. The updated STAR trial results show diminished benefits of raloxifene compared to tamoxifen after cessation of therapy, making it a preferred risk reduction choice for most post-menopausal women desiring non-surgical risk reduction therapy. However, consideration of toxicity (e.g., endometrial cancer or uterine bleeding) may still lead to the choice of raloxifene over tamoxifen in some women.

4. References


Prior Authorization Guideline

GL-54240 High Dollar/Claim Dollar

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>12/1/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>3/26/2017</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>10/16/2019</td>
</tr>
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</table>

Technician Note:

P&T Revision Date: 10/25/2017, 12/19/2018. The intent of this policy is to serve as guidance for clients who would like to implement a High Dollar program. When a prescription exceeds the claim or high dollar threshold, the prescribed drug will be considered for coverage under the pharmacy benefit when the following criteria are met.
1. Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 months, if no PA is on file. Approval duration is granted for length of current PA on file (if existing PA is on file).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - One of the following:

1.1 Medication is being prescribed for an FDA-approved indication

OR

1.2 One of the following:

1.2.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.2.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal**

AND

2 - One of the following:
2.1 The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice

OR

2.2 The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

- American Hospital Formulary Service (AHFS) Compendium
- Thomson Reuters (Healthcare) Micromedex/DrugDex (not Drug Points) Compendium
- Elsevier Gold Standard’s Clinical Pharmacology Compendium
- National Comprehensive Cancer Network Drugs and Biologics Compendium

Notes

**May not apply to all benefit plans.

| Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen |
|----------------------------------|--------------------------------------------------------------------------------|
| Approval Length                  | 12 months, if no PA is on file. Approval duration is granted for length of current PA on file (if existing PA is on file). |
| Guideline Type                   | Administrative                                                               |

Approval Criteria

1 - One of the following:

1.1 Medication is being prescribed for an FDA-approved indication

OR

1.2 One of the following:

1.2.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [2]

OR
1.2.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.2.3 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, B]

OR

1.2.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.2.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, C]

- American Journal of Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
• Leukemia
• The New England Journal of Medicine
• Radiation Oncology

OR

1.2.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

AND

2 - One of the following:

2.1 The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice

OR

2.2 The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

• American Hospital Formulary Service (AHFS) Compendium
• Thomson Reuters (Healthcare) Micromedex/DrugDex (not Drug Points) Compendium
• Elsevier Gold Standard’s Clinical Pharmacology Compendium
• National Comprehensive Cancer Network Drugs and Biologics Compendium

Notes **May not apply to all benefit plans.

2. Background

<table>
<thead>
<tr>
<th>Clinical Practice Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DRUGDEX Strength of Recommendation [5]</strong></td>
</tr>
<tr>
<td>Class</td>
</tr>
<tr>
<td>Class</td>
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<tr>
<td>--------</td>
</tr>
<tr>
<td>Class I</td>
</tr>
<tr>
<td>Class IIa</td>
</tr>
<tr>
<td>Class IIb</td>
</tr>
<tr>
<td>Class III</td>
</tr>
<tr>
<td>Class Indeterminate</td>
</tr>
</tbody>
</table>

**NCCN Categories of Evidence and Consensus [B]**

<table>
<thead>
<tr>
<th>Category</th>
<th>Level of Consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Based upon high-level evidence, there is uniform NCCN consensus intervention is appropriate.</td>
</tr>
<tr>
<td>2A</td>
<td>Based upon lower-level evidence, there is uniform NCCN consensus intervention is appropriate.</td>
</tr>
<tr>
<td>2B</td>
<td>Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.</td>
</tr>
<tr>
<td>3</td>
<td>Based upon any level of evidence, there is major NCCN disagreement intervention is appropriate.</td>
</tr>
</tbody>
</table>

**Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]**

**Strength of Recommendation for Inclusion**

<table>
<thead>
<tr>
<th>Strength (for proposed off-label use)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong (for proposed off-label use)</td>
<td>The evidence persuasively supports the off-label use (ie, Level of Evidence A).</td>
</tr>
<tr>
<td>Equivocal (for proposed off-label use)</td>
<td>The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.</td>
</tr>
<tr>
<td>Against proposed off-label use</td>
<td>The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.</td>
</tr>
</tbody>
</table>

**Level of Evidence Scale for Oncology Off-Label Use**
| A | Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (e.g., results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit. |
| B | Evidence from randomized, controlled trials with important limitations (e.g., inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate. |
| C | Evidence from observational studies (e.g., retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (e.g., when limited options exist for condition). Any estimate of effect is uncertain. |
| G | Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline. |

3. Endnotes

A. OptumRx has high dollar criteria for clients who opt for such a program to help manage prescription costs. If the prescription cost exceeds the claim or high dollar threshold, then an administrative PA will be required. The pharmacist will review the prescription to see if it is in-line with FDA approved labeling or well supported by the approved compendia or a peer-reviewed medical journal.

B. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes
that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

C. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
</table>
1. Indications

**Drug Name:** Horizant (gabapentin enacarbil)

**Indications**

**Restless Legs Syndrome (RLS)** Indicated for the treatment of moderate-to-severe primary restless legs syndrome (RLS) in adults. Horizant is not recommended for patients who are required to sleep during the daytime and remain awake at night.

**Postherpetic Neuralgia (PHN)** Indicated for the management of postherpetic neuralgia (PHN) in adults.
2. Criteria

**Product Name:** Horizant

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Restless Legs Syndrome (RLS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate-to-severe primary restless legs syndrome (RLS)

   AND

2. Trial and failure, contraindication, or intolerance to one of the following [A]:

   - ropinirole
   - pramipexole

**Product Name:** Horizant

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Restless Legs Syndrome (RLS)</th>
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<tbody>
<tr>
<td>Approval Length</td>
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<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
</tbody>
</table>
Guideline Type | Prior Authorization
---|---

**Approval Criteria**

1. Patient has experienced an improvement in RLS disease symptoms (e.g., decrease in symptom onset or severity, improved sleep, or decrease in symptom intensity)

**Product Name:** Horizant

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Postherpetic Neuralgia (PHN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
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<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of postherpetic neuralgia (PHN)

   **AND**

2. One of the following [B]:

   2.1 Patient has tried and had an inadequate response to a dose of at least 1800 mg of generic gabapentin

   **OR**

   2.2 History of intolerance to generic gabapentin

**Product Name:** Horizant
<table>
<thead>
<tr>
<th><strong>Diagnosis</strong></th>
<th>Postherpetic Neuralgia (PHN)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approval Length</strong></td>
<td>12 Month</td>
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<tr>
<td><strong>Therapy Stage</strong></td>
<td>Reauthorization</td>
</tr>
<tr>
<td><strong>Guideline Type</strong></td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Patient has experienced an improvement in PHN disease symptoms (e.g., decrease in pain severity)

### 3. Endnotes

A. Dopamine agonists (such as ropinirole, pramipexole) are the most extensively studied and used therapies for the treatment for daily RLS symptoms. Clinicians can treat patients with levodopa with a dopa decarboxylase inhibitor, opioids, or Horizant (gabapentin enacarbil). Cabergoline may be used if other recommended agents have provided an inadequate response, due to the risk of potential side effects including heart valve damage. Other pharmacologic options include gabapentin, Lyrica (pregabalin), carbamazepine, or clonidine. [2]

B. While Horizant (gabapentin enacarbil) may improve patient convenience (twice daily rather than three times daily dosing), generic gabapentin is a more well-established, cost-effective therapy for PHN. The use of Horizant (gabapentin enacarbil) should be reserved for patients who have experienced treatment failure or intolerance to generic gabapentin. [3, 4]

### 4. References

**Prior Authorization Guideline**

GL-49245 Impavido (miltefosine)

Formulary UHC Core

Formulary Note

Approval Date 4/29/2019

Revision Date 4/29/2019

Technician Note:


**Guideline Effective Date: 6/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Impavido (miltefosine)</th>
</tr>
</thead>
</table>

**Indications**

**Leishmaniasis** Indicated in adults and adolescents greater than or equal to 12 years of age and weighing greater than or equal to 30 kg (66 lbs) for treatment of visceral leishmaniasis due to *Leishmania donovani*, cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*, and mucosal leishmaniasis due to *Leishmania braziliensis*. The efficacy of Impavido in the treatment of other Leishmania species has not been evaluated.
2. Criteria

Product Name: Impavido

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>28 Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of one of the following:

- Visceral leishmaniasis due to Leishmania donovani
- Cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, or Leishmania panamensis
- Mucosal leishmaniasis due to Leishmania braziliensis
- Primary Amebic Meningoencephalitis (PAM) [Off Label]
- Keratitis due to Acanthamoeba [Off label]

3. Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
Supply limits may be in place.

**Background:**

Impavido (miltefosine) is an antileishmanial agent indicated in adults and adolescents greater than or equal to 12 years of age and weighing greater than or equal to 30 kg (66 lbs) for treatment of visceral leishmaniasis due to *Leishmania donovani*, cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*, and mucosal leishmaniasis due to *Leishmania braziliensis*. The efficacy of Impavido in the treatment of other *Leishmania* species has not been evaluated. Impavido should be administered as a dose of one 50 mg capsule two to three times daily for 28 consecutive days.

---

4. **References**

1. Indications

**Drug Name: Ingrezza (valbenazine)**

**Indications**

**Tardive dyskinesia** Indicated for the treatment of adults with tardive dyskinesia.

2. Criteria
**Product Name:** Ingrezza [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**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. One of the following

   3.1 History of failure, contraindication, or intolerance to Austedo (deutetrabenazine)

   **OR**

   3.2 Both of the following:

   3.2.1 Patient is currently on Ingrezza therapy
AND

3.2.2 Patient has not received a manufacturer supplied sample at no cost in the prescriber’s office, or any form of assistance from the Neurocrine Biosciences sponsored Inbrace program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Ingrezza*

AND

4 Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from the Neurocrine Biosciences sponsored Inbrace program shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Ingrezza [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Documentation of positive clinical response to Ingrezza therapy
3. Background

Benefit/Coverage/Program Information

Background:

Ingrezza is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.

Additional Clinical Rules:

Supply limits may be in place

4. References

1. Ingrezza Prescribing Information, Neurocrine Biosciences, Inc. August 2018.
1. Indications

**Drug Name: Alvesco (ciclesonide) Inhalation Aerosol**

**Indications**

**Asthma** Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older. Important Limitations of Use: Alvesco is NOT indicated for the relief of acute bronchospasm or for children under 12 years of age.

**Drug Name: ArmonAir RespiClick (fluticasone propionate) Inhalation Powder**
## Indications

**Asthma** Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Important Limitation of Use: ArmonAir RespiClick is not indicated for the relief of acute bronchospasm or for children under 12 years of age.

### Drug Name: Asmanex HFA (mometasone furoate) Inhalation Aerosol

**Indications**

**Asthma** Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Important Limitations of Use: Asmanex HFA is NOT indicated for the relief of acute bronchospasm.

### Drug Name: Asmanex Twisthaler (mometasone furoate) Inhalation Powder

**Indications**

**Asthma** Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. Important Limitations of Use: Asmanex Twisthaler is NOT indicated for the relief of acute bronchospasm or in children less than 4 years of age.

## 2. Criteria

**Product Name:** Alvesco*, ArmonAir RespiClick*, Asmanex HFA*, Asmanex Twisthaler*

<table>
<thead>
<tr>
<th>Approval Length</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
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</table>

### Approval Criteria

1. Trial and failure, contraindication, or intolerance to two of the following preferred brands:
| Notes | *Product may be excluded depending on the plan. |

### 3. References

2. ArmonAir RespiClick Prescribing Information. Teva Respiratory, LLC. Waterford, IE. December 2018.
Prior Authorization Guideline

GL-55608 Iron Chelators

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<tr>
<td>P&amp;T Revision Date:</td>
<td>9/18/2019</td>
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</table>

1. Indications

**Drug Name:** Exjade (deferasirox), Jadenu (deferasirox)

**Chronic iron overload due to blood transfusions** Indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. The safety and efficacy
of Exjade and Jadenu, when administered with other iron chelation therapy, have not been established. It is recommended that therapy with Exjade or Jadenu be started when a patient has evidence of chronic iron overload, such as the transfusion of approximately 100 mL/kg of packed red blood cells (approximately 20 units for a 40-kg patient) and a serum ferritin consistently greater than 1000 mcg/L.

**Chronic iron overload due to non-transfusion dependent thalassemia syndromes**

Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion dependent thalassemia syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (dw) and a serum ferritin greater than 300 mcg/L. This indication is based on achievement of an LIC less than 5 mg Fe/g dw. An improvement in survival or disease-related symptoms has not been established. [1, 3]

**Drug Name: Ferriprox (deferiprone)**

**Transfusional iron overload due to thalassemia syndromes**

Indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival. Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias. [2]

## 2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Exjade, Jadenu</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
</tr>
<tr>
<td><strong>Approval Length</strong></td>
</tr>
<tr>
<td><strong>Therapy Stage</strong></td>
</tr>
<tr>
<td><strong>Guideline Type</strong></td>
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</tbody>
</table>

**Approval Criteria**

1 - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion [1,3]
Product Name: Exjade, Jadenu

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic Iron Overload Due to Blood Transfusions (i.e., Transfusional Iron Overload)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
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<td>Therapy Stage</td>
<td>Reauthorization</td>
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<td>Guideline Type</td>
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</table>

Approval Criteria

1 - Documentation of positive clinical response to Exjade or Jadenu therapy

Product Name: Ferriprox

<table>
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<th>Diagnosis</th>
<th>Chronic Iron Overload Due to Blood Transfusions (i.e., Transfusional Iron Overload)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - Diagnosis of transfusional iron overload due to thalassemia syndromes [2]

AND

2 - Current chelation therapy is inadequate [e.g., Desferal (deferoxamine), Exjade (deferasirox)] [2]
Therapy Stage | Reauthorization
Guideline Type | Notification

**Approval Criteria**

1 - Documentation of positive clinical response to Ferriprox therapy

Product Name: Exjade, Jadenu

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
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<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome [1,3]

AND

2 - 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 Exjade or Jadenu [1,3]

AND

3 - Patient has serum ferritin levels consistently greater than 300 mcg/L prior to initiation of treatment with Exjade or Jadenu [1,3]
<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
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<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
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</table>

**Approval Criteria**

1. Documentation of positive clinical response to Exjade or Jadenu therapy

---

**3. Background**

**Benefit/Coverage/Program Information**

**Background:**

Exjade (deferasirox) and Jadenu (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. The safety and efficacy of Exjade and Jadenu, when administered with other iron chelation therapy, have not been established. It is recommended that therapy with Exjade or Jadenu be started when a patient has evidence of chronic transfusional iron overload, such as the transfusion of approximately 100 mL/kg of packed red blood cells (approximately 20 units for a 40-kg patient) and a serum ferritin consistently >1000 mcg/L. Exjade and Jadenu are also indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion dependent thalassemia syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (dw) and a serum ferritin greater than 300 mcg/L. This indication is based on achievement of an LIC less than 5 mg Fe/g dw. An improvement in survival or disease-related symptoms has not been established.[1,3]

For patients who are currently on chelation therapy with Exjade tablets for oral suspension and converting to Jadenu tablets, the dose of Jadenu should be approximately 30% lower, rounded to the nearest whole tablet.

Ferriprox (deferiprone) is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival. Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.[2]

**Additional Clinical Rules:**
• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-
authorization based solely on previous claim/medication history, diagnosis codes (ICD-
10) and/or claim logic. Use of automated approval and re-approval processes varies by
program and/or therapeutic class.
• Step therapy may be in place.

4. References

1. Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May
   2019.
3. Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May
   2019.

5. Revision History

<table>
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<tbody>
<tr>
<td>10/17/2019</td>
<td>Annual review. No changes to coverage criteria. Updated references.</td>
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</table>
1. Indications

**Drug Name:** Kapvay (clonidine) extended-release

**Indications**

**Attention Deficit Hyperactivity Disorder (ADHD)** Indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.
2. Criteria

**Product Name:** Brand Kapvay or generic clonidine extended-release

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

**Approval Criteria**

1. History of two of the following generics or preferred brands:

- amphetamine-dextroamphetamine IR
- dexamfetamine IR
- dextroamphetamine IR
- methylphenidate IR or ER
- Vyvanse
- Adderall XR

3. References

1. Indications

Drug Name: Ketek (telithromycin) [1, A]

Indications

Community-acquired pneumonia

It is indicated for the treatment of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae, (including multi-drug resistant isolates [MDRSP*]), Haemophilus influenzae, Moraxella catarrhalis, Chlamyphila pneumoniae, or Mycoplasma pneumoniae, for patients 18 years and above. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ketek and other antibacterial drugs, Ketek should be used only to treat infections that are proven or strongly suspected to be caused by susceptible
bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. *MDRSP, Multi-drug resistant Streptococcus pneumoniae includes isolates known as PRSP (penicillin-resistant Streptococcus pneumoniae), and are isolates resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

2. Criteria

Product Name: Ketek

<table>
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<tr>
<th>Approval Length</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of community-acquired pneumonia in an adult outpatient [1, 2, 3, 9]

   \[ \text{AND} \]

2. All of the following: [2, 3, 9, A]

2.1 History of failure, intolerance, or resistance to one of the following advanced-generation macrolides:

   - azithromycin (eg, Zithromax, Zmax)
   - clarithromycin (eg, Biaxin, Biaxin XL)

   \[ \text{AND} \]

2.2 History of failure, intolerance, or resistance to doxycycline (eg, Vibramycin, Adoxa, Doryx)
2.3 History of failure, intolerance, or resistance to Levaquin (levofloxacin)

3. Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Ketek - Community-acquired pneumonia [1]</td>
<td>800 mg once daily for 7-10 days.</td>
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4. Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
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<tbody>
<tr>
<td>Ketek [1]</td>
<td>400 mg tablets</td>
</tr>
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</table>

5. Background

Clinical Practice Guidelines


For outpatient treatment, patients previously healthy with no risk factors for drug-resistant *S. pneumoniae* (DRSP) infection, a macrolide (azithromycin, clarithromycin, or erythromycin) (*strong recommendation; level I evidence*) and doxycycline (*weak recommendation; level III evidence*) were recommended. In the presence of comorbidities (such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of
immunosuppressing drugs; use of antimicrobials within the previous 3 months [in which case an alternative from a different class should be selected]; or other risks for DRSP infection), a respiratory fluoroquinolone (strong recommendation; level I evidence) and a beta-lactam plus a macrolide (strong recommendation; level I evidence) (High-dose amoxicillin [e.g., 1 g 3 times daily] or amoxicillin-clavulanate [2 g 2 times daily] is preferred; alternatives include ceftriaxone, cefpodoxime, and cefuroxime [500 mg 2 times daily]; doxycycline [level II evidence] is an alternative to the macrolide) are recommended. In regions with a high rate (125%) of infection with high level macrolide resistant \textit{S. pneumonia} (MIC 16 mg/mL), the use of alternative agents listed for patients with or without comorbidities maybe considered (moderate recommendation; level III evidence).

\textbf{Infectious Diseases Society of America (2003) [2, 8]}

Appropriate initial empiric therapy for suspected bacterial CAP in immunocompetent outpatients who were previously healthy with no recent antibiotic therapy would include a macrolide or doxycycline. Those with recent antibiotic therapy should receive a respiratory fluoroquinolone alone, an advanced macrolide plus high-dose amoxicillin, or an advanced macrolide plus high-dose amoxicillin-clavulanate.

\textbf{American Thoracic Society (2001) [3, 8]}

If the patient has no cardiopulmonary disease, and no risks for DRSP, aspiration, or enteric gramnegatives, then the likely organisms will be pneumococcus, atypical pathogens, respiratory viruses, and possibly \textit{H. influenzae} (especially in cigarette smokers). For these therapy should be with an advanced generation macrolide, with doxycycline as a second choice (because of less reliable activity against pneumococcus) for patients who are allergic or intolerant of macrolides. The committee felt that broader spectrum coverage with a new antipneumococcal fluoroquinolone would be effective, but unnecessary, and if used in this setting could promote overusage of this valuable class of antibiotics (Level III evidence). If \textit{H. influenzae} is not likely, because the patient is a nonsmoker without cardiopulmonary disease, any macrolide could be used, including erythromycin. However, the advanced generation macrolides (azithromycin, clarithromycin) have a lower incidence of gastrointestinal side effects than erythromycin and are administered less frequently (once or twice daily) than erythromycin, improving the likelihood of patient compliance with therapy. Although clarithromycin is not as active \textit{in vitro} against \textit{H. influenzae} as azithromycin, clinical experience with both azithromycin and clarithromycin in
CAP has been favorable. This may be explained by the excellent concentrations of macrolides achieved in the epithelial lining fluid and alveolar macrophages, and by the predominance of the efflux mechanism of pneumococcal resistance in North America.

The more complex outpatient (Group II, Table 3) can be managed with either a beta-lactam/macrolide combination or monotherapy with an antipneumococcal fluoroquinolone (Level II evidence). Doxycycline can be used, along with a beta-lactam, as an alternative to a macrolide for these patients.

6. Endnotes

A. Numerous national societies have published their recommendations for the management of CAP. This review article looked at the latest guidelines from two leading organizations – the Infectious Diseases Society of America (IDSA) and the American Thoracic Society (ATS). Using a composite of both guidelines, the treatment regimens for outpatient CAP can be simplified as follows: Monotherapy with either a beta-lactam, a macrolide antibiotic, doxycycline, or a fluoroquinolone antibiotic is sufficient. [8]

B. Because of numerous safety issues including hepatotoxicity, visual disorders, loss of consciousness, and myasthenia gravis, the FDA Anti-Infective Drugs Advisory Committee voted against continued marketing of telithromycin for ABECB (acute bacterial exacerbation of chronic bronchitis) and ABS (acute bacterial sinusitis). The FDA chose to enforce this decision on February 12, 2007.

7. References

Prior Authorization Guideline

GL-53672 Levemir (insulin detemir)

Formulary  UHC Core

Formulary Note

Guideline Note:

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<thead>
<tr>
<th>Effective Date:</th>
<th>1/1/2020</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>7/17/2019</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td></td>
</tr>
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</table>

1. Criteria

<table>
<thead>
<tr>
<th>Product Name: Levemir (insulin detemir)* [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
</tbody>
</table>

[a]
Guideline Type | Non Formulary
---|---

**Approval Criteria**

1. Patient is pregnant

   **AND**

2. History of failure, contraindication, or intolerance to insulin NPH

**Notes**

* Levemir is typically excluded from coverage. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

---

**2. Background**

**Benefit/Coverage/Program Information**

**Background:**

The Endocrine Society recommends insulin NPH, an intermediate acting insulin, as the preferred basal insulin in pregnancy. Patients may be switched to Levemir, a long-acting insulin, when therapy with insulin NPH is inadequate. This program allows for coverage of Levemir for pregnant patients when they have failed therapy with insulin NPH.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

---

**3. References**


### 4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>9/20/2019</td>
<td>New program</td>
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</table>
Prior Authorization Guideline

GL-49187 Lidoderm (Lidocaine Patch 5%)

Formulary UHC Core

Formulary Note

Approval Date 4/25/2019  
Revision Date 4/25/2019

Technician Note :

P&T Approval Date: 2/17/2017; P&T Revision Date: 3/21/2018, 3/20/2019; **Guideline Effective Date: 6/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Lidoderm (Lidocaine Patch 5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
</tbody>
</table>

Pain associated with post-herpetic neuralgia (PHN) Indicated for the relief of pain associated with post-herpetic neuralgia (PHN). The American Academy of Neurology recommends the use of lidocaine patch as an option for the management of PHN. Evidence also exists in support of using lidocaine patch for non-PHN neuropathies.
2. Criteria

**Product Name:** [Brand Lidoderm patch, Generic lidocaine patch]*

<table>
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<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:

   - Diagnosis of post-herpetic neuralgia
   - Diagnosis of neuropathic pain

   **AND**

2. Patch will be applied only to intact skin

**Notes**

*Applies to brand and generic lidocaine patches. Brand Lidoderm is typically excluded from coverage.

**Product Name:** [Brand Lidoderm patch, Generic lidocaine patch]*

<table>
<thead>
<tr>
<th>Approval Length</th>
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<tbody>
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<td>Reauthorization</td>
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<tr>
<td>Guideline Type</td>
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</table>

**Approval Criteria**
1 Documentation of positive clinical response to lidocaine patch therapy

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>*Applies to brand and generic lidocaine patches. Brand Lidoderm is</td>
</tr>
<tr>
<td>typically excluded from coverage.</td>
</tr>
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</table>

3. Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References

Prior Authorization Guideline

GL-53037 Linzess (linclotide), Symproic (naldemedine)

Formulary  UHC Core

Formulary Note

Guideline Note:

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Technician Note:

P&T Approval Date: 9/19/2018; P&T Revision Date: 6/19/2019 **Guideline Effective Date: 9/1/2019**

1. Indications
### Drug Name: Linzess (linaclotide)

**Chronic idiopathic constipation** Indicated for the treatment of chronic idiopathic constipation in adults aged 18 years and older.

**Irritable bowel syndrome** Indicated for the treatment of irritable bowel syndrome with constipation in adults aged 18 years and older.

### Drug Name: Symproic (naldemedine)

**Opioid-induced constipation** Indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

## 2. Criteria

### Product Name: Linzess

<table>
<thead>
<tr>
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<tbody>
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<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

2 - Patient is greater than or equal to 18 years of age

### Product Name: Symproic
Approval Criteria

1 - One of the following:

- Diagnosis of opioid-induced constipation in patients being treated for chronic, non-cancer pain
- Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

Product Name: Linzess or Symproic

Approval Criteria

1 - Documentation of positive clinical response to therapy

3. Background

Benefit/Coverage/Program Information

Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place
Background

Linzess (linaclootide) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults aged 18 years and older. Symproic (naldemedine) is an opioid antagonist indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation. Physicians and patients should periodically assess the need for continued treatment with these agents.

4. References

1. Indications

**Drug Name:** Lokelma (sodium zirconium cyclosilicate), Veltassa (patiromer)

**Indications**

**Hyperkalemia** Indicated for the treatment of hyperkalemia.
2. Criteria

Product Name: [Lokelma, Veltassa] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
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</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of non-life threatening hyperkalemia

AND

2. Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or reduced to the lowest effective dose

AND

3. Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

4. Patient follows a low potassium diet (less than or equal to 3 grams per day)

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage
Product Name: [Lokelma, Veltassa] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Patient has a positive clinical response to Lokelma or Veltassa therapy and continues to require treatment for hyperkalemia

AND

2 Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, NSAIDs) have been discontinued or reduced to the lowest effective dose

AND

3 Patient follows a low potassium diet (less than or equal to 3 grams per day)

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply
3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

**Background:**

Lokelma and Veltassa are indicated for the treatment of hyperkalemia. Lokelma and Veltassa should not be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action. Non-emergent hyperkalemia is generally treated by addressing the reversible causes, such as removing drugs that may be causing impaired renal function, removing or adjusting medications that directly cause hyperkalemia, and initiating therapies for potassium removal.

4. References

**Prior Authorization Guideline**

GL-45393 Long-Acting Bronchodilator Combinations

Formulary UHC Core

Formulary Note

Approval Date 9/28/2018

Revision Date 9/28/2018

Technician Note:

P&T Approval Date: 10/5/2010; P&T Revision Date: 9/28/2016, 3/22/2017, 11/17/2017
**Effective 12/31/2017**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Airduo Respiclick (fluticasone propionate and salmeterol) Inhalation Powder</th>
</tr>
</thead>
</table>

**Indications**

**Asthma** Indicated for the treatment of asthma in patients aged 12 years and older. Important Limitation of Use: Airduo Respiclick is NOT indicated for the relief of acute bronchospasm.

<table>
<thead>
<tr>
<th>Drug Name: Dulera (mometasone/formeterol) Inhalation Aerosol</th>
</tr>
</thead>
</table>
**Indications**

**Asthma** Indicated for the treatment of asthma in patients 12 years of age and older. LABAs, such as formoterol, increase the risk of asthma-related death. Data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, Dulera should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid (ICS) or whose disease severity clearly warrants initiation of treatment with both an ICS and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (eg, discontinue Dulera) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an ICS. Do not use Dulera for patients whose asthma is adequately controlled on low or medium dose ICS. Dulera is NOT indicated for the relief of acute bronchospasm.

**Drug Name: Utibron Neohaler (indacaterol/glycopyrrolate) Inhalation Capsule**

**Indications**

**Chronic Obstructive Pulmonary Disease (COPD)** Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Limitations of Use: Utibron Neohaler is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

2. **Criteria**

**Product Name:** Dulera, Brand Airduo Respliclick

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1. Trial and failure, intolerance, or contraindication to two of the following:

   - Advair Diskus or Advair HFA
   - Symbicort
   - Breo Ellipta
- Fluticasone/salmeterol

**Product Name:** Utibron Neohaler

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

**Approval Criteria**

1. Trial and failure, intolerance, or contraindication to both of the following:

   1.1 One of the following:

      - Advair Diskus or Advair HFA
      - Breo Ellipta
      - Serevent
      - Symbicort

      **AND**

   1.2 Spiriva/Spiriva Respimat

---

**3. References**

Prior Authorization Guideline

GL-47804 Long-Acting Bronchodilators

Formulary UHC Core

Formulary Note

Approval Date 3/25/2019

Revision Date 3/25/2019

Technician Note:


**Effective Date: 5/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Arcapta Neohaler (indacaterol)</th>
</tr>
</thead>
</table>

**Indications**

**Chronic Obstructive Pulmonary Disease (COPD)** Indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Important Limitations of Use: Arcapta Neohaler is not indicated to treat acute deteriorations of chronic obstructive pulmonary disease. Arcapta Neohaler is not indicated to treat asthma. The safety and effectiveness of Arcapta Neohaler in asthma have not been established.
**Drug Name: Striverdi Respimat (olodaterol)**

**Indications**

**Chronic Obstructive Pulmonary Disease (COPD)** Indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Important Limitations of Use: Striverdi Respimat is not indicated to treat acute deteriorations of COPD. Striverdi Respimat is not indicated to treat asthma. The safety and effectiveness of Striverdi Respimat in asthma have not been established.

**Drug Name: Tudorza (aclidinium bromide)**

**Indications**

**Chronic obstructive pulmonary disease (COPD)** Indicated for the long-term, maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.

**Drug Name: Seebri Neohaler (glycopyrrolate)**

**Indications**

**Chronic obstructive pulmonary disease (COPD)** Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

---

**2. Criteria**

**Product Name:** Brand Arcapta Neohaler, Brand Striverdi Respimat

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>
## Approval Criteria

1 Trial and failure, intolerance or contraindication with TWO of the following generics or preferred brands:

- Advair Diskus/HFA
- Breo Ellipta
- fluticasone/salmeterol
- Serevent
- Symbicort
- Wixela Inhub

### Product Name: Brand Tudorza Pressair, Brand Seebri Neohaler

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

## Approval Criteria

1 Trial and failure, intolerance or contraindication to BOTH of the following preferred brands:

- Incruse Ellipta
- Spiriva

## References

1. Indications

**Drug Name:** Arymo ER, Avinza, Dolophone, Duragesic, Embeda, Exalgo, fentanyl transdermal, hydromorphone ER, Hysingla ER, Kadian, methadone, Morphabond ER, morphine sulfate controlled-release, MS Contin, Nucynta ER, Opana ER, oxycodone hcl ER, and OxyContin

**Indications**

**Management of moderate to severe pain** Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for...
use as an as needed analgesic.

**Drug Name:** Oxymorphone ER, Xtampza ER and Zohydro ER

**Indications**

*Management of moderate to severe pain* Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for use as an as needed analgesic.

2. **Criteria**

**Product Name:** [Dolophine, fentanyl transdermal patch (generic Duragesic) 12, 25, 50, 75, 100 mcg/hr, methadone, morphine sulfate controlled-release tablets (generic MS Contin), Nucynta ER, Xtampza ER] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Book of Business: Cancer or End of Life (defined as a &lt;2 year life expectancy) related pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
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</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years)

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 24 months up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the...
medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-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:** [Arymo ER^, Avinza^, Duragesic^, Embeda^, Exalgo^, fentanyl transdermal patch (37.5, 62.5, 87.5 mcg/hr)^, Hysingla ER^, Kadian^, Morphabond ER^, MS Contin, oxymorphone extended release, and Zohydro ER [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]] [a]

<table>
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<tr>
<th>Diagnosis</th>
<th>Book of Business: Cancer or End of Life (defined as a &lt;2 year life expectancy)</th>
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</thead>
<tbody>
<tr>
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<td>24 months up to the dose allowed by supply limit review</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of <2 years)

   **AND**

2. One of the following:

   2.1 History of failure, contraindication or intolerance to a trial of ALL of the following (Document date of trial):

   - Nucynta ER
   - morphine sulfate controlled release tablets (specifically generic MS Contin)
   - Xtampza ER
   - For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic strengths)
### Notes

[a] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 24 months up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-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:** [OxyContin^ and oxycodone controlled-release (Authorized Generic for OxyContin)^] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Book of Business: Cancer or End of Life (defined as a &lt; 2 year life expectancy) related pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>24 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of < 2 years)

    AND

2. One of the following

---

**OR**

2.2 Patient is established on pain therapy with the requested medication for cancer-related or end of life pain (< 2 years life expectancy), and the medication is not a new regimen for the treatment of cancer-related or end of life (< 2 years life expectancy) pain.
2.1 The patient has a history of failure, contraindication or intolerance to ALL of the following (Document date of trial):

- Xtampza ER
- Nucynta ER
- Morphine sulfate controlled-release tablets (specifically generic MS Contin)

OR

2.2 Both of the following

2.2.1 The patient requires more than 320 mg/day of controlled-release oxycodone.

AND

2.2.2 The patient has a history of failure, contraindication or intolerance to both of the following (Document date of trials):

- Nucynta ER
- morphine sulfate controlled release tablets (specifically generic MS Contin)

OR

2.3 Patient is established on pain therapy with the requested medication for cancer-related or end of life pain (< 2 years life expectancy), and the medication is not a new regiment for the treatment of cancer-related or end of life (< 2 years life expectancy) pain.

Notes

[a] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 24 months up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-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: [Dolophine, fentanyl transdermal patch (generic Duragesic) 12, 25, 50, 75, 100 mcg/hr, methadone, morphine sulfate controlled-release tablets (generic MS Contin), Nucynta ER, Xtampza ER] [a]

<table>
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<tr>
<th>Diagnosis</th>
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<tbody>
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<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non Formulary</td>
</tr>
</tbody>
</table>

### Approval Criteria

1 Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention.
- Patient has been screened for substance abuse/opioid dependence.
- 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.
- Pain is moderate to severe and expected to persist for an extended period of time.
- Pain is chronic.
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time).
- Pain management is required around the clock with a long acting opioid.

AND

2 One of the following:

2.1 The patient is new to the plan (as evidenced by coverage effective date of less than or equal to 120 days) and is currently established on the requested long-acting opioid.
OR

2.2 One of the following

2.2.1 All of the following:

2.2.1.1 The patient is being treated for moderate to severe chronic pain that is non-neuropathic (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

AND

2.2.1.2 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid. (Document drug(s) and date of trial).

OR

2.2.2 All of the following:

2.2.2.1 The patient is being treated for moderate to severe neuropathic pain or fibromyalgia

AND

2.2.2.2 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)

AND

2.2.2.3 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)

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the |
requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-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:** [Arymo ER^, Avinza^, Duragesic^, Embeda^, Exalgo^, fentanyl transdermal (37.5, 62.5, 87.5 mcg/hr)^, Hysingla ER^, Kadian^, Morphabond ER^, MS Contin, OxyContin^, oxycodone controlled-release (Authorized Generic of OxyContin)^, oxymorphone extended release, and Zohydro ER [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled-release tablets (generic MS Contin) and fentanyl transdermal patch (generic Duragesic strengths)]] [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Book of Business: Non-cancer and Non-End of Life pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 months up to the dose allowed by supply limit review</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention.
- Patient has been screened for substance abuse/opioid dependence.
- 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.
- Pain is moderate to severe and expected to persist for an extended period of time.
- Pain is chronic.
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time).
• Pain management is required around the clock with a long acting opioid.

    AND

2 One of the following:

2.1 All of the following:

2.1.1 The patient is being treated for moderate to severe chronic pain that is non-neuropathic (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

    AND

2.1.2 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 4 week) trial of a short-acting opioid (Document drug(s) and date of trial)

    AND

2.1.3 The patient has a history of failure, contraindication or intolerance to a trial of all of the following (Document date of trials):

    • Nucynta ER
    • morphine sulfate controlled-release tablets (specifically generic MS Contin)
    • Xtampza ER
    • For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic strengths)

    OR

2.2 All of the following:

2.2.1 The patient is being treated for moderate to severe neuropathic pain or fibromyalgia

    AND

2.2.2 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)
2.2.3 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)

AND

2.2.4 The patient has a history of failure, contraindication or intolerance to a trial of all of the following (Document date of trials):

- Nucynta ER
- morphine sulfate controlled-release tablets (specifically generic MS Contin)
- Xtampza ER
- For Brand Duragesic requests: fentanyl transdermal patch (generic Duragesic strengths)

Notes

[a] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review (please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-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: [Arymo ER®, Avinza®, Dolophine, Duragesic®, Embeda®, Exalgo®, fentanyl transdermal patch (37.5, 62.5, 87.5 mcg/hr)®, Hysingla ER®, Kadian®, methadone, Morphabond ER®, MS Contin, Nucynta ER, OxyContin®, oxymorphone ER, Xtampza ER and Zohydro ER [Applies to all brand and generic versions of listed products]] [a]

<table>
<thead>
<tr>
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<tr>
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<tr>
<td>Therapy Stage</td>
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</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non Formulary</td>
</tr>
</tbody>
</table>
Approval Criteria

1. Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

   AND

2. Identify rationale for not tapering and discontinuing opioid (Document rationale)

   AND

3. Prescriber attests to ALL of the following:
   
   - Treatment goals are defined, including estimated duration of treatment.
   - Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention.
   - Patient has been screened for substance abuse/opioid dependence.
   - If used in patients with 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 information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
   - Pain is moderate to severe and expected to persist for an extended period of time.
   - Pain is chronic.
   - Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time).
   - Pain management is required around the clock with a long acting opioid.

Notes

[a] State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. Authorization will be issued for 6 months for non-cancer and non-end of life pain up to the dose allowed by supply limit review.
(please refer to supply limit criteria). If the patient is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity reauthorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 90-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

3. Background

Clinical Practice Guidelines

CDC and the American Academy of Neurology:

The CDC and the American Academy of Neurology recommends the following best practices in the prescription of long-acting opioids:

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy, treatment goals should be established with patients that include realistic goals for pain and function and should consider how therapy will be discontinued if benefits do not outweigh risks. Track pain and function at every visit (at least every 3 months) using a brief, validated instrument. Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended release/long-acting opioids.
- Document the daily morphine milligram equivalent (MME) in mg/day from all sources of opioids. Access the state prescription drug monitoring program (PDMP) data at treatment initiation and periodically during treatment. Currently all states except for Missouri have a PDMP.
- To avoid increased risk of respiratory depression, long-acting opioids should not be prescribed concurrently with benzodiazepines. Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.
- Use random urine drug screening prior to initiation and periodically during treatment with a frequency according to risk.
- Use a patient treatment agreement, signed by both the patient and prescriber that addresses risks of use and responsibilities of the patient. Avoid escalating doses above 50-90 mg/day MME unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist.
• Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, opioids should be tapered and discontinued. Evaluation should include assessment of substance use disorder/opioid dependence. Validated scales (such as the DAST-10) are available at www.drugabuse.gov.

Benefit/Coverage/Program Information

Background:

Long-acting opioid analgesics, Arymo ER, Avinza, Embeda, Exalgo, fentanyl transdermal, hydromorphone ER, Hysingla ER, Kadian, Morphabond ER, MS Contin, Nucynta ER, Opana ER, oxycodone hcl ER, OxyContin, oxymorphone ER, Xtampza ER and Zohydro ER are indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for use as an as needed analgesic.

Long-acting opioids are not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. They are only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate.

Long-acting opioids should not be used in treatment naïve patients. Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen to opioids in a plan of pain management such as those outlined by the World Health Organization, the Agency for Healthcare Research and Quality, the Federation of State Medical Boards Model Guidelines, or the American Pain Society.

Additional Clinical Rules:

Supply limits may be in place.

MMELIMIT (Cumulative Opioid Review) is in place and can be utilized for individual supply limit reviews.
4. References


Prior Authorization Guideline

GL-46107 Lotronex (alosteron)

Formulary UHC Core

Formulary Note

Approval Date 12/17/2018

Revision Date 12/17/2018

Technician Note :

P&T Approval Date: 5/21/2013; P&T Revision Date: 10/26/2016, 10/25/2017; 10/17/2018

**Effective Date: 2/1/2019**

1. Indications

Drug Name: Lotronex (alosetron)

Indications

Severe diarrhea-predominant irritable bowel syndrome (IBS) Indicated only for use in women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS, anatomical or biochemical abnormalities of the gastrointestinal tract have been excluded and have not responded to conventional therapy.
## 2. Criteria

**Product Name:** Lotronex*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month</th>
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<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### 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. Has not responded adequately to conventional therapy (e.g., loperamide, antispasmodics)

**Notes**

*Brand Lotronex is typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.

**Product Name:** Lotronex*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
</table>
Therapy Stage | Reauthorization
---|---
Guideline Type | Prior Authorization

**Approval Criteria**

1. Lotronex will be approved based on documentation of positive clinical response to Lotronex therapy

**Notes**

*Brand Lotronex is typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.

---

3. **Background**

**Benefit/Coverage/Program Information**

**Additional Clinical Programs:**

Supply limits may be in place.

**Background**

Lotronex (alosteron) is indicated only for use in women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic IBS, anatomical or biochemical abnormalities of the gastrointestinal tract have been excluded and have not responded to conventional therapy.
4. References

Prior Authorization Guideline

GL-57060 Lotronex (alostron) - Notification

Formulary  UHC Core

Formulary Note

Guideline Note:

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<td>P&amp;T Revision Date:</td>
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</table>

1. Indications

**Drug Name: Lotronex (alostron)**

**Severe diarrhea-predominant irritable bowel syndrome (IBS)** Indicated only for use in women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have chronic
IBS, anatomical or biochemical abnormalities of the gastrointestinal tract have been excluded and have not responded to conventional therapy.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Lotronex*</th>
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<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

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 - Has not responded adequately to conventional therapy (e.g., loperamide, antispasmodics)

Notes

*Brand Lotronex is typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.
3 . Background

Benefit/Coverage/Program Information

Additional Clinical Programs:
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-
  authorization based solely on previous claim/medication history, diagnosis codes (ICD-
  10) and/or claim logic. Use of automated approval and re-approval processes varies by
  program and/or therapeutic class.

  Supply limits may be in place.

Background

Lotronex (alosteron) is indicated only for use in women with severe diarrhea-predominant
irritable bowel syndrome (IBS) who have chronic IBS, anatomical or biochemical abnormalities
of the gastrointestinal tract have been excluded and have not responded to conventional
therapy.

4 . References

1. Lotronex Prescribing Information. Promethus Therapeutics and Diagnostics. San Diego,
   CA. July 2016
   JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey M. eds. Pharmacotherapy: A
## 5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>11/18/2019</td>
<td>Annual review. No changes.</td>
</tr>
</tbody>
</table>
1. Indications

**Drug Name:** Lucemyra (Ilofexidine)

**Indications**

**Opioid withdrawal symptoms** Indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.
2. Criteria

**Product Name:** Lucemyra [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>14 days; If Lucemyra was initiated in the inpatient setting, the total course of therapy should not exceed 14 days.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. For symptoms of abrupt opioid withdrawal.

   AND

2. Opioids have been discontinued

   AND

3. One of the following:

   3.1 History of failure, contraindication, or intolerance to clonidine.

   OR

3.2 Lucemyra was initiated in the inpatient setting.

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authORIZATION based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also apply.

4. References

Prior Authorization Guideline

GL-5536 Lyrica (pregabalin) - Step Therapy

Formulary  UHC Core

Formulary Note

Guideline Note:

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<td>Effective Date:</td>
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<td>P&amp;T Approval Date:</td>
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<td>P&amp;T Revision Date:</td>
<td>9/18/2019</td>
</tr>
</tbody>
</table>

1. Indications

**Drug Name:** Lyrica (pregabalin)

**CNS disorders** Indicated for seizure disorders, post herpetic neuralgia, neuropathic pain associated with diabetic peripheral neuropathy, fibromyalgia and neuropathic pain associated...
with spinal cord injury.

**Off Label Uses: Chemotherapy induced peripheral neuropathy** The National Comprehensive Cancer Network recognizes antiepileptic drugs, including gabapentin and Lyrica for treatment of chemotherapy induced peripheral neuropathy.

**Drug Name: Lyrica CR (pregabalin)**

*neuropathic pain* FDA approved for neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia.

## 2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Lyrica CR* [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Both of the following:

1.1 Diagnosis of neuropathic pain and history of failure, contraindication, or intolerance to two of the following medications (Document date of trial):

- gabapentin (generic Neurontin)
- duloxetine (generic Cymbalta)
- One (1) tricyclic antidepressant (e.g. amitriptyline)

**AND**

1.2 History of failure, contraindication, or intolerance to Lyrica immediate release capsules or solution (Document date of trial and reason for failure)

**OR**

2 - All other diagnoses (not specified above) and history of failure, contraindication or intolerance to BOTH of the following: (Document the diagnosis and ensure that the diagnosis is
not associated with nerve pain which would require review as neuropathic pain. (Document date of trial)).

- gabapentin (generic Neurontin)
- Lyrica immediate release capsules or solution

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Lyrica CR is typically excluded from coverage [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</td>
</tr>
</tbody>
</table>

3. Background

**Benefit/Coverage/Program Information**

**Background:**

Lyrica CR (pregabalin) tablets are FDA approved for neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia. Lyrica CR is not approved for partial onset seizures or fibromyalgia as clinical trials failed to demonstrate efficacy for these indications. The National Comprehensive Cancer Network recognizes antiepileptic drugs, including gabapentin and Lyrica for treatment of chemotherapy induced peripheral neuropathy.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. If the member has evidence of Lyrica Capsules or Solution and an antiepileptic drug in the claims history, then Lyrica Capsules or Solution will automatically process.

**Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References


### 5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/15/2019</td>
<td>Added requirement for documentation of drug, date and duration of medication trials. Added criteria for generalized anxiety</td>
</tr>
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</table>
Prior Authorization Guideline

GL-50514 MEDcDUR - Opioid Overutilization Cumulative Drug Utilization Review Criteria (including individual long-acting opioid supply limits)

Formulary UHC Core

Formulary Note

Approval Date 7/3/2019

Revision Date 7/3/2019

Technician Note:

P&T Approval Date: 8/19/2016; P&T Revision Date: 2/17/2017, 9/26/2017, 4/18/2018, 6/20/2018, 9/19/2018, 4/17/2019; **Effective Date: 7/1/2019**

1. Criteria

Product Name: Individual Long-Acting Supply Limits

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Cancer or End of Life (defined as a &lt; 2 year life expectancy) related pain for individual long-acting supply limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>24 Month</td>
</tr>
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<td>Guideline Type</td>
<td>MEDcDUR</td>
</tr>
<tr>
<td>----------------</td>
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</tr>
</tbody>
</table>

**Approval Criteria**

1. Coverage will be approved based on the following criteria:

1.1 Patient requires treatment with opioids due to active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of less than 2 years.)

**Notes**

Authorization for cancer or end of life pain will be issued for 24 months for a quantity of 9999 to prevent further disruption in therapy if the patient’s dose is increased. If the patient is currently taking a high dose opioid regimen where the supply limit is exceeded and does not meet the authorization criteria requirements for approval, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current quantity with up to one additional transition authorization (total of 2 transition authorizations).

**Product Name:** Individual Long-Acting Supply Limits

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-cancer and Non-End of Life Pain for individual long-acting supply limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
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<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>MEDcDUR</td>
</tr>
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</table>

**Approval Criteria**

1. Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic
intervention
• 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
• Patient has been screened for substance abuse/opioid dependence

AND

2 The opioid regimen is not being used in combination with buprenorphine containing products for opioid dependence.

AND

3 Document BOTH of the following:

• The total daily desired morphine milligram equivalent requested for the patient
• The diagnosis associated with the need for pain management

AND

4 State prescription drug monitoring program (PDMP), if available, has been reviewed to identify any concurrently prescribed controlled substances

AND

5 Both of the following

• Patient has tried and failed non-opioid pain medication (document drug name and date of trial)
• Have used opioid medications in lower doses and did not adequately control pain
Authorization will be issued for 6 months for the requested quantity up to the maximum ceiling limit. If the patient is currently taking a high dose opioid regimen where the supply limit is exceeded and does not meet the authorization criteria requirements for approval, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current quantity with up to one additional transition authorization (total of 2 transition authorizations).

**Product Name:** Individual Long-Acting Supply Limits

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<tr>
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<tr>
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<td>Reauthorization</td>
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</tbody>
</table>

**Approval Criteria**

1 Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention.
- 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.
- Patient has been screened for substance abuse/opioid dependence

**AND**
2 The opioid regimen is not being used in combination with buprenorphine containing products for opioid dependence.

AND

3 Identify rationale for not tapering and discontinuing opioid (Document rationale).

AND

4 Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement).

AND

5 Document both of the following

- The total daily desired morphine milligram equivalent requested for the patient
- The diagnosis associated with the need for pain management

AND

6 State prescription drug monitoring program (PDMP), if available, has been reviewed to identify any concurrently prescribed controlled substances

| Notes | Authorization will be issued for 6 months for the requested quantity up to the maximum ceiling limit. If the patient is currently taking a high dose opioid regimen where the supply limit is exceeded and does not meet the authorization criteria requirements for approval, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current quantity with up to one additional transition |
Authorization (total of 2 transition authorizations).

**Product Name:** Cumulative MMELIMIT^

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Cancer or End of Life (defined as a &lt; 2 year life expectancy) related pain for MMELIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>24 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>MEDcDUR</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Cumulative doses exceeding 180 morphine milligram equivalents (MME) will be approved based on the following criteria:

1.1 Patient is being treated for active cancer diagnosis or end of life related pain (document cancer diagnosis or for end of life, expectancy of less than 2 years.)

**Notes**

Authorization for cancer or end of life pain will be issued for 24 months for an MME of 9999 to prevent further disruption in therapy if the patient’s dose is increased. If the patient is currently taking a high dose opioid regimen where the MME exceeds 180 and does not meet the authorization criteria requirements for cumulative opioid overutilization, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current MME with up to one additional transition authorization (total of 2 transition authorizations). A transition authorization should not be granted to patients currently at or below the 180 MME threshold. ^ MMELIMIT refers to Cumulative MME of 180 *If in Ohio, prescribers should reference the Ohio Guidelines created by the Governor’s Cabinet Opiate Action Team when the dose exceeds 80 MME.

**Product Name:** Cumulative MMELIMIT^

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-cancer and Non-End of Life Pain for MMELIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>MEDcDUR</td>
</tr>
<tr>
<td>----------------</td>
<td>---------</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Required to meet all criteria for Non-cancer and Non-End of Life Pain for individual long-acting supply limits (Initial Authorization)

**Notes**

Authorization will be issued for 6 months up to the current requested MME plus 90 MME up to a maximum of 990. If the patient is currently taking a high dose opioid regimen where the MME exceeds 180 and does not meet the authorization criteria requirements for cumulative opioid overutilization, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current MME with up to one additional transition authorization (total of 2 transition authorizations). A transition authorization should not be granted to patients currently at or below the 180 MME threshold. MMELIMIT refers to Cumulative MME of 180 *If in Ohio, prescribers should reference the Ohio Guidelines created by the Governor’s Cabinet Opiate Action Team when the dose exceeds 80 MME.

**Product Name:** Cumulative MMELIMIT^ 

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-cancer and Non-End of Life Pain for MMELIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>MEDcDUR</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Required to meet all criteria for Non-cancer and Non-End of Life Pain for individual long-acting supply limits (Reauthorization)

**Notes**

Authorization will be issued for 6 months up to the current requested MME plus 90 MME up to a maximum of 990. If the patient is currently taking a high dose opioid regimen where the MME exceeds 180 and does not meet the authorization criteria requirements for cumulative opioid overutilization, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current MME with up to one additional transition authorization (total of 2 transition authorizations). A transition authorization should not be granted to patients currently at or below the 180 MME threshold. MMELIMIT refers to Cumulative MME of 180 *If in Ohio, prescribers should reference the Ohio Guidelines created by the Governor’s Cabinet Opiate Action Team when the dose exceeds 80 MME.
opioid overutilization, a denial will be issued and a transition authorization of 90 days may be issued one time up to the current MME with up to one additional transition authorization (total of 2 transition authorizations). A transition authorization should not be granted to patients currently at or below the 180 MME threshold. ^ MMELIMIT refers to Cumulative MME of 180 *If in Ohio, prescribers should reference the Ohio Guidelines created by the Governor’s Cabinet Opiate Action Team when the dose exceeds 80 MME.

2. Background

Clinical Practice Guidelines

The Center for Disease Control (CDC):

The Center for Disease Control (CDC) recommends that clinicians should prescribe the lowest effective dosage when opioids are started. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to 50 morphine equivalent doses (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day.

According to the CDC, if a patient’s opioid dosage for all sources of opioids combined reaches or exceeds 50 MME per day, clinicians should implement additional precautions, including increased frequency of follow-up and considering offering naloxone. Clinicians should avoid increasing opioid dosages to 90 MME or more per day or should carefully justify a decision to increase dosage to 90 MME or more per day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME per day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at 90 MME or more per day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management, consider working with patients to taper opioids to a lower dosage, consider discontinuation of some or all opioids, and evaluate patients for opioid use disorder.

Benefit/Coverage/Program Information
Additional Clinical Programs:

Medical Necessity and Step Therapy may also be in place.

^ MMELIMIT refers to Cumulative MME of 180
** Ceiling limit is based on dose optimization and a maximum of 240 MME

Supply Limit Grid:

*If in Ohio, prescribers should reference the Ohio Guidelines created by the Governor’s Cabinet Opiate Action Team when the dose exceeds 80 MME.

<table>
<thead>
<tr>
<th>Drugs Strength</th>
<th>CDC Max MME (90 MME equivalent*)</th>
<th>Supply Limit/Month</th>
<th>Supply Limit Ceiling Limit for Non-Cancer/ End of Life Pain**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arymo ER 15 mg</td>
<td>90 mg/day</td>
<td>93</td>
<td>93 (3/day)</td>
</tr>
<tr>
<td>Arymo ER 30 mg</td>
<td>90 mg/day</td>
<td>93</td>
<td>93 (3/day)</td>
</tr>
<tr>
<td>Arymo ER 60 mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>124 (4/day)</td>
</tr>
<tr>
<td>Avinza 30 mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>31 (1/day)</td>
</tr>
<tr>
<td>Avinza 45 mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>31 (1/day)</td>
</tr>
<tr>
<td>Avinza 60 mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>31 (1/day)</td>
</tr>
<tr>
<td>Avinza 75 mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>93 (3/day)</td>
</tr>
<tr>
<td>Avinza 90 mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>62 (2/day)</td>
</tr>
<tr>
<td>Avinza 120 mg</td>
<td>90 mg/day</td>
<td>0</td>
<td>62 (2/day)</td>
</tr>
<tr>
<td>Dolophine 10mg</td>
<td>22.5 mg/day</td>
<td>62</td>
<td>186 (6/day)</td>
</tr>
<tr>
<td>Dolophine 5 mg</td>
<td>22.5 mg/day</td>
<td>124</td>
<td>124 tablets (4/day)</td>
</tr>
<tr>
<td>Duragesic 12 mcg/hr</td>
<td>50 mcg q 72 hrs (1/2 patch/day equivalent)</td>
<td>15</td>
<td>15 (0.5/day)</td>
</tr>
<tr>
<td>Duragesic 25 mcg/hr</td>
<td>50 mcg q 72 hrs (1/2 patch/day equivalent)</td>
<td>15</td>
<td>15 (0.5/day)</td>
</tr>
<tr>
<td>Duragesic 50 mcg/hr</td>
<td>50 mcg q 72 hrs (1/2 patch/day equivalent)</td>
<td>10</td>
<td>15 (0.5/day)</td>
</tr>
<tr>
<td>Duragesic 75 mcg/hr</td>
<td>50 mcg q 72 hrs (1 patch/day equivalent)</td>
<td>10</td>
<td>10 (0.33/day)</td>
</tr>
<tr>
<td>Duragesic 100 mcg/hr</td>
<td>50 mcg q 72 hrs (1/2 patch/day equivalent)</td>
<td>10</td>
<td>10 (0.33/day)</td>
</tr>
<tr>
<td>Embeda 20 mg/0.8mg</td>
<td>90 mg/day</td>
<td>62</td>
<td>62 (2/day)</td>
</tr>
<tr>
<td>Embeda 30 mg/1.2mg</td>
<td>90 mg/day</td>
<td>62</td>
<td>62 (2/day)</td>
</tr>
<tr>
<td>Embeda 50 mg/2mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>62 (2/day)</td>
</tr>
<tr>
<td>Embeda 60 mg/2.4mg</td>
<td>90 mg/day</td>
<td>31</td>
<td>62 (2/day)</td>
</tr>
</tbody>
</table>
3. References

Prior Authorization Guideline

GL-10604 Meglitinides and Meglitinide Combination Agents

Formulary UHC Core

Formulary Note

Approval Date 11/12/2013

Revision Date 7/18/2014

Technician Note :

CPS Approval Date: 2/17/2009; CPS Revision Date: 4/8/2014; According to Texas State Law, all diabetic medications used for the treatment of diabetes shall be covered.

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: PrandiMet (repaglinide/metformin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
</tr>
</tbody>
</table>

Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a meglitinide and metformin HCl or who have inadequate glycemic control on a meglitinide alone or metformin HCl alone.
2. Criteria

Product Name: PrandiMet

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1. History of metformin [2,3,4]

3. References

1. PrandiMet Prescribing Information. Novo Nordisk Inc. April 2012
3. AACE Comprehensive Diabetes Management Algorithm, Endocr Pract. 2013;19 (No. 2)
1. Indications

**Drug Name:** Mesalazine delayed-release (generic Lialda)

**Indications**

**Ulcerative Colitis** Indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.
2. Criteria

Product Name: Mesalamine delayed-release (generic Lialda)

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1. History of failure or intolerance to Brand Lialda (list reason for therapeutic failure or intolerance)

3. References

2.
Prior Authorization Guideline

GL-47763 Migraine Quantity Limit

Formulary UHC Core

Formulary Note

Approval Date 3/22/2019

Revision Date 3/22/2019

Technician Note:

P&T Approval Date: 5/19/2016; P&T Revision Date: 11/17/2016, 12/20/2017, 8/17/2017, 7/18/2018, 3/20/2019. **Effective Date: 5/1/2019**

1. Indications

**Drug Name:** Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan) tablets and nasal spray, Onzeta (sumatriptan), Relpax (eletriptan), Zembrace SymTouch (sumatriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan)

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Safety and effectiveness of respective triptan therapy have not been established for cluster headache (not applicable to Zembrace SymTouch). Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first
migraine attack treated with therapy, reconsider the diagnosis of migraine before therapy is administered to treat any subsequent attacks. Therapy is not indicated for the prevention of migraine attacks.

**Drug Name: Axert (almotriptan)**

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

**Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan)**

**Indications**

**Migraine headaches** Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

**Drug Name: Migranal (dihydroergotamine mesylate)**

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.
**Drug Name: Treximet (sumatriptan/naproxen)**

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

**Drug Name: Zomig (zolmitriptan) nasal spray**

**Indications**

**Migraine Headaches** Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

**Drug Name: Imitrex (sumatriptan) injection**

**Indications**

**Migraine Headache** Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine headache attacks.

**Cluster Headaches** Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established. If a patient has no response to the first cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of cluster headache attacks.
Drug Name: Sumavel DosePro (sumatriptan)

Indications

Migraine Headaches Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Sumavel DosePro, reconsider the diagnosis of migraine before Sumavel DosePro is administered to treat any subsequent attacks. Sumavel DosePro is not indicated for the prevention of migraine attacks.

Cluster Headaches Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established.

2. Criteria

Product Name: Brand Amerge, Generic naratriptan, Brand Axert, Generic almotriptan, Brand Frova, Generic frovatriptan, Brand Imitrex, Generic sumatriptan, Brand Maxalt, Generic rizatriptan, Brand Migranal, Generic dihydroergotamine, Onzeta, Brand Relpax, Generic eletriptan, Sumavel DosePro, Brand Treximet, Generic sumatriptan/naproxen, Zembrace SymTouch, Brand Zomig, or Generic zolmitriptan

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Quantity Limit</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of one of the following:

- Acute migraines with or without aura
- Cluster headaches

AND
2 Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 Patient is experiencing 2 or more headaches per month [10-12]

AND

4 Patient will not be treating 15 or more headaches per month

AND

5 Currently receiving prophylactic therapy with at least one of the following: [A]

- Antidepressants
- Anticonvulsants
- Beta-blockers

AND

6 Not used in combination with another triptan or ergotamine-containing product

AND
7 One of the following: [B]

7.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer’s prescribing information

OR

7.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3. Endnotes

A. American Academy of Neurology (AAN)-recommended first-line agents for the prevention of migraine headache are atenolol, metoprolol, nadolol, propranolol, timolol, amitriptyline, venlafaxine, topiramate, and divalproex sodium. [10-12, 17]

B. Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

4. References

Prior Authorization Guideline

GL-49258 Minocycline extended-release tablet (generic Solodyn), Minolira (minocycline extended-release tablet), Solodyn (minocycline extended-release tablet), Ximino (minocycline extended-release capsule)

Formulary UHC Core

Formulary Note

Approval Date 4/29/2019

Revision Date 4/29/2019

Technician Note:

P&T Approval Date: 8/18/2017; P&T Revision Date: 4/18/2018, 2/15/2019. **Guideline Effective Date: 5/1/2019**

1. Indications

**Drug Name: Minolira, Solodyn and Ximino**

**Indications**

**Severe acne vulgaris** Indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.
2. Criteria

Product Name: Minocycline Extended-Release (generic Solodyn) [A]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of moderate to severe inflammatory acne vulgaris

   AND

2. One of the following:

   2.1 Submission of medical records (e.g. chart notes) documenting an inadequate response to a four week trial of minocycline immediate-release capsule (generic Minocin)

   OR

   2.2 Submission of medical records (e.g. chart notes) documenting an intolerance to minocycline immediate-release capsule (generic Minocin) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

Product Name: Minolira, Solodyn and Ximino [A]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria
1 Diagnosis of moderate to severe inflammatory acne vulgaris

AND

2 One of the following:

2.1 Submission of medical records (e.g. chart notes) documenting an inadequate response to a four week trial of minocycline immediate-release capsule (generic Minocin)

OR

2.2 Submission of medical records (e.g. chart notes) documenting an intolerance to minocycline immediate-release capsule (generic Minocin) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

3 One of the following:

3.1 Submission of medical records (e.g. chart notes) documenting an inadequate response to a four week trial of minocycline extended-release (generic Solodyn)*

OR

3.2 Submission of medical records (e.g. chart notes) documenting an intolerance to minocycline extended-release (generic Solodyn)* which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)
### 3. Background

**Benefit/Coverage/Program Information**

**Background:**

Systemic antibiotics are an option for the treatment of acne. They are indicated for use in moderate to severe inflammatory acne and should be used in combination with a topical retinoid, benzoyl peroxide, and/or a topical antibiotic.

Minolira, Solodyn and Ximino are indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. They did not demonstrate any effect on non-inflammatory acne lesions. The safety of Minolira, Solodyn and Ximino has not been established beyond 12 weeks of use.

This program requires a member to try minocycline immediate-release capsule (generic Minocin) and minocycline extended-release (generic Solodyn)* prior to receiving coverage for Minolira, Solodyn or Ximino. In addition, it requires a member to try minocycline immediate-release capsule (generic Minocin) prior to receiving coverage for minocycline extended-release tablet (generic Solodyn)*.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

*Prior Authorization may be required
4. Endnotes

A. State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

5. References

1. Indications

**Drug Name:** Motegrity

**Indications**

**Chronic Idiopathic Constipation** Indicated for the treatment of chronic idiopathic constipation in adults.
2. Criteria

**Product Name:** Motegrity (prucalopride) [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic Idiopathic Constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of chronic idiopathic constipation

   AND

2. History of failure, contraindication or intolerance to one OTC medication used for the treatment of constipation (document duration of trial)

   AND

3. One of the following criteria:

   3.1 History of failure, contraindication, or intolerance to Linzess

   OR

   3.2 Age less than or equal to 17

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage.
Product Name: Motegrity (prucalopride) [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Chronic Idiopathic Constipation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to Motegrity therapy

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

## 3. Background

Clinical Practice Guidelines

**Background:**

Motegrity (prucalopride) is indicated for the treatment of chronic idiopathic constipation in adults. Physicians and patients should periodically assess the need for continued treatment with Motegrity. Linzess (linaclotide) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation in adults aged 18 years and older. Linzess has a black box warning.
regarding the risk of serious dehydration in pediatric patients less than 17 years of age, and use of Linzess should be avoided in pediatric patients.

This program is intended to encourage the use of lower cost alternatives and requires a member to try an over-the-counter medication (OTC) for constipation and Linzess before providing coverage for Motegrity.

4. References

Prior Authorization Guideline

GL-51427 Movantik (naloxegol) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 8/12/2019

Revision Date 8/12/2019

Technician Note:

P&T Approval Date: 7/18/2018. **Effective Date: 10/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Movantik (naloxegol)</th>
</tr>
</thead>
</table>

**Indications**

**Opioid-induced constipation (OIC)** Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
2. Criteria

Product Name: Movantik (naloxegol) [a].*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
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<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 ONE of the following:

1.1 Diagnosis of opioid-induced constipation with chronic, non-cancer pain

OR

1.2 Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 History of failure, contraindication or intolerance to BOTH of the following:

2.1 An OTC laxative (document name and date tried)

AND

2.2 Symproic
Movantik (naloxegol) and Symproic (naldemedine) are opioid antagonists indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

This prior authorization program is intended to encourage the use of lower cost alternatives. This program requires a member to try over-the-counter (OTC) laxative therapy and Symproic before providing coverage for Movantik.
Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Notification/Prior Authorization may be in place.

4. References

1. Indications

**Drug Name: Mulpleta**

**Indications**

**Thrombocytopenia** Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
# 2. Criteria

**Product Name:** Mulpleta

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Thrombocytopenia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of thrombocytopenia

   **AND**

2. Patient has chronic liver disease

   **AND**

3. Patient is scheduled to undergo a procedure

---

# 3. References
Prior Authorization Guideline

GL-50649 Multaq (dronedarone)

Formulary UHC Core

Formulary Note

Approval Date 7/26/2019

Revision Date 7/26/2019

Technician Note:

**Guideline Effective Date: 9/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Multaq (dronedarone)</th>
</tr>
</thead>
</table>

**Indications**

**Atrial fibrillation** Indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.
2. Criteria

Product Name: Multaq

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following:

1.1 All of the following criteria:

1.1.1 Diagnosis of a history of one of the following:

- Paroxysmal atrial fibrillation (AF)
- Persistent AF defined as AF less than 6 months duration

AND

1.1.2 One of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.1.3 Patient has none of the following:

- NYHA Class IV heart failure
- Symptomatic heart failure with recent decompensation requiring hospitalization

OR

1.2 For continuation of current therapy
3. Background

<table>
<thead>
<tr>
<th>Benefit/Coverage/Program Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background:</strong></td>
</tr>
<tr>
<td>Multaq is an antiarrhythmic drug indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.</td>
</tr>
<tr>
<td>Multaq carries a black box warning for increased risk of death, stroke, and heart failure in patients with decompensated heart failure or permanent atrial fibrillation. It is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure, as Multaq doubles the risk of death in these patients. Multaq is also contraindicated in patients in atrial fibrillation who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent atrial fibrillation, Multaq doubles the risk of death, stroke and hospitalization for heart failure.</td>
</tr>
<tr>
<td>Patients currently on Multaq therapy will be allowed to remain on therapy.</td>
</tr>
</tbody>
</table>

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References

Prior Authorization Guideline

GL-49284 Multisource Brand Anticonvulsants

Formulary UHC Core

Formulary Note

Approval Date 4/30/2019

Revision Date 4/30/2019

Technician Note :

P&T Approval Date: 2/15/2019 **Guideline Effective Date: 5/1/2019**

1. Criteria

Product Name: Trileptal, Zonegran

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Epilepsy, Seizures and Status Epilepticus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
Approval Criteria

1 Both of the following:

1.1 History of greater than or equal to a 4 week trial of the therapeutically equivalent generic (document date of trial)

AND

1.2 Documented history of an inadequate response to the therapeutically equivalent generic as evidenced by one of the following (document inadequate response):

- Change in seizure frequency from baseline
- Breakthrough seizures not explained by medication noncompliance or significant provoking factor
- Status epilepticus

OR

2 Documented history of intolerance to the therapeutically equivalent generic which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., change timing of dosing, divide daily dose out for more frequent but smaller doses)

OR

3 Documented history of drug-resistant epilepsy (defined as the failure of two tolerated and appropriately chosen and used anti-epileptic drug schedules [as either mono-therapy or combination therapy] to achieve sustained seizure freedom) (document names of the two medications and dates of trials)

OR
Documented history of a high risk for seizure recurrence defined as one or more of the following:

- Identifiable brain disease
- Mental retardation
- Abnormal neurologic examination
- Seizure onset after the first decade
- Multiple seizure types
- Poor initial response to treatment
- Juvenile myoclonic epilepsy
- Epileptiform discharges on electroencephalogram (EEG)
- Family history of epilepsy
- Hippocampal atrophy or abnormal hippocampal signal on magnetic resonance imaging (MRI)

**Product Name:** Trileptal, Zonegran

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Other Indications (e.g. mania, bipolar disorder, migraine prophylaxis, neuropathy, postherpetic neuralgia)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Both of the following:

1.1 History of greater than or equal to a 4 week trial of the therapeutically equivalent generic (document date of trial)

AND

1.2 Documented history of an inadequate response to the therapeutically equivalent generic (document inadequate response)

OR
2 Documented history of intolerance to the therapeutically equivalent generic which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., change timing of dosing, divide daily dose out for more frequent but smaller doses)

**Product Name:** Trileptal, Zonegran

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to therapy

---

2. **Background**

**Benefit/Coverage/Program Information**

**Background:**

This program requires a member to try the A-rated generic prior to receiving coverage for brand Trileptal or Zonegran unless patient has a history of drug-resistant epilepsy or is at high risk of seizure recurrence.

**Additional Clinical Rules:**

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic
class.

3. References

Prior Authorization Guideline

GL-49289 Noctiva (desmopressin acetate), Nocdurna (desmopressin acetate) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 4/30/2019

Revision Date 4/30/2019

Technician Note :

P&T Approval Date: 5/18/2018; P&T Revision Date: 7/18/2018, 10/17/2018, 02/15/2019;
**Effective Date: 05/1/2019**

1. Indications

Drug Name: Noctiva (desmopressin acetate) nasal spray, Nocdurna (desmopressin acetate)

Indications

nocturia due to nocturnal polyuria Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.
2. Criteria

Product Name: Nocdurna

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

   AND

2. Patient wakes at least twice per night on a reoccurring basis to void

   AND

3. 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.

   AND

4. 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)

AND

5 Prescriber attests that the risks have been assessed and benefits outweigh the risks

Product Name: Noctiva*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 Patient wakes at least twice per night on a reoccurring basis to void

AND

3 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.

AND
4 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)

AND

5 Prescriber attests that the risks have been assessed and benefits outweigh the risks

AND

6 History of failure, contraindication or intolerance to Nocdurna

Notes

*Typically excluded from coverage

Product Name: Noctiva*, Nocdurna

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Documentation of positive clinical response to Noctiva* or 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

| Notes                  | *Typically excluded from coverage |

3. Background

Benefit/Coverage/Program Information

Background

Noctiva* (desmopressin acetate) nasal spray and Nocdurna (desmopressin acetate) sublingual tablets are indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. In clinical trials, nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. Prior to initiating treatment with Noctiva* or Nocdurna, patients should be evaluated for possible causes of nocturia and to optimize the treatment of underlying conditions that may be contributing to the nocturia.

Desmopressin should be avoided in older adults (those 65 or older) due to the risk of hyponatremia. This medication is included in the American Geriatrics Society Beers Criteria. Noctiva* and Nocdurna have a Black Box Warning for hyponatremia listed in the FDA prescribing information. Noctiva* and Nocdurna use is contraindicated in patients with hyponatremia or a history of hyponatremia, SIADH, eGFR <50 mL/min/1.7m², uncontrolled hypertension, and New York Heart Association Class II – IV congestive heart failure. See package insert for full listing of contraindications and safety warnings.
Additionally, two sprays of Noctiva* 0.75 (0.83) mcg are not interchangeable with one spray of 1.5 (1.66) mcg. Noctiva* has not been studied in patients less than 50 years of age. Nocdurna has not been studied in patients less than 18 years of age.

This prior authorization program is intended to ensure appropriate prescribing of Noctiva* and Nocdurna prior to initiating therapy.

Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References

1. Indications

**Drug Name: Ambien CR (zolpidem tartrate extended-release)**

**Indications**

**Insomnia** Indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset). The clinical trials performed in support of efficacy were 3 weeks in duration, although the final formal assessments of sleep latency and maintenance were performed after 2 weeks of treatment.

**Drug Name: Belsomra (suvorexant)**
### Indications

**Insomnia** Indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

---

### Drug Name: Edluar (zolpidem tartrate)

**Indications**

**Insomnia** Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The clinical trials performed with Zolpidem tartrate in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

---

### Drug Name: Rozerem (ramelteon)

**Indications**

**Insomnia** Indicated for the treatment of insomnia characterized by difficulty with sleep onset.

---

### Drug Name: Zolpimist (zolpidem tartrate)

**Indications**

**Insomnia** Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem tartrate has been shown to decrease sleep latency for up to 35 days in controlled clinical studies. The clinical trials performed in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

---

### 2. Criteria

**Product Name:** Edluar or Zolpimist

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

---
Approval Criteria

1 History of zolpidem [C]

Product Name: Brand Ambien CR, Generic zolpidem ER

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month [A]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1 History of failure, contraindication, or intolerance to both of the following: [C]

- Ambien (zolpidem)
- Lunesta (eszopiclone)

Product Name: Rozerem

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month [A]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following:

1.1 History of failure, contraindication, or intolerance to both of the following: [C]

- Ambien (zolpidem)
- Lunesta (eszopiclone)

OR

1.2 History of or potential for a substance abuse disorder [B]

Product Name: Belsomra
<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1. History of one of the following:

- eszopiclone
- temazepam
- zaleplon
- zolpidem
- zolpidem ER

3. **Endnotes**

   A. Recent controlled studies of non-benzodiazepine-BzRAs have demonstrated continued efficacy without significant complications for 6 months, and in open-label extension studies for 12 months or longer. [2]

   B. Ramelteon is not a controlled substance [1]. Zolpidem products are C-IV [3-6].

   C. Sonata has a shorter elimination half-life (~1 hour) compared to the other non-benzodiazepine sedatives such as Ambien CR (~ 2.8-2.9 hrs), Ambien (~2.5-2.6 hours), Edluar (~2.65-2.85 hours), Zolpimist (~2.7-3 hours), Lunesta (~5-6 hours) and Rozerem (~ 1 to 2.6 hours); therefore, Sonata is not considered an appropriate alternative to those agents, per the Clinical Programs Subcommittee (CPS) review. [7]

4. **References**

   1. Rozerem Prescribing Information. Takeda Pharmaceuticals, November 2010.


Prior Authorization Guideline

GL-36177 Non-Formulary Exceptions Process - UHC

Formulary UHC Core

Formulary Note

Approval Date 7/20/2017

Revision Date 7/20/2017

Technician Note:

P&T Approval Date: 2/19/2013; P&T Revision Date: 7/27/2016 The purpose of this guideline is to establish policies and procedures on how to handle non-formulary drugs that do not have official criteria posted or available. This guideline will not apply to drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx. UHC West Non-Formulary Drug Criteria grid link:

http://optumrx.optum.com/sites/CST/CSDM/Shared%20Documents/Forms/AllItems.aspx?RootFolderPath=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FUHC%20Core%20Tables&FolderCTID=0x01200027C80175A8369D45A99A99328B80&View={4B6D25AD-6A95-496D-9937-65CECD43AFE7}

1. Criteria

Product Name: A non-formulary drug
<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Administrative</th>
</tr>
</thead>
</table>

### Approval Criteria

1 In the absence of a drug-specific clinical guideline that has been approved by the P&T Committee to guide the non-formulary exceptions process, the following guideline will be used to establish medical necessity.

1.1 One of the following:

1.1.1 Patient has failed or has contraindications or intolerance to a maximum of three equivalent formulary drugs (or as otherwise stated in the UHC Core Non-Formulary Drug Criteria grid) as determined by one of the following:

- UHC Core Non-Formulary Drug Criteria grid (see Technician Note for the URL)
- Prior Authorization pharmacist, if the non-formulary drug requested is not included in the UHC West Non-Formulary Drug Criteria Grid

OR

1.1.2 No formulary drug is appropriate to treat the patient’s condition.

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the “Indications and Usage” sections of the prescribing information (or package insert) have been met (eg: first line therapies have been tried and failed, any testing requirements have been met, etc)

OR
1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met.
Prior Authorization Guideline

GL-55878 Non-Solid Oral Dosage Forms

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>11/1/2019</th>
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</thead>
<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>6/20/2018</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>8/16/2019</td>
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</tbody>
</table>

Technician Note:

P&T Approval Date: 6/20/2018; P&T Revision Date: 8/16/2019. **Guideline Effective Date: 11/1/2019**

1. Criteria
Product Name: [Carospir, Epaned, Flolipid, Naprosyn suspension, Purixan, Syndros, and Tirosint-Sol] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:

1.1 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

1.2 Patient utilizes a feeding tube for medication administration

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Qbrelis* [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:

1.1 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

1.2 Patient utilizes a feeding tube for medication administration

Notes
[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Typically excluded from coverage.

Product Name: Zegerid suspension* [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following:

1.1 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

1.2 Patient utilizes a feeding tube for medication administration

AND

2 - Patient has a history of trial and failure, intolerance or contraindication to BOTH of the following:

• Nexium suspension
- Prevacid SoluTabs

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. *Typically excluded from coverage.

<table>
<thead>
<tr>
<th>Product Name: [Tiglutik, Katerzia, and Xatmep] [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - One of the following:

1.1 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

1.2 Patient utilizes a feeding tube for medication administration

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

2. Background

**Benefit/Coverage/Program Information**
**Background:**

Coverage criteria outlined below are for patients unable to ingest a solid oral dosage form.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

3. **References**


4. **Revision History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
</table>
1. Indications

**Drug Name: Sprix (ketorolac tromethamine) nasal spray**

**Indications**

**Moderate to moderately severe pain** Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

**Drug Name: Tivorbex (indomethacin) capsules**
**Indications**

**Mild to moderate pain** Indicated for treatment of mild to moderate acute pain in adults.

**Drug Name:** Cambia (diclofenac) powder

**Indications**

**Migraine** Indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older). Limitations of use: Cambia is not indicated for the prophylactic therapy of migraine. The safety and effectiveness of Cambia have not been established for cluster headache, which is present in an older, predominantly male population.

---

**2. Criteria**

**Product Name:** Sprix nasal spray

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>5 Days [A]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of moderate to moderately severe pain

AND

2 One of the following:

2.1 Trial and failure, contraindication, or intolerance to oral ketorolac* tablets
2.2 Patient is unable to take medications orally

| Notes | *Ketorolac is recommended only for patients less than 65 years old. [B, C] |

**Product Name:** Tivorbex*, Cambia*

| Guideline Type | Step Therapy |

**Approval Criteria**

1. Trial and failure, contraindication, or intolerance to two of the following:

- diclofenac or diclofenac ER
- diflunisal
- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meclofenamate
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin

| Notes | *Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including indomethacin, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [C] |
3. Endnotes

A. The total duration of use of Sprix alone or sequentially with other formulations of ketorolac (IM/IV or oral) must not exceed 5 days because of the potential for increasing the frequency and severity of adverse reactions associated with the recommended doses. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with Sprix. [21]

B. This drug is included on the 2012 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults greater than or equal to 65 years old. [24]

C. This drug is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) [25]

4. References

22. Indocin Prescribing Information. IROKO Pharmaceuticals, LLC. November 2012.
Prior Authorization Guideline

GL-32590 Nucynta (tapentadol), Tramadol-containing Products

Formulary UHC Core

Formulary Note

Approval Date 11/28/2016

Revision Date 11/28/2016

Technician Note:

P&T Approval Date: 6/23/2009; P&T Revision Date: 9/28/2016 **Effective 1/1/2017**

1. Indications

Drug Name: ConZip (tramadol) extended-release capsules; generic tramadol ER capsules (100 mg, 200 mg, 300 mg); brand and generic tramadol ER 150 mg capsules; Ultram ER (tramadol) extended-release tablets; and generic tramadol ER tablets [biphasic, non-biphasic]

Indications

Moderate to moderately severe chronic pain Indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time
Drug Name: Nucynta (tapentadol) tablets

**Indications**

**Moderate to severe acute pain** Indicated for the management of moderate to severe acute pain in adults

Drug Name: Ultracet (tramadol/acetaminophen) tablets

**Indications**

**Acute pain** Indicated for the short-term (five days or less) management of acute pain

Drug Name: Ultram (tramadol) tablets

**Indications**

**Moderate to moderately severe pain** Indicated for the management of moderate to moderately severe pain in adults

---

### 2. Criteria

**Product Name:** ConZip or Brand Tramadol ER 100, 150, 200, 300 mg capsules (biphasic)

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate to moderately severe chronic pain
AND

2 History of failure, contraindication, or intolerance to both of the following:

2.1 Tramadol containing product [e.g., Ultram (tramadol), Ultracet (tramadol/acetaminophen)]

AND

2.2 All of the following opioids: [D]

- Acetaminophen with codeine (e.g., Tylenol #3)
- Hydrocodone-containing product [e.g., Vicodin (hydrocodone/acetaminophen), Norco (hydrocodone/acetaminophen)]
- Morphine extended-release (e.g., MS Contin)
- OxyContin (oxycodone extended-release)

**Product Name:** Brand Ultram ER, Generic tramadol ER tablet, or Generic tramadol ER tablet (biphasic)

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

**Approval Criteria**

1 History of one of the following:

- tramadol
- tramadol/acetaminophen

**Product Name:** Brand Ultracet or Brand Ultram

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Non Formulary</th>
</tr>
</thead>
</table>

**Approval Criteria**
1 History of failure, contraindication, or intolerance to two of the following formulary immediate-release (IR) opioids: [B]

- Tramadol containing product (e.g., generic tramadol, generic tramadol/acetaminophen)
- Acetaminophen with codeine (e.g., Tylenol #3)
- Hydrocodone-containing product [e.g., Vicodin (hydrocodone/acetaminophen), Norco (hydrocodone/acetaminophen)]

Product Name: Nucynta

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1 History of failure, contraindication, or intolerance to both of the following formulary immediate-release (IR) opioids:

1.1 Tramadol containing product [e.g., Ultram (tramadol), Ultracet (tramadol/acetaminophen)] [C]

AND

1.2 One of the following: [A]

- Oxycodone immediate-release (e.g., OxyIR)
- Morphine immediate-release (e.g., MSIR)
- Dilaudid (hydromorphone immediate-release)

3. Background
**Benefit/Coverage/Program Information**

**Quantity Limit**

These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

---

4. **Endnotes**

A. Effective June 22, 2009 Nucynta was placed into schedule II of the Controlled Substances Act (CSA). [12] In clinical trials Nucynta was compared to oxycodone IR and morphine. Nucynta 50 mg and 75 mg was found noninferior to oxycodone 10 mg IR. [13]

B. Short-acting, weak opioids, such as Darvon, Darvocet, Tylenol w/codeine, and Vicodin are appropriate alternatives for non-scheduled tramadol products. [15]

C. A trial of Ultram prior to Nucynta is recommended. If a patient has to fail only one drug, then it would be a trial of Ultram, not a CII. All patients should be required to have a trial of Ultram before getting Nucynta, including those who have already tried oxycodone or morphine. It would also be preferable and appropriate to require failure to two agents. [19]

D. Don't have any good efficacy data for Conzip-don't know why the FDA approved this drug. IR component is highly abused: get a rapid increase in opioid concentration. Conzip criteria should include failure of all available opioids (CII and CIII, as well as tramadol). [15]

5. **References**

4. Tramadol Extended-Release Capsules (100 mg, 200 mg, 300 mg) Prescribing Information. Trigen Laboratories, LLC., June 2015.


20. Per clinical consultation with pain specialist, November 1, 2011.


GL-47423 Nuedexta (dextromethorphan/quinidine)

Formulary UHC Core

Formulary Note

Approval Date 1/17/2019

Revision Date 1/17/2019

Technician Note:

P&T Approval Date: 11/17/2017; P&T Revision Date: 11/16/2018; **Effective Date: 2/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Nuedexta (dextromethorphan/quinidine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>Pseudobulbar affect (PBA) Indicated for the treatment of pseudobulbar affect (PBA).</td>
</tr>
</tbody>
</table>

2. Criteria
**Product Name:** Nuedexta

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of pseudobulbar affect

**Product Name:** Nuedexta

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to therapy

### 3. Background

**Benefit/Coverage/Program Information**

**Background:**

Nuedexta, a combination product containing dextromethorphan hydrobromide and quinidine sulfate, is indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur...
out of proportion or are inappropriate to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

**4. References**

Prior Authorization Guideline

GL-53639 Nuplazid (pimavanserin tartrate)

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>11/1/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>7/27/2016</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>8/16/2019</td>
</tr>
</tbody>
</table>

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Nuplazid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parkinson's disease psychosis Indicated for the treatment of hallucinations and delusions</td>
</tr>
</tbody>
</table>
associated with Parkinson's disease psychosis.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Nuplazid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of Parkinson's disease

2. Member is currently experiencing hallucinations and delusions associated with Parkinson's disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson’s disease diagnosis).

<table>
<thead>
<tr>
<th>Product Name: Nuplazid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to Nuplazid therapy.
3. Background

Benefit/Coverage/Program Information

Additional Clinical Rules:
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

Background

Nuplazid (pimavanserin) is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis.

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/19/2019</td>
<td>Annual review. Updated references. Clarified that hallucination and delusion symptoms started after Parkinson’s disease diagnosis.</td>
</tr>
</tbody>
</table>
1. Indications

**Drug Name: Lovaza and Vascepa**

**Indications**

**Severe Hypertriglyceridemia** Indicated as adjunctive therapy to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
## 2. Criteria

**Product Name:** Lovaza\(^{\text{**}}\), Vascepa

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Diagnosis of severe hypertriglyceridemia (pre-treatment triglyceride level greater than or equal to 500 mg/dL)

   **AND**

2. Patient is on an appropriate lipid-lowering diet and exercise regimen

| Notes | \(^{\text{**}}\)Applies to brand and generic Lovaza. * Lovaza (multi-source brand only) is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status. |

**Product Name:** Lovaza\(^{\text{*}}\), Vascepa

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Documentation of positive clinical response to therapy
2 Patient is on an appropriate lipid-lowering diet and exercise regimen

Notes

* Lovaza (multi-source brand only) is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

3. Background

Benefit/Coverage/Program Information

Background:

Omega-3-acid derivatives - Lovaza® and Vascepa®, are highly purified ethyl ester concentrates. Lovaza is a combination of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Vascepa is composed primarily of eicosapentaenoic acid (EPA). These medications are indicated as adjunctive therapy to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Omega-3-acid derivatives should be administered at a dose of 4 grams per day for the treatment of severe hypertriglyceridemia. The effect of omega-3-acid derivatives on the risk of pancreatitis and cardiovascular morbidity and mortality has not been determined.

4. References

Prior Authorization Guideline

GL-35989 Ophthalmic Anti-Allergic Agents

Formulary UHC Core

Formulary Note

Approval Date 7/12/2017

Revision Date 7/12/2017

Technician Note:

CPS Approval Date: 10/4/2005; CPS Revision Date: 8/20/2013

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Alocril (nedocromil) ophthalmic solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
</tbody>
</table>

**Allergic Conjunctivitis** Indicated for the treatment of itching associated with allergic conjunctivitis. [8]

Drug Name: Alomide (Iodoxamine)

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
</table>

**Allergic Conjunctivitis** Indicated in the treatment of the ocular disorders referred to by the terms vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis. [9]

| Drug Name: Bepreve (bepotastine) |
| Indications |
| **Allergic Conjunctivitis** Indicated for the treatment of itching associated with allergic conjunctivitis. [3] |

| Drug Name: Crolom (cromolyn) ophthalmic solution |
| Indications |
| **Allergic Conjunctivitis** Indicated for the treatment of vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis. [6] |

| Drug Name: Bromsite (bromfenac) ophthalmic solution |
| Indications |
| **Postoperative Inflammation and Prevention of Ocular Pain** Indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. |

| Drug Name: Elestat (epinastine) ophthalmic solution |
| Indications |
| **Allergic Conjunctivitis** Indicated for the prevention of itching associated with allergic conjunctivitis. [4] |

| Drug Name: Emadine (emedastine) |
| Indications |
| **Allergic Conjunctivitis** Indicated for the temporary relief of the signs and symptoms of allergic conjunctivitis. [10] |
Drug Name: Lastacaft (alcaftadine) ophthalmic solution

**Indications**

**Allergic Conjunctivitis** Indicated for the prevention of itching associated with allergic conjunctivitis. [13]

Drug Name: Optivar (azelastine)

**Indications**

**Allergic Conjunctivitis** Indicated for the treatment of itching of the eye associated with allergic conjunctivitis. [5]

Drug Name: Pataday (olopatadine)

**Indications**

**Allergic Conjunctivitis** Indicated for the treatment of ocular itching associated with allergic conjunctivitis. [2]

Drug Name: Patanol (olopatadine)

**Indications**

**Allergic Conjunctivitis** Indicated for the treatment of the signs and symptoms of allergic conjunctivitis. [1]

**2. Criteria**

**Product Name:** Bepreve

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Approval Criteria

1 History of one of the following:

- Epinastine
- Azelastine

Product Name: Bromsite

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1 History of failure or intolerance to at least one of the following generic single ingredient ophthalmic NSAID solutions:

- diclofenac
- flurbiprofen
- ketorolac

Product Name: Emadine, Lastacaft, Pataday, or Patanol

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Non Formulary</th>
</tr>
</thead>
</table>

Approval Criteria

1 History of failure, contraindication, or intolerance to both of the following:

- Generic epinastine
- Generic azelastine

Product Name: Alocril, Alomide

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Non Formulary</th>
</tr>
</thead>
</table>
Approval Criteria

1. History of failure, contraindication, or intolerance to generic cromolyn

3. Definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic Conjunctivitis [12]</td>
<td>The types of allergic conjunctivitis include atopic keratoconjunctivitis, simple allergic conjunctivitis, seasonal or perennial conjunctivitis, vernal conjunctivitis, and giant papillary conjunctivitis.</td>
</tr>
</tbody>
</table>

4. References


GL-5934 Ophthalmic Corticosteroids (Alrex, Lotemax, Vexol)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 3/21/2013

Technician Note :

CPS Approval Date: 7/21/2005; CPS Revision Date: 4/10/2012

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Alrex (loteprednol etabonate ophthalmic suspension 0.2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Allergic conjunctivitis [1-3, 16]</td>
</tr>
<tr>
<td>Is indicated for the temporary relief of signs and symptoms of seasonal allergic conjunctivitis.</td>
</tr>
</tbody>
</table>

| Drug Name: Lotemax suspension/drops (loteprednol etabonate ophthalmic suspension 0.5%) [1-3, 16] |
### Indications

**Steroid-responsive inflammatory conditions such as allergic conjunctivitis**

Is indicated for the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctuate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation. Is less effective than prednisolone acetate 1% in two 28-day controlled clinical studies in acute anterior uveitis, where 72% of patients treated with Lotemax experienced resolution of anterior chamber cells, compared to 87% of patients treated with prednisolone acetate 1%. The incidence of patients with clinically significant increases in IOP (≥10 mmHg) was 1% with Lotemax and 6% with prednisolone acetate 1%. Lotemax should not be used in patients who require a more potent corticosteroid for this indication.

**Post-operative inflammation**

Lotemax is also indicated for the treatment of post-operative inflammation following ocular surgery.

### Drug Name: Lotemax ointment (loteprednol etabonate ophthalmic ointment 0.5%)

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-operative inflammation</strong> [1-3, 16]</td>
</tr>
<tr>
<td>Is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.</td>
</tr>
</tbody>
</table>

### Drug Name: Vexol (rimexolone ophthalmic suspension 1%) [1-3, 16]

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-operative inflammation</strong></td>
</tr>
<tr>
<td>Is indicated for the treatment of post-operative inflammation after ocular surgery.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anterior uveitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is indicated for the treatment of anterior uveitis.</td>
</tr>
</tbody>
</table>
2. Criteria

**Product Name:** Alrex or Lotemax suspension

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Allergic Conjunctivitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of allergic conjunctivitis

   **AND**

2. History of failure, contraindication, or intolerance to both of the following: [4]

   - azelastine (Optivar)
   - cromolyn (Crolom)

**Product Name:** Vexol or Lotemax

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Post-Operative Inflammation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Time</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of post-operative ocular inflammation
2 Prescribed by an ophthalmologist

AND

3 One of the following:

3.1 Patients who are intolerant of increase in intraocular pressure (IOP) [5, 6, 7, A, B] (ie, patients with glaucoma)

OR

3.2 History of failure, contraindication, or intolerance to three of the following:

- prednisolone acetate (eg, Pred Forte)
- prednisolone sodium phosphate (eg, Pred-Phosphate)
- fluorometholone (eg, FML, FML Forte, FML Liquifilm)
- dexamethasone (eg, Decadron-phosphate)
- ketorolac (eg, Acular, Acular LS)
- flurbiprofen (Ocufen)

**Product Name:** Vexol

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Anterior Uveitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of anterior uveitis
AND

2 Prescribed by an ophthalmologist

AND

3 One of the following:

3.1 Patients who are intolerant of increase in intraocular pressure (IOP) (ie, patients with glaucoma) [5, 6, 7, B]

OR

3.2 History of failure, contraindication, or intolerance to three of the following:

- prednisolone acetate (eg, Pred Forte)
- prednisolone sodium phosphate (eg, Pred-Phosphate)
- fluorometholone (eg, FML, FML Forte, FML Liquifilm)
- dexamethasone (eg, Decadron-phosphate)

Product Name: Lotemax suspension

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Other Steroid Responsive Conditions [C]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Prescribed by an ophthalmologist

AND
2 One of the following:

2.1 Patients who are intolerant of increase in intraocular pressure (IOP) [5, 6, 7, A] (ie, patients with glaucoma)

OR

2.2 History of failure, contraindication, or intolerance to two of the following:

- prednisolone acetate (eg, Pred Forte)
- prednisolone sodium phosphate (eg, Pred-Phosphate)
- fluorometholone (eg, FML, FML Forte, FML Liquifilm)
- dexamethasone (eg, Decadron-phosphate)

3. Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alrex</td>
<td>One drop in the affected eye(s) four times daily.</td>
</tr>
<tr>
<td>Lotemax suspension - Post-Operative Inflammation:</td>
<td>One to two drop(s) in the conjunctival sac of the affected eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.</td>
</tr>
<tr>
<td>Lotemax suspension - Steroid-responsive Conjunctivitis:</td>
<td>One to two drop(s) in the conjunctival sac of the affected eye(s) four times daily.* *Within the first week may increase up to 1 drop every hour if necessary. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be re-evaluated.</td>
</tr>
<tr>
<td>Lotemax ointment - Post-Operative Inflammation:</td>
<td>Apply a small amount (approximately ½ inch ribbon) into the conjunctival sac(s) 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the</td>
</tr>
</tbody>
</table>
post-operative period.

Vexol - Post-Operative Inflammation:
One to two drop(s) in the conjunctival sac of the affected eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the postoperative period.

Vexol - Anterior Uveitis:
One to two drops in the conjunctival sac of the affected eye every hour while awake for the first week, one drop every two hours while awake during the second week and then taper until uveitis is resolved.

### 4. Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alrex (loteprednol ophthalmic suspension 0.2%)</td>
<td>5 mL, 10mL</td>
</tr>
<tr>
<td>Lotemax (loteprednol ophthalmic suspension 0.5%)</td>
<td>2.5 mL, 5 mL, 10 mL, 15 mL</td>
</tr>
<tr>
<td>Lotemax (loteprednol ophthalmic ointment 0.5%)</td>
<td>3.5 gram tube</td>
</tr>
<tr>
<td>Vexol (rimexolone ophthalmic suspension 1%)</td>
<td>5 mL, 10mL</td>
</tr>
</tbody>
</table>

### 5. Definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
</table>

Allergic Conjunctivitis [7]  The types of allergic conjunctivitis include atopic keratoconjunctivitis, simple allergic conjunctivitis, seasonal or perennial conjunctivitis, vernal conjunctivitis, and giant papillary conjunctivitis.

IOP  Intraocular pressure

Uveitis [6]  Is characterized by inflammation affecting the iris (iritis), ciliary body (cyclitis), and choroid (choroiditis). The inflammation may occur acutely or recurrently or may chronically manifest itself over months or even years. Although uveitis may affect anterior or posterior ocular structures, or both, anterior uveitis is approximately four times as common as posterior uveitis and occurs most frequently between the ages of 20 and 50 years.

6. Endnotes

A. In Novack et al. [5], a meta-analysis of all subjects (healthy volunteers, patients with inflammation, or allergy) in all sponsored loteprednol etabonate studies up to the time of the analysis, loteprednol etabonate appeared to have less propensity to cause clinically significant elevations in IOP (greater than or equal to 10 mmHg) than prednisolone acetate.

B. Leibowitz et al. [14] conducted a double-masked, randomized, single-eye, crossover protocol study on glucocorticoid topical agents in asymptomatic patients. The results showed that rimexolone has IOP-elevating potential that is significantly lower than dexamethasone sodium phosphate and prednisolone acetate.

C. Lotemax suspension/drops is indicated for the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctuate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

7. References


Prior Authorization Guideline

GL-53034 Opioid Dependence

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>9/1/2019</th>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>4/18/2018</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>07/17/2019 ; 6/19/2019</td>
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Technician Note:

P&T Approval Date: 4/18/2018; P&T Revision Date: 6/19/2019. **Guideline Effective Date: 9/1/2019**

1. Criteria
Product Name: Bunavail

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - The prescriber is qualified under DATA 2000 to prescribe buprenorphine products as indicated by a unique DEA identification number

**AND**

2 - The patient is being treated for opioid dependence

**AND**

3 - The medication is not being used solely for pain management

**2. Background**

**Benefit/Coverage/Program Information**

**Background:**

Bunavail is a Schedule III narcotic medication available under the Drug Abuse Treatment Act (DATA) of 2000 for the treatment of opioid dependence. Only qualified prescribers with the necessary DEA (Drug Enforcement Agency) identification number can prescribe or dispense buprenorphine products for opioid addiction therapy.

Bunavail contains naloxone, an opiate antagonist, to guard against misuse. Intravenously administered naloxone will block the effect of opiates and cause withdrawal symptoms.

**Additional Clinical Rules:**
Supply limits may be in place.
Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References


4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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<tbody>
<tr>
<td>8/30/2019</td>
<td>06/2019 - Annual review. Updated references and additional clinical rules.</td>
</tr>
</tbody>
</table>
Prior Authorization Guideline

GL-56174 Opioid-containing cough medicines (including: Flowtuss, Hycofenix, Obredon, Tuzistra XR, Tussionex, Tussicaps, Tuxarin ER, Zutripo, codeine/phenylephrine/promethazine, codeine/promethazine, hydrocodone/homatropine, hydrocodone bitartrate/guaifenesin) - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

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<td>P&amp;T Revision Date:</td>
<td>08/16/2019 ; 8/16/2019</td>
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Technician Note:

P&T Approval Date: 03/21/2018; P&T Revision Date: 3/20/2019, 08/16/2019; **Effective Date: 11/01/2019**
1. Criteria

<table>
<thead>
<tr>
<th>Product Name: Opioid containing cough and cold products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Prescriber attests they are aware of 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).

    AND

2 - 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 greater than 30)

    AND

3 - Patient has tried and failed at least one non-opioid containing cough and cold remedy

2. Background

**Benefit/Coverage/Program Information**

**Background**

Opioid (codeine or hydrocodone) containing cough and cold products are FDA labeled for use in adults 18 years of age and older. Use of prescription opioid cough and cold medicines containing codeine or hydrocodone should be limited in children younger than 18 years old due to serious risks associated with use. Coverage for patients age 18 or greater will process automatically.
Additional Clinical Rules:
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

3. References

5. Tussionex Pennkinetic ER Suspension prescribing information. UCB, Inc. Smyrna, GA. June 2018
8. Approach to Cough in Children. UpToDate. February 2018. FDA Round Table. Use of Cough Supressants in Children; Expert Roundtable Meeting; April 27, 2017
1. Indications

**Drug Name: Aplenzin (bupropion extended-release)**

**Indications**

**Major Depressive Disorder** Indicated for the treatment of major depressive disorder, as defined by the Diagnostic and Statistical Manual (DSM). The efficacy of the immediate-release formulation of bupropion was established in two 4-week controlled inpatient trials and one 6-week controlled outpatient trial of adult patients with MDD. The efficacy of the sustained-release formulation of bupropion in the maintenance treatment of MDD was established in a long-term (up to 44 weeks), placebo-controlled trial in patients who had responded to bupropion in an 8-
week study of acute treatment.

**Seasonal Affective Disorder** Indicated for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD). The efficacy of bupropion hydrochloride extended-release tablets in the prevention of seasonal major depressive episodes was established in 3 placebo-controlled trials in adult outpatients with a history of MDD with an autumn-winter seasonal pattern as defined in the DSM.

**Drug Name: Trintellix (vortioxetine)**

**Indications**

**Major Depressive Disorder** Indicated for the treatment of major depressive disorder (MDD). The efficacy of Brintellix was established in six 6 to 8 week studies (including one study in the elderly) and one maintenance study in adults.

**Drug Name: Fetzima (levomilnacipran extended-release)**

**Indications**

**Major Depressive Disorder** Is indicated for the treatment of major depressive disorder (MDD). The efficacy of Fetzima was established in three 8-week, randomized, double-blind, placebo-controlled studies in adult patients with a diagnosis of MDD. Limitation of use: Is not approved for the management of fibromyalgia. The efficacy and safety of Fetzima for the management of fibromyalgia have not been established.

---

**2. Criteria**

**Product Name:** Aplenzin

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 History of any tier 1 bupropion product
Product Name: Trintellix

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1. History of two of the following:
   - A preferred selective serotonin reuptake inhibitors (SSRIs)
   - A preferred serotonin-norepinephrine reuptake inhibitors (SNRIs)
   - A preferred bupropion
   - A preferred mirtazapine

Product Name: Fetzima or Fetzima Pack

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1. History of two preferred serotonin-norepinephrine reuptake inhibitors (SNRIs)

3. References

Prior Authorization Guideline

GL-47130 Orilissa (elagolix) - PA/ Med Nec

Formulary UHC Core

Formulary Note

Approval Date 1/3/2019

Revision Date 1/3/2019

Technician Note :

P&T Approval Date: 10/17/2018; **Effective Date: 1/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Orilissa (elagolix)</th>
<th></th>
</tr>
</thead>
</table>

Indications

Endometriosis Indicated for the management of moderate to severe pain associated with endometriosis.
2. Criteria

**Product Name:** Orilissa 150 mg [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate to severe pain associated with endometriosis

   **AND**

2. Patient is premenopausal

   **AND**

3. History of trial and failure [b] (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of two analgesics (e.g., ibuprofen, meloxicam, naproxen)

   **AND**

4. History of trial and failure [b], contraindication, or intolerance after a three month trial to one of the following:

   - Hormonal contraceptives
   - Progestins [e.g., norethindrone (generic Aygestin)]
5 Prescribed by or in consultation with one of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required.

Product Name: Orilissa 150 mg [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 month (see Notes for further details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Documentation of positive clinical response to therapy

AND

2 Impact to bone mineral density has been considered

AND
3 Treatment duration has not exceeded a total of 24 months

Notes

Authorization will be issued for 6 months up to a maximum of 24 months. NOTE: Orilissa 150 mg once daily is indicated for a maximum of 24 months. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required.

Product Name: Orilissa 200 mg [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>6 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Diagnosis of moderate to severe pain associated with endometriosis

AND

2 Patient is premenopausal

AND

3 History of trial and failure [b] (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of two analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND
4 History of trial and failure, contraindication, or intolerance after a three month trial [b] to one of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

5 Prescribed by or in consultation with one of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Notes

| NOTE: Orilissa 200 mg twice daily is indicated for a maximum of 6 months (please note: All requests for reauthorization will be denied by OptumRx and must be submitted through the appeals process to the UnitedHealthcare Pharmacy appeals team for consideration.) [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required. |

3. Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

Supply limits may be in place.
4. References

1. Indications

**Drug Name: Osphena (ospemifene)**

**Indications**

**Moderate to severe dyspareunia** Indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause and for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause.
2. Criteria

**Product Name:** Osphena

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Benefit designs covering medications to treat sexual dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of one of the following:

- Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause
- Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause

**Product Name:** Osphena

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Benefit designs excluding medications to treat sexual dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Treatment of moderate to severe vaginal dryness, a symptom of VVA due to menopause

**Product Name:** Osphena
<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to therapy

---

3. **Background**

**Benefit/Coverage/Program Information**

**Additional Clinical Rules:**

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

**Background:**

Osphena (ospemifene) is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause and for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA) due to menopause.
4. References

Prior Authorization Guideline

GL-31907 Overactive Bladder Agents

Formulary UHC Core

Formulary Note

Approval Date 9/22/2016

Revision Date 9/22/2016

Technician Note:

P&T Approval Date: 12/6/2004; P&T Revision Date: 8/18/2016. **Effective 1/1/2017**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Detrol LA (tolterodine extended-release), Myrbetriq (mirabegron)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td><strong>Overactive Bladder</strong> Indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.</td>
</tr>
</tbody>
</table>
2. Criteria

Product Name: Brand Detrol LA or Myrbetriq

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Approval Criteria

1 History of both of the following:

- oxybutynin IR/ER
- VESIcare

3. References

1. Detrol LA Prescribing Information. Pfizer, September 2013.
Prior Authorization Guideline

GL-55324 Oxistat (oxiconazole) cream - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

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<th>Effective Date:</th>
<th>12/1/2019</th>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>8/20/2014</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>9/18/2019</td>
</tr>
</tbody>
</table>

1. Indications

Drug Name: Oxistat

Tinea dermal infections including tinea versicolor (i.e., pityriasis versicolor) Indicated for patients with tinea dermal infections including tinea versicolor (i.e., pityriasis versicolor) a
common superficial fungal infection. Tinea versicolor often presents as hypopigmented, hyperpigmented, or erythematous macules on the trunk and proximal upper extremities. The causative organisms are yeasts in the genus Malassezia (formerly known as Pityrosporum).

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Oxistat Cream [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
</tr>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Diagnosis of tinea versicolor

AND

2 - History of failure, contraindication, or intolerance to one of the following topical antifungal agents:

- Ketoconazole 2% cream (generic Nizoral)
- Ciclopirox 0.77% cream (generic Loprox)

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

**Benefit/Coverage/Program Information**
Additional Clinical Rules:

- Supply limits and/or Step Therapy may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Background:

Oxistat (oxiconazole) cream is indicated for patients with tinea dermal infections including tinea versicolor (i.e., pityriasis versicolor) a common superficial fungal infection. Tinea versicolor often presents as hypopigmented, hyperpigmented, or erythematous macules on the trunk and proximal upper extremities. The causative organisms are yeasts in the genus Malassezia (formerly known as Pityrosporum). Most tinea dermal infections are treatable with over-the-counter medications. Coverage of Oxistat cream will only be provided for tinea versicolor infections after meeting these requirements.

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/15/2019</td>
<td>Annual review. Updated references; added automation language.</td>
</tr>
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</table>
1. Indications
Drug Name: Pancreaze (pancrelipase) and Pertzye (pancrelipase)

**Exocrine Pancreatic Insufficiency** Indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

Drug Name: Viokace (pancrelipase)

**Exocrine Pancreatic Insufficiency** In combination with a proton pump inhibitor, indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Pancreaze, Pertzye, or Viokace</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. History of trial and failure, contraindication, or intolerance to both of the following:

- Creon (pancrelipase) delayed-release capsules
- Zenpep (pancrelipase) delayed-release capsules

3. References

4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/16/2019</td>
<td>2019 Annual Review</td>
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Prior Authorization Guideline

GL-53673 Pancreatic Enzyme Products (PEPs) - Step Therapy

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<th>Effective Date:</th>
<th>10/1/2019</th>
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<td>P&amp;T Approval Date:</td>
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<td>P&amp;T Revision Date:</td>
<td>7/17/2019</td>
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</table>

1. Criteria

<table>
<thead>
<tr>
<th>Product Name: (Pancreaze, Pertzye or Viokace) [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
</tbody>
</table>
### Approval Criteria

1. History of failure, contraindication or intolerance to both of the following medications:
   - Creon
   - Zenpep

### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 2. Background

#### Benefit/Coverage/Program Information

#### Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Creon and Zenpep before providing coverage for Pancreaze, Pertzye or Viokace.

Members, who have received at least a 90 day supply of Pancreaze, Pertzye or Viokace in the past 120 days as documented in claims history, will be allowed continued coverage of their current therapy.

#### Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

### 3. References


4. Revision History

<table>
<thead>
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<th>Notes</th>
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<tbody>
<tr>
<td>9/20/2019</td>
<td>Annual review. Added an authorization look back for current users and updated references.</td>
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</table>
Prior Authorization Guideline

GL-5991 Premenstrual Dysphoric Disorder Agents (Sarafem, Selfemra)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 3/21/2013

Technician Note :
CPS Approval Date: 9/8/2000; CPS Revision Date: 8/16/2011

1. Indications

Drug Name: Sarafem (fluoxetine) and Selfemra (fluoxetine)

Indications

Premenstrual Dysphoric Disorder (PMDD) [1, 2]

Are indicated for the treatment of premenstrual dysphoric disorder (PMDD). The efficacy of fluoxetine in the treatment of PMDD was established in 3 placebo-controlled trials. The essential features of PMDD, according to the DSM-IV, include markedly depressed mood, anxiety or tension, affective lability, and persistent anger or irritability. Other features include decreased interest in usual activities, difficulty concentrating, lack of energy, change in appetite or sleep, and feeling out of control. Physical symptoms associated with PMDD include breast tenderness,
headache, joint and muscle pain, bloating, and weight gain. These symptoms occur regularly during the luteal phase and remit within a few days following onset of menses; the disturbance markedly interferes with work or school or with usual social activities and relationships with others. In making the diagnosis, care should be taken to rule out other cyclical mood disorders that may be exacerbated by treatment with an antidepressant. The effectiveness of fluoxetine in long-term use, that is, for more than 6 months, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use fluoxetine for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

2. Criteria

Product Name: Sarafem or Selfemra

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Prior Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1 Diagnosis of premenstrual dysphoric disorder (PMDD)

AND

2 History of failure, contraindication, or intolerance to two of the following:

- Paxil CR (paroxetine controlled-release)
- Prozac (fluoxetine)
- Zoloft (sertraline)

3. Dosing
Drug Name | Description
---|---
Sarafem or Selfemra [1, 2] | 20 mg/day given continuously (every day of the menstrual cycle) or intermittently (defined as starting daily dose 14 days prior to the anticipated onset of menstruation through the first full day of menses and repeating with each cycle). In a study comparing continuous dosing of fluoxetine 20 and 60 mg/day to placebo, both doses were proven to be effective, but there was no statistically significant added benefit for the 60-mg/day compared with the 20-mg/day dose. Fluoxetine doses above 60 mg/day have not been systematically studied in patients with PMDD. The maximum fluoxetine dose should not exceed 80 mg/day.[1, 2]

4. Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarafem [1, 2]</td>
<td>10 mg, 20 mg Tablets</td>
</tr>
<tr>
<td>Selfemra [1, 2]</td>
<td>10 mg, 20 mg capsules</td>
</tr>
</tbody>
</table>

5. References

**Prior Authorization Guideline**

GL-40869 Prevpac (lansoprazole, amoxicillin and clarithromycin)

Formulary UHC Core

Formulary Note

Approval Date 12/29/2017

Revision Date 12/29/2017

Technician Note:

P&T Approval Date: 6/16/2006; P&T Revision Date: 5/21/2014, 12/20/2017; **Effective Date: 02/01/2018**

1. Indications

**Drug Name: Prevpac (lansoprazole, amoxicillin, and clarithromycin)**

**Indications**

**Eradication of H. pylori infection to reduce the risk of duodenal ulcer recurrence** The components in Prevpac (lansoprazole, amoxicillin, and clarithromycin) are indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Prevpac and other antibacterial drugs, Prevpac
should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

### 2. Criteria

**Product Name:** Brand Prevpac

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. History of one of the following:
   - Omeclamox-Pak
   - Pylera

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOTE TO PRESCRIBER: In patients with persistent H.pylori infection, every effort should be made to avoid antibiotics that have been previously taken by the patient. [4]</td>
</tr>
</tbody>
</table>

### 3. Endnotes
A. In the United States, the recommended primary therapies for H. pylori infection include: a PPI, clarithromycin, and amoxicillin, or metronidazole (clarithromycin-based triple therapy) for 14 days or a PPI or H2RA, bismuth, metronidazole, and tetracycline (bismuth quadruple therapy) for 10–14 days. [4]

B. The most important predictors of treatment failure following anti-H. pylori therapy include poor compliance and antibiotic resistance. It is critical for clinicians to stress the importance of taking the medications as prescribed to minimize the likelihood of treatment failure and development of antibiotic resistance. [4]

4. References

5. Omeclamox-Pak Prescribing Information. Pernix Therapeutics. February 2012.
Prior Authorization Guideline

GL-54242 Prior Authorization Administrative Guideline

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<tr>
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<td>2/15/2011</td>
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<tr>
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<td>10/16/2019</td>
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Technician Note:

P&T Revision Date: 6/22/2016; 12/19/2018 The purpose of this guideline is to establish policies and procedures on how to handle (1) formulary drugs with a prior authorization requirement that do not have official criteria posted or available, and (2) new FDA-approved indications, which are not addressed in the existing drug-specific prior authorization guideline. This guideline will not apply to drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, non-formulary drugs, or drugs that are not reviewed for prior authorization by OptumRx.
### 1. Criteria

<table>
<thead>
<tr>
<th>Product Name: Drugs with a prior authorization requirement for which a guideline is unavailable, OR new FDA-approved indications which are not addressed in the existing drug-specific prior authorization guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

## Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

## Notes

This guideline should not be used to address step therapy.
## 2. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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</table>
Prior Authorization Guideline

GL-11546 Progesterone Products

Formulary UHC Core

Formulary Note

Approval Date 3/13/2013

Revision Date 11/6/2014

Technician Note:

CPS Approval Date: 8/21/1998; CPS Revision Date: 10/14/2014

1. Indications

Drug Name: Crinone 8% (progesterone vaginal gel)

Indications

Assisted Reproductive Technology

Is indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency.

Secondary Amenorrhea

Is indicated for use in women who have failed to respond to treatment with Crinone 4%
**Drug Name: Endometrin (progesterone vaginal insert)**

**Indications**

**Assisted Reproductive Technology**

Is a progesterone indicated to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an Assisted Reproductive Technology treatment program for infertile women.

**Drug Name: Crinone 4% (progesterone vaginal gel)**

**Indications**

**Secondary Amenorrhea**

Is indicated for the treatment of secondary amenorrhea.

**Drug Name: Prometrium (progesterone oral capsules)**

**Indications**

**Secondary Amenorrhea**

Is indicated for use in secondary amenorrhea.

**Endometrial Hyperplasia**

Is indicated for use in the prevention of endometrial hyperplasia in nonhysterectomized postmenopausal women who are receiving conjugated estrogen tablets.

**Drug Name: Progesterone Suppositories (extemporaneously compounded)**

**Off Label Uses**

**Non-FDA Approved Product**

Is used as part of an Assisted Reproductive Technology program and are used to maintain pregnancy in patients who are at high risk for threatened abortions or recurrent miscarriages.
2. Criteria

**Product Name:** Crinone 8% or Endometrin

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Assisted Reproductive Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. To be used as part of an Assisted Reproductive Technology program

   **AND**

2. Not a benefit exclusion

**Product Name:** Crinone 8%

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Secondary Amenorrhea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. For patients with secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause)
2 History of failure, contraindication, or intolerance to Provera (medroxyprogesterone) or Aygestin (norethindrone)

**Product Name:** Progesterone Suppositories

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Assisted Reproductive Technology</th>
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</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>3 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
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</table>

**Approval Criteria**

1. To be used as part of an Assisted Reproductive Technology program

   **AND**

2. Not a benefit exclusion

**Product Name:** Progesterone Suppositories

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Threatened Abortions/Recurrent Miscarriages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Non Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. For high risk pregnancies
Verification of pregnancy is necessary for each authorization

AND

3 Not a benefit exclusion

**Product Name:** Crinone 4%, Brand Prometrium, or generic progesterone micronized capsule

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Secondary Amenorrhea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
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</tr>
</tbody>
</table>

**Approval Criteria**

1. For patients with secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause)

AND

2. History of failure, contraindication, or intolerance to Provera (medroxyprogesterone) or Aygestin (norethindrone)

**Product Name:** Brand Prometrium or generic progesterone micronized capsule

<p>| Diagnosis                                      | Prevention of Endometrial Hyperplasia in Patients Taking Hormone |</p>
<table>
<thead>
<tr>
<th>Therapy</th>
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</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient is concurrently taking Estrogen Therapy [5,6]

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3. **References**

1. Indications

**Drug Name: Aciphex (rabeprazole)**

**Indications**

**Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD) in Adults** Indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with
GERD in adults.

**Healing of Erosive or Ulcerative GERD in Adults** Indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative GERD. For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of Aciphex may be considered.

**Maintenance of Healing of Erosive or Ulcerative GERD in Adults** Indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months.

**Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome in Adults** Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

**Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults** In combination with amoxicillin and clarithromycin as a three drug regimen, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

**Healing of Duodenal Ulcers in Adults** Indicated for short-term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within 4 weeks.

**Short-term Treatment of Symptomatic GERD in Adolescent Patients 12 years of Age and Older** Indicated for the treatment of symptomatic GERD in adolescents 12 years of age and above for up to 8 weeks.

**Treatment of GERD in Pediatric Patients 1 to 11 Years of Age** Indicated for treatment of GERD in children 1 to 11 years of age for up to 12 weeks.

**Drug Name:** Dexilant (dexlansoprazole)

**Indications**

**Symptomatic Non-Erosive GERD** Indicated for the treatment of heartburn associated with symptomatic non-erosive GERD for 4 weeks.

**Healing of Erosive Esophagitis** Indicated for healing of all grades of erosive esophagitis for up
to 8 weeks.

**Maintenance of Healed Erosive Esophagitis** Indicated to maintain healing of erosive esophagitis and relief of heartburn for up to 6 months.

**Drug Name: Esomeprazole strontium**

**Indications**

**Healing of Erosive Esophagitis** Indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of esomeprazole strontium may be considered.

**Maintenance of Healing of Erosive Esophagitis** Indicated to maintain symptom resolution and healing of erosive esophagitis. Controlled studies do not extend beyond 6 months.

**Symptomatic Gastroesophageal Reflux Disease** Indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults.

**Risk Reduction of NSAID-Associated Gastric Ulcer in Adults** Indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk for developing gastric ulcers. Patients are considered to be at risk either due to their age (greater than or equal to 60) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

**H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults** In combination with amoxicillin and clarithromycin, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

**Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome in Adults** Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.

**Drug Name: Nexium (esomeprazole)**

**Indications**
Symptomatic GERD Indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults and children 1 year or older.

Healing of Erosive Esophagitis Indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of Nexium may be considered. In infants 1 month to less than 1 year, Nexium is indicated for short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-medicated GERD.

Maintenance of Healing of Erosive Esophagitis Indicated to maintain symptom resolution and healing of erosive esophagitis. Controlled studies do not extend beyond 6 months.

Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with amoxicillin and clarithromycin, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Risk Reduction of NSAID-Associated Gastric Ulcer Indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk for developing gastric ulcers. Patients are considered to be at risk due to their age (greater than or equal to 60) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

Drug Name: Prevacid (lansoprazole)

Indications

Short-Term Treatment of Active Duodenal Ulcer Indicated for short-term treatment (for 4 weeks) for healing and symptom relief of active duodenal ulcer.

H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with amoxicillin plus clarithromycin as triple therapy, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.
recurrence. In combination with amoxicillin as dual therapy, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

**Maintenance of Healed Duodenal Ulcers** Indicated to maintain healing of duodenal ulcers. Controlled studies do not extend beyond 12 months.

**Short-Term Treatment of Active Benign Gastric Ulcer** Indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of active benign gastric ulcer.

**Healing of NSAID-Associated Gastric Ulcer** Indicated for the treatment of NSAID-associated gastric ulcer in patients who continue NSAID use. Controlled studies did not extend beyond 8 weeks.

**Risk Reduction of NSAID-Associated Gastric Ulcer** Indicated for reducing the risk of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID. Controlled studies did not extend beyond 12 weeks.

**Short-Term Treatment of Symptomatic GERD** Indicated for the treatment of heartburn and other symptoms associated with GERD.

**Maintenance of Healing of Erosive Esophagitis** Indicated to maintain healing of erosive esophagitis. Controlled studies did not extend beyond 12 months.

**Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome** Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

**Short-Term Treatment of Erosive Esophagitis** Indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of all grades of erosive esophagitis. For patients who do not heal with Prevacid for 8 weeks (5 to 10%), it may be helpful to give an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis, an additional 8-week course of Prevacid may be considered.

**Drug Name:** Prilosec (omeprazole)

**Indications**

**Duodenal Ulcer (adults)** Indicated for short-term treatment of active duodenal ulcer in adults. Most patients heal within four weeks. Some patients may require an additional four weeks of
therapy. In combination with clarithromycin and amoxicillin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease (active or up to 1-year history) to eradicate H. pylori in adults. In combination with clarithromycin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori in adults. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. Among patients who fail therapy, Prilosec with clarithromycin is more likely to be associated with the development of clarithromycin resistance as compared with triple therapy. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

**Gastric Ulcer (adults)** Indicated for short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

**Treatment of Symptomatic GERD (adults and pediatric patients)** Indicated for the treatment of heartburn and other symptoms associated with GERD in pediatric patients and adults. The efficacy of Prilosec used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of GERD symptoms (eg, heartburn), additional 4 to 8 week courses of omeprazole may be considered.

**Maintenance of Healing of Erosive Esophagitis (adults and pediatric patients)** Indicated to maintain healing of erosive esophagitis in pediatric patients and adults. Controlled studies do not extend beyond 12 months.

**Pathological Hypersecretory Conditions (adults)** Indicated for the long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis) in adults.

**Erosive Esophagitis (adults and pediatric patients)** Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis that has been diagnosed by endoscopy in pediatric patients and adults. The efficacy of Prilosec used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of erosive esophagitis, additional 4 to 8 week courses of omeprazole may be considered.

**Drug Name: Protonix (pantoprazole)**

**Indications**

**Short-Term Treatment of Erosive Esophagitis Associated With GERD** Indicated in adults and pediatric patients five years of age and older for the short-term treatment (up to 8 weeks) in the healing and symptomatic relief of erosive esophagitis. For those adult patients who have not healed after 8 weeks of treatment, an additional 8-week course of Protonix may be considered.
Safety of treatment beyond 8 weeks in pediatric patients has not been established.

**Maintenance of Healing of Erosive Esophagitis** Indicated for maintenance of healing of erosive esophagitis and reduction in relapse rates of daytime and nighttime heartburn symptoms in adult patients with GERD. Controlled studies did not extend beyond 12 months.

**Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome** Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

**Drug Name: Zegerid (omeprazole/sodium bicarbonate)**

**Indications**

**Duodenal Ulcer** Indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

**Gastric Ulcer** Indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer.

**Symptomatic GERD** Indicated for the treatment of heartburn and other symptoms associated with GERD. The efficacy of Zegerid used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, it may be helpful to give up to an additional 4 weeks of treatment. If there is recurrence of GERD symptoms (eg, heartburn), additional 4-8 week courses of Zegerid may be considered.

**Maintenance of Healing of Erosive Esophagitis** Indicated to maintain healing of erosive esophagitis. Controlled studies do not extend beyond 12 months.

**Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients (40 mg oral suspension only)** Indicated for the reduction of risk of upper GI bleeding in critically ill patients.

**Erosive Esophagitis** Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis which has been diagnosed by endoscopy. The efficacy of Zegerid used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, it may be helpful to give up to an additional 4 weeks of treatment. If there is recurrence of erosive esophagitis, additional 4-8 week courses of Zegerid may be considered.

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2. Criteria
**Product Name:** Brand Aciphex tablets, Generic rabeprazole tablets, Prilosec suspension, Brand Protonix tablets, Protonix suspension

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Once-daily PPI Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 History of two of the following:

- Dexilant
- omeprazole
- pantoprazole

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**Product Name:** Aciphex Sprinkle or Prevacid Solutab

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Once-daily PPI Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
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**Approval Criteria**

1 History of two of the following:

- Dexilant
- omeprazole
- pantoprazole

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<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Twice-daily (BID) PPI Therapy***</th>
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<table>
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<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Criteria</td>
<td></td>
</tr>
</tbody>
</table>

1 One of the following:

1.1 Failure of once-daily PPI regimen

OR

1.2 One of the following diagnoses:

- Barrett's esophagus (with the need for complete acid control) [6]
- Symptomatic GERD [6]
- Presence of extraesophageal symptoms (exacerbation of cough or asthma, non-cardiac chest pain, dysphagia) [7]
- Laryngopharyngeal reflux/spasm [9]
- Zollinger-Ellison syndrome [8]
- H. pylori eradication (esomeprazole, rabeprazole, omeprazole, lansoprazole, and pantoprazole only) [1, 2, 12, 13]*

AND

2 One of the following:

2.1 Dose per day (mg/day) is supported in the dosage and administration section of the manufacturer's prescribing information

OR

2.2 Dose per day (mg/day) is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System
Authorization of therapy will be issued for long-term for all diagnoses, except for H. pylori eradication. For H. pylori eradication, authorization will be issued for 14 days. *Protonix has been used off-label for the treatment of H. pylori eradication. [17] **These products may require step therapy. ***Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline.

3. References

Prior Authorization Guideline

GL-47572 Provigil (modafinil) and Nuvigil (armodafinil)

Formulary UHC Core

Formulary Note

Approval Date 1/29/2019

Revision Date 1/29/2019

Technician Note:

P&T Approval Date: 1/1/2002; Revision Date: 12/21/2016, 12/20/2017, 12/19/2018; **Effective Date: 3/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Modafinil (Provigil*) and armodafinil (Nuvigil*)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>Narcolepsy, obstructive sleep apnea/hypopnea syndrome, shift work sleep disorder. To improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Modafinil</th>
</tr>
</thead>
</table>
**Off Label Uses**

*Idiopathic hypersomnia, fatigue associated with multiple sclerosis, depression augmentation* Has been shown to be beneficial in the treatment of excessive sleepiness in patients with idiopathic hypersomnia, treatment of fatigue associated with multiple sclerosis, and in the augmentation therapy for the treatment of depression.

---

**2. Criteria**

**Product Name:** Provigil* (modafinil) and Nuvigil* (armodafinil)

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapy Stage</strong></td>
<td>Initial Authorization</td>
</tr>
<tr>
<td><strong>Guideline Type</strong></td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:

- Diagnosis of narcolepsy
- Diagnosis of idiopathic hypersomnia
- Diagnosis of excessive sleepiness due to obstructive sleep apnea
- Diagnosis of excessive sleepiness due to shift work disorder
- Diagnosis of fatigue associated with multiple sclerosis
- For adjunctive therapy for the treatment of major depressive disorder or bipolar depression

**Notes**

*Brand Provigil and Nuvigil are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine exclusion status.*
<table>
<thead>
<tr>
<th>Therapy Stage</th>
<th>Reauthorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to therapy

**Notes**

*Brand Provigil and Nuvigil are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

---

**3. Background**

**Benefit/Coverage/Program Information**

**Background:**

Modafinil (Provigil*) and armodafinil (Nuvigil*) are wakefulness-promoting agents for oral administration. Both products are approved by the Food and Drug Administration (FDA) to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work disorder. Modafinil has been shown to be beneficial in the treatment of excessive sleepiness in patients with idiopathic hypersomnia, treatment of fatigue associated with multiple sclerosis, and in the augmentation therapy for the treatment of depression.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- *Brand Provigil and Nuvigil are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.*
4. References

Prior Authorization Guideline

GL-54862 Quantity Limit General

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<tr>
<th>Effective Date:</th>
<th>1/1/2020</th>
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</thead>
<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>5/20/2008</td>
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<tr>
<td>P&amp;T Revision Date:</td>
<td>11/14/2019</td>
</tr>
</tbody>
</table>

Technician Note:

P&T Revision Date: 6/22/2016; 12/19/2018 For all other drugs subject to quantity limits, OptumRx may authorize coverage for additional quantities of medications listed on the Standard QL list for patients who meet the following criteria.
1. **Criteria**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name:</td>
<td>Less than or equal to the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*</td>
</tr>
<tr>
<td>Approval Length</td>
<td>12 Months (except for titration of loading-dose purposes)</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. One of the following:
   1.1 Quantity limit override requests must involve an FDA-approved indication
   
   OR

   1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

   AND

2. One of the following:
   2.1 For titration or loading-dose purposes (one time authorization)

   OR

   2.2 Requested strength/dose is commercially unavailable

   OR

   2.3 Patient is on a dose alternating schedule

   OR

   2.4 For topical applications, patient requires a larger quantity to cover a larger surface area
| Notes | Not to exceed maximum dose as specified in the product prescribing information or compendia for off-label uses. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. *This guideline only applies in the absence of a drug-specific quantity limit override guideline |

**Product Name:** Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*

| Approval Length | 12 Month(s) |
| Guideline Type | Administrative |

**Approval Criteria**

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition
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 following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes

*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. **NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

2 . Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/10/2019</td>
<td>Annual review. No changes.</td>
</tr>
</tbody>
</table>
1. Indications

**Drug Name: Regranex (becaplermin gel)**

**Lower extremity diabetic neuropathic ulcers** Indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue, or beyond, and have an
adequate blood supply. Regranex should be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. The efficacy of Regranex gel has not been established for the treatment of pressure ulcers or venous stasis ulcers.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Regranex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient has a lower extremity diabetic neuropathic ulcer

   **AND**

2. Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control and/or pressure relief)

3. Background

**Benefit/Coverage/Program Information**

**Background:**

Regranex is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue, or beyond, and have an adequate blood supply. Regranex should be used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. The efficacy of Regranex gel has not been established for the treatment of pressure ulcers or venous stasis ulcers. If a member has a prescription for a diabetic medication within the last 180 days of claim’s history, the prescription for Regranex will automatically process.

**Additional Clinical Programs:**
• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
• Supply limits may be in place.

4 . References


5 . Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
</table>
GL-50479 Rexulti (brexpiprazole) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 7/12/2019

Revision Date 7/12/2019

Technician Note:

P&T Approval Date: 2/17/2017; P&T Revision Date: 3/21/2018, 12/19/2018, 06/17/2019.

**Effective Date: 9/1/2019**

1. Indications

Drug Name: Rexulti (brexpiprazole)

Indications

**Major depressive disorder (MDD)** FDA approved for use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD). The use of adjunctive atypical antipsychotics in the treatment of major depressive disorder is reserved for those who fail to demonstrate response to adequate trials of antidepressant monotherapy.

**Schizophrenia** FDA approved for the treatment of schizophrenia. For the treatment of
schizophrenia, the selection of which antipsychotic medication to use for an individual patient with schizophrenia should be made based on patient clinical factors and the side effect profiles of antipsychotic drugs. With the exception of clozapine for patients with refractory symptoms, there is not convincing evidence to favor one antipsychotic over the others based on efficacy.

2. Criteria

Product Name: Rexulti [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following:

1.1 Submission of medical records documenting ALL of the following:

1.1.1 The patient has a diagnosis of schizophrenia

AND

1.1.2 The patient has a history of failure, contraindication or intolerance to a trial of aripiprazole. (Document date and duration of trial).

AND

1.1.3 The patient has a history of failure, contraindication or intolerance to a trial of at least TWO of the following atypical antipsychotics. (Document drug, date and duration of trial):

- risperidone
- quetiapine IR or XR
• ziprasidone
• olanzapine

OR

1.2 Submission of medical records documenting ALL of the following:

1.2.1 The patient has a diagnosis of major depressive disorder

AND

1.2.2 Rexulti is being used in combination with an antidepressant medication.

AND

1.2.3 The patient has a history of failure, contraindication or intolerance to a trial of at least one selective serotonin reuptake inhibitor (SSRI). (Document drug, date and duration of trial).

AND

1.2.4 The patient has a history of failure, contraindication or intolerance to a trial of at least one serotonin norepinephrine reuptake inhibitor (SNRI), mirtazapine, or bupropion. (Document drug, date and duration of trial).

AND

1.2.5 The patient has a history of failure, contraindication or intolerance to a trial of at least one of the following atypical antipsychotics approved by the FDA for the adjunctive treatment of major depressive disorder with an antidepressant (Document drug, date and duration of trial):

• olanzapine
• aripiprazole
• quetiapine extended-release

OR

1.3 Treatment with Rexulti was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Document date of discharge from inpatient admission).
1.4 Both of the following:

1.4.1 Patient is currently on Rexulti therapy

AND

1.4.2 Patient has not received a manufacturer supplied sample at no cost in the prescriber’s office, or any form of assistance from the manufacturer (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rexulti*

OR

1.5 All of the following:

1.5.1 Patient is currently on Rexulti therapy

AND

1.5.2 Patient has received a manufacturer supplied sample at no cost in the prescriber’s office, or any form of assistance from the manufacturer (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Rexulti

AND

1.5.3 Provider attests switching to an alternative preferred agent could lead to deterioration of the patient’s condition requiring emergent medical care.

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from the manufacturer shall be required to meet initial authorization criteria as if patient were new to therapy, unless provider attests to the risk of deterioration with a change in medication.

Product Name: Rexulti [a]
<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to Rexulti

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.
- Prior Authorization/Step Therapy may be in place.

4. References
## 1. Indications

**Drug Name:** Rhofade (oxymetazoline)

**Indications**

**Persistent Facial Erythema** Indicated for the topical treatment of persistent facial erythema associated with rosacea.
2. Criteria

**Product Name:** Rhofade [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of persistent erythema associated with rosacea

   AND

2. History of a 30 day or longer trial and failure, or contraindication or intolerance to Mirvaso

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** Rhofade[a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of a positive clinical response to Rhofade therapy
Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

Benefit/Coverage/Program Information

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

Background:

Rhofade (oxymetazoline) and Mirvaso (brimonidine) are alpha adrenergic agonists indicated for the topical treatment of persistent facial erythema associated with rosacea.

Topical alpha adrenergic agonists reduce the persistent background erythema of rosacea through vasoconstriction of the superficial vasculature of the face and should not be used as an alternative for treatment of inflammatory lesions.

4. References

Prior Authorization Guideline

GL-53338 Savella (milnacipran)

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>12/1/2019</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>10/6/2009</td>
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<td>P&amp;T Revision Date:</td>
<td>10/16/2019</td>
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Technician Note:

P&T Revision Date: 5/21/2014, 7/8/2014, 12/20/2017, 1/17/2018, 12/19/2018

1. Indications
**Drug Name: Savella (milnacipran)**

**Fibromyalgia** is indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

---

### 2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Savella</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - Trial and failure, contraindication, or intolerance to one of the following: [A, B]

- amitriptyline*
- cyclobenzaprine*
- duloxetine
- gabapentin
- Lyrica immediate-release

**Notes**

*Amitriptyline and cyclobenzaprine are recommended only for patients less than 65 years old. [3, B]*

---

### 3. Endnotes

A. Safety and effectiveness of Savella in a fibromyalgia pediatric population below the age of 17 have not been established. The use of Savella is not recommended in pediatric patients. [1]

B. Amitriptyline is part of the Beer’s Criteria for potentially inappropriate medication use in older adults (independent of diagnoses or condition) because of its strong anticholinergic and sedation properties while cyclobenzaprine is listed as most muscle relaxants and antispasmodic drugs are poorly tolerated by elderly patients, since these cause anticholinergic adverse effects, sedation, and weakness. [3] However, amitriptyline and
cyclobenzaprine have the strongest evidence for efficacy in fibromyalgia amongst the tricyclic antidepressants. [2]

4. References


5. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/12/2019</td>
<td>Annual review. No updates to clinical criteria. Background updates only.</td>
</tr>
</tbody>
</table>
Prior Authorization Guideline

GL-53612 Sensipar (cinacalcet) - PA/Med Nec

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
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<tr>
<th>Effective Date:</th>
<th>11/1/2019</th>
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<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>8/19/2016</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>08/16/2019 ; 8/16/2019</td>
</tr>
</tbody>
</table>

1. Indications

**Drug Name: Sensipar (cinacalcet)**

**Secondary hyperparathyroidism** Indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with chronic kidney disease on dialysis.
Parathyroid carcinoma  Indicated for the treatment of hypercalcemia in patients with parathyroid carcinoma.

Primary hyperparathyroidism  Indicated for the treatment of hypercalcemia in patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Sensipar [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Therapy Stage</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

Approval Criteria

1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Diagnosis of secondary hyperparathyroidism with chronic kidney disease

AND

2.1.2 Patient is on dialysis

AND

2.1.3 Both of the following:
• Patient has therapeutic failure, contraindication or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
• Patient has therapeutic failure, contraindication or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.)

OR

2.2 Diagnosis of hypercalcemia with parathyroid carcinoma

OR

2.3 Both of the following:
• Diagnosis of severe hypercalcemia (level greater than 12.5 mg/dL) with primary hyperparathyroidism
• Patient is unable to undergo parathyroidectomy

Notes
[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Sensipar [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria
1 - Patient has experienced a reduction in serum calcium from baseline

Notes
[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. References


4. Revision History

<table>
<thead>
<tr>
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<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>9/18/2019</td>
<td>Annual review. Updated references.</td>
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</table>
Prior Authorization Guideline

GL-56618 SGLT2 Inhibitors

Formulary  UHC Core

Formulary Note

Guideline Note:

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<th>1/1/2020</th>
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<td>7/9/2013</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>12/18/2019</td>
</tr>
</tbody>
</table>

1 . Indications

**Drug Name:** Farxiga (dapagliflozin)

**Type 2 Diabetes** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of Use: Farxiga is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
<table>
<thead>
<tr>
<th>Drug Name: Glyxambi (empagliflozin/linagliptin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Glyxambi on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitation of use: Glyxambi is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Glyxambi has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Glyxambi.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Invokamet (canagliflozin/metformin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with canagliflozin and metformin. Limitation of use: Invokamet is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Invokamet XR (canagliflozin/metformin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate. Limitations of Use: Not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Invokana (canagliflozin), Farxiga (dapagliflozin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of use: Invokana and Farxiga are not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Jardiance (empagliflozin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular Disease</strong> Indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease. <strong>Type 2 Diabetes</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name: Qtern (dapagliflozin and saxagliptin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 2 Diabetes</strong> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) who have inadequate control with dapagliflozin or who are already treated with dapagliflozin and saxagliptin. Limitations of Use: Qtern is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Qtern should</td>
</tr>
</tbody>
</table>
Only be used in patients who tolerate 10 mg dapagliflozin.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Type 2 Diabetes</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Segluromet (ertugliflozin and metformin)</strong></td>
<td>Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.</td>
<td></td>
</tr>
<tr>
<td><strong>Steglatro (ertugliflozin)</strong></td>
<td>Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitation of use: Steglatro is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.</td>
<td></td>
</tr>
<tr>
<td><strong>Steglujan (ertugliflozin and sitagliptin)</strong></td>
<td>Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Limitations of Use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Has not been studied in patients with a history of pancreatitis.</td>
<td></td>
</tr>
<tr>
<td><strong>Synjardy (empagliflozin/metformin)</strong></td>
<td>Indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Synjardy on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitation of use: Synjardy is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.</td>
<td></td>
</tr>
<tr>
<td><strong>Synjardy XR (empagliflozin and metformin hydrochloride extended-release)</strong></td>
<td>Synjardy XR is a combination of empagliflozin and metformin HCl indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Synjardy XR on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established. Limitations of Use: Synjardy XR is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.</td>
<td></td>
</tr>
<tr>
<td><strong>Xigduo XR (dapagliflozin/metformin XR)</strong></td>
<td>Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is</td>
<td></td>
</tr>
</tbody>
</table>
appropriate. Limitation of use: Xigduo XR is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

### 2. Criteria

<table>
<thead>
<tr>
<th>Product Name: Glyxambi, Invokamet, Invokamet XR, Invokana, Jardiance, Synjardy, Synjardy XR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Trial and failure, intolerance or contraindication to one of the following generics:
   - metformin
   - metformin ER
   - glipizide-metformin
   - glyburide-metformin
   - pioglitazone-metformin

<table>
<thead>
<tr>
<th>Product Name: Farxiga, Qtern, Segluromet, Steglatro, Steglujan, Xigduo XR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
</tr>
<tr>
<td>Guideline Type</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Trial and failure, intolerance or contraindication to one of the following generics:
   - metformin
   - metformin ER
   - glipizide-metformin
   - glyburide-metformin
   - pioglitazone-metformin
AND

2 - Trial and failure or intolerance to one of the following:

- Invokana
- Invokamet
- Invokamet XR

AND

3 - Trial and failure or intolerance to one of the following:

- Glyxambi
- Jardiance
- Synjardy
- Synjardy XR

3. References

## 4. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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<tbody>
<tr>
<td>11/6/2019</td>
<td>no updates</td>
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</tbody>
</table>
Prior Authorization Guideline

GL-49323 Short-Acting Bronchodilators

Formulary UHC Core

Formulary Note

Approval Date 5/2/2019

Revision Date 5/2/2019

Technician Note :


1. Indications

**Drug Name: Proventil HFA (albuterol sulfate inhalation aerosol)**

**Indications**

**Bronchospasm** Indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

**Drug Name: Xopenex HFA (levalbuterol tartrate inhalation aerosol)**
**Indications**

**Bronchospasm** Indicated the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

**Drug Name:** Ventolin HFA, Proair HFA (albuterol sulfate inhalation aerosol)

**Indications**

**Bronchospasm** Indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

**Exercise-Induced Bronchospasm** Indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

---

**2. Criteria**

**Product Name:** Proventil HFA, Xopenex HFA, levalbuterol HFA, or albuterol HFA

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 History of both of the following:

- ProAir HFA or ProAir RespiClick
- Ventolin HFA
3. References

1. Criteria

Product Name: Short-Acting Opioids [a]

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Supply Limit</th>
</tr>
</thead>
</table>

Approval Criteria

1. Opioid naïve members (defined as not having filled an opioid in the past 120 days) may
receive greater than the supply limit* based on ALL of the following:

1.1 ONE of the following

1.1.1 Cancer diagnosis

1.1.2 End-of-life pain, including hospice care

1.1.3 Palliative care

1.1.4 Sickle cell anemia

1.1.5 Both of the following:

1.1.5.1 ONE of the following:

- Traumatic injury
- Post-surgical procedures, excluding dental procedures
- Prescriber attests the patient has received an opioid in the past 120 days.

AND

1.1.5.2 Prescriber attests to both of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- If requested for traumatic injury or post-surgical procedure, prescriber attests that based on the injury or surgical procedure performed the member requires greater than a 7 day supply* of short-acting opioids to adequately control pain.
AND

1.2 If the request is for 50 MME or greater ONE of the following

1.2.1 Diagnosis of cancer, end of life pain (including hospice care), palliative care or sickle cell anemia

OR

1.2.2 Patient is new to the plan and is currently exceeding 50 MME and prescriber attests patient has been on an opioid in the past 120 days

OR

1.2.3 All of the following:

1.2.3.1 Document all of the following:

- The diagnosis 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 member requires more than 50 MME per day to adequately control pain. (please note initial fill will be limited to 90 MME)

AND

1.3 Request does not exceed four grams of acetaminophen per day.

Notes

Authorization for cancer, end of life pain or palliative care pain or sickle cell anemia will be issued or a quantity of 9999 for 24 months to prevent further disruption in therapy if the patient’s dose is increased. Members new to plan (coverage effective date of <120 days) will be approved for one month for the requested MME not to exceed the plan’s supply limit. All other approvals will be issued for one month for the requested MME not to exceed the maximum labeled FDA dosing where a maximum exists, the plan’s supply limit OR 90 MME. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage.
criteria. Other policies and utilization management programs may apply. * Patients age 19 years and under new to opioid therapy are restricted to a 3-day supply for initial fill. Members age 20 years and older new to opioid therapy are restricted to up to a 7-day supply for initial fill. Initial fill for all ages is limited to <50 MME.

2. Background

Benefit/Coverage/Program Information

Additional Clinical Programs

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Opioid Cumulative Dose Review may be in place.

EI 90 MME Table for

<table>
<thead>
<tr>
<th>Drug Name and Strength</th>
<th>49 MME Equivalent (Max units/day)</th>
<th>90 MME Equivalent (Max units/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN-CAFFEINE- DIHYDROCODEINE CAP 320.5-30-16 MG</td>
<td>12 capsules/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>ACETAMINOPHEN-CAFFEINE- DIHYDROCODEINE TAB 325-30-16 MG</td>
<td>12 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>ACETAMINOPHEN W/ CODEINE SOLN 120-12 MG/5ML</td>
<td>136mL/day</td>
<td>250mL/day. Plan's supply limit from the master supply limit grid is more restrictive.</td>
</tr>
<tr>
<td>ACETAMINOPHEN W/ CODEINE</td>
<td>13 tablets/day</td>
<td>Requests over 49 MME exceed the FDA</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Daily Dose</td>
<td>Max. Dose</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------</td>
<td>-----------</td>
</tr>
<tr>
<td>TAB 300-15 MG</td>
<td></td>
<td>max.</td>
</tr>
<tr>
<td>CARISOPRODOL W/ ASPIRIN &amp; CODEINE TAB 200-325-16 MG</td>
<td>8 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>CODEINE Sulfate TAB 15 MG</td>
<td>21 tablets/day</td>
<td>40 tablets/day. FDA max dose is 24 tablets/day. 90 MME/plan supply limit will exceed FDA max.</td>
</tr>
<tr>
<td>CODEINE Sulfate TAB 30 MG</td>
<td>10 tablets/day</td>
<td>20 tablets/day. FDA max dose is 12 tablets/day. 90 MME/plan supply limit will exceed FDA max.</td>
</tr>
<tr>
<td>CODEINE Sulfate TAB 60 MG</td>
<td>5 tablets/day</td>
<td>10 tablets/day. FDA max dose is 6 tablets/day. 90 MME/plan supply limit will exceed FDA max.</td>
</tr>
<tr>
<td>DEMEROL (MEPERIDINE HCL) TAB 50 MG</td>
<td>9 tablets/day</td>
<td>18 tablets/day</td>
</tr>
<tr>
<td>DEMEROL (MEPERIDINE HCL) TAB 100 MG</td>
<td>4 tablets/day</td>
<td>9 tablets/day</td>
</tr>
<tr>
<td>DILAUDID (HYDROMORPHONE HCL) LIQD 1 MG/ML</td>
<td>12.25mL/day</td>
<td>22.5mL/day</td>
</tr>
<tr>
<td>DILAUDID (HYDROMORPHONE HCL) TAB 2 MG</td>
<td>6 tablets/day</td>
<td>11 tablets/day</td>
</tr>
<tr>
<td>DILAUDID (HYDROMORPHONE HCL) TAB 4 MG</td>
<td>3 tablets/day</td>
<td>5 tablets/day</td>
</tr>
<tr>
<td>DILAUDID (HYDROMORPHONE HCL) TAB 8 MG</td>
<td>1 tablet/day</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td>HYCET (HYDROCODONE-ACETAMINOPHEN) SOLN 7.5-325 MG/15ML</td>
<td>98mL/day</td>
<td>180mL/day</td>
</tr>
<tr>
<td>HYDROCODONE-ACETAMINOPHEN TAB 2.5-325 MG</td>
<td>12 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>HYDROCODONE-ACETAMINOPHEN TAB 10-300 MG</td>
<td>4 tablets/day</td>
<td>9 tablets/day</td>
</tr>
</tbody>
</table>
| HYDROCODONE-IBUPROFEN TAB                     | 9 tablets/day | Requests over 49 MME exceed the FDA max.
<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Dosage/Day</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCODONE-IBUPROFEN TAB 5-200 MG</td>
<td>6 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>HYDROCODONE-IBUPROFEN TAB 7.5-200 MG</td>
<td>6 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>HYDROCODONE-IBUPROFEN TAB 10-200 MG</td>
<td>4 tablets/day</td>
<td>9 tablets/day. FDA max dose is 5 tablets/day. 90 MME/plan supply limit will exceed FDA max.</td>
</tr>
<tr>
<td>HYDROMORPHONE HCL SUPPOS 3 MG</td>
<td>4 suppositories/day</td>
<td>7 suppositories/day</td>
</tr>
<tr>
<td>LORTAB (HYDROCODONE-ACETAMINOPHEN) SOLN 10-300 MG/15ML</td>
<td>73.5mL/day</td>
<td>135mL/day</td>
</tr>
<tr>
<td>MEPERIDINE HCL ORAL SOLN 50 MG/5ML</td>
<td>49mL/day</td>
<td>90mL/day</td>
</tr>
<tr>
<td>MEPERIDINE W/ PROMETHAZINE CAP 50-25 MG</td>
<td>9 capsules/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>MORPHINE SULFATE ORAL SOLN 10 MG/5ML</td>
<td>24.5mL/day</td>
<td>45mL/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE ORAL SOLN 20 MG/5ML</td>
<td>12.25mL/day</td>
<td>22.5mL/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE ORAL SOLN 100 MG/5ML (20 MG/ML)</td>
<td>2.4mL/day</td>
<td>4.5mL/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE SUPPOS 5 MG</td>
<td>9 suppositories/day</td>
<td>18 suppositories/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE SUPPOS 10 MG</td>
<td>4 suppositories/day</td>
<td>9 suppositories/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE SUPPOS 20 MG</td>
<td>2 suppositories/day</td>
<td>4 suppositories/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE SUPPOS 30 MG</td>
<td>1 suppository/day</td>
<td>3 suppositories/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE TAB 15 MG</td>
<td>3 tablets/day</td>
<td>6 tablets/day</td>
</tr>
<tr>
<td>MORPHINE SULFATE TAB 30 MG</td>
<td>1 tablet/day</td>
<td>3 tablets/day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Daily Dose</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------</td>
<td>--------------------------------------------------------------</td>
</tr>
<tr>
<td>NALOCET TAB 2.5-300</td>
<td>13 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>NORCO (HYDROCODONE-ACETAMINOPHEN) TAB 5-325 MG</td>
<td>9 tablets/day</td>
<td>18 tablets/day. Plan's supply limit from the master supply limit grid is more restrictive.</td>
</tr>
<tr>
<td>NORCO (HYDROCODONE-ACETAMINOPHEN) TAB 10-325 MG</td>
<td>4 tablets/day</td>
<td>9 tablets/day</td>
</tr>
<tr>
<td>NORCO (HYDROCODONE-ACETAMINOPHEN) TAB 7.5-325 MG</td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
<tr>
<td>NUCYNTA (TAPENTADOL HCL) TAB 50 MG</td>
<td>2 tablets/day</td>
<td>4 tablets/day</td>
</tr>
<tr>
<td>NUCYNTA (TAPENTADOL HCL) TAB 75 MG</td>
<td>1 tablet/day</td>
<td>3 tablets/day</td>
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<tr>
<td>NUCYNTA (TAPENTADOL HCL) TAB 100 MG</td>
<td>1 tablet/day</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td>OPANA (OXYMORPHONE HCL) TAB 5 MG</td>
<td>3 tablets/day</td>
<td>6 tablets/day</td>
</tr>
<tr>
<td>OPANA (OXYMORPHONE HCL) TAB 10 MG</td>
<td>1 tablet/day</td>
<td>3 tablets/day</td>
</tr>
<tr>
<td>OXAYDO (OXYCODONE HCL) TAB ABUSE DETER 5 MG</td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
<tr>
<td>OXAYDO (OXYCODONE HCL) TAB ABUSE DETER 7.5 MG</td>
<td>4 tablets/day</td>
<td>8 tablets/day</td>
</tr>
<tr>
<td>OXYCODONE HCL CAP 5 MG</td>
<td>6 capsules/day</td>
<td>12 capsules/day</td>
</tr>
<tr>
<td>OXYCODONE HCL CONC 100 MG/5ML (20 MG/ML)</td>
<td>1.6mL/day</td>
<td>3mL/day</td>
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<tr>
<td>OXYCODONE HCL SOLN 5 MG/5ML</td>
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<td>60mL/day</td>
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<tr>
<td>OXYCODONE HCL TAB 10 MG</td>
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<td>6 tablets/day</td>
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<tr>
<td>OXYCODONE HCL TAB 20 MG</td>
<td>1 tablet/day</td>
<td>3 tablets/day</td>
</tr>
<tr>
<td>OXYCODONE W/ ACETAMINOPHEN</td>
<td>32.6mL/day</td>
<td>60mL/day</td>
</tr>
<tr>
<td>Product Description</td>
<td>Daily Dose 1</td>
<td>Daily Dose 2</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>SOLN 5-325 MG/5ML</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OXYCODONE-ASPIRIN TAB 4.8355-325 MG</td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
<tr>
<td>OXYCODONE-IBUPROFEN TAB 5-400 MG</td>
<td>6 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>PENTAZOCINE W/ NALOXONE TAB 50-0.5 MG</td>
<td>2 tablets/day</td>
<td>4 tablets/day</td>
</tr>
<tr>
<td>PEROCET (OXYCODONE W/ ACETAMINOPHEN) TAB 2.5-325 MG</td>
<td>12 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td>PEROCET (OXYCODONE W/ ACETAMINOPHEN) TAB 5-325 MG</td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
<tr>
<td>PEROCET (OXYCODONE W/ ACETAMINOPHEN) TAB 7.5-325 MG</td>
<td>4 tablets/day</td>
<td>8 tablets/day</td>
</tr>
<tr>
<td>PEROCET (OXYCODONE W/ ACETAMINOPHEN) TAB 10-325 MG</td>
<td>3 tablets/day</td>
<td>6 tablets/day</td>
</tr>
<tr>
<td>PRIMLEV (OXYCODONE W/ ACETAMINOPHEN) TAB 5-300 MG</td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
<tr>
<td>PRIMLEV (OXYCODONE W/ ACETAMINOPHEN) TAB 7.5-300 MG</td>
<td>4 tablets/day</td>
<td>8 tablets/day</td>
</tr>
<tr>
<td>PRIMLEV (OXYCODONE W/ ACETAMINOPHEN) TAB 10-300 MG</td>
<td>3 tablets/day</td>
<td>6 tablets/day</td>
</tr>
<tr>
<td>ROXYBOND TAB 15MG</td>
<td>2 tablets/day</td>
<td>4 tablets/day</td>
</tr>
<tr>
<td>ROXYBOND TAB 30MG</td>
<td>1 tablet/day</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td>ROXICODONE (OXYCODONE HCL) TAB 5 MG</td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
<tr>
<td>ROXICODONE (OXYCODONE HCL) TAB 15 MG</td>
<td>2 tablets/day</td>
<td>4 tablets/day</td>
</tr>
<tr>
<td>ROXICODONE (OXYCODONE HCL) TAB 30 MG</td>
<td>1 tablet/day</td>
<td>2 tablets/day</td>
</tr>
<tr>
<td><strong>SYNAPRYN (TRAMADOL) ORAL SUSP 10MG/ML CPDKT</strong></td>
<td>40mL/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td><strong>TYLENOL/COD TAB #3 (ACETAMINOPHEN W/ CODEINE) TAB 300-30 MG</strong></td>
<td>10 tablets/day</td>
<td>20 tablets/day. Plan's supply limit from the master supply limit grid is more restrictive.</td>
</tr>
<tr>
<td><strong>TYLENOL/COD TAB #4 (ACETAMINOPHEN W/ CODEINE) TAB 300-60 MG</strong></td>
<td>5 tablets/day</td>
<td>10 tablets/day</td>
</tr>
<tr>
<td><strong>ULTRAM (TRAMADOL HCL) TAB 50MG</strong></td>
<td>8 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td><strong>ULTRACET (TRAMADOL-ACETAMINOPHEN) TAB 37.5-325</strong></td>
<td>10 tablets/day</td>
<td>Requests over 49 MME exceed the FDA max.</td>
</tr>
<tr>
<td><strong>XODOL (HYDROCODONE-ACETAMINOPHEN) TAB 5-300 MG</strong></td>
<td>9 tablets/day</td>
<td>18 tablets/day. Plan's supply limit from the master supply limit grid is more restrictive.</td>
</tr>
<tr>
<td><strong>XODOL (HYDROCODONE-ACETAMINOPHEN) TAB 7.5-300 MG</strong></td>
<td>6 tablets/day</td>
<td>12 tablets/day</td>
</tr>
</tbody>
</table>

### 3. References

GL-6092 Silenor (doxepin)

Formulary UHC Core

Formulary Note

Approval Date 3/21/2013

Revision Date 3/21/2013

Technician Note:
CPS Approval Date: 12/7/2010

1. Indications

Drug Name: Silenor (doxepin)

Indications

Insomnia [1]

Is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. The clinical trials performed in support of efficacy were up to 3 months in duration.
2. Criteria

**Product Name:** Silenor (doxepin)

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Non Formulary</th>
</tr>
</thead>
</table>

**Approval Criteria**

1. History of failure, contraindication, or intolerance to both of the following:
   - Ambien (zolpidem)
   - Lunesta (eszopiclone)

3. Dosing

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silenor (doxepin) - Recommended Dose</td>
<td>(1) Adults - 6 mg once daily. A 3 mg once daily dose may be appropriate for some patients, if clinically indicated; (2) Elderly - (greater than or equal to 65 years old): 3 mg once daily. The daily dose can be increased to 6 mg, if clinically indicated.</td>
</tr>
</tbody>
</table>

4. Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silenor</td>
<td>3 mg, 6 mg tablets</td>
</tr>
</tbody>
</table>
5. References

Prior Authorization Guideline

GL-51450 Solaraze (diclofenac 3% gel)

Formulary UHC Core

Formulary Note

Approval Date 8/13/2019

Revision Date 8/13/2019

Technician Note:

P&T Approval Date: 8/19/2015; P&T Revision Date: 7/27/2016, 7/18/2018, 07/17/2019;
**Guideline Effective Date: 10/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Solaraze (diclofenac 3% gel)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>Actinic Keratosis Indicated for the topical treatment of actinic keratosis (AK).</td>
</tr>
</tbody>
</table>
2. Criteria

**Product Name:** Solaraze*

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>3 Month(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Notification</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of actinic keratosis

| Notes | *Applies to brand and generic Solaraze |

3. Background

**Benefit/Coverage/Program Information**

**Background:**

The recommended duration of therapy is from 60 to 90 days.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
4. References

GL-49227 Solosec (secnidazole) - Step Therapy

Formulary UHC Core

Formulary Note

Approval Date 4/29/2019

Revision Date 4/29/2019

Technician Note :

P&T Approval: 4/18/2018; P&T Revision Date: 3/20/2019. **Guideline Effective Date: 6/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Solosec (secnidazole)</th>
</tr>
</thead>
</table>

Indications

bacterial vaginosis Indicated for the treatment of bacterial vaginosis.

2. Criteria
**Product Name:** Solosec [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>1 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. History of failure, contraindication or intolerance to one of the following:

- clindamycin capsules (generic Cleocin)
- clindamycin vaginal cream (generic Cleocin, Clindesse)
- clindamycin vaginal suppository (Cleocin)
- metronidazole tablets (generic Flagyl)
- metronidazole vaginal gel (Metrogel-Vaginal)
- tinidazole tablets (generic Tindamax)

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

---

**3. Background**

**Benefit/Coverage/Program Information**

**Background:**

Solosec (secnidazole) is indicated for the treatment of bacterial vaginosis. Solosec is available as a two gram oral granule and should be taken as a single dose.

Step therapy programs are intended to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try an alternative antibacterial agent before providing coverage for Solosec.
Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

4. References

Prior Authorization Guideline

GL-49791 Statins - NonFormulary and Step Therapy

Formulary UHC Core

Formulary Note

Approval Date 5/28/2019

Revision Date 5/28/2019

Technician Note:

P&T Approval Date: 4/17/2019; **Guideline Effective Date: 6/1/2019**

1. Criteria

Product Name: [Lescol XL (fluvasatin extended-release, brand only)*, Livalo (pitavastatin calcium)*, or Zypitamag (pitavastatin magnesium)*] [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria
1 History of failure, contraindication or intolerance to three of the following:

- atorvastatin (generic Lipitor)
- fluvastatin (generic Lescol)
- lovastatin (generic Mevacor)
- pravastatin (generic Pravachol)
- rosuvastatin (generic Crestor)
- simvastatin (generic Zocor)

| Notes | *Brand Lescol XL, Livalo, and Zypitamag may be excluded from coverage depending on benefit design. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

2. Background

Benefit/Coverage/Program Information

Background:

This program requires a member to try three alternative statin medications before providing coverage for Lescol XL, Livalo, or Zypitamag.

Additional Clinical Rules:

Supply limits may apply.
3. References

1. Indications

**Drug Name: Sublingual Immunotherapy (SLIT) Medications**

**Indications**

**Allergic rhinitis** Indicated for patients who have symptoms of allergic rhinitis with natural exposure to allergens and who demonstrate specific IgE antibodies to the relevant allergen.

**Drug Name: Grastek, Oralair**
**Indications**

**Allergic rhinitis** Indicated for patients with grass pollen-induced allergic rhinitis.

**Drug Name: Odactra**

**Indications**

**Allergic rhinitis** Indicated for house dust mite (HDM)-induced allergic rhinitis.

**Drug Name: Ragwitek**

**Indications**

**Allergic rhinitis** Indicated for ragweed pollen-induced allergic rhinitis.

---

### 2. Criteria

**Product Name:** Grastek [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>grass pollen-induced allergic rhinitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

   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 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 History of failure, contraindication, or intolerance to two of the following:

- 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)
6 Patient does not have unstable and/or uncontrolled asthma

AND

7 Prescribed by or in consultation with a specialist in allergy and immunology

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** Grastek [a]

| Diagnosis | grass pollen-induced allergic rhinitis |
| Approval Length | 12 Month |
| Therapy Stage | Reauthorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**

1 Documentation of positive clinical response to Grastek therapy

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. |

**Product Name:** Oralair [a]
<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>grass pollen-induced allergic rhinitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

   AND

2. Diagnosis confirmed by one of the following:

   2.1 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)]

   OR

   2.2 in vitro testing for pollen-specific IgE 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)]

   AND

3. Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

   AND
4 History of failure, contraindication, or intolerance to two of the following:

- 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

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Oralair [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>grass pollen-induced allergic rhinitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
</tbody>
</table>
Therapy Stage | Reauthorization
Guideline Type | Prior Authorization

**Approval Criteria**

1. Documentation of positive clinical response to Oralair therapy

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**Product Name:** Ragwitek [a]

| Diagnosis | ragweed pollen-induced allergic rhinitis |
| Approval Length | 12 Month |
| Therapy Stage | Initial Authorization |
| Guideline Type | Prior Authorization |

**Approval Criteria**

1. Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis

   **AND**

2. Diagnosis confirmed by one of the following:
   - Positive skin test to short ragweed pollen
   - In vitro testing for pollen-specific IgE antibodies for short ragweed pollen
3 Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 History of failure, contraindication, or intolerance to two of the following:

- 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

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Ragwitek [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>ragweed pollen-induced allergic rhinitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to Ragwitek therapy

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**Product Name:** Odactra [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>house dust mite (HDM)-induced allergic rhinitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**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 antibodies to Dermatophagoides farinae or Dermatophagoides
pteronyssinus house dust mites

AND

3 History of failure, contraindication, or intolerance to two of the following:

- 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

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Odactra [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>house dust mite (HDM)-induced allergic rhinitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
Approval Criteria

1 Documentation of positive clinical response to Odactra therapy

Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

Benefit/Coverage/Program Information

Background:

The sublingual immunotherapy (SLIT) medications are indicated for patients who have symptoms of allergic rhinitis with natural exposure to allergens and who demonstrate specific IgE antibodies to the relevant allergen. Grastek (Timothy grass pollen allergen extract) and Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens allergen extract) are indicated for patients with grass pollen-induced allergic rhinitis, Ragwitek (short ragweed pollen allergen extract) is indicated for ragweed pollen-induced allergic rhinitis and Odactra (Dermatophagoides farinae/Dermatophagoides pteronyssinus allergen extract), is indicated for house dust mite (HDM)-induced allergic rhinitis.

Candidates for allergen immunotherapy are patients whose symptoms are not adequately controlled by medications, and avoidance measures have been ineffective. In addition, patients experiencing unacceptable adverse effects of medications or who wish to reduce the long term use of medications may also be candidates for immunotherapy.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits and/or Notification may be in place.
4. References

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Symlin (pramlintide acetate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>Type 1 Diabetes Mellitus</td>
</tr>
<tr>
<td>Indicated for type 1 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.</td>
</tr>
<tr>
<td>Type 2 Diabetes Mellitus</td>
</tr>
</tbody>
</table>
Indicated for type 2 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.

2. Criteria

Product Name: Symlin

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following diagnoses:

- Type 1 diabetes
- Type 2 diabetes

2 Age greater than or equal to 18 years [A]

3 Concurrent use of insulin therapy
### 4 Not used in patients with gastroparesis

| Notes                              | Symlin is contraindicated in patients with hypoglycemia unawareness and known diagnosis of gastroparesis. |

### 3. Endnotes

A. Symlin has not been evaluated in the pediatric population. Safety and effectiveness of Symlin in pediatric patients have not been established. [1]

### 4. References

2. AACE Comprehensive Diabetes Management Algorithm, Endocr Pract. 2013;19 (No. 2)
**1. Indications**

**Drug Name: Temodar (temozolomide)**

**Indications**

- **Glioblastoma multiforme** Indicated for treatment in patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.[1]

- **Refractory anaplastic astrocytoma** Indicated for treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.
2. Criteria

Product Name: Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Patients less than 19 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. Patient is less than 19 years of age

Product Name: Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Central Nervous Systems (CNS) Tumor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1. One of the following diagnoses:
   - Intracranial and Spinal Ependymoma (Excluding Subependymoma)
   - Low-Grade Infiltrative Supratentorial Astrocytoma/Oligodendroglialoma
   - Medulloblastoma
   - Anaplastic Gliomas
   - Glioblastoma
   - Metastatic lesions of the CNS
- Primary CNS lymphoma

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Central Nervous Systems (CNS) Tumor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient does not show evidence of progressive disease while on Temodar therapy

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Melanoma/Uveal Melanoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of melanoma or uveal melanoma

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Melanoma/Uveal Melanoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Patient does not show evidence of progressive disease while on Temodar therapy

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Neuroendocrine and Adrenal Tumors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Diagnosis of one of the following types of neuroendocrine tumors

- Bronchopulmonary disease
- GI tract, lung, or thymus
- Pancreas
- Pheochromocytoma/paraganglioma

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Neuroendocrine and Adrenal Tumors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria
**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-Hodgkin Lymphoma (NHL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

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

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-Hodgkin Lymphoma (NHL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. **Patient does not show evidence of progressive disease while on Temodar therapy**
<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Soft Tissue Sarcoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 One of the following:

1.1 Diagnosis of angiosarcoma

OR

1.2 Diagnosis of unresectable or progressive retroperitoneal/ intra-abdominal soft tissue sarcoma

OR

1.3 Diagnosis of rhabdomyosarcoma

OR

1.4 Both of the following:

1.4.1 Diagnosis of soft tissue sarcoma of the extremity/ superficial trunk, Head/Neck

AND

1.4.2 One of the following:

- Disease synchronous stage IV
- Disease has disseminated metastases
OR

1.5 Both of the following:

1.5.1 Diagnosis of solitary fibrous tumor/ hemangiopericytoma

AND

1.5.2 Used in combination with Avastin (bevacizumab)

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Soft Tissue Sarcoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

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

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Bone Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Diagnosis of one of the following:
- Ewing's sarcoma family of tumors
- Mesenchymal Chondrosarcoma

**AND**

2 One of the following:

- Disease has relapsed
- Disease is progressive following primary treatment
- Used as second-line therapy for metastatic disease

**AND**

3 Used in combination with Campostar (irinotecan)

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Bone Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

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

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Uterine Sarcoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of uterine sarcoma

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Uterine Sarcoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Patient does not show evidence of progressive disease while on Temodar therapy

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Small Cell Lung Cancer (SCLC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**
1 Diagnosis of small cell lung cancer (SCLC)

AND

2 One of the following:

- Relapse within 6 months following complete or partial response or stable disease with initial treatment
- Primary progressive disease

**Product Name:** Brand Temodar, Generic temozolomide

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Small Cell Lung Cancer (SCLC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

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

**3. Background**

**Benefit/Coverage/Program Information**

**Background:**
Temodar (temozolomide) is an alkylating drug indicated for treatment in patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.[1] It is also indicated for treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine. The National Comprehensive Cancer Network (NCCN) also recommends Temodar for the treatment of CNS cancers - primary astrocytoma/oligodendroglioma or anaplastic glioma central nervous system tumors, ependymoma, metastatic central nervous system lesions, primary central nervous system lymphoma, medulloblastoma; melanoma and uveal melanoma; pancreatic neuroendocrine disorders; NHL – mycosis fungoides (MF) and Sézary syndrome (SS); soft tissue sarcoma (STS), Ewing’s sarcoma; mesenchymal chondrosarcoma; lung neuroendocrine tumors; pheochromocytoma/paraganglioma neuroendocrine and adrenal tumors; uterine sarcoma; or small cell lung cancer (SCLC).[2]

Coverage Information

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

Additional Clinical Rules:

Supply limits may be in place.

4 . References

Prior Authorization Guideline

GL-49285 Topical Androgens

Formulary UHC Core

Formulary Note

Approval Date 5/1/2019

Revision Date 5/1/2019

Technician Note:

P&T Approval Date: 2/18/2014; P&T Revision Date: 2/15/2019. Guideline Effective Date: 5/1/2019.

1. Criteria

Product Name: Preferred products (Androderm, Androgel 1.62%, generic testosterone pump 1%)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Hypogonadism</th>
</tr>
</thead>
</table>

| Approval Length | 6 months for patients new to any topical testosterone therapy; 12 months for patients continuing testosterone therapy |
Therapy Stage | Initial Authorization 
--- | --- 
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 All of the following:

1.2.1 One of the following:

1.2.1.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) 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

1.2.1.2 Both of the following:

1.2.1.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.2.1.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (less than 5 ng/dL or less than 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)
AND

1.2.2 Patient is not taking any of the following:

- One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
- Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

1.2.3 Patient was male at birth

AND

1.2.4 Diagnosis of hypogonadism

AND

1.2.5 One of the following:

- Significant reduction in weight (less than 90% ideal body weight) (eg, AIDS wasting syndrome)
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

Product Name: Non-preferred products (brand Androgel gel and pump 1%, Axiron, Fortesta (brand and generic), Natesto, brand Testim, generic testosterone gel 1%, generic testosterone gel 2%, Striant, Brand Vogelxo gel and pump)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Hypogonadism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 months for patients new to any topical testosterone therapy; 12 months for patients continuing testosterone therapy</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>

**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 All of the following:

1.2.1 One of the following:

1.2.1.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) 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

1.2.1.2 Both of the following:

1.2.1.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.2.1.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (less than 5 ng/dL or less than 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)

AND
1.2.2 Patient is not taking any of the following:

- One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
- Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

1.2.3 Patient was male at birth

AND

1.2.4 Diagnosis of hypogonadism

AND

1.2.5 One of the following:

- Significant reduction in weight (less than 90% ideal body weight) (eg, AIDS wasting syndrome)
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

AND

2 History of failure or intolerance to Androgel 1.62%

**Product Name:** Preferred products (Androderm, Androgel 1.62%, generic testosterone pump 1%)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Gender Dysphoria+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 months for patients new to any topical testosterone therapy; 12 months for patients continuing testosterone therapy</td>
</tr>
</tbody>
</table>
Therapy Stage | Initial Authorization
---|---
Guideline Type | Prior Authorization

**Approval Criteria**

1. Using hormones to change physical characteristics

2. The covered person must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

3. Patient is not taking any of the following:
   - One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
   - aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

**Product Name:** Non-preferred products (brand Androgel gel and pump 1%, Axiron, Fortesta (brand and generic), Natesto, brand Testim, generic testosterone gel 1%, generic testosterone gel 2%, Striant, Brand Vogelxo gel and pump)

| Diagnosis | Gender Dysphoria+
---|---
| Approval Length | 6 months for patients new to any topical testosterone therapy; 12 months for patients continuing testosterone therapy
| Therapy Stage | Initial Authorization
Guideline Type | Prior Authorization
---|---

**Approval Criteria**

1. Using hormones to change physical characteristics

   AND

2. The covered person 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:
   - One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
   - Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

   AND

4. History of failure or intolerance to Androgel 1.62%

**Product Name:** Preferred and Non-preferred products

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Non-Gender Dysphoria and Gender Dysphoria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
</tbody>
</table>
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 Reauthorization will be approved based on both of the following:

1.2.1 One of the following:

1.2.1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab (document value and date)

OR

1.2.1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

OR

1.2.1.3 Both of the following:

1.2.1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)
1.2.1.3.2 One of the following:

1.2.1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e. on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e. on therapy for one year or longer), is within or below the normal male limits of the reporting lab (document lab value and date)

OR

1.2.1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e. on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e. on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

AND

1.2.2 Patient is not taking any of the following:

- One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
- Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

2. Background

Benefit/Coverage/Program Information

Background:

Topical testosterone products are approved by the Food and Drug Administration (FDA) for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadotrophic hypogonadism (congenital or acquired).
Primary hypogonadism originates from a deficiency or disorder in the testicles. Secondary hypogonadism indicates a problem in the hypothalamus or the pituitary gland. Testosterone use has been strongly linked to improvements in muscle mass, bone density, and libido.

The purpose of this program is to provide coverage for androgens and anabolic steroid therapy for the treatment of conditions for which they have shown to be effective and are within the scope of the plan’s pharmacy benefit. Coverage for the enhancement of athletic performance or body building will not be provided.

Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- +Coverage for patient population may be dependent upon benefit design

3. References

2. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version.
1. Indications

Drug Name: Jublia (efinaconazole) and Kerydin (tavaborole)

Onychomycosis Indicated for the treatment of onychomycosis due to Trichophyton rubrum and Trichophyton mentagrophytes. Presence of these organisms may be determined using molecular diagnostic testing. Fungal cultures require a longer turnaround time to obtain diagnosis.
2. Criteria

**Product Name:** Jublia [a] or Kerydin [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>48 Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Submission of medical records (laboratory and clinical documentation) confirming diagnosis of onychomycosis of the toenail with one of the following infections (if request is for a subsequent course of therapy a new test must be performed):

   - Trichophyton rubrum
   - Trichophyton mentagrophytes

   **AND**

2. Treatment is requested due to medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis, patients with diabetes who have additional risk factors for cellulitis, patients who experience pain/discomfort associated with the infected nail)

   **AND**

3. History of failure (subject to minimum treatment durations indicated below [b]), contraindication, or intolerance to two of the following antifungal agents (please document date of trial):

   - Minimum of 12 week treatment with itraconazole (generic Sporanox)
   - Minimum of 12 week treatment with oral terbinafine (generic Lamisil)
- Minimum of 12 week treatment with ciclopirox (generic Penlac)

| Notes | [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply. [b] For Connecticut and Kentucky business, only a 30 day trial will be required. |

### 3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

### 4. References

https://www.uptodate.com/contents/onychomycosis-management?search=onychomycosis%20treatment&source=search_result&selectedTitle=1-85&usage_type=default&display_rank=1  
1. Indications

**Drug Name:** Topical retinoid products

**Indications**

**Cosmetic and medical conditions** Indicated for cosmetic and medical conditions (e.g. acne vulgaris, psoriasis, precancerous skin lesions)
2. Criteria

**Product Name:** Tretinoin cream (generic Retin-A cream)

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non-Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. The member has a non-cosmetic medical condition (e.g. acne vulgaris, psoriasis, precancerous skin lesions, other conditions listed below**, etc.)

   AND

2. Medication is not being requested solely for cosmetic purposes (e.g., photoaging, wrinkling, hyperpigmentation, sun damage, melasma)

**Product Name:** Altreno, Avita, Brand Atralin, Brand Differin, Brand Retin-A, Brand Retin-A Micro, Fabior, Generic adapalene, Generic tretinoin gel and lotion, Generic tretinoin microsphere, and Tretin X

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non-Formulary</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. The member has a non-cosmetic medical condition (e.g. acne vulgaris, psoriasis, precancerous skin lesions, other conditions listed below**, etc.)

   AND
Medication is not being requested solely for cosmetic purposes (e.g., photoaging, wrinkling, hyperpigmentation, sun damage, melasma)

AND

History of failure or intolerance to both of the following:

- OTC Differin gel
- Tretinoin cream (generic Retin-A)*

*Prior Authorization may be required.

Product Name: Tazorac

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization or Non-Formulary</td>
</tr>
</tbody>
</table>

Approval Criteria

1 All of the following:

1.1 Diagnosis of psoriasis

AND

1.2 One of the following:

1.2.1 History of failure, contraindication, or intolerance to two medium to high potency formulary or non-formulary corticosteroid topical treatments†

OR

1.2.2 Prescribed by a dermatologist
2 All of the following:

2.1 Request is for Tazorac 0.1%

AND

2.2 The member has a non-cosmetic medical condition other than psoriasis (e.g., acne vulgaris, precancerous skin lesions, other conditions listed below**, etc.)

AND

2.3 Medication is not being requested solely for cosmetic purposes (e.g., photoaging, wrinkling, hyperpigmentation, sun damage, melasma)

AND

2.4 History of failure or intolerance to both of the following:

- OTC Differin gel
- tretinoin cream (generic Retin-A)*

| Notes | *Prior Authorization may be required. |

3. Background

Benefit/Coverage/Program Information
**Non-cosmetic medical conditions:**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acanthosis nigricans</td>
<td>Keratoderma</td>
</tr>
<tr>
<td>Acne</td>
<td>Keratoderma palmaris et plantaris</td>
</tr>
<tr>
<td>Acne keloidalis nuchae</td>
<td>Keratosis rubra figurata</td>
</tr>
<tr>
<td>Acne rosacea</td>
<td>Kyrle’s disease</td>
</tr>
<tr>
<td>Acne vulgaris</td>
<td>Lamellar ichthyosis</td>
</tr>
<tr>
<td>Actinic cheilitis</td>
<td>Leukoplakia</td>
</tr>
<tr>
<td>Actinic dermatitis</td>
<td>Lichen planus</td>
</tr>
<tr>
<td>Actinic keratosis</td>
<td>Mal de Meleda</td>
</tr>
<tr>
<td>Basal cell carcinoma</td>
<td>Malignancy</td>
</tr>
<tr>
<td>Bowen’s disease</td>
<td>Mendes da Costa syndrome</td>
</tr>
<tr>
<td>Cystic acne</td>
<td>Molluscum contagiosum</td>
</tr>
<tr>
<td>Darier’s disease</td>
<td>Non-bullous congenital ichthyosis</td>
</tr>
<tr>
<td>Darier-White Disease</td>
<td>Papillon-Lefevre syndrome</td>
</tr>
<tr>
<td>Dermal mucinosis</td>
<td>Porokeratosis</td>
</tr>
<tr>
<td>Discoid lupus erythematosis</td>
<td>Pseudofollicular bariae</td>
</tr>
<tr>
<td>Epidermoid cysts</td>
<td>Psuedoacanthosis nigricans</td>
</tr>
<tr>
<td>Epidermolytic hyperkeratosis</td>
<td>Psoriasis</td>
</tr>
<tr>
<td>Erythrokeratoderma variabilis</td>
<td>Psoriasis erythrodermic, palmoplantar</td>
</tr>
<tr>
<td>Favre Raucochet disease</td>
<td>Psoriasis pustular</td>
</tr>
<tr>
<td>Flat warts</td>
<td>Psoriatic arthritis</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>Rosacea</td>
</tr>
<tr>
<td>Fox Fordyce disease</td>
<td>Sebaceous cysts</td>
</tr>
<tr>
<td>Grover’s disease</td>
<td>Senile keratosis</td>
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<tr>
<td>Hidradenitis suppurativa</td>
<td>Solar keratosis</td>
</tr>
<tr>
<td>Hyperkeratosis</td>
<td>Squamous cell carcinoma</td>
</tr>
<tr>
<td>Hyperkeratosis follicularis</td>
<td>Transient acantholytic dermatosis</td>
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<tr>
<td>Hyperkeratotic eczema</td>
<td>Tylotic eczema</td>
</tr>
<tr>
<td>Ichthyoses</td>
<td>X-linked ichthyosis</td>
</tr>
<tr>
<td>Ichthyosis vulgaris</td>
<td>Verucca planae</td>
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<tr>
<td>Keratoacanthoma</td>
<td>Von Zumbusch pustular</td>
</tr>
<tr>
<td>Keratosis follicularis</td>
<td>Warts</td>
</tr>
</tbody>
</table>

† Topical Corticosteroid Therapy:

<table>
<thead>
<tr>
<th>Potency</th>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low potency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hytone®, Cortalid®</td>
<td>Hydrocortisone acetate</td>
<td></td>
</tr>
<tr>
<td>Aclovate®</td>
<td>Alclometasone</td>
<td></td>
</tr>
<tr>
<td>DesOwen®, Tridelison®</td>
<td>Desonide</td>
<td></td>
</tr>
<tr>
<td>Kenalog®</td>
<td>Triamcinolone acetonide</td>
<td></td>
</tr>
<tr>
<td>Synalar®</td>
<td>Fluocinolone acetonide</td>
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<tr>
<td>Valisone®</td>
<td>Betamethasone valerate</td>
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<tr>
<td>Medium potency</td>
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</tr>
<tr>
<td>Product</td>
<td>Active Ingredient</td>
<td></td>
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<tr>
<td>------------------</td>
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<tr>
<td>Cordran®</td>
<td>Flurandrenolide</td>
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<tr>
<td>Cutivate®</td>
<td>Fluticasone</td>
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<tr>
<td>Diprosone®</td>
<td>Betamethasone dipropionate</td>
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</tr>
<tr>
<td>Elocon®</td>
<td>Mometasone</td>
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<td>Kenalog®</td>
<td>Triamcinolone acetonide</td>
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<tr>
<td>Locoid®</td>
<td>Hydrocortisone butyrate</td>
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<tr>
<td>Synalar®</td>
<td>Fluocinolone acetonide</td>
<td></td>
</tr>
<tr>
<td>Topicort® LP</td>
<td>Desoximetasone</td>
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<tr>
<td>Westcort®</td>
<td>Hydrocortisone valerate</td>
<td></td>
</tr>
<tr>
<td><strong>High Potency</strong></td>
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<td></td>
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<tr>
<td>Cyclocort®</td>
<td>Amcinonide</td>
<td></td>
</tr>
<tr>
<td>Diprolene®, Diprolene® AF</td>
<td>Augmented betamethasone dipropionate</td>
<td></td>
</tr>
<tr>
<td>Diprosone®</td>
<td>Betamethasone dipropionate</td>
<td></td>
</tr>
<tr>
<td>Halog®</td>
<td>Halcinonide</td>
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<td>Kenalog®</td>
<td>Triamcinolone acetonide</td>
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</tr>
<tr>
<td>Lidex®</td>
<td>Fluocinonide</td>
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<tr>
<td>Topicort®</td>
<td>Desoximetasone</td>
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<tr>
<td>Psorcon®</td>
<td>Diflorasone diacetate</td>
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<tr>
<td>Temovate®</td>
<td>Clobetasol propionate</td>
<td></td>
</tr>
<tr>
<td>Ultravate®</td>
<td>Halobetasol propionate</td>
<td></td>
</tr>
<tr>
<td>Vanos®</td>
<td>Fluocinonide</td>
<td></td>
</tr>
</tbody>
</table>

**Background:**

Topical retinoid products are indicated for cosmetic and medical conditions (e.g. acne vulgaris, psoriasis, precancerous skin lesions). Cosmetic use is not a covered benefit. Therefore, Prior Authorization/Notification is in place to verify the use is for the diagnosis of a medical condition. For covered medications if members are younger than 30 years of age the topical retinoid prescription will automatically adjudicate without a coverage review.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
4. References

Prior Authorization Guideline

GL-13347 Toujeo (insulin glargine injection)

Formulary UHC Core

Formulary Note

Approval Date 6/10/2015

Revision Date 6/10/2015

Technician Note:

CPS Approval Date: 4/14/2015; According to Texas State Law, all diabetic medications used for the treatment of diabetes shall be covered.

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Toujeo (insulin glargine injection)</th>
</tr>
</thead>
</table>

Indications

Diabetes Mellitus

Indicated to improve glycemic control in adults with diabetes mellitus. Limitations of use: Toujeo is not recommended for the treatment of diabetic ketoacidosis.
2. Criteria

Product Name: Toujeo

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1 History of both of the following:

- Lantus
- Levemir

3. References

GL-14614 Tresiba (insulin degludec)

Formulary UHC Core

Formulary Note

Approval Date 2/2/2016

Revision Date 2/2/2016

Technician Note:

P&T Approval Date: 1/27/2016. According to Texas State Law, all diabetic medications used for the treatment of diabetes shall be covered.

1. Indications

**Drug Name: Tresiba (insulin degludec)**

**Indications**

**Diabetes Mellitus**

Indicated to improve glycemic control in adults with diabetes mellitus. Limitations of Use Tresiba is not recommended for the treatment of diabetic ketoacidosis.
2. Criteria

Product Name: Tresiba

<table>
<thead>
<tr>
<th>Guideline Type</th>
<th>Step Therapy</th>
</tr>
</thead>
</table>

Approval Criteria

1. History of both of the following:

   - Lantus
   - Levemir

3. References

1. Indications

**Drug Name:** Linzess (linaclotide) and Trulance (plecanatide)

**Indications**

**Chronic idiopathic constipation** Indicated for the treatment of chronic idiopathic constipation and for the treatment of adults with irritable bowel syndrome with constipation
2. Criteria

Product Name: Trulance [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 One of the following

1.1 Diagnosis of chronic idiopathic constipation

   OR

1.2 Diagnosis of irritable bowel syndrome with constipation

   AND

2 History of failure, contraindication or intolerance to one OTC medication used for the treatment of constipation (document duration of trial)

   AND

3 History of failure, contraindication, or intolerance to Linzess

Notes [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
**Product Name:** Trulance [a]

<table>
<thead>
<tr>
<th>Approval Length</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Documentation of positive clinical response to Trulance therapy

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

---

**3. Background**

**Benefit/Coverage/Program Information**

**Background:**

Linzess (linaclotide) and Trulance (plecanatide) are indicated for the treatment of chronic idiopathic constipation and for the treatment of adults with irritable bowel syndrome with constipation. Physicians and patients should periodically assess the need for continued treatment with Trulance or Linzess.

This prior authorization program is intended to encourage the use of lower cost alternatives and requires a member to try an over-the-counter medication (OTC) for constipation and Linzess before providing coverage for Trulance.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely
on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.
- Notification/Prior Authorization may be in place

4. References

Prior Authorization Guideline

GL-53044 Uloric (febuxostat) - Step Therapy

Formulary  UHC Core

Formulary Note

Guideline Note:

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>10/1/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>8/19/2015</td>
</tr>
<tr>
<td>P&amp;T Revision Date:</td>
<td>7/26/2017, 7/18/2018, 07/17/2019</td>
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Technician Note:

P&T Approval Date: 8/19/2015; P&T Revision Date: 7/26/2017, 7/18/2018, 07/17/2019.

**Guideline Effective Date: 10/1/2019**

1. Criteria
<table>
<thead>
<tr>
<th>Product Name: Uloric [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length 12 Month(s)</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 - History of failure, contraindication or intolerance to the following:
- allopurinol (generic Zyloprim)

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

---

### 2. Background

**Benefit/Coverage/Program Information**

**Background:**

Uloric is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try allopurinol before providing coverage for Uloric. Members, who have received at least a 90 day supply of Uloric in the past 120 days as documented in claims history, will be allowed continued coverage of their current therapy.

**Additional Clinical Rules:**
• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
• Supply limits may apply

3. References

1. Indications

**Indications**

**plaque psoriasis** Indicated for the treatment of plaque psoriasis.
2. Criteria

Product Name: Ultravate lotion [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Plaque Psoriasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria

1 Submission of medical records documenting a history of failure, contraindication or intolerance to both of the following:

- augmented betamethasone dipropionate 0.05% gel or lotion
- clobetasol propionate 0.05% gel or solution

AND

2 Submission of medical records documenting a history of failure, contraindication or intolerance to one of the following:

- Enstilar
- Taclonex
- calcipotriene 0.005% and betamethasone dipropionate 0.05% used concomitantly

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Rules**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

**Background**

Ultravate is a topical corticosteroid indicated for the treatment of plaque psoriasis. Topical corticosteroids are considered to be first line treatment for patients with psoriasis and limited disease. Topical calcipotriene may be used as an alternative or adjunct to topical corticosteroid therapy. This program requires a member to try one lower cost alternative topical steroid and one combination topical steroid and vitamin D analog before providing coverage for Ultravate lotion.

4. References

1. Indications

Drug Name: Viberzi (eluxadoline)

Indications

Irritable bowel syndrome with diarrhea (IBS-D) Indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults
## 2. Criteria

**Product Name:** Viberzi [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Irritable bowel syndrome with diarrhea (IBS-D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

   **AND**

2. History of failure, contraindication or intolerance to two of the following:

   - antispasmodic agent [e.g., Bentyl (dicyclomine)]
   - antidiarrheal agent (e.g., loperamide)
   - tricyclic antidepressant (e.g., amitriptyline)

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

**Product Name:** Viberzi [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Irritable bowel syndrome with diarrhea (IBS-D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
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<td>----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Approval Criteria</strong></td>
<td></td>
</tr>
<tr>
<td>1 Documentation of positive clinical response to Viberzi therapy</td>
<td></td>
</tr>
</tbody>
</table>

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 3. Background

**Benefit/Coverage/Program Information**

**Background**

Viberzi (eluxadoline) is a mu-opioid receptor agonist, indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. Viberzi stimulates mu-opioid receptors in the GI tract, leading to decreased muscle contractility, inhibition of water and electrolyte secretion, and increased rectal sphincter tone. It also acts as an antagonist at delta-opioid receptors in the gut, which may reduce the risk of iatrogenic constipation and abdominal pain.

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply
4. References

GL-49642 Xifaxan (rifaximin) - PA/Med Nec

Formulary UHC Core

Formulary Note

Approval Date 5/22/2019

Revision Date 5/22/2019

Technician Note:

P&T Approval Date: 8/20/2014; P&T Revision Date: 10/26/2016, 10/25/2017, 4/18/2018, 4/17/2019; **Effective Date: 8/1/2019**

1. Indications

<table>
<thead>
<tr>
<th>Drug Name: Xifaxan (rifaximin)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
</tbody>
</table>

**Travelers' diarrhea** Indicated for the treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in patients 12 years of age and older.

**Hepatic encephalopathy** Indicated for the risk reduction of hepatic encephalopathy recurrence in adults.
**Irritable bowel syndrome with diarrhea** Indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

**Off Label Uses**

**Inflammatory bowel diseases** There is some limited data to support the off label use of Xifaxan for the treatment of inflammatory bowel diseases.

## 2. Criteria

**Product Name:** Xifaxan [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Travelers' Diarrhea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>1 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

### Approval Criteria

1. **Travelers' diarrhea**

   **AND**

2. History of failure, contraindication, or intolerance to one of the following:

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

### Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may
**Product Name:** Xifaxan [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Hepatic Encephalopathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Hepatic Encephalopathy
   
   **AND**

2. One of the following

   2.1 Both of the following

   2.1.1 Used as add-on therapy to lactulose

   **AND**

   2.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

   **OR**

2.2 History of contraindication or intolerance to lactulose

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
### Product Name: Xifaxan [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Irritable Bowel Syndrome with diarrhea (IBS-D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>14 Day</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1. Diagnosis of IBS-D

   **AND**

2. History of failure, contraindication, or intolerance to two of the following:
   - antispasmodic agent [e.g., Bentyl (dicyclomine)]
   - antidiarrheal agent (e.g., loperamide)
   - tricyclic antidepressant (e.g., amitriptyline)

**Notes**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### Product Name: Xifaxan [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Irritable Bowel Syndrome with diarrhea (IBS-D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>14 Day</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>
Approval Criteria

1 Patient has experienced a recurrence of IBS-D after a prior 14 day course of therapy with Xifaxan

AND

2 Patient has had a treatment-free period between courses of therapy

AND

3 Patient has not already received 3 treatment courses of Xifaxan for IBS-D in the previous 6 months

Notes

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Product Name: Xifaxan [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Inflammatory Bowel Disease (e.g., Crohn's Disease, Ulcerative Colitis, Diverticulitis) [Off Label]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>6 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

Approval Criteria
1 Diagnosis of Inflammatory Bowel Disease

AND

2 History of failure, contraindication or intolerance to both of the following:

- Ciprofloxacin (generic Cipro)
- Metronidazole (generic Flagyl)

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**Product Name:** Xifaxan [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Inflammatory Bowel Disease (e.g. Crohn's Disease, Ulcerative Colitis, Diverticulitis) (Off Label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Therapy Stage</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Prior Authorization</td>
</tr>
</tbody>
</table>

**Approval Criteria**

1 Documentation of positive clinical response to Xifaxan therapy

Notes: [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. Background

**Benefit/Coverage/Program Information**

**Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply

**Background**

Xifaxan is an antibacterial agent indicated for the treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* in patients 12 years of age and older, for the risk reduction of hepatic encephalopathy recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D). There is some limited data to support the off label use of Xifaxan for the treatment of inflammatory bowel diseases.

This program requires a member to try an alternative antimicrobial agent before providing coverage for Xifaxan for traveler's diarrhea and for inflammatory bowel disease, lactulose before providing coverage for Xifaxan as add-on therapy for hepatic encephalopathy, or an antidiarrheal agent and/or a tricyclic antidepressant before providing coverage for Xifaxan for IBS-D. Members utilizing Xifaxan 200 mg for Travelers' Diarrhea will automatically be approved if prescribed for a one-time dose of 9 tablets.

4. References


1. Indications

**Drug Name: Zyflo (zileuton), Zyflo CR (zileuton extended-release)**

**Indications**

**Asthma** Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.
2. Criteria

Product Name: (Zyflo, Zyflo CR) [a]

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Length</td>
<td>12 Month</td>
</tr>
<tr>
<td>Guideline Type</td>
<td>Step Therapy</td>
</tr>
</tbody>
</table>

Approval Criteria

1. History of failure, contraindication or intolerance to both of the following:

   - montelukast (generic Singulair)*
   - zafirlukast (generic Accolate)

Notes

*Brand Singulair tablets and chewable tablets are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status. [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Background

Benefit/Coverage/Program Information

Background:

Zyflo and Zyflo CR are leukotriene modifiers indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for
certain therapeutic classes. This program requires a member to try two alternative leukotriene modifiers – montelukast (generic Singulair) and zafirlukast (generic Accolate) prior to receiving coverage for Zyflo or Zyflo CR.

If a member has a prescription for both montelukast (generic Singulair) and zafirlukast (generic Accolate) in the claims history within the previous 12 months, the claim for Zyflo or Zyflo CR will automatically process.

Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

*Brand Singulair tablets and chewable tablets are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

4. References