UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|---|---|
| Program Number | 2024 P 3041-18 |
| Program | Step Therapy |
| Medications | *Orencia® (abatacept)<br>*This step criteria refers to the subcutaneous formulation of abatacept |
| P&T Approval Date | 10/2014, 2/2015, 3/2016, 3/2017, 8/2017, 12/2017, 12/2018, 9/2019, 11/2020, 11/2021, 3/2022, 11/2022, 1/2023, 4/2023, 1/2024, 2/2024 |
| Effective Date | 5/1/2024 |

**1. Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two preferred products before providing coverage for Orencia (abatacept). Infused medications approved for the treatment of rheumatoid arthritis are not part of the criteria.

Orencia (abatacept) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) and for the treatment of patients 2 years of age and older with active psoriatic arthritis (PsA).

Adalimumab is indicated for RA: reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Adalimumab can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs); Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. Adalimumab can be used alone or in combination with methotrexate; PsA: reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA; AS: reducing signs and symptoms in adult patients with active AS. Adalimumab can be used alone or in combination with non-biologic DMARDs; Crohn's Disease (CD): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older; Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older; PsO: treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate; Hidradenitis Suppurativa (HS): treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older; Uveitis (UV): treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older. In ulcerative colitis, effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.

Cimzia® (certolizumab) is indicated for reducing signs and symptoms of CD and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Cimzia is also indicated for the treatment of adults with moderately to severely active RA, treatment of adult patients with active PsA, treatment of adults with active ankylosing spondylitis (SpA), treatment of adults with moderate to severe PsO who are candidates for systemic therapy or phototherapy, and for the treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation.

Simponi® (golimumab) is indicated for the treatment of adult patients with moderately to severely active RA in combination with methotrexate.1 Simponi, alone or in combination with methotrexate, is indicated for the treatment of adult patients with active PsA. It is also indicated for the treatment of adult patients with active AS. Simponi is also indicated in adult patients with moderate to severe UC who have require continuous steroid therapy or who have had an inadequate response to or intolerance to prior treatment. For UC, it is indicated for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.

Rinvoq® (upadacitinib) is indicated for the treatment of adults with moderately to severely active RA who have had an inadequate response or intolerance to one or more TNF blockers, adults with active PsA who have an inadequate response or intolerance to one or more TNF blockers, adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable, adults with moderately to severely active UC who have had an inadequate response or intolerance to one or more TNF blockers, adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, biologic therapies for UC, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Xeljanz/Xeljanz XR® (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active RA, active PsA, AS and moderately to severely active UC, who have had an inadequate response or intolerance to one or more TNF blockers. Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. The use of Xeljanz/Xeljanz XR/Xeljanz Oral Solution in combination with biologic DMARDs, biologic therapies for UC or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Stelara® (ustekinumab) is indicated for the treatment of patients 6 years of age or older with moderate to severe PsO who are candidates for phototherapy or systemic therapy, adult patients with active PsA, alone or in combination with methotrexate, adult patients with moderately to severely active CD and for moderately to severely active UC.

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe PsO who are candidates for systemic therapy or phototherapy and for the treatment of adult patients with active PsA.

Skyrizi® (risankizumab-rzaa) is indicated for the treatment of moderate to severe PsO in adults who are candidates for systemic therapy or phototherapy, moderately to severely active Crohn's disease in adults and active PsA in adults.

Cosentyx® (secukinumab) is indicated for the treatment of moderate to severe PsO in patients 6 years and older who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of active PsA in patients 2 years of age and older, adults with active AS or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. Cosentyx is also indicated for the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.

Enbrel (etanercept) is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age or older, psoriatic arthritis (PsA), ankylosing spondylitis (AS), and plaque psoriasis (PsO) in patients 4 years or older.

Orencia® (abatacept) is also indicated for moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older. Patients with JIA will not be subject to the step therapy criteria.

Members currently on Orencia therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

**2. Coverage Criteria [a]:**

**A. Rheumatoid Arthritis (RA)**

1. **Orencia** will be approved based on **both** of the following criteria:

   a. Diagnosis of moderately to severely active rheumatoid arthritis

   **-AND-**

   b. **One** of the following:

      (1) History of failure, contraindication, or intolerance to **two** of the following preferred products (Document drug, date, and duration of trial):

         (a) Cimzia (certolizumab)
         (b) One of the preferred adalimumab products[b]
         (c) Simponi (golimumab)
         (d) Rinvoq (upadacitinib)
         (e) Xeljanz/Xeljanz XR (tofacitinib)
         (f) Enbrel (etanercept)

      **-OR-**

      (2) **Both** of the following:

         (a) Patient is currently on Orencia therapy

         **-AND-**

         (b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Bristol-Myers Squibb sponsored Orencia® Co-Pay 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 Orencia*

   * 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 Bristol-Myers Squibb sponsored Orencia® Co-Pay Program™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

**B. Psoriatic Arthritis**

1. **Orencia** will be approved based on **both** of the following criteria:

   a. Diagnosis of active psoriatic arthritis

   **-AND-**

   b. **One** of the following:

      (1) **One** of the following:

         (a) History of failure, contraindication, or intolerance to **two** of the following preferred products (Document drug, date, and duration of trial):

            i. Cimzia (certolizumab)
            ii. One of the preferred adalimumab products[b]
            iii. Simponi (golimumab)
            iv. Stelara (ustekinumab)
            v. Tremfya (guselkumab)
            vi. Skyrizi (risankizumab-rzaa)
            vii. Rinvoq (upadacitinib)
            viii. Xeljanz/Xeljanz XR (tofacitinib)
            ix. Enbrel (etanercept)

         **-OR-**

         (b) **Both** of the following:

            i. Patient is less than 18 years of age

            **-AND-**

            ii. History of failure, contraindication, or intolerance to Stelara (ustekinumab) or Enbrel (etanercept) (document date and duration of trial)

      **-OR-**

      (2) **Both** of the following:

         (a) Patient is currently on Orencia therapy

         **-AND-**

         (b) Patient has **not** received a manufacturer supplied sample at no cost in the

prescriber's office, or any form of assistance from the Bristol-Myers Squibb sponsored Orencia® Co-Pay 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 Orencia*

* 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 Bristol-Myers Squibb sponsored Orencia® Co-Pay Program™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

**C. Other Diagnoses**

1. **Orencia** will be approved

**Authorization will be issued for 12 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 a list of preferred adalimumab products please reference drug coverage tools.

**3. 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.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the United Healthcare Drug Policy for Orencia.

**4. References:**


1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; October 2023.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc..; February 2021.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019
5. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
6. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
7. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
8. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020.
9. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; September 2022.
10. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; June 2022.


| Program | Step Therapy - Orencia (abatacept) |
|---|---|
| **Change Control** | |
| 10/2014 | New step therapy program. |
| 2/2015 | Reformatted to clarify intent. Updated sample pack language. |

| | |
|---|---|
| 3/2016 | Annual review. Changed authorization periods from 60 months to 12 months. Added Maryland Continuation of Care. Added reference to UHC drug policy for intravenous infusions. Updated References. |
| 7/2016 | Added Indiana and West Virginia coverage information. |
| 11/2016 | Administrative change. Added California coverage information. |
| 3/2017 | Annual review. Updated coverage criteria to include manufacturer sample language (i.e., Orencia support program); added verbiage to simplify initial authorization criteria. Updated coverage criteria to add documentation language of failure of preferred products (i.e., document drug, date and duration of trial). Updated formatting, background and references. State mandate reference language updated. |
| 8/2017 | Added psoriatic arthritis to the coverage criteria. Updated background and references. |
| 12/2017 | Updated background and clinical criteria for RA requiring trials of, or contraindications to, Actemra and Xeljanz prior to Orencia approval for RA. |
| 12/2018 | Annual review. No changes to clinical coverage criteria. Updated references. |
| 9/2019 | Revised step therapy medications for rheumatoid arthritis adding Xeljanz, Olumiant, and Rinvoq as initial options. Updated background and references. |
| 11/2020 | Added Tremfya as a step therapy medication for psoriatic arthritis. Revised diagnosis requirement to match other programs. Updated background and references. |
| 11/2021 | Annual review with no changes to step therapy requirements. Updated background and references. |
| 3/2022 | Added Skyrizi as a preferred drug for active psoriatic arthritis. Updated reference. |
| 11/2022 | Added Enbrel as a preferred step product for RA. Added Enbrel, Rinvoq, and Xeljanz as preferred step products for PsA. Updated background and references. |
| 1/2023 | Updated step therapy requirements to Humira or Amjevita. Updated background and references. |
| 4/2023 | Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote “For a list of preferred adalimumab products please reference drug coverage tools.” Updated references. |
| 1/2024 | Updated PsA criteria based on new indication for patients 2 years of age and older. Updated background and reference. |
| 2/2024 | Removed Olumiant as a preferred product for RA. |