UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3041-11
Program	Step Therapy
Medications	*Orencia® (abatacept) *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
Effective Date	1/1/2021; Oxford only: N/A

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. Orencia is also indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

Humira® (adalimumab) is indicated for 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 rheumatoid arthritis.[2] Cimzia® (certolizumab) and Simponi® (golimumab) are indicated for the treatment of adults with moderately to severely active rheumatoid arthritis.[3,4] Xeljanz®/Xeljanz® XR (tofacitinib) and Rinvoq (upadacitinib) are indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.[5,8] Olumiant (baricitinib) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.[7] Cimzia, Humira, and Xeljanz may be used alone or in combination with a disease-modifying anti-rheumatic drug (DMARD). Simponi is FDA approved for use with methotrexate (MTX) in these patients.

Humira® (adalimumab) is also indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.[2] Stelara® (ustekinumab), Simponi (golimumab) and Cimzia (certolizumab) are indicated for the treatment of adult patients with active psoriatic arthritis.[3-6] Tremfya (guselkumab) is indicated for the treatment of adult patients with active psoriatic arthritis.

Orencia is also indicated for moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older. Orencia may be used as

monotherapy or concomitantly with MTX.[1] Humira is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Humira can be used alone or in combination with methotrexate.[2] 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) Humira (adalimumab)
(c) Simponi (golimumab)
(d) Olumiant (baricitinib)
(e) Rinvoq (upadacitinib)
(f) Xeljanz/Xeljanz XR (tofacitinib)

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

(a) Cimzia (certolizumab)
(b) Humira (adalimumab)
(c) Simponi (golimumab)
(d) Stelara (ustekinumab)
(e) Tremfya (guselkumab)

-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.

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; June 2020.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc..; January 2019.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; April 2019.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2018.
5. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; September 2020.
6. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
7. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2018.
8. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; August 2019.
9. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020.

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.