UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3104-4
Program	Step Therapy
Medications	Kevzara® (sarilumab)
P&T Approval Date	12/2017, 12/2018, 9/2019, 12/2020
Effective Date	3/1/2021; 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 preferred products before providing coverage for Kevzara (sarilumab).

Kevzara (sarilumab) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs) [1].

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] Actemra® (tocilizumab) 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 disease-modifying anti-rheumatic drugs (DMARDs).[5] Xeljanz®/Xeljanz® XR (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.[6] Cimzia, Humira, Actemra, and Xeljanz/Xeljanz XR 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. 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. Rinvoq (upadacitinib) is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an adequate response or intolerance to methotrexate. Orencia (abatacept) is indicated for moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than JAK inhibitors or biologic DMARDs (e.g., TNF antagonists).

Members currently on Kevzara 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.

UnitedHealthcare®

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. Kevzara will be approved based on **one** of the following criteria:

a. **Both** 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)

-AND-

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

(a) Actemra (tocilizumab)
(b) Orencia (abatacept)

-OR-

b. **Both** of the following:

(1) Patient is currently on Kevzara therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Sanofi and Regeneron sponsored KevzaraConnect® (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 Kevzara*

***** 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 Sanofi and Regeneron sponsored KevzaraConnect® **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Kevzara** 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 may be in place
- Notification may be in place

4. References:

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-Aventis; April 2018.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; March 2020.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
5. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; May 2020.
6. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer Labs; October 2020.
7. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; July 2020.
8. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; July 2020.
9. Orenica [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.

Program	Step Therapy - Kevzara (sarilumab)
Change Control	
12/2017	New step therapy program.
12/2018	Annual review. Updated formatting without changes to clinical intent. Updated references.
9/2019	Revised step therapy medications. Updated background and references.
12/2020	Annual review. Minor updates to the background. Updated references.