UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2199-4
Program	Prior Authorization/Medical Necessity
Medication	Kevzara® (sarilumab) Injection
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

1. Background:

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]. Examples of DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine.[2,3]

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. Initial Authorization

a. Kevzara will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

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

(a) **All** of the following:

i. **One** of the following:

a. History of failure to a 3 month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)[b]

-OR-

b. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab),

Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

-AND-

ii. 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-

iii. 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:

i. Patient is currently on Kevzara therapy as documented by claims history or submission of medical records (Document drug, date, and duration of therapy):

-AND-

ii. 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*

-AND-

(3) Patient is not receiving Kevzara in combination with **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (Baricitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

***** 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.

2. Reauthorization

a. Kevzara will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Kevzara therapy

-AND-

(2) Patient is not receiving Kevzara in combination with **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (Baricitinib)]

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 Connecticut business, only a 60-day trial will be required. For Kentucky business only a 30-day trial will be required.

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.

4. References:

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-Aventis.; April 2018.
2. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.

3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.

Program	Prior Authorization/Medical Necessity – Kevzara (sarilumab)
Change Control	
5/2020	New program.
5/2021	Annual review. Removed prescriber requirement from reauthorization criteria.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting current therapy with Kevzara in order to bypass step if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis with no change to clinical intent. Updated CT/KY footnote.