UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2199-9
Program	Prior Authorization/Medical Necessity
Medication	Kevzara® (sarilumab) Injection
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021, 11/2022, 1/2023, 4/2023, 7/2023, 2/2024
Effective Date	5/1/2024

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] Kevzara is also indicated for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

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 targeted immunomodulator 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), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)]

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

-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 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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

B. Polymyalgia Rheumatica (PMR)

1. **Initial Authorization**

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

(1) Diagnosis of polymyalgia rheumatica (PMR)

-AND-

(2) Patient has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper^

-AND-

(3) Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Kevzara therapy

-AND-

(2) Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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, Kentucky and Mississippi business only a 30-day trial will be required.
[c] For a list of preferred adalimumab products please reference drug coverage tools.
^Tried/failed alternative(s) are supported by FDA labeling.

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.; February 2023.
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.
11/2022	Added Enbrel as a preferred product step option. Added Enbrel as an example where appropriate. Added Mississippi to state mandate footnote.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.
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." Added coverage criteria for polymyalgia rheumatica. Added Rinvoq as an example where appropriate. Updated background and references.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
2/2024	Removed Olumiant as a preferred product for RA. Updated state mandate footnote to 30-day trial for Connecticut.