UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1223-10
Program	Prior Authorization/Notification
Medication	Kevzara® (sarilumab) Injection
P&T Approval Date	7/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 4/2023, 7/2023, 8/2024, 8/2025
Effective Date	11/1/2025

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 and for the treatment of patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).

2. Coverage Criteria[a]:

A. <u>Rheumatoid Arthritis (RA)</u>

1. **<u>Initial Authorization</u>**

a. **Kevzara** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) Patient has had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine)

-AND-

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

Authorization will be issued for 12 months.

2. **<u>Reauthorization</u>**

a. **Kevzara** will be approved based on **<u>both</u>** of the following criteria:

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(1) Documentation of positive clinical response to Kevzara therapy

-AND-

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

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., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

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., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

Authorization will be issued for 12 months.

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C. Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. **Initial Authorization**

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

      (1) Diagnosis of active polyarticular juvenile idiopathic arthritis

      -AND-

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

      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., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

      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 Step Therapy may be in place.

4. References:

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-Aventis.; June 2024.
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.

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3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752

Program	Prior Authorization/Notification – Kevzara (sarilumab)
Change Control	
7/2017	New program.
7/2018	Annual review. Updated references.
7/2019	Annual review. No changes to coverage criteria.
7/2020	Annual review. Updated reauthorization issue duration.
7/2021	Annual review. No changes to coverage criteria.
7/2022	Annual review. Updated language of criterion to match with prescribing information without change in clinical intent. Added state mandate and updated references.
4/2023	Added coverage criteria for polymyalgia rheumatica. Updated Humira to adalimumab and added Rinvoq in drug examples. Updated background and references.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
8/2024	Added clinical coverage criteria for pJIA. Updated background and reference. Alphabetized targeted immunomodulator examples with no change to intent.
8/2025	Annual review with no change to coverage criteria.

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