CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Kevzara (sarilumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Kevzara is an interleukin-6 (IL-6) receptor antagonist that was approved by the FDA in 2017. IL-6 is a pleiotropic proinflammatory cytokine produced by a variety of cell types. Kevzara is 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). It may be used as monotherapy or in combination with methotrexate (MTX) or other conventional DMARDs.

Kevzara (sarilumab) will be considered for coverage when the following criteria are met:

Rheumatoid Arthritis (RA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months; AND
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine.
6. Member must have a trial and failure of, or intolerance to, at least two preferred biologic DMARD therapies. (See Appendix).
7. **Dosage allowed/Quantity limit:** 200 mg once every two weeks given as a subcutaneous injection. (2 syringes/pens per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Kevzara (sarilumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/20/2017	New policy for Kevzara created.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria. Initial and reauthorization length placed for 12 months. ANC level requirement removed. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed.
11/19/2020	Fixed quantity limit from 1 injection to 2 injections every 28 days. Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. Removed repeated TB test in reauth. Replaced the list of excluded diagnoses with the generic statement. Updated references.
02/17/2022	Transferred to new template. Updated references. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1.
04/01/2022	Added required trial of two preferred biologic DMARDs

References:

1. Kevzara [package insert]. Bridgewater, NJ: SANOFI-AVENTIS U.S. LLC; April 2018.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
3. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
4. Genovese MC. Sarilumab Plus Methotrexate in Patients With Active Rheumatoid Arthritis and Inadequate Response to Methotrexate: Results of a Phase III Study. Arthritis Rheumatol. 2015 Jun;67(6):1424-37.
5. 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

Effective date: 04/01/2022
Revised date: 02/17/2022

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Humira • Stelara
Approved for Ulcerative Colitis	• Humira • Stelara • Rinvoq