CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Kevzara (sarilumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 2 injections every 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kevzara (sarilumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately.
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. **Dosage allowed:** 200 mg once every two weeks given as a subcutaneous injection.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kevzara (sarilumab) not medically necessary for the treatment of the diseases that are not listed in this document.

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.
10/1/2021	Updated status to non-preferred

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. United States Food and Drug Administration. Kevzara (sarilumab) injection. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761037Orig1s000TOC.cfm. Accessed on 2/13/19.

Effective date: 10/01/2021
Revised date: 11/19/2020