| Effective Date: 9/1/2018 |
| --- |
| Reviewed Date: 8/2019, 9/2020, 12/2020, 5/2021, 6/2022, 12/2022<br>Scope: Medicaid |

# SPECIALTY GUIDELINE MANAGEMENT

## KEVZARA (sarilumab)

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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)

All other indications are considered experimental/investigational and not medically necessary.

### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests:
   1. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

### III. CRITERIA FOR INTIAL AND CONTINUATION OF THERAPY

**For all indications:**

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication
- Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

## IV. CRITERIA FOR INITIAL APPROVAL

**Moderately to severely active rheumatoid arthritis (RA)**

A. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
   1. Prescribed by, or in consultation with, a specialist in rheumatology.
   1. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         i. Rheumatoid factor (RF)
         ii. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         i. RF
         ii. Anti-CCP
         iii. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   2. Member meets either of the following:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix).

## V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who are using Kevzara for an indication outlined in section II and who achieve or maintain positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

## VI. QUANTITY LIMIT

Kevzara: 2 syringes every 4 weeks (28 days)

| Indication | Dose (subcutaneous) |
| --- | --- |
| Rheumatoid Arthritis | 200mg once every 2 weeks |

## VII. APPENDIX: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy
10. Renal impairment
11. Significant drug interaction

## VIII. REFERENCES

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-aventis, U.S. LLC /Regeneron Pharmaceuticals, Inc.; April 2018.
2. Genovese MC, Fleischmann R, Kivitz AJ, et al. Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a phase III study. *Arthritis Rheumatol.* June 2015;67(6):1424-37.
3. Strand V, Reaney M, Chen C, et al. Sarilumab improves patient-reported outcomes in rheumatoid arthritis patients with inadequate response/intolerance to tumour necrosis factor inhibitors. *RMD Open.* 2017; 3**:**e000416. doi: 10.1136/rmdopen-2016-000416.
4. Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on 21 June 2019 from: https://www.cdc.gov/tb/topic/basics/risk.htm.