Effective Date: 9/1/2018
Reviewed Date: 8/2019, 9/2020, 12/2020, 5/2021, 6/2022, 12/2022, 5/2023, 8/2023 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 Indications

A. 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)
B. Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

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. Rheumatoid arthritis
    1. For initial requests:
        a. 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.
        b. 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).
    2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
3. Polymyalgia rheumatica
    a. Initial requests: 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.
    b. 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.
   2. 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)
   3. 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).
   4. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for adult members for treatment of polymyalgia rheumatica (PMR) and the Kevzara is prescribed by, or in consultation with, a specialist in rheumatology and any of the following criteria is met:

   a. Member has experienced an inadequate response to systemic corticosteroids.
   b. Member has experienced a disease flare during a taper with systemic corticosteroids.

c. Member has experienced an inadequate response to methotrexate.
d. Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix).

V. CONTINUATION OF THERAPY

A. Rheumatoid Arthritis

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.

B. Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for PMR and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Morning stiffness
2. Hip or shoulder pain
3. Hip or shoulder range of motion
4. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

VI. QUANTITY LIMIT

Kevzara: 2 syringes every 4 weeks (28 days)

Indication	Dose (subcutaneous)
Rheumatoid Arthritis & Polymyalgia rheumatica	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

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