Reference number
1957-A

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 (RA) 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.
C. Patients with active polyarticular juvenile idiopathic arthritis (pJIA) who weigh 63 kg or greater

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. Initial requests:
        i. 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.
        ii. 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. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Polymyalgia rheumatica
    1. 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.
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Polyarticular juvenile idiopathic arthritis
    1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a rheumatologist.

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets either of the following criteria:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for adult members for treatment of polymyalgia rheumatica (PMR) when any of the following criteria is met:
1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has experienced a disease flare during a taper with systemic corticosteroids.
3. Member has experienced an inadequate response to methotrexate.
4. Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

C. Polyarticular juvenile idiopathic arthritis

1. Authorization of 12 months may be granted for members weighing 63 kg or greater who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active polyarticular juvenile idiopathic arthritis.

2. Authorization of 12 months may be granted for members weighing 63 kg or greater for treatment of active polyarticular juvenile idiopathic arthritis when any of the following criteria is met:
   i. Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
   ii. Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers

e. Symmetric disease

iii. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and the member also meets one of the following:
   a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
   b. High disease activity.
   c. Is judged to be at high risk for disabling joint disease.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a 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)

C. Polyarticular juvenile idiopathic arthritis

Authorization of 12 months may be granted for all members (including new members) weighing 63 kg or greater who are using the requested medication for active polyarticular juvenile idiopathic arthritis 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. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

VI. OTHER

For all indications: Member has had a documented negative tuberculosis (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 drugs or targeted synthetic drugs 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.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

VII. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VIII. APPENDICES

Appendix A: Examples of Contraindications to Methotrexate

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

IX. REFERENCES

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