| Effective Date: 9/1/2018 |
| --- |
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# 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.
C. Indicated for treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients who weigh 63 kg or greater.

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

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

**For all indications:**

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication
- Kevzara will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Ustekinumab (e.g., Stelara, Wezlana), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)
- 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.

## III. 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. Documentation that 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. Documentation that member meets either of the following:
         i. 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).
         ii. Member has an intolerance or contraindication to methotrexate (see Appendix).
   4. Documentation that 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 has documentation of any of the following criteria:
   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).

**Polyarticular juvenile idiopathic arthritis (pJIA)**Authorization of 12 months may be granted for treatment of pJIA when all of the following criteria are met:
1. Documentation that member weighs 63kg or greater
2. Documented moderate to severe active polyarticular disease;
3. May be used alone or in combination with methotrexate;
4. Documentation that the member has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.);
5. Documentation that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

## IV. CONTINUATION OF THERAPY

### A. Rheumatoid Arthritis

Authorization of 12 months may be granted for all members (including new members) with documentation of 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) when BOTH of the following criteria is met:

1. Documentation that the member is using the requested medication for PMR
2. Documentation of low disease activity or improvement in any of the following signs and symptoms of PMR from baseline:
    a. Morning stiffness
    b. Hip or shoulder pain
    c. Hip or shoulder range of motion
    d. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

### C. Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for all members (including new members) with Documentation of disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g., an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

## V. QUANTITY LIMIT

Kevzara: 2 syringes every 4 weeks (28 days)

| Indication | Dose (subcutaneous) |
| --- | --- |
| Rheumatoid Arthritis & Polymyalgia rheumatica & **Polyarticular juvenile idiopathic arthritis in patients weighing over 63kg** | 200mg once every 2 weeks |

## VI. 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

## VII. REFERENCES

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