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| Effective Date: 9/1/2018                                                                                          |
| Reviewed Date: 8/2019, 9/2020,<br>12/2020, 5/2021, 6/2022, 12/2022,<br>5/2023, 8/2023, 6/2024, 1/2025,<br>07/2026 |
| Scope: Medicaid                                                                                                   |

## 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

1. Moderately to severely active rheumatoid arthritis (RA) in adults who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs)
2. Polymyalgia rheumatica (PMR) in adults who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper
3. Active polyarticular juvenile idiopathic arthritis (pJIA) in patients who weigh at least 63kg

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

#### II. CRITERIA FOR INITIAL APPROVAL

##### **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; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Kevzara will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), etc.) and IL-inhibitors (e.g., ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.); AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND

##### **A. Moderately to severely active rheumatoid arthritis (RA)**

Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted of one of the following criteria:
  - a. Member has been tested for either of the following biomarkers and the test was positive:
    - i. Rheumatoid factor (RF)

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- ii. Anti-cyclic citrullinated peptide (anti-CCP); OR
  - 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); AND
- 4. Documentation has been submitted that the member meets both of the following:
  - a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of methotrexate or any other conventional disease-modifying antirheumatic drug (DMARD) despite adequate dosing; AND
  - b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

**B. Polymyalgia rheumatica (PMR)**

Authorization of 12 months may be granted for treatment of polymyalgia rheumatica (PMR) when all of the following criteria are met:

- 1. Member is at least 18 years of age or older; AND
- 2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
- 3. Documentation has been submitted of any of the following criteria:
  - a. Member has experienced an inadequate response to systemic corticosteroids; OR
  - b. Member has experienced a disease flare during a taper with systemic corticosteroids; OR
  - c. Member has experienced an inadequate response to methotrexate; OR
  - d. Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix).

**C. 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. Member weighs 63kg or greater; AND
- 2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
- 3. Member has documented moderate to severe active polyarticular disease; AND
- 4. May be used alone or in combination with methotrexate; AND
- 5. Documentation has been submitted of one of the following criteria:
  - a. Member has had an inadequate response, intolerance, or contraindication to at least a 1-month trial of either an oral non-steroidal anti-inflammatory drug (NSAID) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.) at an adequate dose and duration; OR
  - b. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B), and also meets one of the following:
    - i. High-risk joints are involved (e.g., cervical spine, wrist, or hip)
    - ii. High disease activity
    - iii. Is judged to be at high risk for disabling joint disease; AND
- 6. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

### III. CONTINUATION OF THERAPY

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**A. Rheumatoid arthritis (RA)**

Authorization of 12 months may be granted for all adult members (including new members) with documentation of using the requested medication for moderately to severely active rheumatoid arthritis 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) with documentation of using the requested medication for polymyalgia rheumatica and low disease activity or improvement in any of the following signs and symptoms of PMR 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 (pJIA)**

Authorization of 12 months may be granted for all members (including new members) who weigh at least 63kg with documentation of using the requested medication for polyarticular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or 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

#### IV. QUANTITY LIMIT

Kevzara: 2 syringes every 4 weeks (28 days)

#### V. DOSING

| Indication                                                                                                                   | Dose (subcutaneous)      |
|------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Rheumatoid arthritis, polymyalgia rheumatica, and polyarticular juvenile idiopathic arthritis in patients weighing over 63kg | 200mg once every 2 weeks |

#### APPENDICES

**Appendix A: Examples of Contraindications to Methotrexate** \_Alcoholism, alcoholic liver disease or other chronic liver disease

1. Breastfeeding
2. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
3. Elevated liver transaminases

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4. History of intolerance or adverse event
5. Hypersensitivity
6. Interstitial pneumonitis or clinically significant pulmonary fibrosis
7. Myelodysplasia
8. Pregnancy or planning pregnancy
9. Renal impairment
10. Significant drug interaction

#### **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

## **VI. REFERENCES**

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