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Effective Date: 4/9/2025			Last Review Date:	11/2023; 2/2025
Applica	□Illinois	□Florida	⊠Florida Kids	
Applies to:	⊠New Jersey	⊠Maryland	□Michigan	
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Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Kevzara under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

- 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).
- 2. Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
- 3. Patients with active polyarticular juvenile idiopathic arthritis (pJIA) who weigh 63 kg or greater.

Compendia Uses

- 1. Immune checkpoint inhibitor-related toxicity inflammatory arthritis
- 2. Giant cell arteritis (GCA)

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

Applicable Drug List:

Preferred: Kevzara

Policy/Guideline:

Documentation:

A. Rheumatoid arthritis

- 1. 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).

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2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Polymyalgia rheumatica and immune checkpoint inhibitor-related toxicity

- 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.

D. Giant cell arteritis (GCA)

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

Prescriber Specialty:

This medication must be prescribed by or in consultation with one of the following:

- 1. Rheumatoid arthritis, polymyalgia rheumatica, polyarticular juvenile idiopathic arthritis, and giant cell arteritis: rheumatologist
- 2. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Criteria for Initial Approval:

A. Rheumatoid arthritis (RA)

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.

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:

1. Member meets either of the following criteria:

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- 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 criteria:
 - 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 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 (pJIA)

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

Authorization of 12 months may be granted for members weighing 63 kg and greater for treatment of active polyarticular juvenile idiopathic arthritis when any of the following criteria is met:

1. 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.

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- 2. 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:
 - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - Presence of erosive disease or enthesitis
 - Delay in diagnosis
 - Elevated levels of inflammation markers
 - Symmetric disease
- 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:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease

D. Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when then member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroguine).
- 2. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

E. Giant cell arteritis (GCA)

Authorization of 12 months may be granted for treatment of giant cell arteritis when the member's diagnosis was confirmed by either of the following:

- 1. Temporal artery biopsy or cross-sectional imaging
- 2. Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])

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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

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 and 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

D. Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory 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.

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E. Giant cell arteritis (GCA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for giant cell arteritis 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. Headaches
- 2. Scalp tenderness
- 3. Tenderness and/or thickening of superficial temporal arteries
- 4. Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- 5. Jaw and/or tongue claudication
- 6. Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- 7. Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- 8. Limb claudication

Other Criteria:

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) 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 (e.g., chest x-ray). 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.

APPENDIX

Appendix A: Examples of Contraindications to Methotraxate

- 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

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- 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

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval: 12 months Renewal Approval: 12 months

Quantity Level Limit:

- Kevzara (sarilumab) 150 mg/1.14 mL single-dose prefilled syringe: 1 pack (2 x 150 mg syringe) per 4 weeks
- Kevzara (sarilumab) 150 mg/1.14 mL single-dose prefilled pen: 1 pack (2 x 150 mg pen) per 4 weeks
- Kevzara (sarilumab) 200 mg/1.14 mL single-dose prefilled syringe: 1 pack (2 x 200 mg syringe) per 4 weeks
- Kevzara (sarilumab) 200 mg/1.14 mL single-dose prefilled pen: 1 pack (2 x 200 mg pen) per 4 weeks
- Rheumatoid arthritis (adult):
 - o 200 mg once every two weeks.
 - Reduce dose to 150 mg once every two weeks for management of neutropenia, thrombocytopenia and elevated liver enzymes.
- Polymyalgia Rheumatica (adult)
 - 200 mg once every two weeks in combination with a tapering course of corticosteroids.
 - Can be used as monotherapy following discontinuation of corticosteroids.
- Polyarticular juvenile idiopathic arthritis in patients weighing 63 kg or greater
 - o 200 mg once every two weeks using the 200 mg/1.14 mL pre-filled syringe.

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