Reference number(s)
1957-A

Specialty Guideline Management
Kevzara

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kevzara	sarilumab

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]

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

Compendial Uses[13]

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

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

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Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis

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.
- 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).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Polymyalgia rheumatica and immune checkpoint inhibitor-related toxicity

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.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Polyarticular juvenile idiopathic arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Giant cell arteritis (GCA)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

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

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

Coverage Criteria

Rheumatoid arthritis (RA)[1-3,5-8]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis within the past 120 days.

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

- Member meets either of the following:
    - Member has been tested for either of the following biomarkers and the test was positive:
        - Rheumatoid factor (RF)
        - Anti-cyclic citrullinated peptide (anti-CCP)
    - Member has been tested for ALL of the following biomarkers:
        - RF
        - Anti-CCP
        - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
    - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
        - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
        - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.

- Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.

- Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
  - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
  - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
  - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
  - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
  - Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix A), discontinues MTX, and meets any of the following conditions:
  - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
  - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
  - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
  - Member has moderate to high disease activity.

Polymyalgia rheumatica (PMR)[1]

Authorization of 12 months may be granted for adult members for treatment of polymyalgia rheumatica when any of the following criteria is met:

- Member has experienced an inadequate response to systemic corticosteroids.
- Member has experienced a disease flare during a taper with systemic corticosteroids.
- Member has experienced an inadequate response to methotrexate.
- Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

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:

- 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.
- 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

Immune checkpoint inhibitor-related toxicity[13]

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

Giant cell arteritis (GCA)[13]

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:

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

Continuation of Therapy

Rheumatoid arthritis (RA) [1-3,5-8]

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.

Polymyalgia rheumatica (PMR)[1,9]

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:

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

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:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

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.

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:

- Headaches
- Scalp tenderness
- Tenderness and/or thickening of superficial temporal arteries
- Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- Jaw and/or tongue claudication
- Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication
- Acute-phase reactants (i.e., erythrocyte sedimentation rate [ESR] or serum C-reactive protein [CRP])

Other[1,4]

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 12 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.

Dosage and Administration

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

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Methotrexate, Hydroxychloroquine, or Leflunomide[10]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease

- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

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