Kevzara (sarilumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Kevzara drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, adalimumab-aacf, Enbrel, Entyvio, Cosentyx, Otezla, Otulfi (ustekinumab-aauz), Rinvoq, Simponi, Skyrizi, Tremfya, Velsipity, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A) Kevzara is indicated for treatment of 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) Kevzara is indicated for treatment of 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.

Compendial Uses

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

POLICY

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

A) Rheumatoid Arthritis

1. Criteria for initial approval for rheumatoid arthritis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Enbrel, adalimumab-aacf, Rinvoq, Simponi, and Xeljanz/Xeljanz XR)
    b) Member has a clinical reason to avoid TNF-inhibitors (Enbrel, adalimumab-aacf, and Simponi) (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred products, Rinvoq AND Xeljanz or Xeljanz XR
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

B) Polyarticular juvenile idiopathic arthritis

1. Criteria for initial approval on polyarticular juvenile idiopathic arthritis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (adalimumab-aacf, Enbrel, and Xeljanz/Xeljanz Oral Solution)
    b) Member has a clinical reason to avoid Enbrel and adalimumab-aacf (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred product Xeljanz or Xeljanz Oral Solution
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

Required Documentation

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

A) Rheumatoid Arthritis

A. For 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).
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B) Polymyalgia Rheumatica

1. For 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).

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

C) Polyarticular juvenile idiopathic arthritis

1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D) Immune Checkpoint inhibitor-related toxicity

1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

E) Giant cell arteritis (GCA):

1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties (initial approvals only)
This medication must be prescribed by or in consultation with:

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

Criteria for Initial Approval
Moderately to severely active rheumatoid arthritis (RA)

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

B. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:
    1. Member meets either of the following criteria:
        i. Member has been tested for either of the following biomarkers and the test was positive/elevated:
            a. Rheumatoid factor (RF)
            b. Anti-cyclic citrullinated peptide (anti-CCP)
        ii. Member has been tested for ALL of the following biomarkers:
            a. RF
            b. Anti-CCP
            c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
    2. Member meets any of the following criteria:

i. 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).
ii. Member has an intolerance or contraindication to methotrexate (see Appendix B).
iii. Member has experienced an inadequate response to an alternative DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine)

Polymyalgia Rheumatica (PMR)

A. Authorization of 12 months may be granted for adult members for treatment of polymyalgia rheumatica when all of the following criteria are met:
1. Member has a diagnosis of polymyalgia rheumatica according to European League Against Rheumatism/American College of Rheumatology (ACR/EULAR) classification criteria.
2. 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. Other possible causes of signs and symptoms have been ruled out, including but not limited to, rheumatoid arthritis, polymyositis, fibromyalgia, osteoarthritis, etc.
4. Member has had an inadequate response to systemic corticosteroids or cannot tolerate a corticosteroid taper.

Polyarticular juvenile idiopathic arthritis

A. 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.
B. 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:
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.
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:
i. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
ii. Presence of erosive disease or enthesitis
iii. Delay in diagnosis
iv. Elevated levels of inflammation markers
v. Symmetric disease
3. 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:
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.

Immune checkpoint inhibitor-related toxicity

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

Giant cell arteritis (GCA)

A. Authorization of 12 months may be granted for treatment giant cell arteritis when the member's diagnosis was confirmed by either of the following:
    1. Temporal artery biopsy of cross-sectional imaging
    2. Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])

Continuation of Therapy

Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) who are using Kevzara for 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.

Polymyalgia Rheumatica (PMR)

Authorization of 12 months may be granted for all members (including new members) who are using Kevzara for polymyalgia rheumatica and who achieve or maintain a positive clinical response as evidenced by 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)

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

Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested mediation 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 (CGA)

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
For all indications: Member has had a documented negative 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 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 (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: Members cannot use the requested medication concomitantly with any other biologic DMARD or targeted synthetic DMARD for the same indication.

Kevzara is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria
Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

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

Quantity Limits

Trade Name	Dosage Form	Generic Name	Quantity Limit
Kevzara®	Pre-filled syringe	Sarilumab	2 syringes per 28 days
Kevzara®	Button-free pen	Sarilumab	2 pens per 28 days

Appendices

Appendix A: Clinical reasons to avoid TNF-inhibitors

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection

4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

Appendix B: Examples of Contraindications to Methotrexate

1. Clinical diagnosis of alcohol use disorder, 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 currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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POLICY HISTORY

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