Kineret (anakinra)

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 Kineret 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, Humira, Enbrel, 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, or the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome.

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)
2. Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Compendial Uses

1. Systemic juvenile idiopathic arthritis (sJIA)
2. Adult-onset Still's disease
3. Multicentric Castleman's disease
4. Recurrent pericarditis
5. Hyperimmunoglobulin D syndrome (HIDS) [Mevalonate Kinase Deficiency (MKD)]

6. Schnitzler's syndrome

Documentation:
Submission of the following information is necessary to initiatite prior authorization review: Medical record documentation of prerequisite therapy listed in the Criteria for Initial Approval section E, if applicable.

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, Humira and Xeljanz/Xeljanz XR)
   b) Member has a clinical reason to avoid Enbrel and Humira (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred product 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

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).

Criteria for Initial Approval

A) Moderately to Severely Active Rheumatoid Arthritis (RA)

1. Authorization of 12 months may be granted for the treatment of RA for members who have previously received Kineret or any other biologic DMARD or targeted synthetic DMARD (e.g., Olumiant, Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
2. Authorization of 12 months may be granted for the treatment of active RA when all of the following criteria are met:
   a. 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), or the member has an intolerance or contraindication to methotrexate.
   b. Member has experienced an inadequate response to at least a 3-month trial of a biologic DMARD or a targeted synthetic DMARD (e.g., Olumiant, Rinvoq, Xeljanz) or has intolerance to a biologic or targeted synthetic DMARD.

B) Adult-onset Still's Disease

Authorization of 12 months may be granted for the treatment of adult-onset Still's disease when all of the following criteria are met:

1. Member has had an inadequate response to a 3-month trial of methotrexate or corticosteroids or has intolerance or contraindication to methotrexate and low dose corticosteroids.
2. Member will receive Kineret concurrently with methotrexate or corticosteroids or has intolerance or contraindication to methotrexate and low dose corticosteroids.

C) Active Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Authorization of 12 months may be granted for the treatment of sJIA for members who have previously received Kineret or another biologic indicated for sJIA (e.g., tocilizumab, canakinumab).
2. Authorization of 12 months may be granted for the treatment of active sJIA when any of the following criteria is met:
    a. Member has had an inadequate response to a 1-month trial of nonsteroidal anti-inflammatory drugs (NSAIDs)
    b. Member has had an inadequate response to a 2-week trial of corticosteroids (e.g., prednisone, methylprednisolone)
    c. Member has had an inadequate response to a 3-month trial of methotrexate or leflunomide

D) Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Authorization of 12 months may be granted for the treatment of cryopyrin-associated periodic syndromes (CAPS), including NOMID (also known as chronic infantile neurologic cutaneous and articular syndrome [CINCA]).

E) Recurrent Pericarditis

Authorization of 12 months may be granted for the treatment of recurrent pericarditis for members who have failed a first-line therapy agent (i.e., colchicine).

F) Multicentric Castleman's Disease

Authorization of 12 months may be granted for the treatment of multicentric Castleman's disease when both of the following criteria are met:

1. The requested drug will be used as a single-agent.
2. The disease has progressed following treatment of relapsed/refractory or progressive disease.

G) Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Authorization of 12 months may be granted for the treatment of HIDS/MKD when all of the following criteria are met:

1. Member has had active flares within the last 6 months
2. Physician's Global Assessment greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L

H) Schnitzler's syndrome

Authorization of 12 months may be granted for the treatment of Schnitzler's syndrome when all of the following criteria are met:

1. Member has an urticarial rash, monoclonal IgM (or IgG) gammopathy and at least two of the following signs and symptoms: fever, joint pain or inflammation, bone pain, palpable lymph nodes, enlargement of the liver or spleen, elevated numbers of white blood cells (leukocytosis), elevated red blood cell (erythrocyte) sedimentation rate or abnormalities on bone morphological study (e.g., increased bone density)
2. Other possible causes of the signs and symptoms have been ruled out, including but not limited to: hyperimmunoglobulin D syndrome, adult-onset Still disease, urticarial hypocomplementemic vasculitis, acquired C1 inhibitor deficiency and cryoglobulinemia.

<u>Continuation of Therapy</u>

A) Multicentric Castleman's disease

Authorization of 12 months may be granted for continued treatment of multicentric Castleman's disease in members requesting reauthorization who have not experienced disease progression or an unacceptable toxicity.

B) All other indications

Authorization of 12 months may be granted for all members (including new members) who are using Kineret for an indication outlined in the Criteria for Initial Approval and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other

A) 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 (e.g., Xeljanz), and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer anakinra to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of treatment.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

The requested drug will not be used concomitantly with any other biologic DMARD (e.g., adalimumab, canakinumab, rilonacept, rituximab, etanercept, infliximab) or targeted synthetic DMARD (e.g. tofacitinib).

Dosage and Administration

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

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

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Kineret®	anakinra	NOMID: Initial dosing of 1mg/kg, maintenance dosing of 3-4mg/kg and maximum dosing of 8mg/kg daily For all other indications: 28 syringes 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. History of intolerance or adverse event
2. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
3. Elevated liver transaminases
4. Interstitial pneumonitis or clinically significant pulmonary fibrosis

5. Renal impairment
6. Pregnancy or currently planning pregnancy
7. Breastfeeding
8. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
9. Myelodysplasia
10. Hypersensitivity
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.

- N/A

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POLICY HISTORY

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