Reference number(s)
1802-A

Specialty Guideline Management
Kineret

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
Kineret	anakinra

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 patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs)
- Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Compendial Uses

- Systemic juvenile idiopathic arthritis (sJIA)[3]
- Adult-onset Still's disease (AOSD)[4-5]
- Multicentric Castleman disease[6]
- Recurrent pericarditis (RP)[16]
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)[17-19]
- Schnitzler syndrome[2,20,21]

- Gout and pseudogout (calcium pyrophosphate deposition)[2,25-27]
- Chimeric antigen receptor (CAR) T-cell-related toxicities[6]
- Erdheim-Chester Disease[6]
- Immune checkpoint inhibitor-related toxicity—immunotherapy-related hemophagocytic lymphohistiocytosis (HLH)-like syndrome[6]

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

Documentation

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

Rheumatoid Arthritis (RA)

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.

Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (sJIA)

Initial requests

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

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

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

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Initial requests: IL1RN gene variant status

Recurrent Pericarditis (RP)

Initial requests

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

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

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

Initial requests: Chart notes, medical record documentation, or laboratory result (if applicable) indicating number of active flares within the last 6 months and Physician's Global Assessment (PGA) score or C-reactive protein (CRP) level.

Gout and Pseudogout Flares, CAR T-Cell-Related Toxicities, 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.

Prescriber Specialties

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

- Rheumatoid arthritis (RA), adult-onset Still's disease (AOSD), systemic juvenile idiopathic arthritis (sJIA), gout, and pseudogout: rheumatologist
- Cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID), deficiency of interleukin-1 receptor antagonist (DIRA), and hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD): rheumatologist or immunologist
- Recurrent pericarditis (RP): cardiologist, rheumatologist, or immunologist
- Schnitzler syndrome: rheumatologist, dermatologist, or immunologist

- Multicentric Castleman disease, CAR T-cell-related toxicities, Erdheim-Chester disease, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

Coverage Criteria

Rheumatoid Arthritis (RA)[1,7-11,31,32]

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 (RA) within the past 120 days.

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:

- Member meets either of the following criteria:
  - 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) 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), 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), 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), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.

Adult-Onset Still's Disease (AOSD)[4,5,14,15,23,24,34]

Authorization of 12 months may be granted for members who have previously received a biologic indicated for active AOSD.

Authorization of 12 months may be granted for treatment of active AOSD when both of the following criteria are met:

- Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
- Member meets any of the following:
    - Member has had an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs).
    - Member has had an inadequate response to a trial of corticosteroids.
    - Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).

Systemic Juvenile Idiopathic Arthritis (sJIA)[3,12,13,35]

Authorization of 12 months may be granted for members who have previously received a biologic indicated for active sJIA.

Authorization of 12 months may be granted for treatment of active sJIA when the member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)[1]

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

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)[1,29]

Authorization of 12 months may be granted for treatment of genetically confirmed deficiency of interleukin-1 receptor antagonist (DIRA) due to IL1RN gene variants.

Recurrent Pericarditis (RP)[16,33,37]

Authorization of 12 months may be granted for treatment of recurrent pericarditis when both of the following criteria are met:

- Member has had at least two episodes of pericarditis.
- Member has failed at least two agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids).

Multicentric Castleman Disease[6]

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

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

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)[17-19]

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

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

Schnitzler Syndrome[2,20,21]

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

- 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, lymphadenopathy, hepatomegaly, splenomegaly, leukocytosis, elevated erythrocyte sedimentation rate (ESR), or abnormalities on bone morphological study (e.g., increased bone density).
- Other possible causes of the signs and symptoms have been ruled out, including but not limited to: hyperimmunoglobulin D syndrome, adult-onset Still's disease, hypocomplementemic urticarial vasculitis, acquired C1 inhibitor deficiency, and cryoglobulinemia.

Gout and Pseudogout Flares[25-38]

Authorization of 12 months may be granted for adult members for treatment of flares for gout and pseudogout (also known as calcium pyrophosphate deposition disease) when both of the following criteria are met:

- Member has experienced at least three gout flares in the last 12 months.
- Member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

Chimeric Antigen Receptor (CAR) T-Cell-Related Toxicities[6]

Authorization of 1 month may be granted for management of chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome when either of the following criteria is met:

- Cytokine release syndrome is refractory to high-dose corticosteroids and anti-IL-6 therapy.
- Kineret will be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable.

Authorization of 3 months may be granted for the prophylaxis of CAR T-cell-induced toxicity in members at high risk of developing high-grade immune effector cell-associated neurotoxicity syndrome (ICANS).

Erdheim-Chester Disease[6]

Authorization of 12 months may be granted for the treatment of Erdheim-Chester disease.

Immune Checkpoint Inhibitor-Related Toxicity[6]

Authorization of 6 months may be granted for the treatment of immune checkpoint inhibitor-related toxicity when the member has immunotherapy-related hemophagocytic lymphohistiocytosis (HLH)-like syndrome and either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.

- Member has an intolerance or contraindication to corticosteroids.

Continuation of Therapy

Rheumatoid Arthritis (RA)[1,7-11,31-32]

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 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.

Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (sJIA)[3-5,12-15,23,24,34]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for adult-onset Still's disease or systemic 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
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)[1,30]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for CAPS, including NOMID (also known as CINCA), 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:

- Fever
- Skin rash
- Joint pain and/or inflammation
- Central nervous system (CNS) symptoms (e.g., meningitis, headache, cerebral atrophy, uveitis, hearing loss)
- Inflammatory markers (e.g., serum amyloid A [SAA], C-reactive protein [CRP], erythrocyte sedimentation rate [ESR])

Recurrent Pericarditis (RP)[16,33]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for recurrent pericarditis and who achieve or maintain a positive clinical response as evidenced by decreased recurrence of pericarditis or improvement in signs and symptoms of the condition when there is improvement in any of the following:

- Pericarditic or pleuritic chest pain
- Pericardial or pleural rubs
- Electrocardiogram (ECG)
- Pericardial effusion
- C-reactive protein (CRP)

Multicentric Castleman Disease

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

CAR T-Cell-Related Toxicities and Immune Checkpoint Inhibitor-Related Toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All Other Indications

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

Other[1,22]

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

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide[36]

- 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

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