AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Kineret	Page:	1 of 8
Effective Date:	8/3/2026	Last Review Date:	7/2026
Applies to:	☒New Jersey		

Intent:

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

Description:

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

- 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) – *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
- Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID) – *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
- Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Compendial Uses

- Systemic juvenile idiopathic arthritis (sJIA) – *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
- Adult-onset Still's disease (AOSD)
- Multicentric Castleman disease
- Recurrent pericarditis (RP)
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
- Schnitzler syndrome – *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
- Gout and pseudogout (calcium pyrophosphate deposition)
- Chimeric antigen receptor (CAR) T-cell-related toxicities
- Erdheim-Chester Disease
- Immune checkpoint inhibitor-related toxicity—immunotherapy-related hemophagocytic lymphohistiocytosis (HLH)-like syndrome

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

Applicable Drug List:

Non-preferred Agent: Kineret

Policy/Guideline:

Documentation for all indications:

The patient is unable to take TWO preferred products (a preferred adalimumab product, a preferred tocilizumab product, Enbrel, Kevzara or tofacitinib), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation

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

Adult-Onset Still's Disease (AOSD)
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.

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:

- Adult-onset Still's disease (AOSD), gout, and pseudogout: rheumatologist
- 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

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

Coverage Criteria

Adult-Onset Still's Disease (AOSD)
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).

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
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)
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
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)
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.

Gout and Pseudogout Flares
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
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
Authorization of 12 months may be granted for the treatment of Erdheim-Chester disease.

Immune Checkpoint Inhibitor-Related Toxicity
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

Adult-Onset Still's Disease (AOSD)
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)

Recurrent Pericarditis (RP)
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

For all indications: Member has been evaluated for tuberculosis (TB) infection prior to initiation of treatment with a biologic or targeted synthetic drug associated with an increased risk of TB.

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

- 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

Approval Duration and Quantity Restrictions:

Initial Approval: Cytokine release syndrome = 1 month; members at high risk of developing ICANS = 3 months; immune checkpoint inhibitor-related toxicity = 6 months; all others = 12 months
Renewal Approval: Cytokine release syndrome = 1 month; members at high risk of developing ICANS = 3 months; immune checkpoint inhibitor-related toxicity = 6 months all others = 12 months

Quantity Level Limit:
100 mg/0.67 mL single-use prefilled syringe: 30 syringes per 30 days
- Exception limit: 360 syringes per 30 days

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