Kineret (anakinra)

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

**Compendial Uses**

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

All other indications are considered experimental/investigational and are not a covered benefit.

**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 Kevzara)
   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 Kevzara
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)
Authorization of 24 months may be granted for members who meet ANY of the following criteria:
   a. Member has experienced an inadequate response to at least a 3-month trial of a biologic DMARD or a targeted synthetic DMARD (e.g., Xeljanz)
   b. Member has experienced intolerance to a biologic or targeted synthetic DMARD

B) Adult Onset Still’s Disease
Authorization of 24 months may be granted for members who meet ANY of the following criteria:
   a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate
   b. Member has intolerance or contraindication to methotrexate (See Appendix B)
   c. Member has a febrile disease

C) Active Systemic Juvenile Idiopathic Arthritis (sJIA)
1. Authorization of 24 months may be granted for the treatment of sJIA for members who have received Actemra or Ilaris in a paid claim through a pharmacy or medical benefit within the previous 120 days.
2. Authorization of 24 months may be granted for the treatment of active sJIA for members who have had an inadequate response to a trial of corticosteroids, methotrexate, or leflunomide.

D) Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Authorization of 24 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) Non-Hodgkin’s Lymphoma – Multicentric Castleman’s Disease
Authorization of 12 months may be granted for the treatment of multicentric Castleman’s disease.

G) Hyperimmunoglobulin D Syndrome [Mevalonate Kinase Deficiency (MKD)]
Authorization of 24 months may be granted for the treatment of hyperimmunoglobulin D syndrome.

Continuation of Therapy

A) Adult Onset Still’s Disease, Rheumatoid Arthritis and Juvenile Idiopathic Arthritis
Authorization of 24 months may be granted for all members (including new members) who have achieved or maintained a positive clinical response after at least 3 months of therapy with Kineret as evidenced by low disease activity or improvement in signs and symptoms of the condition.
B) **Neonatal-Onset Multisystem Inflammatory Disease (NOMID), Castleman’s disease, Recurrent Pericarditis, and Hyperimmunoglobulin D Syndrome**

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

**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 Apply**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kineret®</td>
<td>anakinra</td>
<td>28 syringes per 28 days</td>
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</tbody>
</table>

**APPENDIX**

**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. Alcoholic liver disease or other chronic liver disease
3. Elevated liver transaminases
4. Interstitial pneumonitis or clinically significant pulmonary fibrosis
5. Renal impairment
6. Current pregnancy or 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.

- J3590 Unclassified biologics
- J3490 Unclassified drugs
- C9399 Unclassified drugs or biologicals

**REFERENCES**


*Some content reprinted from CVSHealth*

**POLICY HISTORY**

**Policy #:** 05.02.10  
**Reviewed:** July 2018  
**Revised:** December 2017  
**Current Effective Date:** March 8, 2018