

## SPECIALTY GUIDELINE MANAGEMENT

### KINERET (anakinra)

#### POLICY

##### I. 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.

###### A. FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA)
2. Cryopyrin-Associated Periodic Syndromes (CAPS)
  - a. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

###### B. 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.

##### II. 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)
- 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.

**III. 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.

**IV. APPENDIX: 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

**V. REFERENCES**

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