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
A. Systemic juvenile idiopathic arthritis (sJIA)
B. Adult-onset Still's disease
C. Non-Hodgkin's lymphoma – Castleman's disease
D. Recurrent pericarditis
E. 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. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Authorization of 24 months may be granted for members who are prescribed Kineret for the treatment of cryopyrin-associated periodic syndromes (CAPS), including NOMID (also known as chronic infantile neurologic cutaneous and articular syndrome [CINCA]).

B. Moderately to Severely Active Rheumatoid Arthritis (RA)
1. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Kineret, any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Kineret.

2. 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.

C. Adult Onset Still's Disease
1. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Kineret in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Kineret.

2. Authorization of 24 months may be granted for members who meets 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.
Example: Contraindications to methotrexate
- History of intolerance or adverse event
- Alcoholic liver disease or other chronic liver disease
- Elevated liver transaminases
- Interstitial pneumonitis or clinically significant pulmonary fibrosis
- Renal impairment
- Current pregnancy or planning pregnancy
- Breastfeeding
- Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
- Myelodysplasia
- Hypersensitivity
- Significant drug interaction

c. Member has a febrile disease.

D. Active Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Actemra, Ilaris or Kineret in a paid claim through for a pharmacy or medical benefit within the previous 120 days of the initial request for Kineret.

2. 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 2-week trial of corticosteroids.

   b. Member has experienced an inadequate response to at least a 3-month trial of methotrexate or leflunomide.

E. Non-Hodgkin's Lymphoma – Castleman's Disease

Authorization of 12 months may be granted for members who meet BOTH of the following criteria:
1. Member is prescribed Kineret as a single agent therapy, AND
2. Member has progressed following treatment of relapsed, refractory or progressive disease.

F. Recurrent Pericarditis

Authorization of 12 months may be granted for members who meet BOTH of the following criteria:
1. Kineret is prescribed for the treatment of recurrent pericarditis, AND
2. The member has failed first-line therapy agents (i.e., colchicine).

G. Hyperimmunoglobulin D Syndrome [Mevalonate Kinase Deficiency (MKD)]

Authorization of 24 months may be granted for members who are prescribed Kineret for the treatment of hyperimmunoglobulin D syndrome.

III. CONTINUATION OF THERAPY

A. 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.

B. 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 meet ALL initial authorization criteria and achieve or maintain 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.

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

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