DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: anakinra injection, for subcutaneous use (Kineret® - Swedish Orphan Biovitrum AB) Duration Limit

DATE REVIEWED: 02/17/2021

OVERVIEW

Kineret is an interleukin-1 (IL-1) receptor antagonist indicated to reduce the signs and symptoms and slow the progression of structural damage in adult patients with moderately to severely active rheumatoid arthritis (RA) who have failed one or more disease-modifying antirheumatic drugs (DMARDs),Cryopyrin-Associated Periodic Syndromes (CAPS) for treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID),and Deficiency of Interleukin-1 Receptor Antagonist (DIRA).[1]

Dosing

Rheumatoid Arthritis (RA)

- The recommended dose of Kineret for the treatment of patients with rheumatoid arthritis is 100 mg/day administered daily by subcutaneous injection. The dose should be administered at approximately the same time every day.
- Physicians should consider a dose of 100 mg of Kineret administered every other day for RA patients who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels).

Cryopyrin-Associated Periodic Syndromes (CAPS) for the treatment of NOMID

- The recommended starting dose of Kineret is 1-2 mg/kg daily for NOMID patients. The dose can be individually adjusted to a maximum of 8 mg/kg daily to control active inflammation.
- Physicians should consider administration of the prescribed Kineret dose every other day for NOMID patients who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels)

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- The recommended starting dose of KINERET is 1-2 mg/kg daily for patients with DIRA. The dose can be individually adjusted to a maximum of 8 mg/kg daily to control active inflammation.
- Physicians should consider administration of the prescribed KINERET dose every other day for patients with DIRA who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels).

Kineret 100 mg/0.67 ml prefilled syringe Maximum quantity per 28 days = 28 syringes

A quantity of 28 of the 100 mg/0.67 ml prefilled syringes per 28 days will be allowed without coverage review. This is enough drug to last 28 days at daily dosing. Exceptions are allowed for patients with CAPS for the treatment of NOMID or Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

The objective of this program is to manage potential premature dose escalation of Kineret in the treatment of RA or CAPS for the treatment of NOMID and Deficiency of Interleukin-1 Receptor Antagonist (DIRA). This Drug Quantity Management Policy has been developed to complement the coverage provided by *Inflammatory Conditions - Kineret Prior Authorization Policy*. Consult the *Inflammatory Conditions - Kineret Prior Authorization Policy* for detailed information about evidence-supported approved treatment regimens and durations.[2]

CRITERIA

All approval durations are for 3 years. Authorization for additional quantities of Kineret is recommended in those who meet one of the following criteria:

Kineret 100 mg/0.67 ml prefilled syringe

1. For patients with CAPS using Kineret for the of treatment of Neonatal Onset Multisystem Inflammatory Disease (NOMID), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and/or chronic infantile neurological cutaneous and articular (CINCA) syndrome, a quantity sufficient to allow for dosing of up to 8 mg/kg/day.

REFERENCES

1. Kineret® [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; December 2020.
2. Inflammatory Conditions – Kineret Prior Authorization Policy. , Inc. Updated 01/20/2021.