DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Kineret Drug Quantity Management Policy – Per Days
- Kineret® (anakinra subcutaneous injection – Biovitrim)

REVIEW DATE: 01/04/2023

OVERVIEW

Indication

Kineret, an interleukin-1 (IL-1) receptor antagonist, indicated for the following uses:[1]

- **Cryopyrin-associated periodic syndromes** (CAPS) for treatment of neonatal-onset multisystem inflammatory disease (NOMID).
- **Deficiency of interleukin-1 receptor antagonist** (DIRA).
- **Rheumatoid arthritis**, to reduce the signs and symptoms and slow the progression of structural damage in adult patients with moderately to severely active disease who have failed one or more disease-modifying antirheumatic drugs (DMARDs) given ± DMARDs other than tumor necrosis factor inhibitors (TNFis).

In addition to the FDA-approved uses, guidelines support the use of Kineret for the treatment of systemic juvenile idiopathic arthritis (SJIA) and Still's disease.[2-9]

Kineret has also been granted Emergency Use Authorization for treatment of Coronavirus disease 2019 (COVID-19) in hospitalized adults with positive viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR).[10]

Dosing

Kineret is administered by subcutaneous (SC) injection.[1] A new syringe must be used for each dose. Any unused portion after each dose should be discarded. Regardless of indication, consider administration of the prescribed dose every other day for patients who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels).

- **CAPS:** 1 to 2 mg per kg daily for NOMID patients. The dose may be individually adjusted to a maximum of 8 mg per kg daily to control active inflammation. Adjust doses in 0.5 to 1 mg per kg increments. Once daily dosing is generally recommended, but dose may be split into twice daily administration.
- **DIRA:** 1 to 2 mg per kg per day. The dose may be individually adjusted to a maximum of 8 mg per kg per day to control active inflammation. Adjust doses in 0.5 to 1 mg per kg increments.
- **Rheumatoid arthritis:** 100 mg daily at approximately the same time every day. Higher doses did not result in a higher response.

Off-label dosing of Kineret for the treatment of SJIA and Still's disease varies based on reference, but guidelines support a dose of 4 mg/kg per day.[2-9] However, higher doses may be needed.

Availability

Kineret is available as a 100 mg/0.67 mL prefilled syringes.[1] Each dispensing pack contains either 7 or 28 syringes.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Kineret and to manage potential premature dose escalation. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

Automation: None.

Drug Quantity Limit

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Kineret® (anakinra subcutaneous injection)	100 mg/0.67 mL prefilled syringe	28 syringes	84 syringes

CRITERIA

1. If the patient has cryopyrin-associated periodic syndromes (CAPS) or deficiency of interleukin-1 receptor antagonist (DIRA), approve a quantity sufficient to allow for a dose of up to 8 mg per kg per day for 28 days at retail or for 84 days at home delivery.
Note: CAPS encompasses three rare genetic syndromes: familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and NOMID or chronic infantile neurological cutaneous and articular syndrome (CINCA).

2. If the patient has systemic juvenile idiopathic arthritis (SJIA) or Still's disease, approve a quantity sufficient to allow for a dose of up to 4 mg per kg per day for 28 days at retail or for 84 days at home delivery.

REFERENCES

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