DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 01/04/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 once daily (QD) for patients with NOMID. 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 QD. The dose may be individually adjusted to a maximum of 8 mg per kg QD to control active inflammation. Adjust doses in 0.5 to 1 mg per kg increments.
- **Rheumatoid arthritis:** 100 mg QD 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 per 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]

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.

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

Inflammatory Conditions – Kineret Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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 neonatal-onset multisystem inflammatory disease (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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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. **Kineret 100 mg/0.67 mL prefilled syringe:** New override criteria added to approve for a quantity sufficient for up to 4 mg per kg per day for 28 days at retail or 84 days at home delivery for a patient with systemic juvenile idiopathic arthritis or Still's Disease.	01/04/2023
Annual Revision	No criteria changes.	01/04/2024