

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Arcalyst Drug Quantity Management Policy – Per Days

- Arcalyst® (rilonacept subcutaneous injection – Regeneron)

REVIEW DATE: 01/04/2023

OVERVIEW

Arcalyst, an interleukin-1 blocker, is indicated for the following uses:¹

- **Cryopyrin-associated periodic syndromes (CAPS)**, including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS), for treatment of patients ≥ 12 years of age.
- **Deficiency of interleukin-1 receptor antagonist (DIRA)**, for maintenance of remission in patients weighing at least 10 kg.
- **Pericarditis**, for treatment of recurrent disease and reduction in risk of recurrence in patients ≥ 12 years of age.

Dosing

CAPS, FCAS, MWS, and recurrent pericarditis:

- In adults, initiate treatment with a loading dose of 320 mg delivered as two subcutaneous (SC) injections of 160 mg/2 mL each, administered on the same day at two different injection sites.¹ Continue dosing with a 160 mg once weekly (QW) administered as a single, 2 mL SC injection.
- In pediatric patients 12 years to 17 years of age, initiate treatment with a loading dose of 4.4 mg/kg, up to a maximum dose of 320 mg, administered as one or two SC injections, not to exceed single-injection volume of 2 mL per injection site. If the initial dose is given as two injections, administer on the same day at two different sites. Continue dosing with a QW injection of 2.2 mg/kg, up to a maximum of 160 mg, administered as a single SC injection, up to 2 mL.
- If a QW dose is missed, instruct the patient to administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, instruct the patient to administer the dose, starting a new schedule based on this date.

DIRA:

- In adults, the recommended dose is 320 mg, once weekly, administered as two SC injections on the same day at two different sites with a maximum single-injection volume of 2 mL. Arcalyst should not be given more often than QW.
- In pediatric patients who weigh ≥ 10 kg, the recommended dose is 4.4 mg/kg (up to a maximum of 320 mg) QW, administered as one or two SC injections with a maximum single-injection volume of 2 mL. If the dose is given as two injections, administer both on the same day, each one at a different site.

Based on prescribing information, four of the 220 mg vials are adequate for a 28-day supply. Exceptions can be made for patients initiating therapy or patients with DIRA.

Availability

Arcalyst is supplied as a lyophilized powder in single-dose vials each containing 220 mg of Arcalyst. Each vial is supplied in a carton containing one or four vials.

POLICY STATEMENT

01/04/2023

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This Drug Quantity Management program has been developed to prevent stockpiling and waste and address potential order entry errors with Arcalyst. 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 Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Arcalyst® (rilonacept subcutaneous injection)	220 mg single-dose vial	4 vials	12 vials

CRITERIA

1. If the patient is initiating treatment or requires additional induction dosing for cryopyrin-associated periodic syndromes (CAPS), familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), or recurrent pericarditis, as verified by absence of claims for Arcalyst in the past 130 days, approve a one-time override for 5 vials at retail or 13 vials at home delivery.
Note: The home delivery quantity allows for initial treatment (5 vials), plus 2 months of once weekly maintenance dosing.
2. If the patient has deficiency of interleukin-1 receptor antagonist (DIRA), approve 8 vials per 28 days at retail or 24 vials per 84 days at home delivery.

REFERENCES

1. Arcalyst® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron; May 2021.