DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Arcalyst Drug Quantity Management Policy – Per Days
- Arcalyst® (rilonacept subcutaneous injection – Kiniksa)

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

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.[1] Each vial is supplied in a carton containing one or four vials.

POLICY STATEMENT

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.

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

Inflammatory Conditions – Arcalyst 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 is initiating treatment for cryopyrin-associated periodic syndromes (CAPS), familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), or recurrent pericarditis 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 retail override quantity allows for initial treatment over the first 4 weeks (5 vials). The home delivery override 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: Kiniksa; March 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Override criteria were clarified to allow a patient who has required additional induction dosing for cryopyrin-associated periodic syndromes (CAPS), familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), or recurrent pericarditis, to be approved for 5 vials at retail or 13 vials at home delivery. Previously, criteria only approved for a patient who was initiating treatment.	01/04/2023
Annual Revision	No criteria changes.	01/04/2024