Pharmacy Medical Necessity Guidelines: Arcalyst® (rilonacept)

Effective: May 9, 2023

Guideline Type

☑ Prior Authorization
☐ Non-Formulary
☐ Step-Therapy
☐ Administrative

Applies to:

Commercial Products

☑ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988
☑ Tufts Health Plan Commercial products; Fax: 617-673-0988
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☑ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications
Arcalyst (rilonacept) is an interleukin-1 blocker indicated for:

- **Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)**
  Treatment of CAPS, including FCAS and MWS in adults and children 12 and older.

- **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**
  Maintenance of remission of DIRA in adults and pediatric patients weighing 10 kg or more.

- **Recurrent Pericarditis**
  Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older.

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Arcalyst for Members when all of the following criteria are met:

**Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)**

1. Documented diagnosis of one of the following:
   a. Cryopyrin-Associated Periodic Syndromes
   b. Familial Cold Auto-Inflammatory Syndrome
   c. Muckle-Wells Syndrome

**Deficiency of Interleukin-1 Receptor Antagonist (DIRA)**

1. Documented diagnosis of deficiency of interleukin-1 receptor antagonist
Recurrent Pericarditis

1. Documented diagnosis of recurrent pericarditis AND
2. Prescribed by or in consultation with a cardiologist or rheumatologist AND
3. Documentation of one (1) of the following:
   a. Trial and failure of standard treatment with colchicine and nonsteroidal anti-inflammatory drugs and/or systemic corticosteroids
   b. Clinical inappropriateness to standard treatment with colchicine and nonsteroidal anti-inflammatory drugs and/or systemic corticosteroids

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References


Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.
- May 9, 2023: No changes

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member
eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.