Pharmacy Medical Necessity Guidelines: Arcalyst® (rilonacept)

Effective: February 13, 2024

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

COVERAGE GUIDELINES

The plan may authorize coverage of Arcalyst (rilonacept) 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 (1) 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

None

CODES

None

REFERENCES

1. Arcalyst (rilonacept) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2021.
2. Chiabrando JG, et al, Management of acute and recurrent pericarditis: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020 Jan;75(1):76-92.
3. Church LD, Savic S, McDermott MF. Long term management of patients with cryopyrin-associated periodic syndromes (CAPS): focus on rilonacept (IL-1 Trap). *Biologics*. 2008 Dec;2(4):733-42.
4. Gillespie J, Mathews R, McDermott MF. Rilonacept in the management of cryopyrin-associated periodic syndromes (CAPS). *J Inflamm Res*. 2010;3:1-8.

5. Goldbach-Mansky R, Shroff SD, Wilson M et al. A pilot study to evaluate the safety and efficacy of the long-acting interleukin-1 inhibitor rilonacept (interleukin-1 Trap) in patients with familial cold autoinflammatory syndrome. *Arthritis Rheum*. 2008 Aug;58(8):2432-42.
6. Hoffman HM, Throne ML, Amar NJ et al. Efficacy and safety of rilonacept (interleukin-1 Trap) in patients with cryopyrin-associated periodic syndromes: results from two sequential placebo-controlled studies. *Arthritis Rheum*. 2008 Aug;58(8):2443-52.
7. Hoffman HM, Throne ML, Amar NJ et al. Long-term efficacy and safety profile of rilonacept in the treatment of cryopryin-associated periodic syndromes: results of a 72-week open-label extension study. *Clin Ther*. 2012 Oct;34(10):2091-103.
8. Kubota T, Koike R. Cryopyrin-associated periodic syndromes: background and therapeutics. *Mod Rheumatol*. 2010 Jun;20(3):213-21.
9. Yu JR, Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. *Curr Allergy Asthma Rep*. 2011 Feb;11(1):12-20.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

- May 9, 2023: No changes
- February 13, 2024: 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.

Provider Services