Pharmacy Medical Necessity Guidelines: Arcalyst® (rilonacept)

Effective: September 15, 2020

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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 the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

CAPS disorders are inherited in an autosomal dominant pattern with male and female offspring equally affected. Features common to all disorders include fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis. The FCAS and MWS disorders affect about 300 people in the United States. Fifty percent of CAPS cases are associated with a gene mutation in the CIAS 1 gene. The incidence of CAPS is approximately 1 in 1,000,000 people in the United States.

Rilonacept is a dimeric fusion protein consisting of the ligand-binding domains of the extracellular portions of the human interleukin-1 receptor component (IL-1RI) and IL-1 receptor accessory protein (IL-1RAcP) linked in-line to the Fc portion of human IgG1. CAPS refer to rare genetic syndromes generally caused by mutations in the NLRP-3 (previously known as *CIAS1*) gene and resultant alterations in the protein, cryopyrin, which it encodes. Cryopyrin, active in circulating, infection-fighting, white blood cells, controls the production of a protein called interleukin-1 (IL-1). As part of the body's infection-fighting defense system, IL-1 circulates throughout the body and can trigger inflammatory reactions when it binds to inflammatory cells.

COVERAGE GUIDELINES

The plan may authorize coverage of Arcalyst (rilonacept) for Members, when all of the following criteria are met:

1. Documented diagnosis of one of the following:
    a. Cryopyrin-Associated Periodic Syndromes (CAPS)
    b. Familial Cold Autoinflammatory Syndrome (FCAS)
    c. Muckle-Wells Syndrome (MWS)

AND

2. The prescriber has expertise in the treatment of CAPS, FCAS, or MWS

LIMITATIONS

- Coverage for Arcalyst (rilonacept) will be limited as follows:
    - Arcalyst 220 mg vial: 5 vials per 28 days (initial 4 weeks), then 4 vials per 28 days thereafter.

CODES

None

REFERENCES

1. Arcalyst (rilonacept) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2016.
2. 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.
3. Gillespie J, Mathews R, McDermott MF. Rilonacept in the management of cryopyrin-associated periodic syndromes (CAPS). *J Inflamm Res*. 2010;3:1-8.
4. 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.
5. 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.
6. 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.
7. Kubota T, Koike R. Cryopyrin-associated periodic syndromes: background and therapeutics. *Mod Rheumatol*. 2010 Jun;20(3):213-21.
8. 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

July 8, 2008: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 14, 2009: No changes.
2. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
3. July 13, 2010: No changes.
4. July 12, 2011: No changes.
5. June 12, 2012: No changes.
6. May 9, 2013: No changes.
7. April 8, 2014: No changes.
8. April 14, 2015: No changes.
9. January 1, 2016: Administrative change to rebranded template.
10. March 8, 2016: No changes.
11. April 12, 2016: No changes. Effective 10/01/2016, Medical Necessity Guideline applies to Tufts Health Together.
12. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
13. March 13, 2018: No changes.
14. February 12, 2019: No changes.
15. September 15, 2020: 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.