Pharmacy Medical Necessity Guidelines: Arcalyst® (rilonacept)

**Effective:** April 11, 2017 (All plans except Tufts Health RITogether)  
**Effective:** June 1, 2017 (Tufts Health RITogether)

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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
- RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, refer to the Tufts Health Plan Medicare Preferred prior authorization criteria. Background, applicable product and disclaimer information can be found on the last page.

**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. The Member has a documented diagnosis of a CAPS, FCAS, or MWS **AND**
2. The prescriber has expertise in the treatment of the conditions in Criterion 1

**LIMITATIONS**

1. 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**


**APPROVAL HISTORY**

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

Subsequent endorsement date(s) and changes made:
- July 14, 2009: No changes
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- July 13, 2010: No changes
- July 12, 2011: No changes
- June 12, 2012: No changes
- May 9, 2013: No changes
- April 8, 2014: No changes
- April 14, 2015: No changes
- January 1, 2016: Administrative change to rebranded template
- March 8, 2016: No changes
- April 12, 2016: No changes. Effective 10/01/2016, Medical Necessity Guideline applies to Tufts Health Together.

**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.
Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

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.