Pharmacy Medical Necessity Guidelines: Ilaris® (canakinumab)

Effective: August 7, 2018

Prior Authorization Required √  Type of Review – Care Management
Not Covered  Type of Review – Clinical Review √
Pharmacy (RX) or Medical (MED) Benefit  MED  Department to Review  PRECERT/MM

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:
- Tufts Health Plan
  - Commercial Plans and Tufts Health Freedom Plan products: PRECERT: 617.972.9409
  - Tufts Health Public Plans: MM: 888.415.9055

Note: For Tufts Health Plan Medicare Preferred Members, please 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**
Ilaris (canakinumab) is an interleukin-1β blocker indicated for the treatment of:
- **Cryopyrin-Associated Periodic Syndromes (CAPS)**
- CAPS in adults and children 4 years of age and older including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)
- **Tumor Necrosis Factor Receptor (TNF) Associated Periodic Syndrome (TRAPS)**
  - TNF TRAPS in adult and pediatric patients
- **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)**
  - HIDS/MKD in adult and pediatric patients
- **Familial Mediterranean Fever (FMF)**
  - FMF in adult and pediatric patients
- **Systemic Juvenile Idiopathic Arthritis (SJIA)**
  - Active SJIA in patients aged 2 years and older

**COVERAGE GUIDELINES**
The plan may authorize coverage of Ilaris (canakinumab) for Members, when all of the following criteria are met:

**CAPS, TNF TRAPS, HIDS/MKD, FMF (Periodic Fever Syndromes)**
1. The Member has a documented diagnosis of one of the following:
   - Cryopyrin-Associated Periodic Syndrome
   - Familial Cold Autoinflammatory Syndrome
   - Muckle-Wells Syndrome
   - Tumor Necrosis Factor Receptor Associated Periodic Syndrome
   - Hyperimmunoglobulin D Syndrome
   - Mevalonate Kinase Deficiency
   - Familial Mediterranean Fever
   - AND

2. The prescriber has expertise in the treatment of the conditions in criterion #1
**Systemic Juvenile Idiopathic Arthritis (SJIA)**

1. Documented diagnosis of systemic juvenile idiopathic arthritis AND
2. The prescription is written by a rheumatologist AND
3. The Member is 2 years of age or older AND
4. The Member has a documented inadequate response after three months at optimal doses or an inability to tolerate:
   a) Methotrexate OR
   b) Both of the following:
      • Nonsteroidal anti-inflammatory drugs (NSAIDS)
      • Corticosteroids

**LIMITATIONS**

None

**CODES**

The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0638</td>
<td>Injection, canakinumab, 1 mg</td>
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**REFERENCES**


**APPROVAL HISTORY**

March 9, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- January 1, 2011: Administrative Update: Added reimbursement code J0638
- January 11, 2011: No changes
- January 10, 2012: No changes
- January 15, 2012: No changes
- June 11, 2013: Added pharmacy coverage guidelines for Systemic Juvenile Idiopathic Arthritis (SJIA)
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- June 10, 2014: No changes
- June 9, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- June 14, 2016: No changes
- October 18, 2016: Added approval criteria for tumor necrosis factor receptor associated periodic syndrome, hyperimmunoglobulin D syndrome/mevalonate kinase deficiency, and familial mediterranean fever per updated package labeling.
- September 12, 2017: No changes
- August 7, 2018: 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. 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 CareLink℠ 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, please 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.