Pharmacy Medical Necessity Guidelines: Ilaris® (canakinumab)

Effective: June 1, 2017

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

Fax Numbers:
All plans except Tufts Health Public Plans: PRECERT: 617.972.9409
Tufts Health Direct – Health Connector: MM: 888.415.9055
Tufts Health Together – A MassHealth Plan: RxUM: 617.673.0988

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 the following autoinflammatory Periodic Fever Syndromes:

Cryopyrin-Associated Periodic Syndromes (CAPS)
Treatment CAPS, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children 4 years of age and older.

Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome (TRAPS)
Treatment of TNF receptor TRAPS in adult and pediatric patients.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Treatment of HIDS/MKD in adult and pediatric patients.

Familial Mediterranean Fever (FMF)
Treatment of FMF in adult and pediatric patients.

Ilaris (canakinumab) is also indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (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:

For Autoinflammatory Periodic Fever Syndromes
1. The Member has a documented diagnosis of one of the following:
   a. Cryopyrin-Associated Periodic Syndrome
   b. Familial Cold Autoinflammatory Syndrome
   c. Muckle-Wells Syndrome
   d. Tumor Necrosis Factor Receptor Associated Periodic Syndrome
   e. Hyperimmunoglobulin D Syndrome
   f. Mevalonate Kinase Deficiency
   g. Familial Mediterranean Fever

2. The prescriber has expertise in the treatment of the conditions in criterion #1
For Systemic Juvenile Idiopathic Arthritis
1. The Member has a 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 types of drugs
   • 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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<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)
- 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.

**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, 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.