Pharmacy Medical Necessity Guidelines: Ilaris® (canakinumab)

Effective: August 17, 2020

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

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:

Tufts Health Plan Commercial Plans and Tufts Health Freedom Plan products:
PRECERT: 617.972.9409

Tufts Health Public Plans:
MM: 888.415.9055

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

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 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
- **Still's disease (Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA])**
  Active Still's disease, including AOSD and 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:
   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

AND

2. The prescriber has expertise in the treatment of the conditions in criterion #1

Still's Disease

1. Documented diagnosis of one of the following:
    a. Systemic juvenile idiopathic arthritis
    b. Adult-Onset Still's Disease

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:

Code	Description
J0638	Injection, canakinumab, 1 mg

REFERENCES

1. 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):2443-2452.
2. Hoffman HM, Yasothan U, Kirkpatrick P. Fresh from the pipeline: Rilonacept. *Nat Rev Drug Discov*. 2008; 7(5):385-86.
3. Gul A, Ozdogan H, Erer B, et al. Efficacy and safety of canakinumab in adolescents and adults with colchicine-resistant familial Mediterranean fever. Arthritis Res Ther. 2015 Sep 4;17:243.
4. Ilaris (canakinumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
5. Kanariou M, Tantou S, Varela I, et al. Successful management of cryopyrin-associated periodic syndrome with canakinumab in infancy. Pediatrics. 2014 Nov;134(5):e1468-73.
6. Kuemmerle-Deschner JB, Hachulla E, Cartwright R, et al. Two-year results from an open-label, multicentre, phase III study evaluating the safety and efficacy of canakinumab in patients with cryopyrin-associated periodic syndrome across different severity phenotypes. *Ann Rheum Dis*. 2011 Dec;70(12):2095-102.
7. Kuemmerle-Deschner JB, Ramos E, Blank N, et al. Canakinumab (ACZ885, a fully human IgG1 anti-IL-1β mAb) induces sustained remission in pediatric patients with cryopyrin-associated periodic syndrome (CAPS). *Arthritis Res Ther*. 2011 Feb 28;13(1):R34.
8. La Torre F, Muratore M, Vitale A, et al. Canakinumab efficacy and long-term tocilizumab administration in tumor necrosis factor receptor-associated periodic syndrome (TRAPS). *Rheumatol Int*. 2015 Nov;35(11):1943-7.
9. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of Canakinumab in the Cryopyrin-Associated Periodic Syndrome. *N Engl J Med* 2009 360: 2416-2425
10. Neven B, Prieur AM, Quartier dit Maire P. Cryopyrinopathies: update on pathogenesis and treatment. *Nat Clin Pract Rheumatol*. 2008;4(9):481-9.
11. Ruperto N, Brunner HI, Quartier P et al. Two randomized trials of canakinumab in systemic juvenile idiopathic arthritis. *N Engl J Med*. 2012 Dec 20;367(25):2396-406.
12. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. *Clin Exp Dermatol*. Jan 2008;33(1):1-9.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. January 1, 2011: Administrative Update: Added reimbursement code J0638
2. January 11, 2011: No changes
3. January 10, 2012: No changes

4. January 15, 2012: No changes
5. June 11, 2013: Added pharmacy coverage guidelines for Systemic Juvenile Idiopathic Arthritis (SJIA)
6. June 10, 2014: No changes
7. June 9, 2015: No changes
8. January 1, 2016: Administrative change to rebranded template.
9. June 14, 2016: No changes
10. 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.
11. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
12. September 12, 2017: No changes
13. August 7, 2018: No changes
14. September 10, 2019: No changes
15. August 11, 2020: Updated coverage criteria for the expanded indication in Still's Disease, including Adult-Onset Still's Disease.

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.