Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Ilaris (canakinumab)

Effective: September 15, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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 Associated Periodic Syndrome (TRAPS)**

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

- **Active Still's Disease**

Active Still's disease, including Adult-Onset Still's Disease and Systemic Juvenile Idiopathic Arthritis in patients 2 years of age and older

- **Gout flares**

Gout flares in adults in whom non-steroidal anti-inflammatory drugs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate

Clinical Guideline Coverage Criteria

The plan may authorize Ilaris (canakinumab) for Members when the criteria are not met:

CAPS, TNF TRAPS, HIDS/MKD, FMF (Periodic Fever Syndromes)

1. Documented diagnosis of **one (1)** 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

Still's Disease

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

AND

2. The prescription is written by or in consultation with a rheumatologist

AND

3. The Member is 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response to treatment with optimal doses of methotrexate for a trial lasting at least 3 months, documented intolerance to optimal doses of methotrexate, or the provider has indicated the clinical inappropriateness of methotrexate therapy.
    b. Inadequate response after three months at optimal doses or an inability to tolerate both of the following:
        i. Nonsteroidal anti-inflammatory drugs (NSAIDS)
        ii. Corticosteroids

Gout Flares

1. Documented diagnosis of gout flare

AND

2. The prescription is written by or in consultation with a rheumatologist

AND

3. Documentation of **both** of the following:
    a. Inadequate response, adverse event or contraindication to non-steroidal anti-inflammatory drugs
    b. Inadequate response, adverse event or contraindication to colchicine

AND

4. Documentation repeated courses of corticosteroids are not appropriate

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	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; November 2024.
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 And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: Added coverage criteria for supplemental indication of gout flares. Removed language limiting authorizations to 12 months (effective 11/1/2023).
- September 10, 2024: No changes.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: No changes.
- September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment, or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.