Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Ilaris® (canakinumab)

Effective: January 1, 2026

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

Public Plans Products

☒ 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

Approval of Ilaris for CAPS was based on tCAPS Study which had three parts. Part 1 was an eight week open-label, single-dose period where all patients received Ilaris. The majority of patients achieved complete clinical response at Weeks 1 (71%) and 8 (97%) after the first dose of Ilaris. Patients who achieved a complete response and did not relapse by week eight, were randomized to Part 2, a 24-week, double-blind, placebo-controlled withdrawal period. In part two of the study, after 3 doses of Ilaris, 100% of patients remained flare free through 24 weeks. In addition, all 15 patients treated with Ilaris in Part 2 had absent or minimal disease activity and skin disease.

Approval of Ilaris the treatment of Periodic Fever Syndrome was based on results demonstrating a significantly greater proportion of patients receiving Ilaris achieving rapid resolution of index flare at Day 15, with no new flares through Week 16, compared to placebo. Across the conditions, percentages of patients receiving Ilaris achieving complete response were 61% (FMF), 35% (HIDS/MKD), and 46% (TRAPS) respectively.

Approval of Ilaris for the treatment of Still's Disease was based on two, placebo-controlled, Phase 3 trials in patients aged 2 to less than 20 years old with a confirmed diagnosis of systemic juvenile idiopathic arthritis (SJIA) and active disease. In Study 1, a higher proportion of patients receiving Ilaris achieved ACR30, 50 and 70 responses at Days 15 and 29 compared to placebo. Ilaris demonstrated favorable effects on corticosteroid dose tapering and time to flare. Efficacy in Adult-onset Still's Disease is based on the pharmacokinetic exposure and extrapolation of the established efficacy of Ilaris in SJIA patients, and a placebo-controlled trial of 36 patients aged 22 to 70 years of age which demonstrated efficacy data that was generally consistent with the results of a pooled efficacy analysis of SJIA patients.

Approval of Ilaris for the treatment of gout flares was based on two 12-week, active-controlled trials in patients with gout flares for whom non-steroidal anti-inflammatory drugs (NSAIDs) and/or colchicine were contraindicated, not tolerated or ineffective. Pain intensity of the most affected joint (0-100 mm VAS) at 72 hours post-dose was consistently lower for patients treated with Ilaris compared with triamcinolone acetonide in the subpopulation of patients unable to use NSAIDs and colchicine. Time to new flare over 12 weeks from randomization showed a reduction in the risk of a new flare when treated with Ilaris compared with triamcinolone acetonide 40 mg in the subpopulation of patients unable to use NSAIDs and colchicine.

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 coverage of Ilaris for Members when the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
   a. Cryopyrin-Associated Periodic Syndrome (CAPS)
   b. Familial Cold Autoinflammatory Syndrome (FCAS)
   c. Muckle-Wells Syndrome (MWS)
   d. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
   e. Hyperimmunoglobulin D Syndrome (HIDS)
   f. Mevalonate Kinase Deficiency (MKD)
   g. Familial Mediterranean Fever (FMF)
   h. Systemic juvenile idiopathic arthritis
   i. Adult-Onset Still's Disease
   j. Gout flare

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0638	Injection, canakinumab, 1 mg

References

1. Ilaris (canakinumab). East Hanover, NJ: Novartis Pharmaceuticals Corporation; Aug 2023.

Approval And Revision History

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

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Added gout flares to the approvable diagnoses list based on the supplemental indication. Removed the Limitation Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan (eff 1/1/24).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.