Canakinumab (Ilaris®)	Place of Service Office Administration Home Health Infusion Outpatient Facility Administration Infusion Center Administration HCPCS: J0638 per 1 mg

Conditions listed in policy (*see criteria for details*)

- Adult-onset Still's disease
- Cryopyrin-associated periodic syndromes (CAPS)
- Gout flares
- Systemic juvenile idiopathic arthritis (SJIA)
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- Hyperimmunoglobulin D syndrome (HIDS)/ Mevalonate kinase deficiency (MKD)
- Familial Mediterranean Fever (FMF)

AHFS therapeutic class: Miscellaneous therapeutic agent

Mechanism of action: interleukin-1 beta blocker monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION **

MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract),** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF ILARIS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is receiving the first dose of Ilaris or is being re-initiated on Ilaris after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event to Ilaris based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events to Ilaris based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for (Ilaris®) canikinumab not listed in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Adult-onset Still's disease (AOSD) or Systemic juvenile idiopathic arthritis (SJIA)

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Patient is 2 years of age or older

Covered Doses
4 mg/kg (up to max of 300 mg) given subcutaneously every 4 weeks for patients with a body weight ≥ 7.5 kg

Coverage Period
Initial: 12 weeks
Reauthorization: Yearly, based on continued response

ICD-10:
M06.1, M08.2X

Cryopyrin-associated periodic syndromes (CAPS)

1. Diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle Wells syndrome (MWS), **AND**
2. Patient is 4 years of age or older

Covered Doses
Weight ≥ 15 kg to ≤ 40 kg: Up to 3 mg/kg given subcutaneously every 8 weeks
Weight > 40 kg: Up to 150 mg given subcutaneously every 8 weeks

Coverage Period
Indefinite

ICD-10:
M04.2

Gout flares

1. Patient is 18 years of age or older, **AND**

2. Patient had ≥3 gout flares in the past year, **AND**
3. Inadequate response, intolerance, or contraindication to all of the following:
    a. NSAIDs, and
    b. Colchicine, and
    c. Corticosteroids

Covered Doses
Up to 150 mg subcutaneously every 12 weeks

Coverage Period
Indefinite

ICD-10:
M10

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for (Ilaris®) canikinumab Not listed in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Familial mediterranean fever (FMF), Hyperimmunoglobulin D syndrome (HIDS), Mevalonate kinase deficiency (MKD), OR Tumor necrosis factor receptor associated periodic syndrome (TRAPS)

Covered Doses
≤ 40 kg: up to 4 mg/kg given subcutaneously every 4 weeks
> 40 kg up to 300 mg given subcutaneously every 4 weeks

Coverage Period
Indefinite

ICD-10: M04.1

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:
150 mg/mL solution (single-dose vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care Res 2020; 72:744-760.
- Ilaris® (canakinumab) [Prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 8/2023.

- Ringold S, Weiss PF Beukelman T et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. Arthritis Care & Research 2013;65(10): 1551–1563.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- New indication in Section (2): Add coverage for gout flares

  Rationale: In August 2023, FDA approved Ilaris for the treatment of gout flares in adults in whom NSAIDs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee