CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs
Ilaris® (canakinumab)

Effective: January 1, 2026

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

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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 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

- 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).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes
- 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

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.

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.