Reference number(s)
2479-A

Standard Medicare Part B Management Ilaris

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ilaris	canakinumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- Cryopyrin-associated periodic syndromes (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) in adult and pediatric patients
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD) in adult and pediatric patients
- Familial Mediterranean Fever (FMF) in adult and pediatric patients
- Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older
- Symptomatic treatment of adult patients with gout flares in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not

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provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Cryopyrin-Associated Periodic Syndromes (CAPS)[1]

Authorization of 12 months may be granted for treatment of cryopyrin-associated periodic syndromes (CAPS) including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS).

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)[1]

Authorization of 12 months may be granted for treatment of tumor necrosis factor receptor associated periodic syndrome (TRAPS).

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)[1]

Authorization of 12 months may be granted for treatment of hyperimmunoglobulin D syndrome (HIDS) or mevalonate kinase deficiency (MKD).

Familial Mediterranean Fever (FMF)[1]

Authorization of 12 months may be granted for treatment of Familial Mediterranean Fever (FMF).

Systemic Juvenile Idiopathic Arthritis (sJIA)[1]

Authorization of 12 months may be granted for treatment of active systemic juvenile idiopathic arthritis.

Active Adult-Onset Still's Disease (AOSD)[1]

Authorization of 12 months may be granted for treatment of active adult-onset Still's disease.

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Gout Flares[1]

Authorization of 12 months may be granted for the treatment of gout flares when the member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Ilaris.
- Ilaris is being used to treat an indication in the coverage criteria.
- The member is receiving benefit from therapy as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Ilaris.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Ilaris are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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References

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2024.

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