Reference number(s)
2479-A

STANDARD MEDICARE PART B MANAGEMENT

ILARIS (canakinumab)

POLICY

I. 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.

A. 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)
2. Tumor necrosis factor receptor associated periodic syndrome (TRAPS) in adult and pediatric patients
3. Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD) in adult and pediatric patients
4. Familial Mediterranean Fever (FMF) in adult and pediatric patients
5. Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older

B. Compendial Use
Acute flares of gouty arthritis

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

II. CRITERIA FOR INITIAL APPROVAL

A. Cryopyrin-associated periodic syndromes (CAPS)
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).

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

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

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

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

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

G. **Gouty arthritis**
Authorization of 6 months may be granted for the management of acute flares of gouty arthritis when either of the following criteria is met:
1. Member has had an inadequate response or intolerance to maximum tolerated doses of non-steroidal anti-inflammatory drugs (NSAIDs), colchicine and oral and injectable corticosteroids.
2. Member has a contraindication to NSAIDs and colchicine and has a clinical reason to avoid repeated courses of corticosteroids.

III. 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:
A. The member is currently receiving therapy with Ilaris
B. Ilaris is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Ilaris.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. 2020 American College of Rheumatology Guideline for the Management of Gout.

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

V. EXPLANATION OF RATIONALE

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

Support for using Ilaris to treat acute gout flares can be found in the 2020 American College of Rheumatology Guidelines for the Management of Gout. Colchicine, NSAIDs, or glucocorticoids (oral, intraarticular, or intramuscular) are recommended as first-line treatment for gout flares over interleukin-1 (IL-1) inhibitors, including Ilaris. If other antiinflammatory therapies are poorly tolerated or contraindicated, IL-1 inhibitors are suggested. For patients who cannot take drugs orally, glucocorticoids (intramuscular, intravenous, or intraarticular) are recommended over IL-1 inhibitors.

VI. REFERENCES

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2020.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 7, 2022.
3. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care Res (Hoboken).* 2020 Jun;72(6):744-760.