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 in patients who had contraindications for, intolerance to, or unresponsiveness to non-steroid anti-inflammatory drugs (NSAIDS) and/or colchicine

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. Active 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 treatment of acute flares of gouty arthritis in members with an inadequate response to, or a clinical reason to avoid, non-steroidal anti-inflammatory drugs or colchicine.

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 for 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 medication has been effective for treating the diagnosis or condition.

IV. 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 15, 2020.