Ilaris (canakinumab)

**Line(s) of Business:**
HMO; PPO; QUEST Integration
Akamai-Medicare Advantage

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
09/01/2017
04/01/2019

**POLICY**

**A. 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**

Ilaris is an interleukin 1β antibody indicated for the treatment of:

- Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Tumor Necrosis Factor (TNF) 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 Systemic Juvenile Idiopathic Arthritis (sJIA) in patients aged 2 years and older

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:

- For CAPS, initial therapy:
  - Results of molecular genetics testing demonstrating a mutation in the NLRP3 gene (also known as CIAS1) (for FCAS and MWS) and/or a mutation in the NLRP12 gene (for FCAS)
  - In the absence of genetic testing or if no genetic mutation is identified, chart notes or medical record documentation of member’s diagnosis must be submitted.
- For sJIA, initial therapy:
  - Documentation supporting inadequate response, intolerance or contraindication to previous therapy
- For CAPS, TRAPS, HIDS/MKD, FMF, or sJIA, continuation of therapy:
  - Documentation supporting a positive clinical response to therapy with Ilaris (e.g., chart notes, medical records)
C. CRITERIA FOR INITIAL APPROVAL

1. Cryopyrin-Associated Periodic Syndromes (CAPS)
   Authorization for 12 months may be granted when the following criterion is met:
   a. Member has a documented diagnosis of CAPS (including FCAS and MWS)

2. Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome (TRAPS),
   Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), and Familial
   Mediterranean Fever
   Authorization for 12 months may be granted for members with a diagnosis of TRAPS, HIDS/MKD
   or FMF.

3. Systemic Juvenile Idiopathic Arthritis (sJIA)
   Authorization for 12 months may be granted when the following criteria are met:
   a. Member has a diagnosis of active sJIA
   b. Member has experienced an inadequate response to ANY of the following therapies:
      i. At least a 2 week trial of corticosteroids
      ii. At least a 3 month trial of methotrexate
      iii. At least a 3 month trial of leflunomide

D. CONTINUATION OF THERAPY

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior
   authorization) must meet criteria for initial approval in section C.

2. Reauthorization:
   Authorization of an additional 12 months may be granted to members requesting authorization for
   continuation of therapy who are benefiting from Ilaris therapy and were previously authorized by
   HMSA/CVS.
   All members, including new members, requesting authorization for therapy must meet ALL initial
   authorization criteria. Approval for an additional 12 months of therapy may be granted when
   documentation supporting a positive clinical response to Ilaris therapy is provided.

E. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted
   compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not
   intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended
   to discourage or prohibit providing other medical advice or treatment deemed appropriate by the
   treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are
   any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES


