Ilaris (canakinumab)

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

**Effective Dates:**
- **Original Effective Date:** 10/01/2015
- **Current Effective Date:** 09/01/2017

**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 for members who are prescribed Ilaris 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.

2.3 Systemic Juvenile Idiopathic Arthritis (sJIA)
   Authorization for 12 months may be granted for members who are prescribed Ilaris when the following criteria are met:
   a. Member has a diagnosis of active sJIA
   a-b. Member has experienced an inadequate response to ANY of the following therapies:
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
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.

G.H. REFERENCES


**Document History**

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<td>10/01/2015</td>
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<tr>
<td>10/20/2016</td>
<td>Added new indications (TRAPS, HIDS/MKD, FMF)</td>
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<td>11/23/2016</td>
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