Ilaris® (canakinumab)  
(Subcutaneous)  

I. Length of Authorization  
Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits  

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:  
   - Ilaris 150 mg: 2 vials every 28 days

B. Max Units (per dose and over time) [Medical Benefit]:
   
   Cryopyrin-Associated Periodic Syndromes
   - 150 billable units every 8 weeks (56 days)

   Systemic Juvenile Idiopathic Arthritis
   - 300 billable units every 4 weeks (28 days)

   Tumor Necrosis Factor Receptor Associated Periodic Syndrome
   - 300 billable units every 4 weeks (28 days)

   Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency
   - 300 billable units every 4 weeks (28 days)

   Familial Mediterranean Fever
   - 300 billable units every 4 weeks (28 days)

III. Initial Approval Criteria  
Coverage is provided in the following conditions:

   • Patient has been evaluated and screened for the presence of latent TB infection prior to
     initiating treatment; AND

   • Patient does not have an active infection, including clinically important localized infections;
     AND

   • Must not be administered concurrently with live vaccines; AND
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept, etc.): AND
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib): AND

**Cryopyrin-Associated Periodic Syndromes (CAPS) †**
- Patient is over the age of 4: AND
- Must be used as a single agent: AND
- Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA]): AND
- Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3: AND
  - Diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS): OR
  - Diagnosis of Muckle-Wells Syndrome (MWS): AND
- Patient has two or more of any of the CAPS-typical symptoms:
  - urticaria-like rash
  - cold-triggered episodes
  - sensorineural hearing loss
  - musculoskeletal symptoms
  - chronic aseptic meningitis
  - skeletal abnormalities

**Systemic Juvenile Idiopathic Arthritis (sJIA) †**
- Patient is over the age of 2: AND
- Patient has active Systemic Juvenile Idiopathic Arthritis (sJIA): AND
- Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR a systemic glucocorticoid (prednisone, methylprednisolone, etc.): AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool

**Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) †**
- Patient is over the age of 2: AND
- Patient has chronic or recurrent disease (defined as 6 or more flares per year): AND
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

**Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) †**
- Patient is over the age of 2: AND
- Patient has a confirmed diagnosis based on genetic/enzymatic laboratory findings: **AND**
- Patient has a documented prior history of greater than or equal to 3 febrile acute flares within a 6 month period: **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

**Familial Mediterranean Fever (FMF) †**
- Patient is over the age of 2: **AND**
- Patient has failed on colchicine therapy or has a documented allergy or intolerance: **AND**
- Patient has active disease defined as at least one flare per month: **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

† FDA Approved Indication(s)

**IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria in Section III: **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, serious infections (including but not limited to tuberculosis), and macrophage activation syndrome (MAS): **AND**
- Patient is receiving ongoing monitoring for presence of TB or other active infections: **AND**

**Cryopyrin-Associated Periodic Syndromes**
- Disease response as indicated by improvement in patient’s symptoms from baseline **AND** improvement in serum levels of inflammatory proteins (e.g. CRP and/or SAA, etc) from baseline

**Systemic Juvenile Idiopathic Arthritis**
- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables]

**Tumor Necrosis Factor Receptor Associated Periodic Syndrome; Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency; Familial Mediterranean Fever**
- Disease response as indicated by improvement in patient’s symptoms from baseline **AND** improvement of serum levels of CRP.
V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<td>Cryopyrin-Associated Periodic Syndromes</td>
<td>Weight greater than 40 kg</td>
</tr>
<tr>
<td></td>
<td>• 150 mg subcutaneously every 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Weight equal to 15-40 kg</td>
</tr>
<tr>
<td></td>
<td>• 2 mg/kg subcutaneously every 8 weeks. May be increased to 3 mg/kg if</td>
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<tr>
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<td>inadequate response.</td>
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<tr>
<td>Systemic Juvenile Idiopathic Arthritis</td>
<td>Weight is greater than or equal to 7.5 kg</td>
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<tr>
<td></td>
<td>• 4 mg/kg (with a maximum of 300mg) subcutaneously every 4 weeks.</td>
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<td>All other indications</td>
<td>Weight greater than 40 kg</td>
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<tr>
<td></td>
<td>Weight less than or equal to 40 kg</td>
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<td>• 2 mg/kg subcutaneously every 4 weeks. May be increased to 4 mg/kg if</td>
</tr>
<tr>
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<td>inadequate response.</td>
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VI. Billing Code/Availability Information

Jcode:
- J0638 – Injection, canakinumab, 1 mg : 1 billable unit = 1 mg

NDC:
- Ilaris 150 mg single-dose solution vial: 00078-0734-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

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<tr>
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<th>ICD-10 Description</th>
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<td>Periodic fever syndromes</td>
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<tr>
<td>M04.2</td>
<td>Cryopyrin-associated periodic syndromes</td>
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**Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

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<td>Noridian Healthcare Solutions, LLC</td>
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<td>KS, NE, IA, MO</td>
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<td>MN, WI, IL</td>
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### Medicare Part B Administrative Contractor (MAC) Jurisdictions

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<td>M (11)</td>
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<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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