SmartHealth Ascension

Canakinumab

(Ilaris®) J0638 (1mg)

Covered with prior authorization

Canakinumab (Ilaris®) may be authorized when the following criteria are met:

Cryopyrin-Associated Periodic Syndromes (CAPS)

- The medication is being used for treatment of **ONE** of the following:
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  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
  - Neonatal-Onset Multisystem Inflammatory Disease (NOMID) also known as Chronic infantile neurological cutaneous and articular (CINCA) syndrome

  AND
- Medication is being prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist.

Familial Mediterranean Fever (FMF)

- Individual is 2 years of age or older; **AND**
- Prior to starting,the patient meets **BOTH** of the following:
  - C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; **AND**

  EITHER of the following:
  - Active disease despite treatment with colchicine
  - Documentation of contraindication per FDA label, significant intolerance, or is not a candidate for colchicine.

  AND
- Medication is being prescribed by, or in consultation with, a rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, or hematologist.

Hyperimmunoglobulin D Syndrome (HIDS) /Mevalonate Kinase Deficiency (MKD)

- Individual is 2 years of age or older; **AND**
- Prior to starting, the patient meets **BOTH** of the following:
  - C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; **AND**

  EITHER of the following:
  - History of at least three febrile acute flares within the previous 6-month period
  - Individual was hospitalized for a severe flare

  AND

- Medication is being prescribed by, or in consultation with, a rheumatologist, nephrologist, geneticist, oncologist, or hematologist.

Adult Onset Still's Disease (AOSD)

- Individual is 18 years of age or older; **AND**
- Medication is being prescribed by, or in consultation with, a rheumatologist.

Juvenile Idiopathic Arthritis (JIA); previously referred to as Juvenile Rheumatoid Arthritis

- **I**ndividual is 2 years of age or older; **AND**
- Medication is being prescribed by, or in consultation with, a rheumatologist.

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

- Individual is 2 years of age or older; **AND**
- Individual meets **BOTH** of the following:
  - C-reactive protein level is ≥ 10 mg/L, OR elevated to at least two times the upper limit of normal for the reporting laboratory; **AND**

  EITHER of the following:
  - Individual has a history of at least six flares per year
  - Individual was hospitalized for a severe flare

  AND
- Medication is being prescribed by, or in consultation with, a rheumatologist, geneticist, nephrologist, oncologist, or hematologist.

Gout (acute flares):

- Individuals with frequent flares; **AND**
- Failure or intolerance of NSAIDs, colchicine and oral/intravenous corticosteroids **OR**
- Contraindication to first line therapy (NSAIDs and colchicine) and repeated courses of corticosteroids should be clinically avoided

Exclusion criteria:

- Behcet's Disease
- Cardiovascular risk reduction and disorder prevention
- Concurrent biologic therapy
- COVID-19 (Coronavirus Disease 2019)
- Majeed Syndrome
- Rheumatoid Arthritis
- Schnitzler Syndrome
- Diabetes (type 1 and 2)
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Reauthorization approval duration is up to 12 months.

Canakinumab is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Canakinumab (Ilaris®) is an interleukin-1β (IL-1β) antagonist, is indicated for the following autoinflammatory periodic fever syndromes:

- **Cryopyrin-Associated Periodic Syndromes (CAPS)**, including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, for treatment of patients who are ≥ 4 years of age.
- **Familial Mediterranean fever (FMF)**, in adult and pediatric patients age ≧ 2 years of age
- **Hyperimmunoglobulin D syndrome/mevalonate kinase deficiency (HIDS/MKD)**, in adult and pediatric patients age ≧ 2 years of age.
- **Still's disease,** including active **adult-onset Still's disease (AOSD)** and **juvenile idiopathic arthritis (JIA)**, in patients ≥ 2 years of age.
- **Tumor necrosis factor receptor associated periodic syndrome (TRAPS)**, in adult and pediatric patients age ≧ 2 years of age.

References:

1. de Konig HD, et al. Sustained efficacy of the monoclonal anti-interleukin-1 beta antibody canakinumab in a 9-month trial in Schnitzler's syndrome. Ann Rheum Dis. 2013;72:1634-8.
2. Hensen J, Howard CP, Walter V, Thuren T. Impact of interleukin-1β antibody (canakinumab) on glycaemic indicators in patients with type 2 diabetes mellitus: Results of secondary endpoints from a randomized, placebo-controlled trial. Diabetes Metab 2013; 39: 524-31
3. Ilaris® for subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2020.
4. Khanna D, Khanna PP, Fitzgerald JD, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 2: Therapy and Antiinflammatory Prophylaxis of Acute Gouty Arthritis. Arthritis Care Res 2012; 64 (10): 1447–61.
5. Ridker P, Everett B, Thuren T. Antiinflammatory Therapy with Canakinumab for Atherosclerotic Disease. N Engl J Med 2017;377:1119-1131.
6. Rissanen A, Howard CP, Botha J, Thuren T for the Global Investigators. Effect of anti-IL-1β antibody (canakinumab) on insulin secretion rates in impaired glucose tolerance or type 2 diabetes: results of a randomized, placebo-controlled trial. Diabetes Obes Metab 2012; 14: 1088-96.
7. Schlesinger N, Alten RE, Bardin T, et al. Canakinumab for acute gouty arthritis in patients with limited treatment options: results from two randomised, multicentre,

active-controlled, double-blind trials and their initial extensions. Ann Rheum Dis 2012; 71(11):1839-48.
8. Troels H, Bente F, Mette B, et al. Efficacy of anti-IL-1 treatment in Majeed syndrome. Ann Rheum Dis. 2013 Mar; 72(3): 410-413.
9. Vanderschueren S, Knockaert D. Canakinumab in Schnitzler syndrome. Semin Arthritis Rheum. 2013;42:413-6.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.