

Ilaris® (canakinumab)

When requesting Ilaris® (canakinumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Ilaris is indicated for the treatment of:

- Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome
- Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome (TRAPS)
- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
- Familial Mediterranean Fever (FMF)
- Active Systemic Juvenile Idiopathic Arthritis (sJIA) in patients 2 years of age and older
- Adult-onset Still's Disease
- Gout Flares

Coverage Guidelines

The individual must meet **all** the following criteria for initial authorization of select indications:

Cryopyrin-Associated Periodic Syndromes (CAPS)

- Is 4 years of age or older;
- Ilaris is prescribed by or in consultation with a rheumatologist, geneticist, allergist, immunologist, or dermatologist.

Familial Mediterranean Fever (FMF)

- Is 2 years of age or older;
- Has tried colchicine, unless contraindicated;
- Will be taking Ilaris in combination with colchicine, unless colchicine is contraindicated or not tolerated;
- Prior to starting Ilaris, C-reactive protein level is ≥ 10 mg/L OR elevated at least two times the upper limit of normal;
- Has a history of at least one flare per month despite use of colchicine OR has been hospitalized for a severe flare;
- Ilaris is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, or hematologist.

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

- Is 2 years of age or older;
- Prior to starting Ilaris, C-reactive protein level is ≥ 10 mg/L OR elevated at least two times the upper limit of normal;
- Has a history of at least three febrile acute flares within the previous 6-month period OR has been hospitalized for a severe flare;
- Ilaris is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, oncologist, or hematologist.

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

- Is 2 years of age or older;
- Prior to starting Ilaris, C-reactive protein level is ≥ 10 mg/L OR elevated at least two times the upper limit of normal;
- Has a history of at least six flares per year OR has been hospitalized for a severe flare;
- Ilaris is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, oncologist, or hematologist.

Systemic Juvenile Idiopathic Arthritis (sJIA)

- Is 2 years of age or older;
- Ilaris is prescribed by or in consultation with a rheumatologist.

Still's disease, Adult onset

- Is 18 years of age or older;
- Ilaris is prescribed by or in consultation with a rheumatologist.

Note: If the patient is <18 years of age, refer to criteria for systemic juvenile idiopathic arthritis (sJIA)

Gout Flares

- Is 18 years of age or older;
- Meets one of the following:
 - o Has an intolerance, contraindication, or inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine for the treatment of acute gout flares; OR
 - o Has been previously treated with corticosteroids (oral or injectable) for an acute gout flare and is unable to be retreated with a repeat course of corticosteroids;
- Is currently receiving or will be treated with a concomitant urate lowering agent for the prevention of gout unless contraindicated (e.g., allopurinol, febuxostat, probenecid);
- Ilaris is prescribed by or in consultation with a rheumatologist.

The individual must meet **both** the following criteria for reauthorization (all indications except gout flares):

- Has been established on Ilaris therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Ilaris, is reviewed under initial authorization criteria.
- Meets one of the following;

- o Has experienced an improvement in at least one objective measure compared with baseline (e.g., resolution of fever, improvement in rash or skin manifestations, improvement of serum markers [e.g., C-reactive protein, amyloid A], reduction in proteinuria, and/or stabilization of serum creatinine); OR
- o Has experienced an improvement in at least one symptom compared with baseline (e.g., less joint pain/tenderness, stiffness, or swelling, improved function or activities of daily living).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

Cryopyrin-Associated Periodic Syndromes (CAPS)

The recommended dose is 150 mg, for patients with body weight greater than 40 kg, administered subcutaneously every 8 weeks.

The recommended dose is 2 mg/kg, for patients with body weight 15 kg to 40 kg, administered subcutaneously every 8 weeks. For children 15 kg to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg.

Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)

For body weight less than or equal to 40 kg: The recommended dose is 2 mg/kg administered subcutaneously every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.

For body weight greater than 40 kg: The recommended dose is 150 mg administered subcutaneously every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.

Systemic Juvenile Idiopathic Arthritis, Still's disease

The recommended dose with a body weight greater than or equal to 7.5 kg is 4 mg/kg (with a maximum of 300 mg) administered subcutaneously every 4 weeks.

Gout Flares

The recommended dose is 150 mg administered subcutaneously. May retreat at an interval of at least 12 weeks.

References

1. Ilaris® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; November 2024.
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3. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. *Ann Rheum Dis.* 2016;75(4):644-651.

4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in *Arthritis Care Res (Hoboken)*. 2020 Aug;72(8):1187] [published correction appears in *Arthritis Care Res (Hoboken)*. 2021 Mar;73(3):458]. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
5. Kimura Y, Morgan DeWitt E, Beukelman T, et al. Adding Canakinumab to the Childhood Arthritis and Rheumatology Research Alliance Consensus Treatment Plans for Systemic Juvenile Idiopathic Arthritis: comment on the article by DeWitt et al. *Arthritis Care Res (Hoboken)*. 2014;66(9):1430-1431.
6. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. *Arthritis Rheumatol*. 2022 Apr;74(4):553-569.
7. Alten R, Gomez-Reino J, Durez P, et al. Efficacy and safety of the human anti-IL-1 β monoclonal antibody canakinumab in rheumatoid arthritis: results of a 12-week, Phase II, dose-finding study. *BMC Musculoskelet Disord*. 2011;12:153.