

Ilaris® (canakinumab)



When requesting Ilaris® (canakinumab), the individual requiring treatment must be diagnosed with an FDA-approved indication 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), in adults and children 4 years of age and older including:

- Familial Cold-Autoinflammatory Syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

Ilaris is indicated for the treatment of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) in adults and pediatric patients.

Ilaris is indicated for the treatment of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients.

Ilaris is indicated for the treatment of Familial Mediterranean Fever (FMF) in adult and pediatric patients.

Ilaris is indicated for the treatment of active systemic Juvenile Idiopathic Arthritis (sJIA) in patients aged 2 years and older.

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

For all indications, the individual must meet **all** of the following criteria for approval:

- Does not have active or chronic infection
- Ilaris (canakinumab) will not be given in combination with tumor necrosis factor (TNF) – inhibitor (e.g., adalimumab, etanercept, golimumab, infliximab)

Cryopyrin-Associated Periodic Syndromes (CAPS):

- Must have either one of the following CAPS subtype: Familial Cold Auto-inflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)

Systemic Juvenile Idiopathic Arthritis (sJIA):

- For re-authorization request, member's condition has improved or stabilized with Ilaris therapy
- For an initial authorization request:
 - o Has an inadequate response or intolerance to prior biologic agent OR

- o Has an active systemic features (e.g., fever, evanescent erythematous rash, hepatomegaly, splenomegaly, or serositis) and had an inadequate response to corticosteroids OR
- o Had an inadequate response or intolerance to methotrexate or leflunomide unless contraindicated in an individual with no active systemic features

Approval duration (initial and 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 and 2 mg/kg for patients with body weight 15 to 40 kg administered subcutaneously every 8 weeks. The dose can be increased to 3 mg/kg in patients 15 to 40 kg with an inadequate response.

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 starting dose is 2 mg/kg 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 starting dose is 150 mg 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:

The recommended dose is 4 mg/kg, with a maximum of 300 mg, for patients with a body weight greater than or equal to 7.5 kg every 4 weeks.

References

1. Ilaris prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. December 2016.
2. Yu JR, Leslie KS. Cryopyrin-Associated Periodic Syndrome: An Update on Diagnosis and Treatment Response. *Curr Allergy Asthma Rep.* 2011(11):12-20.
3. American College of Rheumatology. Cryopyrin-Associated Autoinflammatory Syndromes. Available at: <https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Cryopyrin-Associated-Autoinflammatory-Syndrome-CAPS-Juvenile>.
4. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. *Arthritis & Rheumatism.* 2013;65:2499-2512.