

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 patients 4 years of age and older
- 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.

Coverage Guidelines

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

Cryopyrin-Associated Periodic Syndromes (CAPS)

- An individual is 4 years of age or older; **AND**
- Ilaris is prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist.

Familial Mediterranean Fever (FMF)

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

Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) OR Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

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

Systemic Juvenile Idiopathic Arthritis (sJIA)

- An individual is 2 years of age or older; **AND**
- Ilaris is prescribed by or in consultation with a rheumatologist; **AND**
- An individual meets one of the following conditions:
 - Has tried at least 2 other biologic agents (e.g., tocilizumab, Kineret, abatacept, etanercept, adalimumab, infliximab); **OR**

- o Has features of poor prognosis (e.g., arthritis of the hip, radiographic damage, active systemic disease such as fever, elevated inflammatory markers) and has tried Actemra or Kineret; **OR**
- o Has active systemic features with concerns of progression to macrophage activation syndrome (MAS) and has tried Kineret.

The individual must meet the following criteria for reauthorization (all indications):

- An individual is responding to Ilaris therapy.

Approval duration (initial): 3 months (*applies to CAPS and sJIA*)

Approval duration (initial): 4 months (*applies to FMF, TRAPS, and HIDS/MKD*)

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 and 2 mg/kg for patients with body weight 15 to 40 kg administered subcutaneously every 8 weeks.

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 administered subcutaneously every 4 weeks. The dose may be increased to 4 mg/kg every 4 weeks if the clinical response is inadequate.

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 inadequate.

Systemic Juvenile Idiopathic Arthritis:

The recommended dose is 4 mg/kg, for patients 2 years of age or older with body weight 7.5 kg or greater, administered subcutaneously every 4 weeks. The maximum dosage is 300mg per dose.

References

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