

**Prior Authorization Criteria**

**Drug: Ilaris (canakinumab)**

**P&T Reviewed: 9/09, 9/10**

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**Description:**

Canakinumab is a recombinant, human anti-human-IL-1 $\beta$  monoclonal antibody that belongs to the IgG1/ $\kappa$  isotype subclass. Canakinumab blocks the activity of interleukin-1 (IL-1), a protein involved in inflammation.

**FDA Labeled indications:**

Ilaris (canakinumab) is an interleukin-1 $\beta$  blocker 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)

**Criteria:**

ConnectiCare considers Ilaris (canakinumab) to be medically necessary in patients with cryopyrin-associated periodic syndromes (CAPS) who meet all of the following criteria:

1. Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1- sometimes referred to as the NLRP3).
2. There is clinical documentation that the patient is experiencing classic symptoms of CAPS in either criteria below:
  - a. Familial Cold Auto-Inflammatory Syndrome (FCAS)- recurrent episodes of rash, fever/chills, and joint pain following exposure to mild cold environment. (e.g. cool breeze, air conditioning) Symptoms generally last for up to 24 hours.
  - b. Muckle-Wells Syndrome (MWS)- Chronic fever and rash sometimes exacerbated by generalized cold exposure. Episodes can last up to 2-3 days.
3. There is clinical documentation of significant functional impairment leading to limitations of activities of daily living (ADLs).

**Dosing:**

The recommended dose of Ilaris is 150 mg for CAPS patients with body weight greater than 40 kg. For CAPS patients with body weight between 15 kg and 40 kg, the recommended dose is 2 mg/kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg.

Ilaris is administered every 8 weeks as a single dose via subcutaneous injection.

**Prior Authorization and Limitations:**

- Initial approval for 1 month
- Subsequent approval (up to 1 year) will be based on current progress notes from the physician documenting disease stability and improvement.

**The above criteria is based on the following reference(s):**

1. Ilaris full prescribing information. East Hanover, NJ. Novartis Pharmaceuticals. June 2009.