PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ilaris (canakinumab)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ilaris is an interleukin-1β blocker that was initially approved by the FDA in 2009. It is indicated for the treatment of certain autoinflammatory Periodic Fever Syndromes (CAPS, TRAPS, FMF, HIDS/MKD), Active Still's Disease (Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA]), and gout flares. Ilaris binds to IL-1β and neutralizes its activity by blocking its interaction with IL-1 receptors, but it does not bind IL-1α or IL-1 receptor antagonist (IL-1ra).
Cryopyrin-Associated Periodic Syndrome (CAPS) refer to rare genetic syndromes generally caused by mutations in the NLRP-3 gene (also known as CIAS1). The NLRP-3 gene encodes the protein cryopyrin, an important component of the inflammasome. Cryopyrin controls the activation of IL-1β. Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1β that drives inflammation.
Still's disease is a severe autoinflammatory disease, driven by innate immunity by means of proinflammatory cytokines such as IL-1β. AOSD and SJIA are thought to represent a continuum of the same disease entity.

Ilaris (canakinumab)

4. **Dosage allowed/Quantity limit:** Body weight ≤ 40 kg: 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. Body weight > 40 kg: 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.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing response to therapy such as reduced severity and/or frequency of flares.

If all the above requirements are met, the medication will be approved for an additional 12 months.

> 40 kg: 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.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing response to therapy such as reduced severity and/or frequency of flares.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Gout Flare

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a diagnosis of gout with documentation of at least 3 flares in the past year; AND
4. Member has documentation of trial and failure of ALL 3 of the following:
   a) Non-steroidal anti-inflammatory drugs (NSAIDs)
   b) Colchicine
   c) Corticosteroids; AND
5. Member has a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:**