

<b>Clinical Policy Title:</b>	Ilaris (canakinumab)
<b>Policy Number:</b>	RxA.911
<b>Drug(s) Applied:</b>	Ilaris (canakinumab)
<b>Original Policy Date:</b>	11/1/2025
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	Amazon Business Only

## Criteria

### I. Initial Approval Criteria

#### A. Adult-Onset Still's Disease (AOSD) (must meet all):

1. Diagnosis of Adult-Onset Still's Disease (AOSD);
2. Patient has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

#### B. Systemic Juvenile Idiopathic Arthritis (SJIA) (must meet all):

1. Diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA);
2. Trial and failure of at least one conventional systemic therapy (methotrexate, leflunomide), unless contraindicated or clinically significant adverse effects are experienced.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

#### C. Gout Flares (must meet all):

1. Diagnosis of Gout Flares;
2. Patient has experienced at least 3 gout flares in the last 12 months;
3. Both of the following (i AND ii):
  - i. Non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerate, or do not provide an adequate response;
  - ii. Repeated courses of corticosteroids are not appropriate.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

#### D. Periodic Fever Syndromes (must meet all):

1. Diagnosis of Periodic Fever Syndromes;
2. Patient has documented evidence of one of the following (i, ii, iii or iv):
  - i. Cryopyrin-associated periodic syndromes (CAPS) including:
    1. Familial Cold Autoinflammatory Syndrome (FCAS);

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- 2. Muckle-Wells Syndrome (MWS);
  - ii. Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome (TRAPS);
  - iii. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD);
  - iv. Familial Mediterranean Fever (FMF).

**Approval duration**

**All Lines of Business (except Medicare):** 12 months

**II. Continued Therapy Approval**

**A. All Indications:**

- 1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy

**Approval duration**

**All Lines of Business (except Medicare):** 12 months

**References**

- 1. Ilaris [package insert]. East Hanover, New Jersey; Novartis Pharmaceuticals Corporation; November 2024; Accessed September 2025.
- 2. Onel KB, Horton DB, 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 & Rheumatology*. 2022;74(4):553-569. Cited in Clarivate, Incidence & Prevalence Database, <https://www.tdrdata.com>; Accessed March 5, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Approved by P&T Committee	9/4/2025	10/9/2025
Policy reviewed	12/11/2025	12/11/2025