

canakinumab (Ilaris)**Medical Benefit Drug Policy**Place of Service

Home Infusion

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details**USP Category:** IMMUNOLOGICAL AGENTS**Mechanism of Action:** interleukin-1 beta blocker monoclonal antibody**HCPCS:**

J0638:Injection, canakinumab, 1 mg

How Supplied:

150 mg/mL solution (single-dose vials)

Condition(s) listed in policy *(see coverage criteria for details)*

- Adult-Onset Still's Disease (AOSD) or Systemic Juvenile Idiopathic Arthritis (SJIA)
- Cryopyrin-Associated Periodic Syndromes (CAPS)
- Familial Mediterranean Fever (FMF), Hyperimmunoglobulin D Syndrome (HIDS), Mevalonate Kinase Deficiency (MKD), OR Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
- Gout Flares

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Adult-Onset Still's Disease (AOSD) or Systemic Juvenile Idiopathic Arthritis (SJIA)****Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a rheumatologist
2. Age is consistent with the FDA approved indication (2 years and older)

Covered Doses:

Up to 4 mg/kg (up to max of 300 mg) given subcutaneously every 4 weeks for patients with a body weight ≥ 7.5 kg

Coverage Period:

Initial: 12 weeks

Reauthorization: Yearly, based on continued response

ICD-10:

M06.1, M08.20, M08.21, M08.22, M08.23, M08.24, M08.25, M08.26, M08.27, M08.28, M08.29

Cryopyrin-Associated Periodic Syndromes (CAPS)**Meets medical necessity if all the following are met:**

1. Diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
2. Age is consistent with the FDA approved indication (4 years and older)

Covered Doses:

Weight ≥ 15 kg to ≤ 40 kg: Up to 3 mg/kg given subcutaneously every 8 weeks

Weight > 40 kg: Up to 150 mg given subcutaneously every 8 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

M04.2

Familial Mediterranean Fever (FMF), Hyperimmunoglobulin D Syndrome (HIDS), Mevalonate Kinase Deficiency (MKD), OR Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**Meets medical necessity if all the following are met:****Covered Doses:**

≤ 40 kg: up to 4 mg/kg given subcutaneously every 4 weeks

> 40 kg up to 300 mg given subcutaneously every 4 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

M04.1

Gout Flares**Meets medical necessity if all the following are met:**

1. Age is consistent with the FDA approved indication (18 years and older)
2. Patient had ≥ 3 gout flares in the past year
3. Inadequate response, intolerance, or contraindication to all of the following:
 - a. NSAIDs
 - b. Colchicine
 - c. Corticosteroids

Covered Doses:

Up to 150 mg given subcutaneously every 12 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

M10

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care Res* 2020; 72:744-760.
4. Ilaris (canakinumab) Prescribing Information. Novartis Pharmaceuticals Corporation, East Hanover, NJ: 11/2024.
5. Onel KB, Horton DB, Lovell DJ, 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 Rheumatol*. 2022;74(4):553-569.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*