canakinumab (Ilaris)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF ILARIS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first infusion of Ilaris or is being re-initiated on Ilaris after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Ilaris based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Ilaris based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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

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

The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.

Familial Mediterranean Fever (FMF), Hyperimmunoglobulin D Syndrome (HIDS), Mevalonate Kinase Deficiency (MKD), OR Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

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

ICD-10:
M04.1

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