Drug Coverage Policy

Effective Date.....05/01/2026
Coverage Policy Number.....IP0235
Policy Title.....Ilaris Prior Authorization Policy

Inflammatory Conditions – Ilaris Prior Authorization Policy

- Ilaris® (canakinumab subcutaneous injection – Novartis)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Ilaris, an interleukin-1β (IL-1β) blocker, is indicated for the following uses:[1]

- **Periodic Fever Syndromes:**
  - Cryopyrin-associated periodic syndromes (CAPS), including familial cold auto-inflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS), for treatment of patients ≥ 4 years of age.
  - **Familial Mediterranean fever** (FMF), in adult and pediatric patients.
  - **Hyperimmunoglobulin D syndrome** (HIDS)**/mevalonate kinase deficiency** (MKD), in adult and pediatric patients.
  - **Tumor necrosis factor receptor associated periodic syndrome** (TRAPS), in adult and pediatric patients.
- **Active Still's disease**, including active **adult-onset Still's disease** (AOSD) and **systemic juvenile idiopathic arthritis** (SJIA), in patients ≥ 2 years of age.
- **Gout flares** in adults in whom nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

In the pivotal trial for periodic fevers (TRAPS, HIDS/MKD, and FMF), patients were required to be at least 2 years of age with a disease flare, defined as a C-reactive protein level ≥ 10 mg/L.[1] Prior to starting Ilaris, a minimum level of disease activity at baseline was required for FMF (at least one flare per month despite colchicine), HIDS/MKD (≥ three febrile acute flares within the previous 6 month period), and TRAPS (≥ six flares per year). In this study, patients were assessed for a response following 4 months of treatment with Ilaris.

Dosing Information for CAPS

The FDA-approved dose of Ilaris for the treatment of CAPS is weight based and administered subcutaneously every 8 weeks.[1] However, the European Alliance of Associations for Rheumatology (EULAR) and American College of Rheumatology (ACR) guidelines for IL-1 mediated autoinflammatory diseases (2021) include recommendations for the management of CAPS, TRAPS, MKD, and deficiency of IL-1 receptor antagonist (DIRA) and recognize the FDA approved dosing may be insufficient for some patients with more severe disease phenotypes or incomplete clinical response.[2] The guidelines indicate that higher and more frequent dosing than that approved by the FDA of Ilaris may be required to control disease activity in more severe cases and/or younger children to prevent complications. Patients with CAPS may require doses of Ilaris up to 600 mg SC every 4 weeks if the patient has not achieved remission.

Guidelines

Ilaris is used for treatment of a variety of periodic fever syndromes and inflammatory conditions.

CAPS, HIDS/MKD, and TRAPS

EULAR and ACR (2021) provide treatment guidelines for interleukin-1 (IL-1) mediated autoinflammatory diseases: cryopyrin-associated periodic syndromes, tumor necrosis factor receptor-associated periodic syndrome, mevalonate kinase deficiency, and deficiency of the IL-1 receptor antagonist.[2] Guidelines indicate IL-blocking therapy has become the preferred treatment and a therapeutic trial with IL-1 blocking treatment may be started when strong clinical suspicion of a diagnosis of CAPS, TRAPS, MKD, or DIRA is suspected.[2] The guidelines also provide additional diagnosis-specific treatment recommendations:

- **CAPS:** CAPS encompasses three rare genetic syndromes (familial cold autoinflammatory syndrome, Muckle-Wells syndrome, and neonatal onset multisystem inflammatory disease formerly known as chronic infantile neurological cutaneous and articular syndrome) that are thought to be one condition along a spectrum of disease severity.[2] IL-1 blockers are recommended as standard of care across the spectrum of disease for improved symptom control and reduced systemic and tissue/organ inflammation. The dose and/or frequency

of administration should be adjusted to control disease activity, normalize markers of systemic inflammation, and support appropriate weight gain and development in the growing patient.

- **HIDS/MKD**: In patients without chronic inflammation, on demand IL-1 blockage should be attempted at the onset of flares. In children, IL-1 blocking therapy is generally required.[2]
- **TRAPS:** IL-1 blockers are more effective than traditional disease-modifying antirheumatic drugs (DMARDs) and other biologic DMARDs in achieving disease remission and preventing long-term complications.[2]

FMF
Guidelines for Familial Mediterranean fever from EULAR (2024 update) and Pediatric Rheumatology European Society (PReS) indicate colchicine should be initiated as soon as a clinical diagnosis of FMF is made and is considered lifelong prophylaxis, with adherence emphasized as a cornerstone of management.[3] If an adherent patient has an inadequate response despite the maximum tolerated colchicine dose, guidelines recommend adding biologic therapy, with the highest level of evidence supporting IL-1–targeting agents.

Gout
Guidelines for the management of gout flares from the ACR (2020) recommend colchicine, NSAIDs, or glucocorticoids (oral, intraarticular, or intramuscular) as appropriate first-line therapy.[4] If a patient is unable to tolerate or has contraindications to any of the first line conventional alternatives, IL-1 inhibitors are conditionally recommended.

Still's disease (SJIA and AOSD)
The EULAR and PReS joint clinical guidelines for management of Still's disease (2024) indicate SJIA and AOSD are the same disease, differing in age of onset, and can be referred to collectively as Still's disease.[5] Guidelines recommend an IL-1 or IL-6 inhibitor be initiated as early as possible after diagnosis. No preferred agent is provided.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Ilaris. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ilaris, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ilaris to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information.

Ilaris is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, or 7):

FDA-Approved Indications

1. **Cryopyrin-Associated Periodic Syndromes (CAPS).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: This includes familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and neonatal onset multisystem inflammatory disease (NOMID) formerly known as chronic infantile neurological cutaneous and articular syndrome (CINCA).
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i, ii, and iii):
     - **i.** Patient is ≥ 4 years of age; AND
     - **ii.** The patient has a confirmed diagnosis of Cryopyrin-Associated Periodic Syndromes **[documentation required]**; AND
     - **iii.** The medication is prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist; OR
   - **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on this medication for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least ONE of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
         Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, amyloid A), reduction in proteinuria, and/or stabilization of serum creatinine.
       - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom.
         Note: Examples of improvement in symptoms include fewer cold-induced attacks; less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

   Dosing. Approve one of the following dosing regimens (A or B):
   - **A)** Patient is ≥ 15 kg and ≤ 40 kg: Approve up to 8 mg/kg per dose administered subcutaneously no more frequently than once every 4 weeks; OR
   - **B)** Patient is > 40 kg: Approve up to 600 mg per dose administered subcutaneously no more frequently than once every 4 weeks.

2. **Familial Mediterranean Fever (FMF).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 2 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b)
       - **a)** Patient meets BOTH of the following [(1) and (2)]
         - **(1)** Patient has tried colchicine at the maximum tolerated dose; AND
         - **(2)** Patient will be taking the requested medication in combination with colchicine; OR
       - **b)** According to the prescriber, colchicine is contraindicated or not tolerated; AND
     - **iii.** Prior to starting the medication, the patient meets BOTH of the following (a and b):

a) C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
b) Patient has a history of at least one flare per month despite use of colchicine, OR was hospitalized for a severe flare; AND

iv. The medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, or hematologist; OR

B) Patient is Currently Receiving Ilaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on this medication for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include decreased frequency of attacks, resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, amyloid A), reduction in proteinuria, and/or stabilization of serum creatinine.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom.
Note: Examples of improvement in symptoms include decreased pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve one of the following dosing regimens (A or B):

A) Patient is ≤ 40 kg: Approve up to 4 mg/kg per dose administered subcutaneously no more frequently than once every 4 weeks; OR

B) Patient is > 40 kg: Approve up to 300 mg per dose administered subcutaneously no more frequently than once every 4 weeks.

3. Gout, Acute Flare. Approve for 6 months if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. Patient meets BOTH of the following (a and b):

a) Patient has an intolerance, contraindication, or lack of response to nonsteroidal anti-inflammatory drugs (NSAIDs) for the treatment of acute gout flares; AND

b) Patient has an intolerance, contraindication, or lack of response to colchicine for the treatment of acute gout flares; OR

ii. Patient meets BOTH of the following (a and b):

a) Patient has been previously treated with corticosteroids (oral or injectable) for an acute gout flare; AND

b) According to the prescriber, patient is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flares; AND

C) According to the prescriber, patient is receiving or will be taking concomitant urate lowering medication for the prevention of gout unless contraindicated; AND
Note: Examples of uric acid lowering drugs include allopurinol, febuxostat, or probenecid.

D) The medication is prescribed by or in consultation with a rheumatologist.

Dosing. Approve up to 150 mg administered subcutaneously no more frequently than once every 12 weeks.

4. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD).
Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient is ≥ 2 years of age; AND
- **ii.** Prior to starting Ilaris, the patient meets BOTH of the following (a and b):
  - **a)** C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
  - **b)** Patient has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare; AND
- **iii.** The medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, oncologist, or hematologist; OR

B) Patient is Currently Receiving Ilaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on this medication for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).
- **ii.** Patient meets at least ONE of the following (a or b):
  - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
    Note: Examples of objective measures include decreased frequency of attacks, resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, amyloid A), reduction in proteinuria, and/or stabilization of serum creatinine.
  - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom.
    Note: Examples of improvement in symptoms include decreased pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve one of the following dosing regimens (A or B):

A) Patient is ≤ 40 kg: Approve up to 4 mg/kg per dose administered subcutaneously no more frequently than once every 4 weeks; OR

B) Patient is > 40 kg: Approve up to 300 mg per dose administered subcutaneously no more frequently than once every 4 weeks.

5. Stills Disease, Adult Onset. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) are considered the same disease (Still's disease) but differ in age of onset. For a patient < 18 years of age, refer to the SIJA indication below.

A) Initial Therapy. Approve for 6 months (which is adequate for three doses) if the patient meets BOTH of the following (i and ii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient is Currently Receiving Ilaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on this medication for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).
- **ii.** Patient meets at least ONE of the following (a or b):
  - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR

Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom.
Note: Examples of improvement in symptoms include less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve up to 4 mg/kg to a maximum of 300 mg per dose administered subcutaneously no more frequently than once every 4 weeks.

6. **Systemic Juvenile Idiopathic Arthritis (SJIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Systemic juvenile idiopathic arthritis (SJIA) and adult-onset Still's disease (AOSD) are considered the same disease (Still's disease) but differ in age of onset. For a patient ≥ 18 years of age, refer to AOSD indication above.
   A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i, and ii):
      i. Patient is ≥ 2 years of age; AND
      ii. The medication is prescribed by or in consultation with a rheumatologist.
   B) Patient is Currently Receiving Ilaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):
      i. Patient has been established on this medication for at least 6 months; AND
      Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).
      ii. Patient meets at least ONE of the following (a or b):
         a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
         Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
         b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom.
         Note: Examples of improvement in symptoms include less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

   Dosing. Approve up to 4 mg/kg to a maximum of 300 mg per dose administered subcutaneously no more frequently than once every 4 weeks.

7. **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
      i. Patient is ≥ 2 years of age; AND
      ii. Prior to starting the medication, the patient meets BOTH of the following (a and b):
         a) C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
         b) Patient has a history of at least six flares per year OR was hospitalized for a severe flare; AND

iii. The medication is prescribed by or in consultation with a rheumatologist, geneticist, nephrologist, oncologist, or hematologist; OR

B) Patient is Currently Receiving Ilaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on this medication for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include decreased frequency of attacks, resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, amyloid A), reduction in proteinuria, and/or stabilization of serum creatinine.

b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom.
Note: Examples of improvements in symptoms include such as decreased pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve one of the following dosing regimens (A or B):

A) Patient is ≤ 40 kg: Approve up to 4 mg/kg per dose administered subcutaneously no more frequently than once every 4 weeks; OR

B) Patient is > 40 kg: Approve up to 300 mg per dose administered subcutaneously no more frequently than once every 4 weeks.

Conditions Not Covered

Ilaris for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Biologic Therapy.** Ilaris has not been evaluated and should not be administered in combination with another biologic agent for an inflammatory condition (see Appendix for examples).[1] An increased incidence of serious infections has been associated with another IL-1 blocker, Kineret, when given in combination with tumor necrosis factor inhibitor in patients with rheumatoid arthritis. Concomitant administration of Ilaris and other agents that block IL-1 or its receptors is not recommended.

2. **Rheumatoid Arthritis.** Efficacy is not established. In a 12-week, Phase II, placebo-controlled, double-blind study, 277 patients who had failed methotrexate were randomized to Ilaris or placebo.[7] Although the ACR 50 at Week 12 was higher for Ilaris 150 mg (given every 4 weeks) compared with placebo (26.5% vs. 11.4%, respectively; P = not significant), there was not a statistically significant difference in ACR 50 for the other Ilaris treatment groups (Ilaris 300 mg every 2 weeks; Ilaris 600 mg loading dose followed by 300 mg every 2 weeks).

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0638	Injection, canakinumab, 1 mg

References

1. Ilaris® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; June 2025.
2. Romano M, Arici ZS, Piskin D, et al. The 2021 EULAR/American College of Rheumatology points to consider for diagnosis, management and monitoring of the interleukin-1 mediated autoinflammatory diseases: cryopyrin-associated periodic syndromes, tumour necrosis factor receptor-associated periodic syndrome, mevalonate kinase deficiency, and deficiency of the interleukin-1 receptor antagonist. *Ann Rheum Dis*. 2022;81(7):907-921.
3. Ozen S, Sağ E, Oton T, et al. EULAR/PReS endorsed recommendations for the management of familial Mediterranean fever (FMF): 2024 update. *Ann Rheum Dis*. 2025;84(6):899-909.
4. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in Arthritis Care Res (Hoboken). 2020 Aug;72(8):1187] [published correction appears in Arthritis Care Res (Hoboken). 2021 Mar;73(3):458]. *Arthritis Care Res* (Hoboken). 2020;72(6):744-760.
5. Fautrel B, Mitrovic S, De Matteis A, et al. EULAR/PReS recommendations for the diagnosis and management of Still's disease, comprising systemic juvenile idiopathic arthritis and adult-onset Still's disease. *Ann Rheum Dis*. 2024;83(12):1614-1627.
6. 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 Apr;74(4):553-569.
7. Alten R, Gomez-Reino J, Durez P, et al. Efficacy and safety of the human anti-IL-1β monoclonal antibody canakinumab in rheumatoid arthritis: results of a 12-week, Phase II, dose-finding study. *BMC Musculoskelet Disord.* 2011;12:153.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Updated policy title, previously was Canakinumab **For All Indications:** Added clarification throughout the policy for all indications that for a Patient Currently Receiving Ilaris. "Patient has been established on this medication for at least 6 months; Note: For a patient who has not received 6 months of therapy or who is restarting therapy with this medication, refer to Initial Therapy criteria" **Cryopyrin-Associated Periodic Syndromes (CAPS)** - Added patient is ≥ 4 years of age	7/1/2024

	Stills Disease, Adult Onset and Systemic Juvenile Idiopathic Arthritis (SJIA) - Added requirements for ONE of the following: trial of ONE other biologic; OR patient was started on Ilaris in the hospital. **Conditions Not Covered:** Removed Behcet's Disease, Cardiovascular risk reduction and disorder prevention, Majeed Syndrome, Schnitzler Syndrome, Type 1 or 2 Diabetes. All continue to be considered experimental, investigational, or unproven. This was list maintenance and does not imply any updates to coverage status.	
Selected Revision	Updated policy title from "Inflammatory Conditions – Ilaris" to "Inflammatory Conditions – Ilaris Prior Authorization Policy" Added "Policy Statement"	11/01/2024
Annual Revision	**Cryopyrin-Associated Periodic Syndromes:** The dosing requirement for a patient ≥ 15 kg and ≤ 40 mg was increased from 3 mg/kg every 8 weeks to allow up to 8 mg/kg every 4 weeks and for a patient > 40 kg from 150 mg every 8 weeks to allow up to 600 mg every 4 weeks. **Still's Disease, Adult-Onset**: The following Note was added "Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) are considered the same disease (Still's disease) but differ in age of onset. For a patient < 18 years of age, refer to the SIJA indication below." **Systemic Juvenile Idiopathic Arthritis**: The following Note was added "Systemic juvenile idiopathic arthritis (SJIA) and adult-onset Still's disease (AOSD) are considered the same disease (Still's disease) but differ in age of onset. For a patient ≥ 18 years of age, refer to AOSD indication above." Updated Appendix.	05/01/2025
Selected Revision	**COVID-19 (Coronavirus Disease 2019):** Removed from Conditions Not Covered.	06/01/2025
Selected Revision	**Still's Disease, Adult Onset** and **Systemic Juvenile Idiopathic Arthritis:** For initial therapy, the requirement that the patient has tried one other biologic was removed.	07/15/2025
Annual Revision	**Cryopyrin-Associated Periodic Syndromes (CAPS).** Added The patient has a confirmed diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) with documentation requirements.	05/01/2026

	Familial Mediterranean Fever: The requirement that patient has tried "colchicine unless contraindicated" was separated and clarified that patient has tried colchicine at the "maximum tolerated dose". Throughout the policy, the following Note was updated from "For a patient who has not received 6 months of therapy or who is restarting therapy with this medication, refer to Initial Therapy criteria above." to "A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy)."	

The policy effective date is in force until updated or retired.

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA

Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO, AS, nr-axSpA, PsA
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; HS – Hidradenitis suppurativa; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug.