Mass General Brigham
Health Plan

Ilaris (canakinumab)
Effective 5/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

FDA-Approved Indications

1. Periodic Fever Syndromes:
   a. Cryopyrin-Associated Periodic Syndromes (CAPS)
      - Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).

   b. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
      - Treatment of TRAPS in adult and pediatric patients.

   c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
      - Treatment of HIDS and MKD in adult and pediatric patients.

   d. Familial Mediterranean Fever (FMF)
      - Treatment of FMF in adult and pediatric patients.
2. Still's disease (Adult-onset Still's Disease [AOSD] and systemic Juvenile Idiopathic Arthritis [sJIA]):
   - Treatment of active Still's disease, including AOSD and sJIA in patients aged 2 years and older.
3. Gout flares
   - Treatment of gout flares in adults in whom non-steroidal anti-inflammatory drugs and colchicine are contraindicated, are not tolerated, or do not provide adequate response, and in whom repeated courses of corticosteroids are not appropriate.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following diagnosis-specific criteria are met:

A. Periodic fever syndromes

1. **Cryoprin-Association Periodic Syndromes (CAPS)** ALL of the following criteria are met:
   a. Diagnosis of Cryoprin-Associated Periodic Syndromes (CAPS)
   b. Member is 4 years of age or older

c. ONE of the following:
    a. Member has a diagnosis of familial cold autoinflammatory syndrome (FCAS) with classic signs and symptoms (i.e., recurrent, intermittent fever and rash that were often exacerbated by exposure to generalized cool ambient temperature)
    b. Muckle-Wells syndrome (MWS) with classic signs and symptoms (i.e., chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature).
d. Member has functional impairment limiting the activities of daily living.
e. Requested medication is prescribed by or in consultation with a rheumatologist or immunologist.

2. **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**
ALL of the following criteria are met:
a. Diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
b. Submission of medical records (e.g., chart notes) documenting BOTH of the following:
    a. Chronic or recurrent disease activity with active flares within the last 6 months
    b. ONE of the following:
        i. Physician's Global Assessment (PGA) score greater than or equal to 2
        ii. C-reactive protein (CRP) greater than 10 mg/L
c. Requested medication is prescribed by or in consultation with a rheumatologist or immunologist.

3. **Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency (HIDS/MKD)**
ALL of the following criteria are met:
a. Diagnosis of Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency (HIDS/MKD)
b. Submission of medical records (e.g., chart notes) documenting BOTH of the following:
    a. Member has had active flares within the last 6 months
    b. ONE of the following:
        i. Physician's Global Assessment (PGA) score greater than or equal to 2
        ii. C-reactive protein (CRP) greater than 10 mg/L
c. Requested medication is prescribed by or in consultation with a rheumatologist or immunologist.

4. **Familial Mediterranean Fever (FMF)**
ALL of the following criteria are met:
    a. Diagnosis of Familial Mediterranean Fever (FMF)
    b. Submission of medical records (e.g., chart notes) documenting BOTH of the following:
        i. Member has active disease with flares within the last 6 months
    c. C-reactive protein (CRP) greater than 10 mg/L Submission of medical records (e.g., chart notes) or claims history supporting trial and failure, contraindication, or intolerance to colchicine, including response to therapy (if applicable). If therapy is not advisable, documentation of clinical reason to avoid therapy
    d. Requested medication is prescribed by or in consultation with a rheumatologist or immunologist.

B. Systemic juvenile idiopathic arthritis (sJIA)

1. Diagnosis of active systemic juvenile idiopathic arthritis (sJIA)
2. Member is 2 years of age or older
3. ONE the of following:
    a. Submission of medical records (e.g., chart notes) documenting member previously received a biologic indicated for active systemic juvenile idiopathic arthritis, including response to therapy (if applicable)
    b. BOTH of the following:
        i. Member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).
        ii. Member has had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids with chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
4. The medication must be prescribed by or in consultation with a rheumatologist.

C. Adult-onset Still's disease (AOSD)

1. Authorization may be granted for adult members who have previously received a biologic indicated for active AOSD.

2. Authorization may be granted for adult members for treatment of active AOSD when both of the following criteria are met:
    a. Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
    b. Member meets any of the following:
        i. Member has had an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs).
        ii. Member has had an inadequate response to a trial of corticosteroids.
        iii. Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).
3. The medication must be prescribed by or in consultation with a rheumatologist.

D. Management of gout and pseudogout flares

Authorization may be granted for the management of flares for gout or pseudogout (also known as calcium pyrophosphate deposition disease) when the following criteria is met:

1. Member has had an inadequate response or intolerance to maximum tolerated doses of non-steroidal anti-inflammatory drugs (NSAIDs), colchicine and oral and injectable corticosteroids.
2. Member has a contraindication to NSAIDs and colchicine and has a clinical reason to avoid repeated courses of corticosteroids.
3. Submission of chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy OR if therapy is not advisable, documentation of clinical reason to avoid therapy.

4. The medication must be prescribed by or in consultation with a rheumatologist.

Continuation of Therapy

A. Systemic juvenile idiopathic arthritis (sJIA)

Authorization may be granted for all members 2 years of age or older (including new members) who are using the requested medication for sJIA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability
4. Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

B. Adult-onset Still's disease (AOSD)

Authorization may be granted for all adult members (including new members) who are using the requested medication for AOSD and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability
4. Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

C. Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)

1. Member is 4 years of age or older (including new members)
2. Member demonstrates a positive clinical response to therapy, as evidenced by low disease activity or improvement in signs and symptoms of the condition.

D. All other diagnoses

Authorization may be granted for all members (including new members) who are using the requested medication for an indication outlined in Section IV and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

3. Initial approvals for the management of gout and pseudogout will be granted for 6 months.
4. Initial approvals for all other indications will be granted for 12 months.
5. Reauthorizations will be approved for 12 months.
6. For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

References

1. De Benedetti F, Gattorno M, Anton J, et al; Canakinumab for the treatment of autoinflammatory recurrent fever syndromes. N Engl J Med. 2018;378:1908-19.Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al; Canakinumab in CAPS Study Group. Use of canakinumab in the cryopyrin-associated periodic syndrome. *N Engl J Med*. 2009;360(23):2416-2425.
2. Efthimiou P, Kontzias A, Hur P, et al. Adult-onset Still's disease in focus: Clinical manifestations, diagnosis, treatment, and unmet needs in the era of targeted therapies. *Semin Arthritis Rheum*. 2021;51(4):858-874.
3. 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]. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
4. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 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
6. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2017;76:29–42.
7. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Care Res*. 2013;65(10):1551-63.
8. Schlesinger N, Alten RE, Bardin T, et al: Canakinumab for acute gouty arthritis in patients with limited treatment options: results from two randomized, multicentre, active-controlled, double-blind trials and their initial extensions. *Ann Rheum Dis*. 2012; 71(11):1839-1848.
9. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 3, 2022 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
10. Zhang W, Doherty M, Pascual E, et al. EULAR recommendations for calcium pyrophosphate deposition. Part II: Management. *Ann Rheum Dis*. 2011;70:571–575.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024
10/08/2025 – Reviewed and updated at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from "documentation is submitted" to "submission of medical records (e.g., chart notes…" and updating language for members who are new to the Plan. Effective 05/01/2026.