Mass General Brigham
Health Plan

Ilaris (canakinumab)
Effective 01/01/2024

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

A. FDA-Approved Indications
   1. Periodic Fever Syndromes:
      a. Cryopyrin-Associated Periodic Syndromes (CAPS)
         Ilaris is indicated for the 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)
         Ilaris is indicated for the treatment of TRAPS in adult and pediatric patients.
      c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
         Ilaris is indicated for the treatment of HIDS and MKD in adult and pediatric patients.
      d. Familial Mediterranean Fever (FMF)
         Ilaris is indicated for the treatment of FMF in adult and pediatric patients.
   2. Still's disease (Adult-onset Still's Disease [AOSD] and systemic Juvenile Idiopathic Arthritis [sJIA]):
      Ilaris is indicated for the treatment of active Still's disease, including AOSD and sJIA in patients aged 2 years and older.

B. Compendial Use
   Gout and pseudogout

All other indications are considered experimental/investigational and not medically necessary.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following diagnosis-specific criteria is met:

A. Periodic fever syndromes

1. Authorization may be granted for members 4 years of age or older for treatment of CAPS when both of the following criteria are met:
   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) or 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).
   b. Member has functional impairment limiting the activities of daily living.

2. Authorization may be granted for treatment of TRAPS when both of the following criteria are met:
   a. Member has chronic or recurrent disease activity with active flares within the last 6 months confirmed by chart notes or medical record documentation.
   b. Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L confirmed by laboratory result, chart notes, or medical record documentation.

3. Authorization may be granted for treatment of HIDS/MKD when both of the following criteria are met:
   a. Member has had active flares within the last 6 months confirmed by chart notes or medical record documentation.
   b. Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L confirmed by laboratory result, chart notes, or medical record documentation.

4. Authorization may be granted for treatment of FMF when all of the following criteria are met:
   a. Member has active disease with flares within the last 6 months confirmed by chart notes or medical record documentation.
   b. C-reactive protein (CRP) greater than 10 mg/L conformed by laboratory result, chart notes, or medical record documentation.
   c. Member has had an inadequate response or intolerance to or has a contraindication to colchicine. 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.

5. For all Cryopyrin-associated periodic syndromes (CAPS, TRAPS, HIDS/MKD, and FMF): The medications must be prescribed by or in consultation with a rheumatologist or immunologist.

B. Systemic juvenile idiopathic arthritis (sJIA)

1. Authorization may be granted for members 2 years of age or older who have previously received a biologic indicated for active sJIA.

2. Authorization may be granted for members 2 years of age or older for treatment of active sJIA when the following criteria are met:
    a. Member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).
    b. 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.
3. 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)

Authorization may be granted for all members 4 years of age or older (including new members) who are using the requested medication for CAPS, including FCAS and MWS, and who achieve or maintain a positive clinical response 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

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

References

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2020.
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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.
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5. 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.
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.
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9. 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.
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11. 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.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024