Mass General Brigham
Health Plan

Targeted Immunomodulators
Ilaris (canakinumab)
Effective 06/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
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		
Notes	Ilaris is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Ilaris (canakinumab) is a human monoclonal IL-1β antibody that is indicated for Active Stills disease (including Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA]), Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), Familial Mediterranean fever (FMF), Mevalonate kinase deficiency (MKD); also known as Hyperimmunoglobulin D syndrome (HIDS) and Tumor necrosis factor receptor associated periodic syndrome (TRAPS).

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Adult-Onset Still's Disease (AOSD)
1. Diagnosis of adult-onset Still's disease
2. Member is ≥ 2 years of age
3. Inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids
4. Inadequate response, adverse reaction, or contraindication to Kineret (anakinra)
5. Appropriate dosing

Cryopyrin-Associated Periodic Syndromes, including: Familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)

1. Diagnosis of one of the following:
    a. Familial cold autoinflammatory syndrome (FCAS)
    b. Muckle-Wells syndrome (MWS)
2. Member is ≥ 4 years of age
3. ONE of the following:
    a. Evidence of symptoms indicative of the disease
    b. Confirmation of diagnosis through genetic testing
4. Appropriate dosing

Familial Mediterranean fever (FMF)

1. Diagnosis Familial Mediterranean Fever
2. Inadequate response, adverse reaction, or contraindication to colchicine
3. ONE of the following:
    a. Evidence of symptoms indicative of the disease (see Appendix for examples)
    b. Confirmation of diagnosis through genetic testing
4. Appropriate dosing

Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD)

1. Diagnosis of one of the following:
    a. Hyperimmunoglobulin D syndrome
    b. Mevalonate kinase deficiency
2. ONE of the following:
    a. Evidence of symptoms indicative of the disease (see Appendix for examples)
    b. Confirmation of diagnosis through genetic testing
3. Appropriate dosing

Systemic juvenile idiopathic arthritis (SJIA)

1. Diagnosis of systemic juvenile idiopathic arthritis
2. Member is ≥ 2 years of age
3. Inadequate response or adverse reaction to ONE or a contraindication to ALL corticosteroids
4. Inadequate response, adverse reaction, or contraindication to Kineret (anakinra)
5. Appropriate dosing

Tumor necrosis factor receptor associated periodic syndrome (TRAPS)

1. Diagnosis of tumor necrosis factor receptor associated periodic syndrome
2. ONE of the following:
    a. Evidence of symptoms indicative of the disease (see Appendix for examples)
    b. Confirmation of diagnosis through genetic testing
3. Appropriate dosing

Gout Flares

1. Diagnosis of acute gout flares
2. Member is ≥ 18 years of age
3. Inadequate response, adverse reaction, or contraindication to ALL of the following:
    a. Colchicine
    b. Corticosteroids

    c. NSAIDs
4. Appropriate dosing

Continuation of Therapy

Management of acute gout flares with members who require retreatment, a new dose may be administered after an interval of at least 12 weeks.

All other indications: Reauthorization by prescriber will infer a positive response to therapy and dosing is appropriate.

Limitations

1. Initial approvals will be granted for the following:
    a. Acute gout flares: one dose to be given within 1 month
    b. All other indications: 6 months
2. Reauthorizations will be granted for the following:
    a. Acute gout flares: one dose to be given within 1 month. (New dose may be administered after an interval of at least 12 weeks)
    b. All other indications: 12 months

Appendix

Disease Symptoms

- **Tumor necrosis factor receptor associated periodic syndrome (TRAPS):** characterized by recurrent fevers over months or years every five to six weeks, focal myalgias, conjunctivitis, periorbital edema, abdominal pain, monoarticular arthritis, and rash.

- **Recurrent pericarditis**: The predominant feature of recurrent pericarditis is usually pleuritic chest pain (often sharp, worse when lying flat, and alleviated when leaning forward), which may follow exertion. Some members may also report dyspnea or malaise.

- **Familial cold autoinflammatory syndrome (FCAS):** mildest phenotype; characterized by intermittent cold-induced rash with fever and arthralgia.

- **Muckle-Wells syndrome (MWS):** characterized by recurrent episodes of fever and urticaria associated with joint and ocular manifestations, deafness and reactive amyloid A amyloidosis.

- **Neonatal onset multisystem inflammatory disease (NOMID):** most severe spectrum of the disease; characterized by erythematous rash resembling urticaria, fever, impaired growth, chronic meningitis, hearing loss, uveitis, lymphadenopathy and hepatosplenomegaly. Limb and joint pain is common.

- **Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD):** characterized by episodic attacks of fever lasting three to seven days are accompanied, in most cases, by chills, cervical lymphadenopathy, abdominal pain, vomiting, and/or diarrhea. Other symptoms include headache, arthralgias/arthritis, aphthous ulceration, a pleomorphic rash, and splenomegaly. Elevated levels of immunoglobulin D (IgD) are often present.

References

1. Ilaris [package insert]. Hanover (NJ): Novartis Pharmaceuticals Corp. 2024 Nov

Review History
06/14/2023 - Created for P&T in order to match MH UPPL. Effective 7/1/23.
05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. Added indication of acute gout flares. Effective 6/1/25