Mass General Brigham
Health Plan

Ilaris (canakinumab)
Effective 07/01/2023

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
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)
ALL of the following:
1. Diagnosis of adult-onset Still's disease
2. Member is ≥ 2 years of age
3. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids
4. Paid claims or physician attestation of 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)

ALL of the following:

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)

ALL of the following:

1. Diagnosis Familial Mediterranean Fever
2. Paid claims or physician attestation of 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)

ALL of the following:

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)

ALL of the following:

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

Tumor necrosis factor receptor associated periodic syndrome (TRAPS)

ALL of the following:

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

Continuation of Therapy
Reauthorization by prescriber will infer a positive response to therapy and dosing is appropriate.

Limitations
1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. Dosing information:

Ilaris® (canakinumab) Single-use 1 mL vial containing 150 mg of solution QTY 1 mL=150 mg	**Pediatric Dosing**	**Adult Dosing**
	CAPS (includes FCAS, MWD) (≥4 years of age): *Members weighing >40 kg:* SQ injection: 150 mg every eight weeks *Members weighing >15 kg and ≤40 kg:* SQ injection: 2 mg/kg every eight weeks; dose can be increased to 3 mg/kg every eight weeks if response is inadequate **FMF, HIDS/MKD and TRAPS:** *Members weighing >40 kg:* SQ injection: 150 mg every four weeks; dose can be increased to 4 mg/kg every four weeks if response is inadequate *Members weighing ≤40 kg:* SQ injection: 2 mg/kg every four weeks; dose can be increased to 4 mg/kg every four weeks if response is inadequate **AOSD and SJIA (≥2 years of age):** *Members weighing ≥7.5 kg:* 4 mg/kg (maximum: 300 mg) every four weeks via SQ injection	**CAPS (includes FCAS, MWD):** *Members weighing >40 kg:* SQ injection: 150 mg every eight weeks *Members weighing >15 kg and ≤40 kg:* SQ injection: 2 mg/kg every eight weeks; dose can be increased to 3 mg/kg every eight weeks if response is inadequate **FMF, HIDS/MKD and TRAPS:** *Members weighing >40 kg:* SQ injection: 150 mg every four weeks; dose can be increased to 4 mg/kg every four weeks if response is inadequate *Members weighing ≤40 kg:* SQ injection: 2 mg/kg every four weeks; dose can be increased to 4 mg/kg every four weeks if response is inadequate **AOSD and SJIA:** 4 mg/kg (maximum: 300 mg) every four weeks via SQ injection

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. 2020 Sep

Review History

06/14/2023 - Created for P&T in order to match MH UPPL. Effective 7/1/23.