BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Arcalyst and Ilaris – Unified Formulary

Policy Number: 9.145
Version Number: 2.0
Version Effective Date: 1/1/2022

Product Applicability ☐ **All Plan[+] Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☒ MassHealth - MCO
☒ MassHealth - ACO
☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

Drugs that require PA	No PA
Arcalyst® (rilonacept)	
Ilaris® (canakinumab)	

Procedure:

Approval Diagnosis:	• Familial cold autoinflammatory syndrome (FCAS) • Familial Mediterranean fever (FMF) • Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD) • Muckle-Wells syndrome (MWS) • Systemic juvenile idiopathic arthritis (SJIA) • Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
Approval Criteria: **Arcalyst®** (rilonacept)	Prescriber provides documentation of **ALL** of the following: 1. Age ≥ 12 years old 2. Diagnosis of **ONE** of the following: a. FCAS b. MWS

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	3. **ONE** of the following: a. Evidence of symptoms indicative of the disease (see appendix section Disease Symptoms) b. Confirmation of diagnosis through genetic testing 4. An inadequate response, adverse reaction or contraindication to Ilaris® (canakinumab) (*History of claims are sufficient for failed trial*) 5. Appropriate dosing (see availability and dosage section) *Notes:* • *Requests for member <12 years will be reviewed on a case-by-case basis* • *Member weight can be taken over the phone to verify correct dosing*
Approval Criteria: **Ilaris®** (canakinumab) FCAS MWS	Prescriber provides documentation of **ALL** of the following: 1. Age ≥ 4 years old 2. Diagnosis of **ONE** of the following: a. FCAS b. MWS 3. **ONE** of the following: a. Evidence of symptoms indicative of the disease (see appendix section Disease Symptoms) b. Confirmation of diagnosis through genetic testing 4. Appropriate dosing (see availability and dosage section) *Notes:* • *Requests for member <4 years will be reviewed on a case-by-case basis* • *Member weight can be taken over the phone to verify correct dosing*
Approval Criteria: **Ilaris®** (canakinumab) FMF HIDS/MKD TRAPS	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of **ONE** of the following: a. FMF b. HIDS/MKD c. TRAPS 2. For diagnosis of FMF, an inadequate response, adverse reaction or contraindication to colchicine (*History of claims are sufficient for failed trial*) 3. **ONE** of the following: a. Evidence of symptoms indicative of the disease (see appendix section Disease Symptoms) b. Confirmation of diagnosis through genetic testing 4. Appropriate dosing (see availability and dosage section) *Notes:* • *Member weight can be taken over the phone to verify correct dosing*
Approval Criteria: **Ilaris®** (canakinumab) SJIA	Prescriber provides documentation of **ALL** of the following: 1. Age ≥ 2 years old 2. Diagnosis of SJIA 3. An inadequate response, adverse reaction or contraindication to ONE NSAID (*History of claims are sufficient for failed trial*)* 4. An inadequate response, adverse reaction or contraindication to ONE corticosteroid (*History of claims are sufficient for failed trial*)* 5. An inadequate response, adverse reaction or contraindication to Kineret® (anakinra) (*History of claims are sufficient for failed trials*) 6. Appropriate dosing (see availability and dosage section)

	Notes: • *Requests for member <2 years will be reviewed on a case-by-case basis* • **Although claims history counts for the trial requirement, the Smart PA rule is not coded to look for the NSAID or corticosteroid. Please manually review claims history for preferred trials.* • *Member weight can be taken over the phone to verify correct dosing*
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration of Authorization:	Prior authorization may be issued initially for up to 2 months.
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and request can be recertified for up to 12 months.

Appendix:

Stability

If prescriber is requesting Ilaris® (canakinumab) or Arcalyst® (rilonacept) for a member who is stable on the requested agent for an FDA-approved indication at FDA-approved dosing, the request can be approved.

Grandfathering

Information is not applicable.

Additional Information

Disease Symptoms

Potential indicators of CAPS: All three conditions share common features that include: spontaneous generalized painful or pruritic erythematous rash, fever, and flulike symptoms of headache, fatigue, myalgia, arthralgia and leukocytosis consistent with systemic inflammation.

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.

Familial Mediterranean fever (FMF): characterized by episodic attacks of fever lasting one to three days and accompanied, in most cases, by abdominal pain, pleurisy, and arthralgias/arthritis from accompanying serositis and synovitis.

Hyperimmunoglobin 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.

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.

Off-Label Uses

IL-1 is involved in a variety of inflammatory conditions such as rheumatoid arthritis or gout. Both Arcalyst® (rilonacept) and Ilaris® (canakinumab) have been studied for use in gout.

Given unclear risk/benefit ratio and lack of FDA approval, the 2012 American Academy of Rheumatology guideline consider the role of IL-1 inhibitor therapy in acute gout as uncertain. However, IL-1 inhibitor may be an option for severe attacks of acute gouty arthritis refractory to all other agents.

Both agents are still considered investigational for gout. As such, and given the large variety of LCAs available for gout, **requests for either agent for a diagnosis of gout should be denied as non-FDA approved indication.** Compelling requests may be consulted with a clinical reviewer.

Applicable Coding:

Code	Medication
J2793	Arcalyst® (rilonacept)
J0638	Ilaris® (canakinumab injection)

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Created policy for Arcalyst and Ilaris for MH Unified Formulary	1/1/2021	P&T Committee
8/12/2021	No recommended changes	1/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.