Pharmacy Policy

Ilaris

Policy Number: 9.122
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☐ 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:

- Ilaris (canakinumab)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded.
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: 1. Periodic Fever Syndromes including: Cryopyrin-Associated Periodic Syndromes (CAPS); Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS); Tumor necrosis factor receptor associated periodic syndrome (TRAPS); Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD);***AND*** a. Symptoms consistent with the above diagnoses are present (i.e. recurrent

[+] *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.

	intermittent fever and urticarial rash, or amyloidosis); ***AND*** b. Dose does not exceed one of the following: i. CAPS, FCAS or MWS: 1. Weight 15-40kg: 3mg/kg/dose every 8 weeks; 2. Weight >40kg: 150mg every 8 weeks; ii. TRAPS, HIDS/MKD: 1. Weight ≤40kg: 4mg/kg/dose every 4 weeks; 2. Weight >40kg: 300mg every 4 weeks; ***OR*** 2. Familial Mediterranean fever (FMF); ***AND*** a. An inadequate response, resistance, or documented history of use to a 6-month of greater trial of colchicine therapy at the maximum tolerated dose unless contraindicated or clinically significant adverse effects are experienced.; **AND** b. Dose does not exceed the following: i. Weight ≤40kg: 4mg/kg/dose every 4 weeks; ii. Weight >40kg: 300mg every 4 weeks; ***OR*** 3. Active systemic juvenile idiopathic arthritis (sJIA); ***AND*** a. One of the below: i. An inadequate response to a minimum of a three month trial of methotrexate or leflunomide at maximally indicated doses unless contraindicated or adverse effects experienced; ***OR*** ii. An inadequate response to a minimum of a two week trial of one formulary systemic glucocorticoid unless contraindicated or adverse effects experienced; **AND** b. Dose does not exceed 300mg every 4 weeks
Age Restrictions	FCAS, MWS, or CAPS: 4 years old or older TRAPS, HIDS/MKD, FMF, or sJIA: 2 years old or older
Prescriber Restriction	Prescribed by or in consultation with a rheumatologist
Coverage Duration	Initial: • FCAS or MWS – 3 months • CAPS, TRAPS, HIDS/MKD, or FMF – 6 months • sJIA – 6 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. Currently receiving medication via Wellsense benefit or member has previously met initial approval criteria; **AND** 2. Clinical condition has improved or stabilized; **AND** 3. Dose does not exceed: a. CAPS, FCAS or MWS: i. Weight 15-40kg: 3mg/kg/dose every 8 weeks; ii. Weight >40kg: 150mg every 8 weeks; b. FMF, TRAPS, HIDS/MKD: i. Weight ≤40kg: 4mg/kg/dose every 4 weeks; ii. Weight >40kg: 300mg every 4 weeks;

	c. SJIA – 300mg every 4 weeks

Applicable Coding:

Code	Medication
J0638	Ilaris® (canakinumab injection)

Clinical Background Information and References

1. Ben-Chetrit E. Management of familial Mediterranean fever. Available at UptoDate®. Last updated: January 14 2020. Accessed April 10 2020.

1. Gul A, Ozdogan H, Erer B, et al. Efficacy and safety of canakinumab in adolescents and adults with colchicine-resistant familial Mediterranean fever. Arthritis Res Ther. 2015 Sep 4;17:243.

2. Hoffman HM, Throne ML, Amar NJ, et al. Efficacy and safety of rilonacept (interleukin-1 Trap) in patients with cryopyrin-associated periodic syndromes: results from two sequential placebocontrolled studies. Arthritis Rheum. 2008 Aug;58(8):2443-2452.

3. Hoffman HM, Yasothan U, Kirkpatrick P. Fresh from the pipeline: Rilonacept. Nat Rev Drug Discov. 2008; 7(5):385-86.

4. Ilaris (canakinumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2016.

5. Kanariou M, Tantou S, Varela I, et al. Successful management of cryopyrin-associated periodic syndrome with canakinumab in infancy. Pediatrics. 2014 Nov;134(5):e1468-73.

6. Kuemmerle-Deschner JB, Hachulla E, Cartwright R, et al. Two-year results from an open-label, multicentre, phase III study evaluating the safety and efficacy of canakinumab in patients with cryopyrin-associated periodic syndrome across different severity phenotypes. Ann Rheum Dis. 2011 Dec;70(12):2095-102.

7. Kuemmerle-Deschner JB, Ramos E, Blank N, et al. Canakinumab (ACZ885, a fully human IgG1 anti-IL-1β mAb) induces sustained remission in pediatric patients with cryopyrin-associated periodic syndrome (CAPS). Arthritis Res Ther. 2011 Feb 28;13(1):R34.

8. La Torre F, Muratore M, Vitale A, et al. Canakinumab efficacy and long-term tocilizumab administration in tumor necrosis factor receptor-associated periodic syndrome (TRAPS). Rheumatol Int. 2015 Nov;35(11):1943-7.

9. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of Canakinumab in the CryopyrinAssociated Periodic Syndrome. N Engl J Med 2009 360: 2416-2425

10. Neven B, Prieur AM, Quartier dit Maire P. Cryopyrinopathies: update on pathogenesis and treatment. Nat Clin Pract Rheumatol. 2008;4(9):481-9.

Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. Annals of the Rheumatic Diseases 2016;75:644-651.

11. Ruperto N, Brunner HI, Quartier P et al. Two randomized trials of canakinumab in systemic juvenile idiopathic arthritis. N Engl J Med. 2012 Dec 20;367(25):2396-406.
12. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. Clin Exp Dermatol. Jan 2008;33(1):1-9.

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.185 Ilaris Policy retired, new policy created. Added colchicine requirement for FMF, correcting vial size, removing adherence requirement	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

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.