BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Arcalyst (rilonacept)

Policy Number: 9.114
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:

- Arcalyst (rilonacept)

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	Use of Arcalyst in combination with another biologic
Required Medical Information	Diagnosis of: 1. Cryopyrin-Associated Periodic Syndromes (CAPS) including: Familial Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS); ***AND*** a. Symptoms consistent with the above diagnoses are present (i.e. recurrent intermittent fever and urticarial rash, or amyloidosis); ***AND*** b. Laboratory evidence of a genetic mutation in the NLRP3 gene (also called CIAS1).

[+] *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.

	2. Deficiency of Interleukin-1 Receptor Antagonist (DIRA); **AND** a. DIRA confirmed by presence of loss-of-function ILRN mutations; **AND** b. The member will be using Arcalyst for maintenance of remission and has been stable for ≥6 months; **AND** c. The member weighs 10kg or more. 3. Recurrent pericarditis (RP) **AND** a. Member has been diagnosed with recurrent pericarditis demonstrated by the return of acute pericarditis symptoms after a symptom-free interval of least four to six weeks; **AND** b. An inadequate response or adverse reaction to BOTH a nonsteroidal anti-inflammatory drug (NSAID) AND colchicine (minimum of 6 months of therapy with colchicine) AND/OR systemic corticosteroids.
Age Restrictions	CAPS, FCAS, MWS, and DIRA: 12 years old or older
Prescriber Restriction	Prescribed by, in consultation with, or by recommendation or an immunologist, allergist, dermatologist, rheumatologist, neurologist, cardiologist or other medical specialist
Coverage Duration	12 months
Other criteria	**Reauthorization:** 1. Member has met initial criteria. 2. Clinical condition has improved or stabilized

Applicable Coding:

Code	Medication
J2793	Arcalyst® (rilonacept)

Clinical Background Information and References

1. Andreis A, Imazio M, Casula M, Avondo S, Brucato A. Recurrent pericarditis: an update on diagnosis and management. Intern Emerg Med. 2021 Apr;16(3):551-558.
2. Arcalyst (rilonacept) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; Accessed July 2021.
3. Church LD, Savic S, McDermott MF. Long term management of patients with cryopyrin-associated periodic syndromes (CAPS): focus on rilonacept (IL-1 Trap). Biologics. 2008 Dec;2(4):733-42. 2 Pharmacy Medical Necessity Guidelines: Arcalyst® (rilonacept)

4. Gillespie J, Mathews R, McDermott MF. Rilonacept in the management of cryopyrin-associated periodic syndromes (CAPS). J Inflamm Res. 2010;3:1-8.
5. Goldbach-Mansky R, Shroff SD, Wilson M et al. A pilot study to evaluate the safety and efficacy of the long-acting interleukin-1 inhibitor rilonacept (interleukin-1 Trap) in patients with familial cold autoinflammatory syndrome. Arthritis Rheum. 2008 Aug;58(8):2432-42.
6. 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):2443-52.
7. Hoffman HM, Throne ML, Amar NJ et al. Long-term efficacy and safety profile of rilonacept in the treatment of cryopryin-associated periodic syndromes: results of a 72-week open-label extension study. Clin Ther. 2012 Oct;34(10):2091-103.
8. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). Ann Rheum Dis 2017; 76:942.
9. Kubota T, Koike R. Cryopyrin-associated periodic syndromes: background and therapeutics. Mod Rheumatol. 2010 Jun;20(3):213-21.
10. Schnellbacher C, Ciocca G, Menendez R, et al. Deficiency of interleukin-1 receptor antagonist responsive to anakinra. Pediatr Dermatol. 2013;30(6):758-760.
11. Welch, T. Management of Acute and Recurrent Pericarditis. Journal of the American College of Cardiology. 2020 Jan. 7; 75:76-92.
12. Yu JR, Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. Curr Allergy Asthma Rep. 2011 Feb;11(1):12-20.

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**
6/12/2018	Moved from Policy 9.126 Systemic Immunomodulators	11/01/2018	P&T Committee
05/09/2019	P&T Annual review. No criteria changes	09/02/2019	P&T Committee and NH DHHS
12/1/2020	9.177 Arcalyst Policy retired, new policy created. Removed adherence requirement	1/1/2021	P&T Committee

Policy Revisions History			
8/12/2021	P&T Annual review: Addition of two newly approved indications, Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and Recurrent Pericarditis (RP) and associated criteria; addition of cardiologist to accepted prescribers; addition of meeting initial criteria as a reauthorization criteria.	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.