

Pharmacy Policy

Uplizna

Policy Number: 9.725

Version Number: 1.0

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan⁺ Products	
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

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

Prior Authorization Policy

Products Affected:

- Uplizna® (inebilizumab-cdon) injection, for intravenous use

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	<ol style="list-style-type: none"> 1. Diagnosis of Neuromyelitis Optica spectrum disorder (NMOSD); AND 2. Member must have NMOSD confirmed by blood serum test for aquaporin-4 (AQP4) IgG antibodies; AND

* 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.

	<p>3. Member must have tried and failed therapy with rituximab or have a clinical rationale why they cannot trial, prior to Uplizna; AND</p> <p>4. The medication is being prescribed by or in consultation with a neurologist.</p>
Age Restriction	Member is 18 years of age or older; AND
Prescriber Restriction	Prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other criteria	<p>Reauthorization criteria:</p> <ol style="list-style-type: none"> 1. Meets initial criteria; AND 2. Member has had clinical benefit as evidenced by reduction in relapse rate, reduction in symptoms, or a slowing progression of symptoms.

Applicable coding:

Code	Medication
J1823	Injection, inebilizumab-cdon, 1 mg

Clinical Background Information and References

1. Chang VTW, Chang HM. Review: recent advances in the understanding of the pathophysiology of neuromyelitis optica spectrum disorder. *Neuropathol Appl Neurobiol.* 2020; 46(3):199-218.
2. Uplizna (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio Inc; December 2020. Accessed April 2021.
3. UpToDate. Inebilizumab drug information. Topic 128443 Version 47.0. Accessed April 2021.
4. Zhu W, Zhang Y, Wang Z, Fu Y, Yan Y. Monoclonal antibody-based treatments for neuromyelitis optica spectrum disorders: from bench to bedside. *Neurosci Bull.* Published online June 12, 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Department	P&T Committee

Policy Revisions History

* 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.

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

5/2022

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.

^{*} 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.