BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Mepsevii

Policy Number: 9.316
Version Number: 2.0
Version Effective Date: 9/1/2021

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:

- **Mepsevii (vestroinidase afla-vjbk)**

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	1. Documented diagnosis of Mucopolysaccharidosis VII confirmed by leukocyte or fibroblast glucuronidase enzyme assay or genetic testing; ***AND*** 2. Presence of clinical signs and symptoms of the disease (e.g., enlarged liver and spleen, joint limitations, airway obstruction or pulmonary problems, limitation of mobility while still ambulatory, etc.); ***AND*** 3. Dose does not exceed 4 mg/kg IV every 2 weeks.

+ *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.

Age Restriction	5 months of age or older
Prescriber Restriction	Prescribed by or in consultation with a specialist with expertise in lysosomal storage diseases (e.g., pediatric endocrinologist, pediatric geneticist)
Coverage Duration	1 year
Other criteria	Reauthorization: Documentation of the following: 1. Initial criteria continue to be met; ***AND*** 2. Provider attests member has experienced improvement in clinical signs and symptoms from baseline without treatment related adverse events

Applicable Coding:

Code	Medication
J3397	**Mepsevii (vestronidase alfa-vjbk)**

Clinical Background Information and References

1. Mepsevii (vestronidase alfa-vjbk) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; November 2017.
2. Vestronidase alfa: Drug information. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on April 1, 2019).

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	9.082 Mepsevii Policy retired, new policy created	1/1/2021	P&T Committee
5/13/2021	P&T Annual review: No changes	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.