BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Egrifta®

Policy Number: 9.304
Version Number: 2
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid ☐ NH Health Protection Program ☐ _____	**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:

- Egrifta® (tesamorelin)
- Egrifta SV (tesamorelin)

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	Documentation of the following: 1. A diagnosis of lipodystrophy with excess abdominal fat due to antiretroviral therapy; ***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.

	2. Current treatment with antiretroviral therapy for at least 8 weeks; ***AND*** 3. The waist circumference is currently > 40 inches for men or >35 inches for women; ***AND*** 4. **<u>One</u>** of the following: a. There is a medical complication secondary to excess abdominal fat (must document the medical complication), ***OR*** b. Member has at least one other major CHD risk factors defined by American Heart Association besides the high waist circumference; ***AND*** 5. Participation in an exercise program for the past 2 months with no reduction in waist circumference; ***AND*** 6. Current fasting glucose level is <150 mg/dL
Age Restriction	None
Prescriber Restriction	None
Coverage Duration	Up to 6 months
Other criteria	Reauthorization: 1. A reduction in waist circumference within the first 6 months of Egrifta® treatment and the reduction has been maintained throughout the duration of therapy; ***AND*** 2. Current fasting glucose level is < 150 mg/dL; ***AND*** 3. There have been no adverse reactions or intolerance with Egrifta® therapy.

Clinical Background Information and References

1. Morris Schambelan, Constance A.Benson, et al. Management of Metabolic Complications Associated with Antiretroviral Therapy for HIV-1 Infection: Recommendations of an International AIDS Society- USA Panel. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2002; 31:257-275.
2. Egrifta® prescribing information. EMD Serono, Inc. Rockland, MA 02370. Accessed December 28, 2016. Available at: http://www.egrifta.com/Pdfs/Prescribing_Information.pdf
3. Dominic C. Chow, MD, Larry J. Day, MD, et al. Metabolic Complications of HIV Therapy. HIV InSite Knowledge Base Chapter. May 2006. Available at: http://hivinsite.ucsf.edu/InSite?page=kb-03-02-10.
4. Glesby MJ. Treatment of HIV-associated lipodystrophy. UptoDate®. Last updated Oct 06, 2015. Accessed Dec 14, 2016. Available from http://www.uptodate.com

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

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	P&T Committee; discontinued policy 9.032 and created a new policy for QHP	1/1/2021	P&T Committee
5/13/2021	Annual policy 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.