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Pharmacy Policy

Cerdelga®

Policy Number: 9.313
Revision Number: R1
Version Effective Date: 1/1/2021

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:

- Cerdelga® (eliglustat)

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

+ *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.

Required Medical Information	Documentation of the following: 1. Member has been diagnosed with Type 1 Gaucher's Disease and is symptomatic (i.e. radiologic evidence of skeletal disease, platelet count 2.5 times normal size, spleen > 15 times normal size); ***AND*** 2. Member has been tested using an FDA cleared test to determine the patient's CYP2D6 genotype and has been classified as an extensive metabolizers (EMs), intermediate metabolizers (IM) or poor metabolizers (PM); ***AND*** 3. Either one of the following: a. Member is a EM or IM and requested dose is 84mg twice daily; ***OR*** b. Member is a PM and requested dose is 84 mg once daily;
Age Restriction	18 years of age or older
Prescriber Restriction	None
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Patient is responding to treatment (improved platelet count, decreased hepatomegaly and splenomegaly); ***AND*** 2. Patient is tolerating treatment

Applicable Coding:

None

Clinical Background Information and References

1. Cerdelga (eliglustat) [prescribing information]. Waterford, Ireland: Genzyme Ireland; August 2014.
2. Cox TM, Drelichman G, Cravo R, et al. Eliglustat compared with imiglucerase in patients with Gaucher's disease type 1 stabilised on enzyme replacement therapy: a phase 3, randomised, open-label, non-inferiority trial. Lancet 2015; 385:2355.

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.069 Cerdelga Policy retired, new policy created	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.