Cerdelga™ (eliglustat)

Effective: 2/16/15

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<tr>
<th>Clinical Documentation and Prior Authorization Required</th>
<th>Type of Review – Case Management</th>
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<td>Not Covered</td>
<td>✅ Type of Review – Clinical Review</td>
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<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Fax: 617-673-0988</td>
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<td>RX Department to Review</td>
<td>RxUM</td>
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OVERVIEW

FDA-APPROVED INDICATIONS
Cerdelga (eliglustat) is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are cytochrome P450 (CYP) 2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

Limitations of Use:
- Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of Cerdelga (eliglustat) to achieve a therapeutic effect.
- A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Cerdelga (eliglustat) for Members when all of the following criteria are met:

- Documented diagnosis of type 1 Gaucher disease.
- Documentation the member is a cytochrome P450 2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) as detected by an FDA-cleared test.
- Member is over 18 years of age.

DENIAL TEXT: Our guidelines for Cerdelga (eliglustat) require that you have the diagnosis of type 1 Gaucher disease.

DENIAL TEXT: Our guidelines for Cerdelga (eliglustat) require that you are a cytochrome P450 2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) as detected by an FDA-cleared test.

DENIAL TEXT: Our guidelines for Cerdelga (eliglustat) require that you be over 18 years of age.

LIMITATIONS
1. Cerdelga (eliglustat) will be limited as follows:
   a. For Extensive (EMs) and Intermediate metabolizers (IMs) – 60 capsules per 30 days
   b. For Poor metabolizers (PMs) – 30 capsules per 30 days

CODES
None

REFERENCES
5. Cox TM, Drellichman G, Cravo R et al. ENCORE: A multi-national, randomized, controlled, open-label, non-inferiority study comparing eliglustat with imiglucerase in Gaucher disease type 1 patients on enzyme replacement therapy who have reached therapeutic goals. Poster presented at Lysosomal Disease Network World Symposium. San Diego, CA; 2014 February 12.

APPROVAL HISTORY

- February 10, 2015: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to fully insured Tufts Health Direct offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Together (MassHealth), please refer to the Tufts Health Together Pharmacy Medical Necessity Guidelines.

For Tufts Health Unity (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unity Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to
member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.