Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Cerdelga® (eliglustat)**

Effective: May 12, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Cerdelga (eliglustat) is a glucosylceramide synthase inhibitor indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers as detected by an Food and Drug Administration cleared test.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Cerdelga for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of Type 1 Gaucher disease

AND

2. Documentation diagnosis is confirmed by at least **one (1)** of the following:
   a. An enzyme assay test showing reduced activity of the enzyme glucocerebrosidase
   b. Genetic testing

AND

3. The patient is at least 18 years of age or older

AND

4. Documentation the patient is symptomatic (e.g., thrombocytopenia, anemia, hepatomegaly, splenomegaly, bone disease).

AND

5. Documentation the patient is a CYP2D6 extensive metabolizer, intermediate metabolizer, or poor metabolizer as detected by a Food and Drug Administration cleared test

Limitations

None

Codes

None

References

1. Cerdelga (eliglustat) [prescribing information]. Waterford, Ireland: Genzyme Ireland, Ltd.; August 2018.
2. Charrow, et al. Gaucher Disease: Recommendations on Diagnosis, Evaluation and Monitoring (Special Article). Archives of Internal Medicine 1998; 158:1754-1760.
3. Gaucher Disease. Current Issues in Diagnosis and Treatment. JAMA 1996; 275:7 548-553.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- May 9, 2023: No changes
- March 12, 2024: No changes
- January 14, 2025: No changes (eff 1/14/25).
- May 12, 2026: No changes, Template updated to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity 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 service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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.