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Specialty Guideline Management Cerdelga

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cerdelga	eliglustat

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Cerdelga is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 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 to achieve a therapeutic effect. A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).

All other indications are considered experimental/investigational and not medically necessary.

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Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial Request:

- Beta-glucocerebrosidase (glucosidase) enzyme assay or genetic testing results supporting diagnosis.
- The results of the CYP2D6 test.
- Chart notes or medical records documenting clinical signs and symptoms of disease at baseline (e.g. bone disease, splenomegaly, hepatomegaly, cytopenia).

Continuation Requests:

- Chart notes or medical records documenting benefit from therapy (e.g. improvement in liver volume, spleen volume, hemoglobin concentration, platelet count).

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of metabolic disease and/or lysosomal storage disorders.

Coverage Criteria

Gaucher disease type 1[1-3]

Authorization of 12 months may be granted for treatment of Gaucher disease type 1 when all of the following criteria are met:

- Member is 18 years of age or older.
- Diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.
- Member is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer as detected by an FDA-cleared test.
- Member exhibits clinical signs and symptoms of disease at baseline (e.g. bone disease, splenomegaly, hepatomegaly, cytopenia).

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Continuation of Therapy

Gaucher disease type 1[1]

Authorization of 12 months may be granted for continued treatment of an indication listed in the coverage criteria section when all of the following criteria are met:

- Member meets the criteria for initial approval.
- The member is receiving benefit from therapy (e.g. improvement in liver volume, spleen volume, hemoglobin concentration, platelet count) and is not experiencing any intolerable adverse events.

References

1. Cerdelga [package insert]. Cambridge, MA: Genzyme Corporation; January 2024.
2. ClinicalTrials.gov. A Study of the Efficacy and Safety of Eliglustat Tartrate (Genz-112638) IN Type 1 Gaucher Patients. NCT00358150. Updated July 21, 2016. Accessed November 28, 2025.
3. Hughes DA, Pastores GM. Gaucher Disease. 2000 Jul 27 [Updated 2023 Dec 7]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025.