POLICY Document for CERDELGA (eliglustat)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
GAUCHER DISEASE AGENTS

PREFERRED PRODUCTS: CEREZYME, VPRIV

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Gaucher disease products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Gaucher Disease Products

	Product(s)
Preferred*	• **Cerezyme** (imiglucerase) • **Vpriv** (velaglucerase alfa)
Targeted	• **Elelyso** (taliglucerase alfa) • **Cerdelga** (eliglustat)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when member has a documented inadequate response, contraindication, or intolerable adverse event to both preferred products.

Section 2: Clinical Criteria

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.

Documentation

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

- Beta-glucocerebrosidase (glucosidase) enzyme assay or genetic testing results supporting diagnosis, and
- The results of the CYP2D6 test.

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]

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.

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.
- Member is not experiencing an inadequate response or any intolerable adverse events from therapy.

REFERENCES:

SECTION 1

1. Cerdelga [package insert] Waterford, Ireland: Genzyme Ireland, Ltd; August 2018.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.

3. Elelyso [package insert]. New York, NY: Pfizer, Inc; July 2024.
4. VPRIV [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; July 2024.

SECTION 2

1. Cerdelga [package insert]. Cambridge, MA: Genzyme Corporation; January 2024.