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5.85.018

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	September 19, 2014
Subject:	Cerdelga	**Page:**	1 of 6

Last Review Date: March 6, 2026

Cerdelga

Description

Cerdelga (eliglustat)

Background
Gaucher disease is lysosomal storage disorder that results in the inability to produce glucocerebrosidase, an enzyme necessary for fat metabolism. The enzyme deficiency causes the formation of cells with excess lipids/fats, called Gaucher cells, to collect in the spleen, liver, and bone marrow, and other organs. Accumulation of lipids in these areas may result in the enlargement of the liver and spleen, anemia, thrombocytopenia, lung disease and bone abnormalities (1).

Cerdelga is an orally administered drug for the long-term treatment of adult patients with the type 1 form of Gaucher disease. The drug inhibits the accumulation of lipids/fats and hence Gaucher cells (1).

Regulatory Status
FDA-approved indication: 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 (1).

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) (1).

Physicians should select patients with Gaucher disease type 1 based on their CYP2D6 metabolizer status. Patient genotypes must be established using an FDA-cleared test for determining CYP2D6 genotype (1).

Cerdelga is a CYP2D6 and CYP3A substrate. Drugs that inhibit CYP2D6 and CYP3A metabolism pathways may significantly increase the exposure to Cerdelga and result in prolongation of the PR, QTc, and/or QRS cardiac intervals that could result in cardiac arrhythmias. Cerdelga is contraindicated in those patients due to the risk of significantly increased eliglustat plasma concentrations which may result in cardiac arrhythmias. Some inhibitors of CYP2D6 and CYP3A are contraindicated with Cerdelga depending on the patient's metabolizer status. Extensive metabolizers (EMs) or intermediate metabolizers (IMs) taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor would be at risk for cardiac arrhythmias. And intermediate metabolizers (IMs) or PM poor metabolizers (PMs) taking a strong CYP3A inhibitor are also at risk for cardiac arrhythmias. Co-administration of Cerdelga with other CYP2D6 and CYP3A inhibitors may require dosage adjustment depending on the patient's CYP2D6 metabolizer status to reduce the risk of potentially significant adverse reactions (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Cerezyme, Elelyso, VPRIV, Zavesca

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cerdelga may be considered **medically necessary** if the conditions indicated below are met.

Cerdelga may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Type 1 Gaucher disease

AND ALL of the following:

1. Patient must be either CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test
2. **NO** dual therapy with another medication for Type 1 Gaucher disease (see Appendix 1)

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Type 1 Gaucher disease

AND the following:

1. **NO** dual therapy with another medication for Type 1 Gaucher disease (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Cerdelga is indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. 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). Drugs that inhibit CYP2D6 and CYP3A metabolism pathways may significantly increase the exposure to Cerdelga and result in prolongation of the PR, QTc, and/or QRS cardiac intervals that could result in cardiac arrhythmias. Safety and effectiveness in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cerdelga while maintaining optimal therapeutic outcomes.

References

1. Cerdelga [package Insert]. Waterford, Ireland: Genzyme Ireland Ltd.; January 2024.

Policy History

Date	Action
September 2014	Addition to PA
December 2014	Annual editorial review and reference update
December 2015	Annual editorial review and reference update Addition of no dual therapy with a hydrolytic lysosomal glucocerebroside agent
December 2016	Annual editorial review and reference update Policy Code changed from 5.10.18 to 5.85.18
September 2017	Annual editorial review and reference update
September 2018	Annual editorial review
September 2019	Annual editorial review and reference update. Changed approval duration from lifetime to 2 years
September 2020	Annual review
March 2021	Annual review
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.85.018
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review and reference update
March 2025	Annual review

June 2025	Annual review
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.

Appendix 1 - List of Medications for Type 1 Gaucher Disease

Generic Name	Brand Name
eliglustat	Cerdelga
imiglucerase	Cerezyme
miglustat	Zavesca/Yargesa
taliglucerase alfa	Elelyso
velaglucerase alfa	VPRIV