

Effective Date: 11/15/2020
Reviewed Date: 9/2020, 4/2021, 3/2022, 2/2023, 2/2024, 2/2025, 3/2026
Scope: Medicaid

CERDELGA (eligustat)

POLICY

I. 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

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.

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

II. CRITERIA FOR INITIAL APPROVAL

Gaucher disease type 1

Authorization of 6 months may be granted for treatment of Gaucher disease type 1 when all of the following are met:

- A. Documented diagnosis of Gaucher disease that was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing,
- B. Documentation that the patient has one of the following as detected by an FDA-cleared test:
 - a. CYP2D6 extensive metabolizer
 - b. CYP2D6 intermediate metabolizer
 - c. CYP2D6 poor metabolizer

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for Gaucher disease type 1 who meet all of the following:

- A. Documentation that the patient meets the criteria for initial approval
- B. Documentation that the patient is not experiencing an inadequate response or any intolerable adverse events from therapy.

IV. QUANTITY LIMIT

Cerdelga: CYP2D6 extensive and intermediate metabolizer: 2 capsules daily

Cerdelga: CYP2D6 poor metabolizer: 1 capsule daily

V. REFERENCES

1. Cerdelga [package insert]. Waterford, Ireland: Genzyme Corporation, Ltd.; January 2024. Accessed February 2024.