

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

SPECIALTY GUIDELINE MANAGEMENT

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. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: genetic testing results supporting diagnosis and FDA-cleared test to determine CYP2D6 metabolizer type.

III. CRITERIA FOR INITIAL APPROVAL

Gaucher disease type 1

Authorization of 6 months may be granted for treatment of Gaucher disease type 1 when the diagnosis of Gaucher disease was confirmed by genetic testing, and 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

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for Gaucher disease type 1 who are not experiencing an inadequate response or any intolerable adverse events from therapy.

V. QUANTITY LIMIT

Cerdelga: CYP2D6 extensive and intermediate metabolizer: 2 capsules daily

Cerdelga: CYP2D6 poor metabolizer: 1 capsule daily

VI. REFERENCES

1. Cerdelga [package insert]. Waterford, Ireland: Genzyme Corporation, Ltd.; July 2021.