Effective Date: 11/15/2020
Reviewed Date: 9/2020, 4/2021, 3/2022, 2/2023, 2/2024, 2/2025 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. 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 meet:

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.