Reference number
2050-A

SPECIALTY GUIDELINE MANAGEMENT

CERDELGA (eliglustat)

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 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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Beta-glucocerebrosidase enzyme assay or genetic testing results supporting diagnosis, and
B. The results of the CYP2D6 test.

III. CRITERIA FOR INITIAL APPROVAL

Gaucher disease type 1
Authorization of 12 months may be granted for treatment of Gaucher disease type 1 when all of the following criteria are met:
A. Diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.
B. Member is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer as detected by an FDA-cleared test.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of an indication listed in Section III when all of the following criteria are met:
A. Member meets the criteria for initial approval.
B. Member is not experiencing an inadequate response or any intolerable adverse events from therapy.

V. REFERENCES

1. Cerdelga [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.