PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Gaucher Disease – Substrate Reduction Therapy Preferred Specialty Management Policy
- Cerdelga™ (eliglustat capsules – Genzyme)
- Zavesca® (miglustat capsules – Actelion, generic)

REVIEW DATE: 08/31/2022

OVERVIEW

Cerdelga and miglustat capsules (Zavesca, generic) are substrate reduction therapy agents indicated for **long-term therapy in patients with a confirmed diagnosis of Type 1 Gaucher disease**.[1,2] Cerdelga is specifically indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are cytochrome P450 2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers as detected by an FDA-cleared test.[1] Miglustat capsules (Zavesca, generic) are indicated as monotherapy for the treatment of adult patients with mild to moderate Gaucher disease type 1 for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).[2]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try both of the Preferred Products prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). Patients meeting the standard *Prior Authorization Policy* criteria for the Non-Preferred Product who have not tried the Preferred Products will be offered a review for one of the Preferred Products. All approvals for are provided for the duration noted below.

Documentation: Documentation is required for use of Cerdelga and generic miglustat as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Product: Cerdelga, generic miglustat
Non-Preferred Product: Zavesca

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Zavesca	**1. <u>Gaucher Disease Type I</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the standard *Gaucher Disease Substrate Reduction Therapy – Miglustat Prior Authorization* criteria; AND **ii.** Patient meets BOTH of the following criteria (a <u>and</u> b): **a)** Patient has tried BOTH Cerdelga (eliglustat capsules) **[documentation required]** and generic miglustat **[documentation required]**; AND **b)** Brand Zavesca is being requested due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the Brand and the bioequivalent generic product, which, per the prescriber has or would result in a significant allergy or serious adverse reaction. **B)** For a patient who has not tried Cerdelga and generic miglustat and does not meet the exception criteria (criteria 1Aii), offer to review for one of the Preferred Products using the standard *Gaucher Disease Substrate Reduction Therapy – Cerdelga Prior Authorization* criteria or *Miglustat Prior Authorization* criteria. **2. <u>Other Conditions</u>.** Approve for 1 year if the patient meets the standard *Gaucher Disease Substrate Reduction Therapy – Miglustat Prior Authorization* criteria.

REFERENCES

1. Cerdelga™ capsules [prescribing information]. Waterford, Ireland: Genzyme; July 2021.
2. Zavesca® capsules [prescribing information]. South San Francisco, CA: Actelion; October 2021.