CARE VALUE POLICY

POLICY: Gaucher Disease – Substrate Reduction Therapy Care Value Policy
- Cerdelga™ (eliglustat capsules – Genzyme)
- Zavesca® (miglustat capsules – Actelion Pharmaceuticals; generic)

REVIEW DATE: 08/18/2021

OVERVIEW

Cerdelga and Zavesca/generic miglustat (AB-rated generic to Zavesca) 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] Zavesca is 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 Care Value Policy has been developed to encourage the use of Preferred Products. For all Non-Preferred Products, 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 (Cerdelga and generic miglustat) prior to the approval of a Non-Preferred Product. Patients meeting the Prior Authorization criteria for the Non-Preferred Product who have not tried both of the Preferred Products will be directed to one of the Preferred Products. The Preferred Products (Cerdelga and generic miglustat) do not require Prior Authorization. Requests for coverage of the Non-Preferred Product will be determined by exception criteria (below). All approvals 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 Products: Cerdelga, generic miglustat
Non-Preferred Product: Zavesca

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Zavesca	**1. <u>Gaucher Disease Type I</u>.** Approve for 1 year if the patient meets the following criteria (A <u>and</u> B): **A)** Patient meets the standard *Gaucher Disease Substrate Reduction Therapy – Miglustat (Zavesca) Prior Authorization* criteria; AND **B)** Patient meets BOTH of the following criteria (i <u>and</u> ii): **i.** Patient has tried BOTH Cerdelga (eliglustat capsules) **[documentation required]** and generic miglustat **[documentation required]**; AND **ii.** 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. **2. <u>Other Conditions</u>.** Approve for 1 year if the patient meets the standard *Gaucher Disease Substrate Reduction Therapy – Miglustat (Zavesca) Prior Authorization* criteria.

REFERENCES

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