VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Gaucher Disease – Substrate Reduction Therapy Care Value Policy
- Cerdelga™ (eliglustat capsules – Genzyme)
- Zavesca® (miglustat capsules – Actelion, generic)
- Yargesa® (miglustat capsules – Edenbridge [generic only])

REVIEW DATE: 07/12/2023; selected revision: 12/06/2023

OVERVIEW

Cerdelga and miglustat capsules (Zavesca,Yargesa) are substrate reduction therapy agents indicated for long-term therapy of **Type 1 Gaucher disease** in patients with a confirmed diagnosis.[1-3] Amongst the miglustat formulations, Yargesa is a branded generic product. 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 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 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 all of the Preferred Products prior to the approval of the 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 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, Yargesa, 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, Yargesa
Non-Preferred Product: Zavesca

RECOMMENDED EXCEPTION CRITERIA

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

REFERENCES

1. Cerdelga™ capsules [prescribing information]. Waterford, Ireland: Genzyme; December 2022.
2. Zavesca® capsules [prescribing information]. South San Francisco, CA: Actelion; August 2022.
3. Yargesa® capsules [prescribing information]. Parsippany, NJ: Edenbridge; October 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/31/2022
Annual Revision	No criteria changes.	07/12/2023
Selected Revision	Added Yargesa, a branded generic miglustat product, to the Policy as a Preferred Product. Removed criteria regarding other conditions for approval.	12/06/2023