

## PREFERRED SPECIALTY MANAGEMENT POLICY

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

**REVIEW DATE:** 09/06/2023; selected revision: 12/06/2023

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### 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.<sup>1-3</sup> 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.<sup>1</sup> 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).<sup>2</sup>

### 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 all 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, 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 Product:** Cerdelga, generic miglustat, Yargesa  
**Non-Preferred Product:** Zavesca

## **RECOMMENDED EXCEPTION CRITERIA**

### **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.