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

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 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.

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

Gaucher Disease – Substrate Reduction Therapy non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Zavesca	**1. Gaucher Disease Type I.** **A)** Approve for 1 year if the patient meets the following (i, ii, and iii): **i.** Patient meets the standard *Gaucher Disease Substrate Reduction Therapy – Miglustat Prior Authorization* criteria; AND **ii.** Patient has tried Cerdelga (eliglustat capsules) **[documentation required]**; AND **iii.** Patient meets BOTH of the following (a and b): **a)** Patient has tried one of Yargesa or generic miglustat capsules **[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 meets criteria 1Ai but does not meet criteria 1Aii and 1Aiii, 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.

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.	09/06/2023
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