UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cerdelga and Zavesca

Program	Prior Authorization
Medications	Cerdelga (eliglustat) and Zavesca (miglustat)
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2015
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Cerdelga (eliglustat) is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

Zavesca (miglustat) is indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).

2. Coverage Criteria:

A. Initial Authorization

1. **Cerdelga** will be approved based on **both** of the following criteria:

   a. Diagnosis of Gaucher disease type 1

   -AND-

   b. Patient is **one** of the following as detected by an FDA-cleared test:

      (1) CYP2D6 extensive metabolizer
      (2) CYP2D6 intermediate metabolizer
      (3) CYP2D6 poor metabolizer

   Authorization will be issued for 12 months.

2. **Zavesca** will be approved based on **both** of the following criteria:

   a. Diagnosis of mild to moderate type 1 Gaucher disease

   -AND-

b. Patient is unable to receive enzyme replacement therapy due to **one** of the following conditions

(1) Allergy or hypersensitivity to enzyme replacement therapy
(2) Poor venous access
(3) Unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV)

Authorization will be issued for 12 months.

B. Reauthorization

1. Cerdelga or Zavesca will be approved based on the following criterion:

a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Cerdelga [package insert]. Genzyme Ireland, Ltd. Waterford, Ireland. August 2018.
2. Zavesca [package insert]. Actelion Pharmaceuticals US Inc., June 2019.

Program	Prior Authorization
Change Control	
12/2014	New program.
11/2015	Annual review. Updated to align with Indication Section of FDA label.
11/2016	Changed policy name from “Gaucher Disease Oral Agents” to “Cerdelga and Zavesca” Added Zavesca to reauthorization criteria
9/2017	Annual Review. No changes to criteria. Updated references.
9/2018	Annual review. No changes to criteria. Updated references.
9/2019	Annual review. Updated references.

9/2020	Annual review. No changes to coverage criteria. Added Additional Clinical Rules section.