UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1148-11
Program	Prior Authorization/Notification
Medications	Cerdelga® (eliglustat)
P&T Approval Date	12/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Cerdelga® (eliglustat) is a glucosylceramide synthase inhibitor indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. CYP2D6 ultra-rapid metabolizers may not achieve adequate concentrations of Cerdelga to achieve a therapeutic effect. A specific dosage cannot be recommended for CYP2D6 indeterminate metabolizers.[1]

2. Coverage Criteria[a]:

A. <u>Initial Authorization</u>

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

   a. Diagnosis of Gaucher disease type 1

   -AND-

   b. Patient is **<u>one</u>** 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.

B. <u>Reauthorization</u>

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

   a. Documentation of positive clinical response to **Cerdelga** therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- 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.
- Supply limits may be in place.

3. References:

1. Cerdelga [package insert]. Genzyme Ireland, Ltd. Waterford, Ireland. January 2024.

Program	Prior Authorization/Notification - Cerdelga (eliglustat)
Change Control	
12/2014	New program.
11/2015	Annual review. Updated to align with Indication Section of FDA label.
9/2016	Annual review. No changes to coverage criteria.
9/2017	Annual review. No changes.
9/2018	Annual review. No changes.
9/2019	Annual review. No changes to coverage criteria. Updated background and references.
9/2020	Annual review. No changes to coverage criteria.
10/2021	Annual review. Updated reauthorization duration. Updated reference.
10/2022	Annual review. No changes to coverage criteria. Added state mandate. Updated reference.
10/2023	Annual review. No changes to coverage criteria. Updated reference.
10/2024	Annual review. No changes to coverage criteria. Updated reference.