UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1148-5
Program	Prior Authorization/Notification
Medications	Cerdelga™ (eliglustat)
P&T Approval Date	12/2014, 11/2015, 9/2016, 9/2017, 9/2018
Effective Date	12/1/2018; Oxford only: 12/1/2018

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[1]

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.

B. Reauthorization

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

a. Documentation of positive clinical response to Cerdelga therapy

Authorization will be issued for 24 months.

3. Additional Clinical Programs:

- Supply limits may be in place.

4. References:

1. Cerdelga Prescribing Information. Genzyme Ireland, Ltd. Waterford, Ireland. August 2014.

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.