Commercial/Healthcare Exchange PA Criteria

Effective: July 27, 2016

Prior Authorization: Cerdelga

Products Affected: Cerdelga (eliglustat) oral capsule

Medication Description:

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.

Gaucher disease is caused by a deficiency of the lysosomal enzyme acid β-glucosidase. Acid β-glucosidase catalyzes the conversion of the sphingolipid glucocerebroside into glucose and ceramide. The enzymatic deficiency causes an accumulation of glucosylceramide (GL-1) primarily in the lysosomal compartment of macrophages, giving rise to foam cells or "Gaucher cells". Cerdelga is a specific inhibitor of glucosylceramide synthase (IC50 = 10 ng/mL), and acts as a substrate reduction therapy for GD1. In clinical trials Cerdelga reduced spleen and liver size, and improved anemia and thrombocytopenia.

In this lysosomal storage disorder (LSD), clinical features are reflective of the accumulation of Gaucher cells in the liver, spleen, bone marrow, and other organs. The accumulation of Gaucher cells in the liver, spleen, and bone marrow leads to organomegaly and skeletal disease. Presence of Gaucher cells in the bone marrow and spleen lead to clinically significant anemia and thrombocytopenia.

Covered Uses: 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

Exclusion Criteria:

1. Patients who are CYP2D6 ultra-rapid metabolizers
2. Patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers)
3. Hepatic impairment

Required Medical Information:

1. Diagnosis
2. CYP2D6 metabolizer status
3. Previous therapies tried

Age Restrictions: 18 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

A. Patient has a confirmed diagnosed of Type 1 Gaucher's Disease; AND

B. Patient has been tested using an FDA cleared test to determine the CYP2D6 metabolizer status and has been classified as an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM); AND
C. Patient has tried and failed or is unable to tolerate enzyme replacements therapy (Cerezyme, Vpriv, Elelyso) for at least 6 months

References:

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

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/3/16
2	Update	Update policy to FDA label	Exclusion Criteria	12/6/2019
3	Update	CCI to adopt EH Policy and Template. Remove from CCI Gaucher policy	All	1/3/2020