

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Cerdelga (eliglustat)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Cerdelga (eliglustat)

### APPROVAL CRITERIA

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of Type 1 Gaucher disease confirmed by either of the following (Weinreb et al. 2004, Wang et al. 2011):
  - A. Glucocerebrosidase activity less than or equal to 30% of normal activity in the white blood cells or skin fibroblasts; **OR**
  - B. Genotype testing indicates mutation of two alleles of the glucocerebrosidase genome;

### **AND**

- III. There are clinically significant manifestations of Gaucher disease, including **any** of the following:
  - A. Skeletal disease as demonstrated by radiologic evidence of **any** of the following (Weinreb et al. 2004):
    1. Avascular necrosis; **OR**
    2. Erlenmeyer flask deformity (failure of bone remodeling); **OR**
    3. Lytic disease; **OR**
    4. Marrow infiltration; **OR**
    5. Osteopenia; **OR**
    6. Osteosclerosis; **OR**
    7. Pathological fracture; **OR**
    8. Joint deterioration or replacement;
  - OR**
  - B. Presents with **at least two** of the following (Weinreb et al. 2004, Mistry et al. 2015):
    1. Clinically significant splenomegaly as confirmed by medical imaging [such as but not limited to, volumetric magnetic resonance imaging (MRI)]; **OR**
    2. Clinically significant hepatomegaly as confirmed by medical imaging (such as but not limited to, volumetric

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MRI); **OR**

3. Hemoglobin less than or equal to 11.5 g/dL for females and less than 12.5 g/dL for males, or 1.0g/dL below lower limit for normal for age and sex; **OR**
4. Platelet count less than or equal to 120,000mm<sup>3</sup>

**AND**

IV. Individual is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as confirmed by a FDA-approved genotype test.

Cerdelga (eliglustat) may **not** be approved for the following:

- I. Individual has any of the following diagnoses:
  - A. Moderate renal impairment, severe renal impairment, or end-stage renal disease (ESRD); **OR**
  - B. Mild, moderate, or severe hepatic impairment or cirrhosis; **OR**
  - C. Pre-existing cardiac disease or long QT syndrome;

**OR**

- II. When given in conjunction with any of the following:
  - A. Zavesca (miglustat); **OR**
  - B. Gaucher disease enzyme replacement therapies [Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), or VPRIV (velaglucerase alfa)]; **OR**
  - C. Class IA (for example, quinidine, procainamide) or Class III (for example, amiodarone, sotalol) antiarrhythmic; **OR**
  - D. Moderate or strong CYP2D6 inhibitor (for example, paroxetine, terbinafine) with a moderate or strong CYP3A inhibitor (for example, ketoconazole) in CYP2D6 EM or IM individuals; **OR**
  - E. Moderate or strong CYP3A inhibitor (for example, ketoconazole, fluconazole) in CYP2D6 IM individuals; **OR**
  - F. Weak, moderate, or strong CYP3A inhibitor (for example, ranitidine, ketoconazole, fluconazole) in CYP2D6 PM individuals; **OR**
  - G. Strong CYP3A inducers (for example, rifampin, phenytoin) in CYP2D6 EM, IM, or PM individuals;

**OR**

- III. Individuals who are CYP2D6 ultra-rapid or indeterminate metabolizers.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed on: April 10, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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