Updated: 06/2018
PARP Approved: 06/2018

Gateway Health
Prior Authorization Criteria
Cerdelga (eliglustat)

All requests for Cerdelga (eliglustat) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Cerdelga (eliglustat)Prior Authorization Criteria:

Coverage may be provided with a diagnosis of Gaucher Disease Type 1 and the following criteria is met:

- Confirmation of Type 1 Gaucher Disease diagnosis by one of the following:
  - A beta-glucosidase leukocyte (BGL) test
  - A genetic test
- Member must have one or more of the following (supported by the corresponding documentation):
  - Anemia
    - Documentation of a baseline low hemoglobin level (laboratory reference range must be submitted)
  - Thrombocytopenia
    - Documentation of a baseline low platelet level (laboratory reference range must be submitted)
  - A provider attestation that the member has one of the following:
    - hepatomegaly or splenomegaly supported by documentation of a current baseline liver or spleen size
- The member is 18 years of age or older
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Documentation the member is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-cleared test
- The member must not have an FDA labeled contraindication to Cerdelga
- Coverage is not provided for CYP2D6 ultra-rapid metabolizers. Cerdelga is not indicated in patients who are CYP2D6 ultra-rapid metabolizers, since they may not achieve adequate concentrations of Cerdelga to achieve a therapeutic effect.

- **Initial Duration of Approval:** 12 months

- Reauthorization requires documentation of the following:
  - Documentation the member had a positive clinical response or stabilization as demonstrated by one of the following:
    - An increase in hemoglobin level from baseline (taken within last 12 months)
    - An increase in platelet levels from baseline (taken within last 12 months)
    - A reduction in liver or spleen size from baseline (taken within last 12 months)

- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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CERDELGA (ELIGLUSTAT)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Member's Diagnosis: ☐ Type 1 Gaucher Disease ☐ Other _____ (please submit documentation of confirmation of the diagnosis)

Does the member have any of the following: ***please select all that apply***

- ☐ Anemia
- ☐ Thrombocytopenia
- ☐ Hepatomegaly or splenomegaly

Please provide the following and laboratory reference range:

Baseline hemoglobin level: _____ Date taken:_____

Baseline platelet level: _____ Date taken:_____

Baseline spleen size:_____ Date taken:_____

Baseline liver size:_____ Date taken:_____

What type of CYP2D6 metabolizer is the member? (please provide documentation of an FDA-cleared test)

☐ Extensive Metabolizer
☐ Intermediate Metabolizer
☐ Poor Metabolizer
☐ Ultra-Rapid Metabolizer

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member tolerated therapy and shown improvement ☐ Yes ☐ No

Please provide the following:

Current hemoglobin level:_____ Date taken:_____
Current platelet level: _____ Date taken:_____
Current spleen size:_____ Date taken:_____
Current liver size:_____ Date taken:_____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date