HIGHMARK HEALTH OPTIONS

Updated: 07/2022
DMMA Approved: 07/2022

Request for Prior Authorization for Gaucher Disease: Enzyme Replacement and Substrate Reduction Therapy
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Gaucher Disease: Enzyme Replacement and Substrate Reduction Therapy require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Gaucher Disease: Enzyme Replacement and Substrate Reduction Therapy Prior Authorization Criteria:

Coverage may be provided with a diagnosis of Type 1 Gaucher Disease 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
- Is age appropriate according to FDA approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Member must also 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:
    - Bone Disease
    - Hepatomegaly or splenomegaly supported by documentation of a current baseline liver or spleen size
- For Cerdelga (eliglustat):
  - Documentation the member is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-cleared test
  - Coverage is not provided for CYP2D6 ultra-rapid metabolizers.
- For Zavesca (miglustat):
  - Documentation the member is unable to use enzyme replacement therapy.

- **Initial Duration of Approval:** 6 months

- **Reauthorization criteria**:

- 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 6 months)
  - An increase in platelet levels from baseline (taken within last 6 months)
  - An attestation from the provider of an improvement in bone disease
  - A reduction in liver or spleen size from baseline (taken yearly)

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

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GAUCHER DISEASE ERT AND SRT THERAPY PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient?
☐ Yes ☐ No

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

1. **Member's Diagnosis:** ☐ Type 1 Gaucher Disease ☐ Other

2. **If requesting for Type 1 Gaucher Disease how was the diagnosis confirmed?** ***Please provide supporting documentation*** ☐
   Beta-glucosidase leukocyte (BGL) test ☐ Genetic Testing

3. **Does the member have any of the following:** ***please select all that apply***
   ☐ Anemia
   ☐ Thrombocytopenia
   ☐ Bone Disease
   ☐ Hepatomegaly or splenomegaly

4. **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:_____
   _____

For Cerdelga(eliglustat) Only:

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

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Member Name: **DOB:**
Member ID:

For Zavesca (miglustat) only:
Please provide documentation of why the member is not a candidate for enzyme replacement therapy:

CURRENT OR PREVIOUS THERAPY

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

REAUTHORIZATION

1. **Has the member tolerated therapy and shown improvement** ☐ Yes ☐ No

2. **If the member has bone disease has the member shown improvement** ☐ Yes ☐ No ☐ N/A

3. **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 Physician Signature	Date