HIGHMARK WHOLECARE

Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Enzyme Replacements, Gaucher Disease

A. Prescriptions That Require Prior Authorization

All prescriptions for Enzyme Replacements, Gaucher-Disease agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Enzyme Replacement, Gaucher Disease agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Enzyme Replacements, Gaucher Disease agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)- approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a history of a contraindication to the prescribed medication; **AND**

5. Is prescribed the Enzyme Replacements, Gaucher Disease agent by or in consultation with a specialist in the treatment of Gaucher disease; **AND**

6. For a non-preferred Enzyme Replacements, Gaucher Disease agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Enzyme Replacements, Gaucher Disease agents approved or medically accepted for the beneficiary's indication. See the Preferred Drug List (PDL) for the list of preferred Enzyme Replacement, Goucher Disease agents at: https://papdl.com/preferred-drug-list; **AND**

7. For a diagnosis of Gaucher disease, has documentation of both of the following:

    a. One of the following:
        i. Enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) activity
        ii. DNA testing confirming the diagnosis

    b. One of the following:
        i. Anemia
        ii. Bone disease
        iii. Hepatomegaly
        iv. Interstitial lung disease
        v. Splenomegaly
        vi. Thrombocytopenia

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NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ENZYME REPLACEMENTS, GAUCHER DISEASE AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Enzyme Replacements, Gaucher Disease agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Is prescribed the Enzyme Replacements, Gaucher Disease agent by or in consultation with a specialist in the treatment of Gaucher disease; **AND**

3. Has documentation of improvement in disease severity since initiating treatment with the requested Enzyme Replacements, Gaucher Disease agent

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Enzyme Replacements, Gaucher-Disease agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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ENZYME REPLACEMENTS, GAUCHER DISEASE PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	# of pages: ________	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.

Drug requested:	Strength:	
Dose/directions:	Quantity:	Refills:
Diagnoses (*submit documentation*):	Dx codes (*required*):	

INITIAL requests	
Does the beneficiary have a diagnosis of Gaucher disease supported by one of the following? *Check all that apply.* ☐enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) activity ☐DNA testing confirming the diagnosis	☐Yes ☐No *Submit documentation.*
Does the beneficiary have any of the following? *Check all that apply.* ☐anemia ☐hepatomegaly ☐splenomegaly ☐bone disease ☐interstitial lung disease ☐thrombocytopenia	☐Yes ☐No *Submit documentation.*
For Cerdelga: What is the beneficiary's CYP2D6 metabolizer status? *Check ONE.* ☐poor metabolizer (PM) ☐extensive metabolizer (EM) ☐intermediate metabolizer (IM) ☐ultra-rapid metabolizer	*Submit documentation.*
For a non-preferred medication: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of the preferred agents? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes ☐No *Submit documentation.*
RENEWAL requests	
Did the beneficiary experience improvement in disease severity since initiating treatment with the requested medication?	☐Yes ☐No *Submit documentation.*

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date:

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