Updated: 09/2022
DMMA Approved: 09/2022

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

All requests for Enzyme Replacement Therapy*, Pompe Disease require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

*Enzyme Replacement Therapy, Pompe Disease medications include Lumizyme (alglucosidase alfa) and Nexviazyme (avalglucosidase alfa-ngpt). New products with this classification will require the same documentation.

Enzyme Replacement Therapy, Pompe Disease Prior Authorization Criteria:

Coverage may be provided with a diagnosis of **Pompe Disease** and the following criteria is met:

- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
    - For Nexviazyme (avalglucosidase alfa-ngpt), must be at least 1 year of age.
- Medication must be prescribed by or in consultation with a metabolic specialist and/or biochemical geneticist.
- Must have GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy.
- For members 12 years and older, must have pulmonary function testing (PFT) and muscle strength evaluation with documentation of baseline percent predicted forced vital capacity (FVC) and baseline 6-minute walk test.
- For late-onset Pompe disease only, must have completed genetic testing to identify the specific mutation to confirm the diagnosis of late-onset Pompe disease.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - For members 12 years of age or older, clinical documentation of improvement defined by improvement in percent predicted FVC and/or 6-minute walk test compared to baseline.
    - For members under the age of 12, reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only

the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

HIGHMARK HEALTH OPTIONS

Updated: 09/2022
DMMA Approved: 09/2022

Enzyme Replacement Therapy, Pompe Disease
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 Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

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

Diagnosis: ☐ Infantile-onset Pompe disease ☐ Late-onset (non-infantile) Pompe disease ICD-10: _____
☐ Other: _____ ICD-10: _____
Was diagnosis confirmed by GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy? ☐ Yes ☐ No
For late-onset Pompe disease, was genetic testing done to confirm the diagnosis? ☐ Yes ☐ No
Has baseline pulmonary function testing (PFT) and muscle strength evaluation been completed? ☐ Yes ☐ No

REAUTHORIZATION

Please indicate which of the following apply as a result of treatment:

☐ Improvement in FVC:
Baseline: _____ Date:_____
Recent FVC: _____ Date: _____

☐ Improvement in 6-min walk or other muscle strength evaluation:
Baseline: _____ Date: _____
Recent 6-min walk: _____ Date: _____

☐ Other improvements (please describe or attach chart documentation): _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

HIGHMARK HEALTH OPTIONS

Updated: 09/2022
DMMA Approved: 09/2022