Gateway Health℠ It's Wholecare.

Updated: 09/2020
PARP Approved: 10/2020

Prior Authorization Criteria

Lumizyme (alglucosidase alfa)

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

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

- 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 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.

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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LUMIZYME (ALGLUCOSIDASE ALFA)
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℠ 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)

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