Updated: 10/2018
PARP Approved: 11/2018

Gateway Health
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.

For all requests for Lumizyme (alglucosidase alfa) all of the following criteria must be met:
Coverage may be provided with a diagnosis of **Pompe Disease** and the following criteria is met:

- Member must have clinical documentation of a diagnosis of the late-onset (non-infantile) Pompe disease OR a diagnosis of infantile-onset Pompe disease supported by ALL of the following:
    - GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy.
    - Baseline pulmonary function testing (PFT) and muscle strength evaluation. (This only applies to members 12 years of age or older)
    - For late-onset Pompe disease only, genetic testing to identify the specific mutation to confirm the diagnosis of late-onset Pompe disease.
- Medication must be prescribed by or in consultation with a metabolic specialist and/or biochemical geneticist.
- Member must have clinical documentation of baseline percent predicted forced vital capacity (FVC) and baseline 6-minute walk test. (This only applies to member 12 years of age or older)
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Clinical documentation of baseline percent predicted forced vital capacity (FVC) and baseline 6-minute walk test. (This only applies to 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. (This only applies to members 12 years of age or older)
    - 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[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)

1) Does the member have clinical documentation of a diagnosis of the late-onset (non-infantile) Pompe disease OR a diagnosis of infantile-onset Pompe disease supported by ANY of the following (Please attach all appropriate clinical documentation)?

a. GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy
☐ Yes ☐ No

b. Baseline pulmonary function testing (PFT) and muscle strength evaluation. (This only applies to member 12 years of age or older)
☐ Yes ☐ No

c. For late-onset Pompe disease only, genetic testing to identify the specific mutation to confirm the diagnosis of late-onset Pompe disease.
☐ Yes ☐ No

2) Will the medication be prescribed by or in consultation with a metabolic specialist and/or biochemical geneticist?
☐ Yes ☐ No

3) Please provide the following baseline values (This only applies to member 12 year of age of older):
Baseline percent predicted forced vital capacity (FVC):

Baseline 6-minute walk test:

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Please provide the following baseline values (This applies to member 12 years of age or older):

Baseline percent predicted forced vital capacity (FVC):

Baseline 6-minute walk test:

Please provide current values:

Post-treatment percent predicted forced vital capacity (FVC):

Post-treatment 6-minute walk test:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date