SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Lumizyme® (alglucosidase alfa) **(J0221) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]:
- ❑ Lumizyme 50 mg vial: 46 vials every 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:
- ❑ 230 billable units every 14 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

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All of the following criteria must be met:

- ❑ Lumizyme will **NOT** be used in combination with other enzyme replacement therapies i.e., Nexviazyme® (avaglucosidase alfa-ngpt)
- ❑ Member has **NOT** experienced a severe hypersensitivity reaction including anaphylaxis to Lumizyme®
- ❑ Member is **NOT** susceptible to fluid volume overload, or has an acute underlying respiratory illness or compromised cardiac or respiratory function for whom fluid restriction is indicated
- ❑ Member has a diagnosis of Pompe disease (acid alpha-glucosidase (GAA) deficiency) confirmed by **ONE** of the following:
  - ❑ Deficiency of acid alpha-glucosidase (GAA) enzyme activity which shows reduced enzyme activity less than 40% of the lab specific normal mean value
  - ❑ Detection of biallelic pathogenic variants in the GAA gene by molecular genetic testing
- ❑ Member has one or more of the following baseline values that corresponds with at least one diagnosis **(please submit labs):**
  - ❑ Infantile-onset disease
    - ❑ Muscle weakness
    - ❑ Motor function
    - ❑ Respiratory function
    - ❑ Cardiac involvement
    - ❑ Percent predicted forced vital capacity (FVC)
    - ❑ 6 minute walk test (6MWT)
  - ❑ Late-onset (non-infantile) disease
    - ❑ Percent predicted forced vital capacity (FVC)
    - ❑ 6 minute walk test (6MWT)

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

All of the following criteria must be met:

- ❑ Member continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial approval criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g. anaphylaxis and hypersensitivity reactions, immune-mediated cutaneous reactions, systemic immune-mediated reactions, acute cardiorespiratory failure, cardiac arrhythmia and sudden cardiac death during general anesthesia)
- ❑ Member has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following that corresponds with at least one diagnosis **(please submit labs)**:

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- ❑ Infantile-onset disease; **stabilization or improvement in**:
  - ❑ Muscle weakness
  - ❑ Motor function
  - ❑ Respiratory function
  - ❑ Cardiac involvement
  - ❑ Percent predicted forced vital capacity (FVC)
  - ❑ 6 minute walk test (6MWT)
- ❑ Late-onset (non-infantile) disease; **stabilization or improvement in**:
  - ❑ Percent predicted forced vital capacity (FVC)
  - ❑ 6 minute walk test (6MWT)
- ❑ Member is being monitored for antibody formation (including neutralizing antibodies)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 11/18/2021
REVISED/UPDATED: 2/4/2022