Alglucosidase alfa (Lumizyme®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration HCPCS: J0221 per 10 mg

Condition(s) listed in policy (*see criteria for details*)

- Infantile-onset Pompe disease
- Late-onset Pompe disease

AHFS therapeutic class: Enzyme

Mechanism of action: Produced by recombinant DNA technology, Lumizyme consist of the human enzyme acid α-glucosidase (GAA), encoded by the most predominant of nine observed haplotypes of this gene.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION **

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.
For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF LUMIZYME IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is initiating therapy (allowed for the first 2 infusions) with Lumizyme or is being re-initiated on Lumizyme after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

   Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Lumizyme based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on Lumizyme based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for alglucosidase alfa (Lumizyme®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Infantile or late-onset Pompe disease

1. Diagnosis is infantile or late-onset Pompe Disease (also known as Glycogen Storage Disease Type II or acid maltase deficiency), **AND**
2. One of the following:
    a. Genetic testing showing acid αlpha-glucosidase (GAA) mutation, or
    b. An enzyme assay showing absent or decreased acid αlpha-glucosidase (GAA) activity in blood, skin or muscle tissues

Covered Doses
Up to 20 mg/kg IV every 2 weeks

Coverage Period
Cover indefinitely

ICD-10:
E74.02

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for alglucosidase alfa must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
Lumizyme: 50 mg vials, as lyophilized powder (single-use)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Lumizyme® (alglucosidase alfa) [Prescribing information]. Cambridge, MA: Genzyme Corporation; 5/2022.
- The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Consensus Treatment Recommendations for Late-Onset Pompe Disease Muscle Nerve 2012 Mar 45(3): 319-333.

(7) Policy Update

Date of initial review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- New policy

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee