Alglucosidase alfa (Lumizyme®)	**Place of Service** **Office Administration** **Infusion Center Administration** **Home Infusion Administration** **Lumizyme** Use HCPC: J0221 per 10mg NDC: 58468-0160-01, 58468-0160-02

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 a-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.

(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:

- Diagnosis is infantile or late-onset Pompe Disease (also known as Glycogen Storage Disease Type II or acid maltase deficiency),

AND

- For initial treatment: an enzyme assay showing absent or decreased acid a-glucosidase activity (GAA) from blood, skin or muscle tissues.

Covered Doses
Up to 20mg/kg every 2 weeks as an intravenous infusion

Coverage Period
Cover indefinitely

ICD-9:
271.0

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 COVERED for the following condition(s)

The following conditions and other indications not listed in this policy do not meet the coverage criteria established by the Blue Shield of CA P&T Committee and are NOT COVERED. Please refer to the user guide for more information.

(5) Additional Information

How supplied:

Lumizyme: 50 mg vials, as lyophilized powder

(6) References

- Lumizyme® prescribing information. Genzyme Corporation. August 2014.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

1. Pompe disease diagnosis and management guideline. American College of Medical Genetics (ACMG) Work Group on Management of Pompe Disease. Genet Med 2006 May;8(5):267-88.

(7) Policy Update

Date of last revision: 3Q2017
Date of next review: 3Q2018
Changes from previous policy version:

- No change to policy following routine review

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