

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Lumizyme (alglucosidase alfa)

CG-DRUG-28

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications
Lumizyme (alglucosidase alfa)

### APPROVAL CRITERIA

- I. Lumizyme (alglucosidase alfa) may be approved for individuals with infantile-onset Pompe disease when **all** of the following are met:
  - A. Diagnosis of infantile-onset Pompe disease is confirmed with acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean **or** by GAA gene sequencing; **AND**
  - B. Presence of symptoms (for example respiratory and/or skeletal muscle weakness) of infantile-onset Pompe disease; **AND**
  - C. Evidence of hypertrophic cardiomyopathy.

**OR**

- II. Lumizyme (alglucosidase alfa) may be approved for individuals with non-infantile onset (late-onset) Pompe disease when **all** of following are met:
  - A. Diagnosis of late-onset Pompe disease based on
    1. GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value; **AND**
    2. Confirmed by a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA gene sequencing;
  - AND**
  - B. Forced vital capacity (FVC) 30 -79% of predicted value;
  - AND**
  - C. Ability to walk 40 meters on a 6-minute walk test (assistive devices permitted);
  - AND**
  - D. Muscle weakness in the lower extremities.

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Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.