# Lumizyme (alglucosidase alfa)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | 1 year |

| Medications | Dosing Limit |
|---|---|
| Lumizyme (alglucosidase alfa) 50 mg vial | 20 mg/kg every 2 weeks |

## APPROVAL CRITERIA

Initial requests for Lumizyme (alglucosidase alfa) may be approved if the following criteria are met:

I. Individual has a diagnosis of infantile-onset Pompe disease as confirmed by all of the following:
   A. Documentation is provided for acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing (AANEM 2009); **AND**
   B. Individual has symptoms (for example respiratory and/or skeletal muscle weakness); **AND**
   C. Individual has evidence of hypertrophic cardiomyopathy;

**OR**

II. Individual has a diagnosis of non-infantile onset (late-onset) Pompe disease as confirmed by all of following(ACMG 2006):
   A. Documentation is provided for GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value; **AND**
   B. Documentation is provided for a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA gene sequencing (AANEM 2009); **AND**
   C. Forced vital capacity (FVC) 30 -79% of predicted value, and documentation is provided; **AND**
   D. Ability to walk 40 meters on a 6-minute walk test (assistive devices permitted), and documentation is provided;
   **AND**
   E. Muscle weakness in the lower extremities;

Continuation requests for Lumizyme (alglucosidase alfa) may be approved if the following criteria are met:

I. Individuals are using Lumizyme for the treatment of infantile-onset Pompe disease;
**OR**
II. Individuals with non-infantile onset (late-onset) Pompe disease are responding to therapy (including improvement, stabilization, or slowing of disease progression)

Lumizyme (alglucosidase alfa) may not be approved for the following:

I. In combination with Nexviazyme (avalglucosidase alfa-ngpt); **OR**
II. In combination with Pombiliti; **OR**
III. When the above criteria are not met and for all other indications.

**Key References**:


1. American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM). Pompe. Available at: https://www.aanem.org/Patients/Disorders/Pompe. Accessed on August 5, 2022.
2. American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Consensus Committee on Late-onset Pompe Disease. Consensus treatment recommendations for late-onset Pompe disease. Muscle Nerve. 2012 Mar;45(3):319-33. Accessed: August 3, 2022.
3. American College of Medical Genetics (ACMG) Work Group on Management of Pompe Disease. Pompe disease diagnosis and management guideline. Genetics in Med. 2006; 8(5):267-288.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
5. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 5, 2022
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
8. Lumizyme [Package insert], Cambridge, MA. Genzyme Corporation; 2022.