Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Lumizyme (alglucosidase alfa)

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

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

APPROVAL CRITERIA

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. Confirmationof 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. Confirmation of symptoms (for example respiratory and/or skeletal muscle weakness); **AND**
   C. Confirmed 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. Confirmation of GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value; **AND**
   B. Confirmation of 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**
   D. Ability to walk 40 meters on a 6-minute walk test (assistive devices permitted); **AND**
   E. Muscle weakness in the lower extremities.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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

Key References:

1. American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM). Pompe. Available at: https://www.aanem.org/Patients/Disorders/Pompe. Accessed on August 29, 2019.
2. 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.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 29, 2019.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. Lumizyme [Package insert], Cambridge, MA. Genzyme Corporation; 2014.