

Lumizyme® (alglucosidase alfa)



When requesting Lumizyme® (alglucosidase alfa), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- Lumizyme® (alglucosidase alfa) is indicated for the treatment of individuals with Pompe disease.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards

Coverage Guidelines

Pompe Disease

Has a diagnosis of Pompe disease confirmed by enzyme assay demonstrating a deficiency of alpha-glucosidase enzyme activity or by genetic testing^{1,3}

Approval duration: 12 months

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Life-threatening anaphylactic reactions and severe hypersensitivity reactions have been observed in some individuals during and after infusions.
- Infantile-onset Pompe disease individuals with compromised cardiac or respiratory function may be at risk of serious acute exacerbation of their cardiac or respiratory compromise due to fluid overload, and require additional monitoring.
- Monitor individuals for the development of systemic immune-mediated reactions involving skin and other organs.
- Individuals with compromised cardiac or respiratory function may be at risk of acute cardiorespiratory failure. Caution should be exercised when administering Lumizyme® (alglucosidase alfa) to individuals susceptible to fluid volume overload.

References

1. Lumizyme® prescribing information. Cambridge, MA: Genzyme Corporation: Revised August 2014. <https://www.lumizyme.com/patients.aspx>. Accessed February 16, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 16, 2017. <https://www.micromedexsolutions.com>
3. ACMG Work Group on Management of Pompe Disease. Pompe disease diagnosis and management guideline. *Genet Med*. 2006;8:267-288. Accessed February 16, 2016. https://www.acmg.net/staticcontent/staticpages/pompe_disease.pdf