

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 Indication

Lumizyme (alglucosidase alfa) is indicated for the treatment of individuals with Pompe disease (acid α -glucosidase deficiency).

Coverage Guidelines

Pompe Disease

The individual must meet **all** of the following criteria for approval:

- Diagnosis is confirmed by one of the following:
 - o Laboratory test demonstrating deficient acid α -glucosidase activity in blood, fibroblasts, or muscle tissue; OR
 - o Molecular genetic test demonstrating acid α -glucosidase gene mutation
- Lumizyme is prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

Approval duration: 12 months

Dosing Recommendation

Approve up to 20 mg/kg administered intravenously no more frequently than once every 2 weeks.

References

1. Lumizyme® injection [prescribing information]. Cambridge, MA: Genzyme Corporation; August 2014.
2. Chien YH, Hwu WL, Lee NC. Pompe disease: Early diagnosis and early treatment make a difference. *Pediatr Neonatol*. 2013;54:219-227.
3. Llerena Junior JC, Nascimento OJM, Oliveira ASB, et al. Guidelines for the diagnosis, treatment and clinical monitoring of patients with juvenile and adult Pompe disease. *Arq Neuropsiquiatr*. 2016;74:166-176.
4. Cupler EJ, Berger KI, Leshner RT, et al. Consensus treatment recommendations for late-onset Pompe disease. *Muscle Nerve*. 2012;45:319-333.