blue california
Promise Health Plan

alglucosidase alfa (Lumizyme)

Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: human enzyme acid α-glucosidase (GAA)

HCPCS:
J0221:Injection, alglucosidase alfa, (lumizyme), 10 mg

How Supplied:
50 mg vial, as lyophilized powder (single-use)

Condition(s) listed in policy *(see coverage criteria for details)*

- Infantile or Late-Onset Pompe Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Infantile or Late-Onset Pompe Disease
Meets medical necessity if all the following are met:

1. Diagnosis is infantile or late-onset Pompe Disease (also known as Glycogen Storage Disease Type II or acid maltase deficiency)
2. Meets ONE of the following:
   a. Genetic testing showing acid alpha-glucosidase (GAA) mutation
   b. An enzyme assay showing absent or decreased acid alpha-glucosidase (GAA) activity in blood, skin or muscle tissues

Covered Doses:
Up to 20 mg/kg given intravenously every 2 weeks

Coverage Period:
Through 9/30/2025: Indefinitely

Effective 10/1/2025 and after:
Initial: 1 year
Reauthorization: Yearly if there is continued benefit from therapy

ICD-10:
E74.02

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Lumizyme (alglucosidase alfa) Prescribing Information. Genzyme Corporation, Cambridge, MA: 12/2024.
4. The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Consensus Treatment Recommendations for Late-Onset Pompe Disease Muscle Nerve 2012 Mar 45(3): 319-333. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3534745/.
5. Stevens D, Milani-Nejad S, Mozaffar T. Pompe Disease: a Clinical, Diagnostic, and Therapeutic Overview. *Curr Treat Options Neurol*. 2022 Nov;24(11):573-588. Epub 2022 Aug 4. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10035871/pdf/nihms-1847668.pdf.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- Pompe Disease: Updated Coverage Period to require yearly reauthorization based on response to drug

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee