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**5.30.034**

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Endocrine and Metabolic Agents	<b>Original Policy Date:</b>	July 1, 2010
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**Last Review Date:** March 6, 2026

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## Lumizyme

### Description

#### Lumizyme (alglucosidase alfa)

#### Background

Lumizyme is indicated for Pompe disease, a rare genetic disorder. In Pompe disease, a gene mutation prevents the body from making an enzyme or making enough of the enzyme called acid alpha-glucosidase (GAA), necessary for proper muscle functioning. GAA is used by the heart and muscle cells to convert a form of sugar called glycogen into energy. Without the enzyme action, glycogen builds up in the cells and, ultimately, weakens the heart and muscles. Lumizyme replaces the deficient GAA, thereby reducing the accumulated glycogen in heart and skeletal muscle cells (1).

#### Regulatory Status

FDA-approved indication: Lumizyme (alglucosidase alfa) is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (acid  $\alpha$ -glucosidase (GAA) deficiency) (1).

Acute cardiorespiratory failure has been observed in a few infantile-onset Pompe disease patients with underlying cardiac hypertrophy, possibly associated with fluid overload with intravenous administration of alglucosidase alfa (1).

Lumizyme has a boxed warning that anaphylactic, severe allergic and immune mediated reactions have been observed during administration and up to 3 hours after. Patients with acute underlying respiratory illness or compromised cardiac and/or respiratory function may be at risk

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of serious exacerbation of their cardiac or respiratory compromise during infusions. Appropriate medical support should be available during infusion (1).

Patients should be monitored for IgG antibody formation every 3 months for 2 years and then annually thereafter. Testing for IgG titers may also be considered if patients develop allergic or other immune mediated reactions. Patients who experience anaphylactic or allergic reactions may also be tested for IgE antibodies to alglucosidase alfa and other mediators of anaphylaxis. Patients who develop IgE antibodies to alglucosidase alfa appear to be at a higher risk for the occurrence of anaphylaxis and severe allergic reactions. Therefore, these patients should be monitored more closely during administration of Lumizyme (1).

The safety and effectiveness of alglucosidase alfa have been established in pediatric patients with Pompe disease (1).

## Related policies

Nexviazyme

### [Policy](#)

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Lumizyme may be considered **medically necessary** if the conditions indicated below are met.

Lumizyme may be considered **investigational** for all other indications.

## Prior-Approval Requirements

### Diagnosis

Patient must have the following:

Pompe disease (acid alpha-glucosidase (GAA) deficiency)

**AND** the following:

1. Monitored for IgG antibody formation every 3 months for 2 years and then annually thereafter

## Prior – Approval *Renewal* Requirements

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## Diagnosis

Patient must have the following:

Pompe disease (acid alpha-glucosidase (GAA) deficiency)

**AND** the following:

1. Monitored for IgG antibody formation every year

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 2 years

### Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Lumizyme (alglucosidase alfa) is a lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (acid  $\alpha$ -glucosidase (GAA) deficiency). Lumizyme has a boxed warning that anaphylactic, severe allergic and immune mediated reactions have been observed. Patients with acute underlying respiratory illness or compromised cardiac and/or respiratory function may be at risk of serious exacerbation of their cardiac or respiratory compromise during infusions. Appropriate medical support should be available during infusion. Patients should be monitored for IgG antibody formation every 3 months for 2 years and then annually thereafter (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lumizyme while maintaining optimal therapeutic outcomes.

### References

1. Lumizyme [package Insert]. Cambridge, MA: Genzyme Corporation; March 2024.

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## Policy History

Date	Action
September 2011	New Policy
September 2012	Annual editorial review and reference update.
June 2013	Annual editorial review and reference update
August 2014	Removal of age limit and the Lumizyme ACE Program and the revision of the diagnosis to Pompe disease to align with the new package insert.
September 2014	Annual editorial review and reference update
September 2015	Annual editorial review
September 2016	Annual editorial review and reference update Policy number change from 5.08.15 to 5.30.34
December 2017	Annual review
September 2018	Addition of no history of cardiomyopathy to requirements
November 2018	Annual review
December 2019	Annual editorial review and reference update. Changed approval duration from lifetime to 2 years
December 2020	Annual review and reference update
June 2021	Annual review
December 2021	Annual review
June 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.30.034. Per SME, removed initiation requirement of no cardiac hypertrophy or cardiomyopathy
March 2024	Annual review and reference update
March 2025	Annual review and reference update
March 2026	Annual review

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**