

<b>Policy Name:</b>	<b>Lumizyme (alglucosidase)</b>	<b>Policy #:</b>	<b>2477P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Lumizyme (alglucosidase).

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Lumizyme(alglucosidase) under the Specialty Medical benefit when the following criteria have been met.

## Criteria

### 1. Coverage Criteria for the Treatment of Pompe disease

- 1.1 Diagnosis of Pompe disease, supported by the following:
  - i Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle
  - ii Genetic testing showing a mutation in the GAA gene
- 1.2 Age 1 year or older
- 1.3 Prescribed by a geneticist (gene specialist) or specialist in Pompe disease
- 1.4 Documentation and imaging to rule out presence of an enlarged heart (cardiomyopathy)
- 1.5 Documentation showing baseline percent-predicted forced vital capacity (FVC) and 6-minute walk test (6MWT)
- 1.6 Review of chart notes documenting diagnosis and confirming that patient has met all above requirements for treatment with Nexviazyme by both a pharmacist and medical director

### 2. Exclusion Criteria

- 2.1 Use along with Nexviazyme is considered a duplication and is excluded from coverage.

### 3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reapproval: 12 months with documentation of positive clinical response and toleration of treatment

CPT Codes	
96360 – 96361	Intravenous infusion, hydration
96365 – 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

HCPCS Codes	
J0221	Injection, alglucosidase alfa, 10mg (Lumizyme)

## References

1. Kishnani PS, Corzo D, Leslie ND, et al. Early treatment with alglucosidase alpha prolongs long-term survival of infants with Pompe disease. *Pediatr Res* 2009; 66:329.
2. Lumizyme [package insert]. Cambridge, MA: Genzyme Corporation, May 2023.
3. Nicolino M, Byrne B, Wraith JE, et al. Clinical outcomes after long-term treatment with alglucosidase alfa in infants and children with advanced Pompe disease. *Genet Med* 2009; 11:210.
4. Poelman E, van den Dorpel JJA, Hoogeveen-Westerveld M, et al. Effects of higher and more frequent dosing of alglucosidase alfa and immunomodulation on long-term clinical outcome of classic infantile Pompe patients. *J Inher Metab Dis* 2020; 43:1243.

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