Pharmacy Drug Policy & Procedure

Policy Name:	Lumizyme (alglucosidase)	Policy #:	2477P

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 Inherit Metab Dis 2020; 43:1243.

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