

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 8, 2021

POMPE DISEASE AGENTS
LUMIZYME® (alglucosidase alfa) and NEXVIAZYME™ (avalglucosidase alfa-ngpt)

LENGTH OF AUTHORIZATION: Up to 1 year

INITIAL REVIEW CRITERIA:

- Patient must be \geq 1 year of age for Nexviazyme.
- Patients of all ages can be prescribed Lumizyme.
- Patient must have a diagnosis of Pompe Disease (lysosomal acid alpha-glucosidase [GAA] deficiency).

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as the following:
 - Lumizyme®: 50 mg powder in single-dose vial for reconstitution.
 - Nexviazyme™: 100 mg powder in single-dose vial for reconstitution.