Nexviazyme® (avalglucosidase alfa-ngpt)

When requesting Nexviazyme® (avalglucosidase alfa-ngpt), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

**FDA-approved indication**

Nexviazyme (avalglucosidase alfa-ngpt) is indicated for the treatment of individuals with late-onset Pompe disease (lysosomal acid α-glucosidase deficiency).

**Coverage Guidelines**

**Late-onset Pompe Disease**

The individual must meet all of the following criteria for approval:

- Patient is 1 year of age or older
- Diagnosis is confirmed by one of the following:
  - Laboratory test demonstrating deficient acid α-glucosidase activity in blood, fibroblasts, or muscle tissue; OR
  - Molecular genetic test demonstrating acid α-glucosidase gene mutation
- Nexviazyme is prescribed by or in consultation with a geneticist, a neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

**Approval duration: 12 months**

**Dosing Recommendation**

Approve up to 40 mg/kg administered intravenously not more frequently than once every 2 weeks.

**References**