

STANDARD MEDICARE PART B MANAGEMENT

NEXVIAZYME (avalglucosidase alfa-ngpt)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Nexviazyme is indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Initial requests: acid alpha-glucosidase enzyme assay or genetic testing results supporting diagnosis.
- B. Continuation requests: chart notes documenting a positive response to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, respiratory function, muscle strength).

III. CRITERIA FOR INITIAL APPROVAL

Late-onset Pompe disease

Authorization of 12 months may be granted for treatment late-onset Pompe disease when all of the following criteria are met:

- A. Member is 1 year of age or older
- B. Diagnosis was confirmed by enzyme assay demonstrating a deficiency of acid alpha-glucosidase enzyme activity or by genetic testing

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Nexviazyme
- B. Nexviazyme is being used to treat an indication enumerated in Section III
- C. The member is receiving benefit from therapy (e.g., improvement, stabilization or slowing of disease progression for motor function, walking capacity, respiratory function, or muscle strength).

V. REFERENCES

1. Nexviazyme [package insert]. Cambridge, MA: Genzyme Corporation; August 2021.