Reference number(s)
4890-A

SPECIALTY GUIDELINE 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 Indication
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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
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 of 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

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for late-onset Pompe disease who are responding to 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.

Reference number(s)
4890-A