Reference number(s)
2690-A

STANDARD MEDICARE PART B MANAGEMENT

LUMIZYME (alglucosidase alfa)

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
Lumizyme is indicated for patients with Pompe disease (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. CRITERIA FOR INITIAL APPROVAL

Pompe disease
Indefinite authorization may be granted for treatment of Pompe disease when the diagnosis of Pompe disease was confirmed by enzyme assay demonstrating a deficiency of acid alpha-glucosidase enzyme activity or by genetic testing.

III. CONTINUATION OF THERAPY

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

Indefinite authorization may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Lumizyme
B. Lumizyme is being used to treat an indication enumerated in Section II
C. The medication has been effective for treating the diagnosis or condition.

IV. REFERENCES

1. Lumizyme [package insert]. Cambridge, MA: Genzyme Corporation; May 2019.