| Reference number |
| --- |
| 2055-A |

# SPECIALTY GUIDELINE 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 are considered experimental/investigational and are not a covered benefit.

### II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: acid alpha-glucosidase enzyme assay or genetic testing results supporting diagnosis.

### III. CRITERIA FOR INITIAL APPROVAL

**Pompe disease**
Authorization of 12 months 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.

### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for Pompe disease who are responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, cardiorespiratory function, decrease in left ventricular mass index (LVMI), delay in death).

### V. REFERENCES

1. Lumizyme [package insert]. Cambridge, MA: Genzyme Corporation; August 2014.






CVS caremark™