Lumizyme (alglucosidase)

Effective Date: January 1, 2021
Number: MG.MM.PH.304

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Definitions

Lumizyme (alglucosidase) is a human hydrolytic lysosomal glycogen-specific enzyme (acid α-glucosidase) produced in Chinese hamster ovary cell line via recombinant DNA technology. After administration of Lumizyme, it is internalized into cells and transported to lysosomes where it catalyzes the breakdown of glycogen to glucose. Lumizyme is indicated for patients with Pompe disease (acid α-glucosidase deficiency).

Dosing

- Each dose must not exceed 20 mg/kg administered intravenously no more frequently than once every 2 weeks.

Length of Coverage

- Approvals will be granted for 12 months

Guideline

Acid Alpha-Glucosidase Deficiency (Pompe Disease)

- The diagnosis is established by one of the following:
  - Patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue; OR
- Patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation; **AND**
  - Lumizyme is prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

**Limitations/Exclusions**
- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

**Applicable Procedure Codes**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0221</td>
<td>Injection, alglucosidase alfa, (Lumizyme), 10 mg; 1 billable unit = 10 mg</td>
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*Note: J0220 Injection, alglucosidase alfa, 10 mg, not otherwise specified – applicable to Myokymia (Genzyme Corporation) -NDC inactive as of 3/24/16* 

**Applicable NDCs**

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<tr>
<th>NDC</th>
<th>Description</th>
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<tr>
<td>58468-0160-xx</td>
<td>Lumizyme 50 mg single-use vial for injection</td>
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**Applicable Diagnosis Codes**

<table>
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<tr>
<th>Code</th>
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<tr>
<td>E74.02</td>
<td>Pompe disease</td>
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**Revision History**

<table>
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<th>Date</th>
<th>Description</th>
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<tr>
<td>1/1/2021</td>
<td>Criteria apply to Commercial, Medicare, and Medicaid members.</td>
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**REFERENCES**