Lumizyme® (alglucosidase alfa)
(Intravenous)

Last Review Date: January 1, 2019
Number: MG.MM.PH.92

Medical Guideline Disclaimer

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LENGTH OF AUTHORIZATION

Coverage will be provided for 12 months and may be renewed.

DOSING LIMITS

Max Units (per dose and over time) [Medical Benefit]:

- 230 billable units every 14 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

Pompe disease (Acid alpha-glucosidase (GAA) deficiency) †

- Diagnosis has been confirmed by one of the following:
  - Deficiency of acid alpha-glucosidase enzyme activity; OR
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing; AND

- Documented baseline values for one or more of the following:
  - Infantile-onset disease: muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6 minute walk test (6MWT); OR
  - Late-onset (non-infantile) disease: FVC and/or 6MWT
† FDA approved indication(s)

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

• Patient continues to meet the criteria in section I; **AND**

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe allergic and anaphylactic reactions, severe cutaneous and systemic immune-mediated reactions, acute cardiorespiratory failure, cardiac arrhythmia and sudden cardiac death during general anesthesia, etc.; **AND**

• No evidence that patient has developed IgG antibodies to alglucosidase alfa at a sustained titer level of ≥ 12,800; **AND**

• Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:

  o Infantile-onset disease: stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, and/or 6MWT

  o Late-onset (non-infantile) disease: stabilization or improvement in FVC and/or 6MWT

Limitations/Exclusions

Lumizyme is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

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 Myozyme (Genzyme Corporation) -NDC inactive as of 3/24/16

Applicable NDCs

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

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

N/A
References