Elelyso™ (taliglucerase alfa)
(Intravenous)

Last Review Date: January 1, 2020  Number: MG.MM.PH.77

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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]:

• 700 billable units every 14 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

Type 1 Gaucher’s Disease †

• Patient at least 4 years of age; AND

• Patient has a documented diagnosis of Type 1 Gaucher Disease as confirmed by reduced glucocerebrosidase activity in peripheral leukocytes; AND

• Adults only criteria (patient at least 18 years or older): Patient’s disease results in one or more of the following:
  • Anemia [hemoglobin less than or equal to 11 g/dL (women) or 12 g/dL (men) ]; OR
• Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); OR

• Skeletal disease (e.g. lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis, etc.); OR

• Symptomatic disease (e.g. bone pain, fatigue dyspnea, angina, abdominal distension, diminished quality of life, etc.); OR

• Thrombocytopenia (platelet count less than or equal to 120,000/mm3); **AND**

• Must be used as a single agent

† FDA Approved Indication(s)

II. **RENEWAL CRITERIA**

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

• Disease response as indicated by one or more of the following (compared to pre-treatment baseline):
  • Improvement in symptoms (e.g. bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, etc.)
  • Reduction in size of liver or spleen
  • Improvement in hemoglobin/anemia
  • Improvement in skeletal disease
  • Improvement in platelet counts; **AND**

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, etc.

**Limitations/Exclusions**

Elelyso 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>J3060</td>
<td>Injection, taliglucerase alfa, 10 units; 1 billable unit = 10 units</td>
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**Applicable NDCs**

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<tr>
<th>Code</th>
<th>Description</th>
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<td>00069-0106-xx</td>
<td>Elelyso 200 unit powder 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>E75.22</td>
<td>Gaucher Disease</td>
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Revision History

N/A

References