I. Length of Authorization

Coverage will be for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Elelyso 200 unit powder for injection: 35 vials every 14 days

B. Max Units (per dose and over time) [Medical Benefit]:
   - 700 billable units every 14 days

III. Initial Approval Criteria

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

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 a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; 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)
IV. Renewal Criteria

- Patient continues to meet the criteria in Section III: **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.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Type 1 Gaucher Disease</td>
<td>Up to 60 units/kg every other week as a 60-120-minute intravenous infusion</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

**Jcode:**
- J3060 – Injection, taliglucerase alfa, 10 units; 1 billable unit = 10 units

**NDC:**
- Elelyso 200 unit powder for injection, single-use vial: 00069-0106-xx

VII. References


**Appendix 1 – Covered Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<td>E75.22</td>
<td>Gaucher disease</td>
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**Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

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<td>E (1)</td>
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<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>KS, NE, IA, MO</td>
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<td>8</td>
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<td>N (9)</td>
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<td>First Coast Service Options, Inc.</td>
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<tr>
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<td>M (11)</td>
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<td>CGS Administrators, LLC</td>
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