Cerezyme® (imiglucerase) (Intravenous)

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]:
   - Cerezyme 200 unit injection: 70 vials per 28 days
   - Cerezyme 400 unit injection: 36 vials per 28 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 Disease †

- Patient age at least 2 years or older: 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 volume) or splenomegaly (spleen size 5 or more times normal volume): 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).
- 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 hypersensitivity reactions.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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| Type 1 Gaucher Disease      | • Initial dosages range from 2.5 U/kg of body weight 3 times a week to 60 U/kg once every 2 weeks based on disease severity. Cerezyme is administered by intravenous infusion over 1–2 hours.  
  • Dosage adjustments should be made on an individual basis and may increase or decrease, based on achievement of therapeutic goals as assessed by routine comprehensive evaluations of the patient’s clinical manifestations. |

VI. Billing Code/Availability Information

Jcode:
- J1786 – Injection, imiglucerase, 10 units: 1 billable unit = 10 unit

NDC:
- Cerezyme 200 unit injection: 58468-1983-xx
- Cerezyme 400 unit injection: 58468-4663-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

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<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>Noridian Healthcare Solutions, LLC</td>
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<td>Novitas Solutions, Inc.</td>
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