Clinical Policy: Imiglucerase (Cerezyme)

Reference Number: ERX.SPMN.33
Effective Date: 10/16
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that imiglucerase (Cerezyme®) is medically necessary when one of the following criteria is met:

I. Initial Approval Criteria
   A. Type 1 Gaucher Disease (GD1) (must meet all):
      1. Age ≥ 2 years;
      2. Diagnosis of type 1 Gaucher disease confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity;
      3. Any one of the following conditions resulting from GD1:
         a. Anemia;
         b. Thrombocytopenia;
         c. Hepatomegaly or splenomegaly;
         d. Bone disease.

      Approval duration: 6 months

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy

II. Continued Approval
   A. Type 1 Gaucher Disease (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria.

      Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.
Background

Description/Mechanism of Action:
Imiglucerase is an analogue of the human enzyme β-glucocerebrosidase, produced by recombinant DNA technology. β-Glucocerebrosidase (β-D-glucosyl-N-acylsphingosine glucohydrolase, E.C. 3.2.1.45) is a lysosomal glycoprotein enzyme which catalyzes the hydrolysis of the glycolipid glucocerebroside to glucose and ceramide. Imiglucerase catalyzes the hydrolysis of glucocerebroside to glucose and ceramide.

Gaucher disease is characterized by a deficiency of β-glucocerebrosidase activity, resulting in accumulation of glucocerebroside in tissue macrophages which become engorged and are typically found in the liver, spleen, and bone marrow and occasionally in lung, kidney, and intestine. Secondary hematologic sequelae include severe anemia and thrombocytopenia in addition to the characteristic progressive hepatosplenomegaly, skeletal complications, including osteonecrosis and osteopenia with secondary pathological fractures. Cerezyme (imiglucerase for injection) catalyzes the hydrolysis of glucocerebroside to glucose and ceramide. In clinical trials, Cerezyme improved anemia and thrombocytopenia, reduced spleen and liver size, and decreased cachexia to a degree similar to that observed with Ceredase® (alg glucerase injection).

FDA Approved Indication:
Cerezyme is an intravenous infusion indicated for:
- Type 1 Gaucher disease in patients who develop disease-related complications.

Appendices

Appendix A: Abbreviation Key
ERT: enzyme replacement therapy
GD1: type 1 Gaucher disease

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1786</td>
<td>Injection, imiglucerase, 10 units</td>
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Reviews, Revisions, and Approvals

<table>
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<th>Date</th>
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<tbody>
<tr>
<td>Policy split from USS.SPMN.33 Lysosomal Storage Disorders and converted to new template. Added age restriction per PI. Removed preferencing for Elelyso and VPRIV as they are not PDL. Modified approval duration to 6 months for initial and 12 months for re-auth.</td>
<td>08/16</td>
<td>09/16</td>
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References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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