Clinical Policy: Velaglucerase alfa (VPRIV)
Reference Number: ERX.SPMN.139
Effective Date: 10/16
Last Review Date: 09/16

Coding Implications
Revision Log

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 velaglucerase alfa (VPRIV®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Type 1 Gaucher Disease (must meet all):
      1. Age ≥ 4 years;
      2. Diagnosis of type 1 Gaucher disease confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity.

      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:
Velaglucerase alfa is produced by gene activation technology in a human fibroblast cell line. Velaglucerase alfa is a glycoprotein of 497 amino acids containing the same amino acid sequence as the naturally occurring human enzyme, glucocerebrosidase. Gaucher disease is an autosomal recessive disorder caused by mutations in the GBA gene, which results in a deficiency of the lysosomal enzyme beta-glucocerebrosidase. Glucocerebrosidase catalyzes the conversion of the sphingolipid glucocerebroside into glucose and ceramide. The enzymatic deficiency causes an accumulation of glucocerebroside primarily in the lysosomal compartment of macrophages, giving rise to foam cells or “Gaucher cells”. Velaglucerase alfa catalyzes the hydrolysis of glucocerebroside, reducing the amount of accumulated glucocerebroside.
FDA Approved Indication(s):
VPRIV is a hydrolytic lysosomal glucocerebroside-specific enzyme/intravenous solution indicated for:

- Long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.

Appendices
Appendix A: Abbreviation Key
ERT: enzyme replacement therapy

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.

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J3385</td>
<td>Injection, velaglucerase alfa, 100 units</td>
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Reviews, Revisions, and Approvals
Policy split from USS.SPMN.33 Lysosomal Storage Disorders and converted to new template. Added age restriction per PI. Modified approval duration to 6 months for initial and 12 months for re-auth.

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<th>Date</th>
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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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