VPRIV® (velaglucerase alfa)
(Intravenous)

Medical Guideline Disclaimer

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Definition

Velaglucerase alfa for injection is indicated for long-term enzyme replacement therapy (ERT) in adults and pediatric patients 4 years and older with type 1 Gaucher disease. Clinical studies have demonstrated the efficacy of velaglucerase alfa in non-neuropathic Gaucher disease as initial treatment among patients with no prior ERT exposure and among patients switching from imiglucerase to velaglucerase alfa.

LENGTH OF AUTHORIZATION

Coverage will be for 12 months and may be renewed.

DOSES LIMITS

Max Units (per dose and over time) [Medical Benefit]:

- 72 billable units every 14 days

Guideline

I. INITIAL APPROVAL CRITERIA

Type 1 Gaucher’s Disease †

- Patient age at least 4 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) 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 above; **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**

Vpriv 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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<td>Injection, velaglucerase alfa, up to 60 units</td>
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**Applicable NDCs**

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**Applicable Diagnosis Codes**

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Revision History

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References


