DESCRIPTION: Velaglucerase alfa is a hydrolytic lysosomal glucocerebrosidase-specific enzyme. Velaglucerase alfa contains predominately high mannose type N linked glycan chains. The mannose glycan chains are specifically recognized and internalized via the mannose receptor present on the surface of the macrophages, the cells that accumulate glucocerebroside in Gaucher disease. Velaglucerase alfa catalyzes the hydrolysis of the glycolipid glucocerebroside to glucose and ceramide in the lysosome.

INDICATION(S): Velaglucerase alfa is indicated for long-term enzyme replacement therapy for pediatric and adult patients with Type 1 Gaucher disease

Dose: 60 units per kilogram every other week

REASONS FOR PA: ☒ Cost ☒ Potential for misuse ☒ Toxicity

CRITERIA for APPROVAL:
1. Patient is diagnosed with Type 1 Gaucher disease
2. Dosing 60 units per kilogram every other week.

REASONS for DENIAL of BENEFIT:
1. Patient has a known hypersensitivity to valaglucerase alfa or any other component of the product.
2. Patient does not meet above criteria

RENEWAL CRITERIA: Review of past demonstrates a reduced frequency of clinical exacerbations and improved health-related quality of life

BENEFIT APPROVAL: Initial approval for a period of 3 months. Renewal approval period: 12 months

References: Vpriv™ Product information, Shire Human Genetic Therapies, Inc. 700 Main Street, Cambridge, MA