VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

VPRIV (Velaglucerase alfa)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18

(Archived 1/22/19)

Velaglucerase alfa, which contains the same amino acid sequence as endogenous glucocerebrosidase, catalyzes the hydrolysis of glucocerebroside to glucose and ceramide in the lysosome. In patients with type 1 Gaucher's disease, glucocerebrosidase deficiency results in accumulation of glucocerebroside in macrophages, thereby causing the associated signs and symptoms. Velaglucerase alfa is used to diminish hepatosplenomegaly and improve anemia, thrombocytopenia, and bone disease.

Pre-Authorization Criteria
Vpriv is prescribed for long-term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease.

VCHCP requires that Vpriv be prescribed by a physician specializing in the condition being treated.

Restricted Distribution in US:
[1-866-888-0660 or www.vpriv.com for more info]

Dosing: Adult:
Gaucher's disease (type 1): I.V.: 60 units/kg administered every 2 weeks; adjust dose based upon disease activity (range: 15-60 units/kg evaluated in clinical trials)
Note: When switching from imiglucerase to velaglucerase alfa in stable patients, initiate treatment at the same dose.

Dosing: Pediatric:
Gaucher's disease (type 1): Children ≥4 years and Adolescents: Refer to adult dosing.

Dosing: Geriatric:
Refer to adult dosing.

Dosing: Renal Impairment:
No dosage adjustment provided in manufacturer's labeling.

Dosing: Hepatic Impairment:
No dosage adjustment provided in manufacturer's labeling.

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Solution Reconstituted, Intravenous [preservative free]:

Vpriv: 400 units (1 ea)

Generic Equivalent Available: U.S.-No

Administration:
I.V.: Infuse over 1 hour; use an inline, low protein-binding 0.2 micron filter during infusion. Do not infuse other products in the same infusion tubing.

Adverse Reactions:
10%: Headache, fatigue, fever, dizziness, abdominal pain, aPPT prolonged, upper respiratory tract infections, infusion-related reactions.
Other Serious Less Common Reactions:Antibody formation, hypersensitivity reactions

References:

1. Baldellou A, Andria G, Campbell PE, et al, "Paediatric Non-Neuronopathic Gaucher Disease: Recommendations for Treatment and Monitoring," *Eur J Pediatr*, 2004, 163(2):67-75. [PubMed 14677062]
2. Charrow J, Andersson HC, Kaplan P, et al, "Enzyme Replacement Therapy and Monitoring for Children With Type 1 Gaucher Disease: Consensus Recommendations," *J Pediatr*, 2004, 144(1):112-20. [PubMed 14722528]
3. Jmoudiak M and Futerman AH, "Gaucher Disease: Pathological Mechanisms and Modern Management," *Br J Haematol*, 2005, 129(2):178-88. [PubMed 15813845]
4. Pastores GM, Weinreb NJ, Aerts H, et al, "Therapeutic Goals in the Treatment of Gaucher Disease," *Semin Hematol*, 2004, 41(4 Suppl 5):4-14. [PubMed 15468045]
5. Weinreb NJ, Aggio MC, Andersson HC, et al, "Gaucher Disease Type 1: Revised Recommendations on Evaluations and Monitoring for Adult Patients," *Semin Hematol*, 2004, 41(4 Suppl 5):15-22. [PubMed 15468046]

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