VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

CEREZYME (Imiglucerase)

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, 1/22/19
(Archived 1/22/19)

Cerezyme is an analogue of glucocerebrosidase; it is produced by recombinant DNA technology using mammalian cell culture. Glucocerebrosidase is an enzyme deficient in Gaucher's disease. It is needed to catalyze the hydrolysis of glucocerebroside to glucose and ceramide.

Pre-Authorization Criteria:

long-term enzyme replacement therapy for patients with type 1 Gaucher disease that results in at least one of the following: anemia, bone disease, hepatomegaly or splenomegaly, and thrombocytopenia

Off-label (Canadian labeling): long-term enzyme replacement therapy for patients with type 1 Gaucher disease or patients with type 3 Gaucher disease who display non-neurological manifestations (anemia, bone disease, hepatomegaly or splenomegaly, and thrombocytopenia) of the disease.

VCHCP requires that Cerezyme be prescribed by and administered under the supervision of a physician experienced in treatment of Gaucher disease.

Registry: A registry has been established and all patients with Gaucher disease, and physicians who treat Gaucher disease are encouraged to participate. Information on the International Collaborative Gaucher Group (ICGG) Gaucher Registry may be obtained at https://www.registrynxt.com, or by calling 1-800-745-4447 (ext.15500).

Dosing: Adult:
Gaucher disease, type 1: I.V. (dose is individualized): Initial range: 2.5 units/kg 3 times weekly, up to 60 units/kg every 2 weeks. Note: Dosage adjustments are made based on assessment and therapeutic goals. Most benefits observed with doses of 30-60 units/kg every 2 weeks (Charrow, 2004). Consider premedication with antihistamine, corticosteroid.

Dosing: Pediatric:
Children ≥2 years and Adolescents: Refer to adult dosing.

Dosing: Geriatric:
Refer to adult dosing.

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

VENTURA COUNTY
HEALTH CARE PLAN

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

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Solution Reconstituted, Intravenous:
Cerezyme: 200 units (1 ea); 400 units (1 ea)

Generic Equivalent Available: U.S.-No

Administration:
I.V.: Infuse over 1-2 hours; may use an in-line, low protein-binding 0.2 micron filter during infusion
Infusion times <1 hour are not recommended (Martins, 2009).

Adverse Reactions:
Tachycardia, chills, dizziness, fatigue, fever, headache, pruritus, rash, abdominal discomfort, diarrhea, nausea, vomiting, hypersensitivity reaction.

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. Martins AM, Valadares ER, Porta G, et al, "Recommendations on Diagnosis, Treatment, and Monitoring for Gaucher Disease," *J Pediatr*, 2009, 155(4 Suppl):10-8. [PubMed 19765407]
5. 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]
6. 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]
7. Zimran A, Morris E, Mengel E, et al, "The Female Gaucher Patient: The Impact of Enzyme Replacement Therapy Around Key Reproductive Events (Menstruation, Pregnancy and Menopause)," *Blood Cells Mol Dis*, 2009, 43(3):264-88. [PubMed 19502088]
8. www.uptodate.com: Imiglucerase: Drug Information
9. www.epocrates.com: Cerezyme Drug information

Revision History:
Date Approved by P&T Committee: 1/28/14

VENTURA COUNTY
HEALTH CARE PLAN

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/Updated: 2/17/15 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check MCG