

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

Generic Name:	velaglucerase alfa
Brand Name:	VPRIV
Strength:	400U/vial powder for solution for injection
Manufacturer:	Shire Human Genetic Therapies Inc.
Indication:	Long-term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease
Rapid Review:	Requested & Denied

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	09/11/2010	02/12/2010	EO decision rendered	Funding available through the Exceptional Access Program (EAP)

Rapid Review:

Details of the Rapid Review process can be found at:

www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html

Review Status:

- *Screening – Ministry is screening the manufacturer's submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.*
- *Submission incomplete – Manufacturer did not meet the necessary requirements to allow review to proceed.*
- *Submission complete & under review – Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.*
- *Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.*
- *Committee to Evaluate Drugs (CED) review completed – A recommendation was made by the CED.*
- *Executive Officer (EO) decision rendered.*

Funding Decision:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision can be found at: www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html

Updated: January 4, 2012

