

Ontario Public Drug Programs Drug Submission Status

Generic Name: vemurafenib

Brand Name: Zelboraf

Strength: 240mg FC tablet

Manufacturer: Hoffmann-La Roche Ltd.

Indication: For the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma

Rapid Review: Not Requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	15/02/2012	07/05/2012	EO decision rendered	Funding considered through the Exceptional Access Program(EAP)
Reconsideration (Resubmission #1)	03/03/2014	07/04/2014	EO decision rendered	Funding criteria expanded beyond the current criteria under Exceptional Access Program(EAP)

Rapid Review:

Details of the Rapid Review process can be found at:

[Rapid Review Process](#)

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.
- Ontario Steering Committee for Cancer Drugs (OSCCD) review completed-A recommendation was made by the OSCCD.
- Executive Officer (EO) decision rendered.

Funding Status:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at:

[The CED recommendation and the EO decision](#)

Updated: November 30, 2015