

Ontario Public Drug Programs Drug Submission Status

Generic Name: ivacaftor

Brand Name: Kalydeco

Strength: 150mg tablet

Manufacturer: Vertex Pharmaceuticals Canada Inc.

Indication: Treatment of cystic fibrosis (CF) in patients age 18 years and older with an R117H mutation in the CFTR gene.

Rapid Review: Not Requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	02/10/2015	08/12/2015	CED review completed	N/A

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: February 29, 2016