Ministry of Health and Long Term Care

Ontario Public Drug Programs
Drug Submission Status

Generic Name: ibrutinib

Brand Name: Imbruvica

Strength: 140mg capsule

Manufacturer: Janssen Inc.

Indication: Treatment of patients with chronic lymphocytic leukemia (CLL), including those with 17p deletion, who have received at least one prior therapy, or for the frontline treatment of patients with CLL with 17p deletion.

Rapid Review: Not Requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	22/12/2014	04/02/2015	EO decision rendered	Funding considered through the 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.

Ontario

- 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: August 4, 2015