

# Ontario Public Drug Programs Drug Submission Status

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Generic Name: ombitasvir/ paritaprevir/ ritonavir & dasabuvir

Brand Name: Holkira Pak

Strength: 12.5mg/75mg/50mg & 250mg FC tablet

Manufacturer: AbbVie Corporation

Indication: For the treatment of hepatitis C virus (HCV) genotype 1.

Rapid Review: Not Requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	09/01/2015	08/05/2015	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.
- 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: June 29, 2015