

# Ontario Public Drug Programs Drug Submission Status

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Generic Name: darunavir ethanolate

Brand Name: Prezista

Strength: 800mg tablet

Manufacturer: Janssen Inc.

Indication: Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult patients, when taken in combination with low-dose ritonavir and other antiretroviral

Rapid Review: Not Requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	28/01/2013	11/03/2013	EO decision rendered	Listed on the Ontario Drug Benefit Formulary a General Benefit for physicians approved for the Facilitated Access mechanism

## 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 27, 2015