

# Ontario Public Drug Programs

## Drug Submission Status

**Generic Name:** prasugrel hydrochloride

**Brand Name:** Effient

**Strength:** 10mg tablet

**Manufacturer:** Eli Lilly Canada Inc.

**Indication:** Prevention of atherothrombotic events in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI)

**Rapid Review:** Not requested

<b>Submission Type:</b>	<b>Date Submission Received:</b>	<b>Date Submission Deemed Complete:</b>	<b>Review Status:</b>	<b>Funding Decision:</b>
First Review, <b>Pre-Notice of Compliance</b> (Initial Submission)	07/04/2010	04/05/2010	EO decision rendered	Funding not considered through Ontario Public Drug Programs
Second Review (Resubmission #1)	19/10/2010	30/11/2010	CED review completed	N/A
Reconsideration (Resubmission #2)	25/03/2011	08/04/2011	EO decision rendered	Funding considered through the Exceptional Access Program (EAP)
Reconsideration (Resubmission #3)	20/07/2011	03/08/2011	CED review completed	N/A
Reconsideration (Resubmission #4)	27/01/2012	01/03/2012	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as a Limited Use Benefit

## Rapid Review:

Details of the Rapid Review process can be found at:

[http://www.health.gov.on.ca/en/pro/programs/drugs/drug\\_submissions/rapid\\_review\\_process.aspx](http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/rapid_review_process.aspx)

## 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.
- 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:

[http://www.health.gov.on.ca/en/pro/programs/drugs/ced\\_rec\\_table.aspx](http://www.health.gov.on.ca/en/pro/programs/drugs/ced_rec_table.aspx)

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