

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

Generic Name:	fentanyl citrate
Brand Name:	Onsolis
Strength:	200mcg, 400mcg, 600mcg, 800mcg and 1200mcg buccal soluble film
Manufacturer:	Meda Valeant Pharma Canada Inc.
Indication:	For the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving, and who are intolerant to, opioid therapy for their persistent baseline cancer pain
Rapid Review:	Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	05/12/2011	12/01/2012	EO decision rendered	Funding not considered through Ontario Public Drug Programs

Rapid Review:

Details of the Rapid Review process can be found at:

www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html

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 Decision:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision can be found at: www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html

Updated: May 30, 2012