

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

Generic Name:	cetuximab
Brand Name:	Erbitux
Strength:	2mg/mL injection
Manufacturer:	ImClone Systems Inc.
Indication:	- In combination with irinotecan, for the treatment of EGFR-expressing metastatic colorectal carcinoma in patients who are refractory to other irinotecan-based regimens. - As a single agent for the treatment of EGFR-expressing metastatic colorectal carcinoma in patients who are intolerant to irinotecan-based chemotherapy (New indication)
Rapid Review:	Requested & Denied

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	12/11/2008	20/11/2008	EO decision rendered	Funding provided through Cancer Care Ontario's New Drug Funding Program

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: October 16, 2009