

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

Generic Name:	lapatinib ditosylate
Brand Name:	Tykerb
Strength:	250mg tablet
Manufacturer:	GlaxoSmithKline Inc.
Indication:	In combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress Her2
Rapid Review:	Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	03/07/2009	27/07/2009	EO decision rendered	Funding not available through Ontario Public Drug Programs
Reconsideration (Resubmission #1)	29/03/2010	23/04/2010	EO decision rendered	Funding not available through Ontario Public Drug Programs
Reconsideration (Resubmission #2)	13/12/2010	10/01/2011	EO decision rendered	Funding available through the Exceptional Access Program (EAP)

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: January 4, 2012