

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

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| Generic Name: | trastuzumab |
| Brand Name: | Herceptin |
| Strength: | 440 mg/vial water 20mL/vial powder for solution |
| Manufacturer: | Hoffmann-La Roche Ltd. |
| Indication: | Herceptin in combination with Xeloda for the treatment of metastatic breast cancer beyond progression with initial Herceptin treatment |
| Rapid Review: | Not requested |

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|--|
| First Review (Initial Submission) | 01/05/2009 | 14/05/2009 | EO decision rendered | Funding not available through Cancer Care Ontario's New Drug Funding Program |
| Reconsideration (Resubmission #1) | 15/03/2010 | 23/03/2010 | EO decision rendered | Funding considered 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: January 17, 2012