

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

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|----------------------|---|
| Generic Name: | paclitaxel |
| Brand Name: | Abraxane for Injectable Suspension |
| Strength: | 100mg/vial |
| Manufacturer: | Abraxis BioScience Canada Inc. |
| Indication: | Metastatic breast cancer, requesting broader funding criteria |
| Rapid Review: | Not requested |

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review (Initial Submission) | 20/10/2009 | 28/01/2010 | EO decision rendered | Funding criteria not be expanded beyond the current criteria under Cancer Care Ontario's New Drug Funding Program |
| Reconsideration (Resubmission #1) | 30/06/2010 | 12/07/2010 | EO decision rendered | Funding criteria not be expanded beyond the current criteria under 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: June 30, 2011