

# Ontario Public Drug Programs

## Drug Submission Status

**Generic Name:** clostridium botulinum toxin type A

**Brand Name:** Botox

**Strength:** 50 units/vial, 100 units/vial and 200 units/vial

**Manufacturer:** Allergan Inc.

**Indication:** For the treatment of urinary incontinence due to neurogenic detrusor overactivity resulting from neurogenic bladder associated with multiple sclerosis or subcervical spinal cord injury in adults who had an inadequate response to or are intolerant of anticholinergic medications (New indication)

**Rapid Review:** Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	12/06/2012	09/07/2012	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as a Limited Use Benefit

### 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](http://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 Status:**

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at: [www.health.gov.on.ca/english/providers/program/drugs/ced\\_rec\\_table.html](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)

Updated: January 2, 2013