

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

<b>Generic Name:</b>	glatiramer acetate
<b>Brand Name:</b>	Copaxone
<b>Strength:</b>	20mg/1mL pre-filled syringe
<b>Manufacturer:</b>	Teva Pharmaceutical Industries Ltd.
<b>Indication:</b>	Clinically Isolated Syndrome (CIS), after a first demyelinating event
<b>Rapid Review:</b>	Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	29/07/2009	13/11/2009	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](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 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](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)

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