# Ministry of Health and Long-Term Care

## **Ontario Public Drug Programs**

## **Drug Submission Status**

Generic Name:	interferon beta-1b		
Brand Name:	Betaseron Initiation Pack		
Strength:	0.3mg/vial powder for solution		
	(New format)		
Manufacturer:	Bayer Inc.		
Indication:	Treatment of clinically isolated syndrome (CIS) and		
maication.	clinically definite multiple sclerosis (CDMS)		
Rapid Review:	Not requested		

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	06/10/2009	02/03/2010	EO decision rendered	Funding not available through Ontario Public Drug Programs

#### 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.
- o 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: August 24, 2011



