

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

<b>Generic Name:</b>	etravirine
<b>Brand Name:</b>	Intelence
<b>Strength:</b>	200mg tablet (New strength)
<b>Manufacturer:</b>	Janssen Inc.
<b>Indication:</b>	In combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in treatment-experienced adult patients who have failed prior therapy and have HIV-1 strains resistant to multiple antiretroviral agents, including NNRTIs
<b>Rapid Review:</b>	Not requested

<b>Submission Type:</b>	<b>Date Submission Received:</b>	<b>Date Submission Deemed Complete:</b>	<b>Review Status:</b>	<b>Funding Decision:</b>
First Review (Initial Submission)	21/12/2011	03/02/2012	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as a General Benefit for physicians approved for the Facilitated Access mechanism

#### **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)*

Updated: May 29, 2012