

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

<b>Generic Name:</b>	omalizumab
<b>Brand Name:</b>	Xolair
<b>Strength:</b>	150mg powder for solution for injection
<b>Manufacturer:</b>	Novartis Pharmaceuticals Canada Inc.
<b>Indication:</b>	Treatment of moderate to severe asthma
<b>Rapid Review:</b>	Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	29/09/2009	18/12/2009	CED review completed, manufacturer requesting reconsideration	N/A
Reconsideration (Resubmission #1)	07/06/2011	30/06/2011	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)

Updated: January 18, 2012