

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

|                      |   |
|----------------------|---|
| <b>Generic Name:</b> | denosumab   |
| <b>Brand Name:</b>   | Prolia  |
| <b>Strength:</b>     | 60mg/mL pre-filled syringe  |
| <b>Manufacturer:</b> | Amgen Canada Inc.   |
| <b>Indication:</b>   | Treatment of postmenopausal women with osteoporosis at high risk for fracture |
| <b>Rapid Review:</b> | Not requested   |

| Submission Type:                     | Date Submission Received: | Date Submission Deemed Complete: | Review Status:       | Funding Decision:   |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review<br>(Initial Submission) | 12/10/2010                | 28/10/2010                       | 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 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: February 21, 2012

