## About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

## Details of Drug Reviewed

<table>
<thead>
<tr>
<th>Drug</th>
<th>denosumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Xgeva®</td>
</tr>
<tr>
<td>Dosage Form</td>
<td>120 mg vial as a solution for injection</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Amgen Canada Inc.</td>
</tr>
<tr>
<td>Submission Type</td>
<td>Request for Advice</td>
</tr>
<tr>
<td>Use Reviewed</td>
<td>For reducing the risk of developing cancer-related complications, such as broken bones and/or bone pain, in patients with bone metastases from breast cancer or solid tumors other than breast or prostate cancer.</td>
</tr>
</tbody>
</table>

**Common Drug Review (CDR)**

Yes, CDR recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CDR website for more details: [www.cadth.ca/sites/default/files/cdr/complete/SR0433-001_complete_Xgeva_OST-Mar-28_16-e.pdf](http://www.cadth.ca/sites/default/files/cdr/complete/SR0433-001_complete_Xgeva_OST-Mar-28_16-e.pdf) and [www.cadth.ca/sites/default/files/cdr/complete/SR0433-000_complete_Xgeva_BC-Mar_1_16_e.pdf](http://www.cadth.ca/sites/default/files/cdr/complete/SR0433-000_complete_Xgeva_BC-Mar_1_16_e.pdf)

**Drug Benefit Council (DBC)**

The DBC (Drug Benefit Council) met on April 4, 2016. DBC considered various inputs including: the final reviews completed by the CDR on February 25, 2016 and March 23, 2016, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC also considered Patient Input Questionnaire responses from one Patient Group, CDR Patient Group Input Submissions, Clinical Practice Reviews from two specialists, and a Budget Impact Assessment.

## Drug Coverage Decision

**Status Quo (Palliative Care Drug Plan Benefit)**

**Date**

January 17, 2017

**Reasons**

- Drug coverage decision is consistent with the DBC recommendation.
  - In patients with bone metastases from solid tumors other than breast or prostate cancer, the drug did not demonstrate advantages over zoledronic acid with respect to efficacy. The drug was not compared to other drug comparators, such as pamidronate or clodronate.
  - In patients with bone metastases from breast cancer, the drug demonstrated advantages over zoledronic acid in some efficacy outcomes, but did not demonstrate advantages over zoledronic acid in other outcomes.
  - Based on economic considerations and the submitted product price, the drug was not cost effective or did not offer optimal value for money.
  - The CDR recommended that denosumab be listed similar to zoledronic acid for these indications. Both drugs are eligible for coverage for patients covered under Palliative Care Drug Plan.

**Other Information**

None
The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry. The DBC looks at:
- whether the drug is safe and effective
- advice from a national group called the Common Drug Review (CDR)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:
- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit the The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.