

Drug Coverage Decision for B.C. PharmaCare

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

Drug	denosumab
Brand Name	Prolia [®]
Dosage Form	60 mg/mL solution for injection
Manufacturer	Amgen Canada Inc.
Submission Type	New Indication & Request for Advice
Use Reviewed	For the treatment of men with osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
Common Drug Review (CDR)	Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions . Visit the CDR website for more details: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports
Drug Benefit Council (DBC)	DBC met on October 5, 2015. DBC considered various inputs including: the final review completed by the CDR, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC), input from two general practitioners, and input from two patient groups.
Drug Coverage Decision	Limited Coverage Benefit. Access the Prolia[®] criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	February 14, 2017
Reasons	<p>Drug coverage decision is inconsistent with the DBC recommendation.</p> <ul style="list-style-type: none"> • Denosumab Limited Coverage criteria was restricted to treatment of postmenopausal women. • The DBC recommended not to provide coverage for men based on clinical evidence available from one clinical trial however PharmaCare criteria will be modified to provide coverage for patients with osteoporosis regardless of gender. • The drug demonstrated some advantage over placebo with respect to efficacy in increasing bone mineral density and was similar to placebo with respect to safety in men with osteoporosis.
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.