

BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit [Ministry of Health - PharmaCare](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an “indication”). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare’s drug coverage review process, see the last page of this information sheet.

Information about the drug	
Generic name (scientific name)	denosumab
Brand name	Prolia[®]
Manufacturer	Amgen Canada
Indication	osteoporosis in men
Has the drug been reviewed by the Common Drug Review (CDR)? (see the note below this table.)	Yes. For more information about the CDR’s review of denosumab (Prolia [®]), you can Search the CDR Reports .
Public input start date	Wednesday July 22, 2015
Public input closing date	Wednesday August 19, 2015 AT MIDNIGHT
How is the drug taken?	Prolia [®] is taken as a single injection under the skin (subcutaneously).
How often is the drug is taken?	Prolia [®] is taken every 6 months.

Information about the drug	
General drug and/or drug study information	<p>Bone is constantly changing. There are special cells in the body called osteoclasts whose primary function is to remove bone. There is another type of cell called osteoblasts, which are bone-forming cells. In normal bone, there is a balance between the actions of these two cells. In people with osteoporosis, this balance no longer exists. Instead, the cells that remove bone work overtime removing bone faster than new bone can be created. The result is bone that is thinner, weaker and more likely to break.</p> <p>Prolia® works differently than other osteoporosis medications. It is a RANK ligand inhibitor. RANK ligand is a protein which activates the cells that break down bone (osteoclasts). Prolia® blocks RANK ligand to stop the cells that break down bone. This action strengthens the bones by increasing bone mass and lowers the chance of breaking bones of the hip, spine and nonspinal sites.</p> <p>Studies looked at the following:</p> <ul style="list-style-type: none"> • Changes in bone mineral density (increases , decrease, or no change) • Bad reactions: back pain, nasopharyngitis, osteoarthritis, myalgia, headache, hypertension and constipation. • Serious bad reactions: prostate cancer, arterial thrombosis limb, pancreatitis, peripheral ischemia, heart attack and chest pain. • Withdrawals due to bad reactions • Bad reactions of interest: cardiac disorders, serious infections, eczema and malignancies.
Other considerations	None

Note:

The Common Drug Review (CDR) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare's drug review process, including the role of the CDR in that process, see [The Drug Review Process in B.C. - Overview](#).

Cost of the drug under review compared to other drugs used to treat the same indication			
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Usual Dose	Yearly Cost of Therapy
denosumab (Prolia)	Under Review	One injection every 6 months	\$773
Treatment of Primary Osteoporosis in Men			
zoledronic acid (Aclasta®, generics)	Limited Coverage	One yearly infusion	\$362
alendronate (generics)	Limited Coverage	One tablet weekly or once daily	\$115 - \$157

Cost of the drug under review compared to other drugs used to treat the same indication			
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Usual Dose	Yearly Cost of Therapy
alendronate- cholecalciferol (Fosavance®, generics)	Limited Coverage	One tablet weekly	\$115
risedronate sodium (generics)	Limited Coverage	One tablet weekly	\$139
<i>To increase bone mass in men with primary or hypogonadal severe osteoporosis</i>			
teriparatide (Forteo®)	Non-Benefit	One tablet daily	\$11,399 ¹

¹Cost from Quebec Formulary (June 2015)

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 \(Council\)](#) gives advice to the Ministry. The Council 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 Council
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: [The Drug Review Process in B.C. - Overview](#).

This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.