

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	Xgeva[®]
Manufacturer	Amgen Canada Inc.
Indication	Xgeva [®] is used to reduce the risk of developing skeletal-related events in patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer and other solid tumours.
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 (Xgeva [®]), you can Search the CDR Reports .
Public input start date	Wednesday December 16, 2015
Public input closing date	Wednesday January 20, 2016 AT MIDNIGHT
How is the drug taken?	Xgeva [®] is taken by injection into the skin of the stomach, upper thigh or upper arm (subcutaneous injection).
How often is the drug is taken?	Xgeva [®] is taken once every 4 weeks.

Information about the drug	
General drug and/or drug study information	<p>Bone metastases occur when a cancer spreads to the bone from its primary site. Sometimes only one area of bone is affected, but some people develop several bone metastases, often in different bones in the body. The most common areas of bone metastases include: the spine, the pelvis, the ribs, the upper leg bone, the upper arm bone and the skull.</p> <p>In healthy bone, there are cells that remove old bone and other cells that rebuild bone. Key signals help regulate this process. When cancer spreads to bone, there are higher levels of these key signal products, which increase the rate at which bone is broken down in that area. Overtime these bones can weaken, leading to bone problems, such as fractures.</p> <p>Xgeva® is a monoclonal antibody, which blocks this key signal and may interrupt the process.</p> <p>Studies looked at the following to see if Xgeva® (denosumab) is safe and effective in reducing the risk of developing skeletal-related events in patients with bone metastases :</p> <ul style="list-style-type: none"> • Skeletal-related events • Pain control and use of pain-killers • Quality of life • Bad reactions • Bad reactions that lead to patients leaving the trials • Death
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	Annual Cost of Therapy
denosumab (Xgeva®)	Under Review (PharmaCare benefit under Plan P-Palliative Care)	120 mg every 4 weeks (one prefilled syringe)	\$8,081
pamidronate (Aredia®, generics)	Limited Coverage	One infusion every 3 to 4 weeks	\$3,655 - \$4,780
zoledronic acid (Zometa®, generics)	PharmaCare benefit under Plan P, Palliative Care	One infusion every 3 to 4 weeks	\$4,082 - \$5,338

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	Annual Cost of Therapy
clodronate (Clasteon [®])	Regular Benefit	4 to 6 capsules daily	\$1,905 - \$2,858
clodronate (Bonefos [®])	Regular Benefit	4 to 6 capsules daily	\$3,088 - \$4,632

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.