Common Drug Review
Patient Group Input Submissions

Denosumab (Prolia™) for osteoporosis, men

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Osteoporosis Canada — permission granted to post.

CADTH received patient group input for this review on or before September 08, 2015.

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Osteoporosis Canada

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Denosumab (Prolia™) for the indication of men with osteoporosis
Name of the patient group		Osteoporosis Canada
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		
Patient group's contact information:	Email	[redacted]
	Telephone	416-696-2663
	Address	301-1090 Don Mills Rd., Toronto M3C 3R6
	Website	www.osteoporosis.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

Osteoporosis Canada, a registered charity, is the only national organization dedicated to serving people who have, or are at risk for, osteoporosis and osteoporotic fractures. The organization works to educate, empower and support individuals and communities in the risk reduction and treatment of osteoporosis and fractures. Osteoporosis Canada provides up to date, medically accurate information to patients, healthcare professionals and the public.

Our membership consists of individuals living with osteoporosis, caregivers, healthcare professionals, educators and members of the general public.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

As a national patient organization, Osteoporosis Canada is supported by individual and corporate donations, government grants, and unrestricted educational grants from pharmaceutical companies. All of our interactions with pharmaceutical companies are transparent and governed by a professional Code of Conduct that ensures that our policy and procedures remain patient-driven and without influence from the industry. Amgen Canada Inc., Eli Lilly Inc. and Merck Canada Inc. are the pharmaceutical companies that currently support Osteoporosis Canada through unrestricted educational grants.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

We have no conflicts of interest to declare.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information gathered is based on experiential information that is representative of all of the internal stakeholders of Osteoporosis Canada. Information has also been gathered from the publication of Osteoporosis Canada's 2010 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada.

2.2 Impact of Condition on Patients

Despite evidence to the contrary, osteoporosis is still thought of by many to be a disease that affects elderly women. But at least one in five men will experience a fracture from osteoporosis during their lifetime. About 30,000 hip fractures occur in Canada yearly; one-quarter of these are in men. Men are more likely to die of complications from a hip fracture than women. 37% of men who suffer a hip fracture will die within the following year, as compared to 28% of women. The care gap for men is greater than for women; in general fewer than 20% of fracture patients receive assessment and treatment for underlying osteoporosis. For men, that percentage is fewer than 10%. **(**Reference: **Papaioannou A**, et al CaMos Research Group. *The Osteoporosis Care Gap in Men with Fragility Fractures: The Canadian Multicentre Osteoporosis Study. Osteoporos Int. 2007 19:581-587.*)

Fragility fractures are the main consequence of osteoporosis and their effects can be devastating – loss of independence, decreased mobility, isolation, depression and, in some cases, death. As with women, the current oral options for treatment carry with them certain side effects, particularly gastrointestinal disorders. Additionally, many patients are unable to take current oral options due to contraindications. As a result, patients may stop taking their medication resulting in an increased risk of further bone loss and attendant fractures. Men do not have equal access to medications and the facts indicate that this needs to change.

2.3 Patients' Experiences With Current Therapy

Bisphosphonates have historically been the most commonly prescribed medications for men with osteoporosis, in large part because they have proven benefit at reducing the risk of vertebral, non-vertebral and hip fractures.

Men who are able to tolerate oral options do find oral bisphosphonates inconvenient to take (first thing in the morning, on an empty stomach and needing to wait before breakfast or that first cup of coffee, needing to stay upright).

For some male patients, oral bisphosphonates are a suitable therapeutic option. For others, oral bisphosphonates are not at all an option. For men with gastrointestinal disorders, problems swallowing or who suffer other side effects, oral bisphosphonates are simply not safe, and therefore not an option.

2.4 Impact on Caregivers

When an individual fractures, a significant burden can be placed on the patient's family and caregivers who are often required to assume additional responsibilities as a result of their family member's disability and decreased mobility. Many times the family and the caregiver are one, and the additional responsibilities placed on that person could be financial (possibly needing to work extra to compensate for the patient's loss of income or conversely take time off work to care for their family members). The impact could be personal (the time needed to care for the patient resulting in a loss of freedom) and almost always it is a significant emotional stress for all involved. The fracture patient may be unable to perform many routine personal care activities, including those that embarrass and humiliate both the

patient and the caregiver. Many patients say that the emotional stress can be more significant than having to deal with the excruciating pain of a broken bone.

For individuals bedridden or otherwise incapable of taking their own medication, the onus falls on the caregiver to remember to administer the medication. Administration of a non-oral alternative could help overcome both of these hurdles for patients and caregivers alike.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information specific to denosumab stated previously was obtained through published data and from anecdotal information from patients currently on denosumab (who have failed on oral treatment options).

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

It is expected that for a subgroup of patients, denosumab will be the best option to protect their bones from osteoporotic fracture, and better than the alternative agents. As the administration of denosumab is non-oral, it is expected that patients who are unable to tolerate oral agents will have fewer adverse side effects associated with oral options, thereby increasing the probability of these individuals to live full, vital and fragility fracture free lives.

Evidence has shown that denosumab increases bone mass and bone strength in both cortical and trabecular bone. It significantly reduces fracture risk at the hip, spine and wrist, which are sites most at risk for osteoporotic fracture. Additionally, as a non-oral option, denosumab is well tolerated by patients, and one-on-one interviews with patients on denosumab illustrate that patients prefer the administrations schedule of denosumab, further increasing the likelihood of patients staying on this option, therefore reducing their risk of further bone loss and future fragility fracture.

Clearly, adherence to treatment will result in decreased fracture rates and therefore decreased utilization for inpatient and outpatient services related to these unnecessary fractures. This serves to not only improve the utilization of public dollars to needed acute care patients, but to improve the quality of lives of these individuals who will now have a decreased probability of fracture and associated disability.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Section 4 — Additional Information

It is critical to mention that in other parts of the world, for example the US, denosumab has already been recommended for the prevention of osteoporotic fractures in postmenopausal women and in men. Canadian men want and deserve access to osteoporosis medications similar to other G8 countries. Canadian men have the right to the same osteoporosis medication options that are available in other developed countries and to the women in our own country.

We thank you for your careful consideration of this submission and the opportunity for patient groups to provide their voice to the CADTH process.

If you require any additional information, please do not hesitate to contact [redacted].