CADTH

CADTH Reimbursement Review

Patient Input

romosozumab (Evenity)

(Amgen Canada Inc.)

Indication: Osteoporosis, postmenopausal women.

CADTH received patient input from:
Osteoporosis Canada

February 26, 2021

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CADTH Reimbursement Review
Patient Input Template

Name of the Drug and Indication	**Romosozumab for postmenopausal women at high risk of fracture**
Name of the Patient Group	**Osteoporosis Canada**
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

Osteoporosis Canada is the only national organization dedicated to serving people who have or are at risk of osteoporosis. The organization works to educate, empower and support individuals and communities in the risk reduction of osteoporosis and related fractures. Our vision is a Canada without osteoporotic fractures and to this end we educate Canadians about osteoporosis, advocate for optimal osteoporosis care and invest strategically in osteoporosis research. Our web address is osteoporosis.ca.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

Romosozumab is the newest treatment option that has become available for osteoporosis that offers a different mechanism of action compared to current conventional options to effectively reduce fractures. Romosozumab is currently being prescribed for individuals who are considered at very high risk of fracture and those who have had inadequate response or intolerance to standard current therapies. We asked several physicians on our Scientific Advisory Council for permission to speak directly with patients who have either completed the year of romosozumab or been on it for a number of months. During the past month, we were able to interview four patients in the Greater Toronto Area whose average age is 70, regarding their personal experience with romosozumab.

Recognizing that our information gathering on direct patient experience with the drug is limited, we found that there have been no further fractures in patients interviewed at very high risk of fracture; these patients have tolerated the drug well with no or minimal side effects, and valued the opportunity to be treated on this new drug.

Patient Engagement in Clinical Guidelines Development: Input from >1,000 Members of the Canadian Osteoporosis Patient Network. In 2018, in anticipation of updating the 2010 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis (currently underway), Osteoporosis Canada conducted a survey of patients to find out what issues and health outcomes were important to patients living with osteoporosis in order to ensure that the new guidelines addressed priorities most relevant to patients. Over 1,000 members of the Canadian Osteoporosis Patient Network responded and the results were published in the journal *Osteoporosis International.* Regarding pharmacotherapy, four key issues were raised from the survey:

- Benefits and harms
- New or best medication
- Duration of therapy
- Other (such as cost)

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

It is well recognized that the most important and feared consequence of osteoporosis is an increased risk of fracture. These can occur at a number of sites but are of significant concern when affecting the spine, hip, wrist or shoulder.

From the patient perspective, the impact of a fracture can be substantial: fractures in the older population are associated with acute and often chronic pain, changes in levels of, or loss of, independence, decreased mobility, social isolation resulting in depression, or institutionalization as a result of a fragility fracture. It is estimated that up to 40-50%of the elderly who sustain a hip fracture will have a significant decline in their ability to live independently. Even death may result. 28% of women and 37% of men who suffer a hip fracture will die within the year from complications.

However, even a relatively simple fracture such as a wrist fracture will interfere with a person's daily activities. For the younger senior, this may result in time away from work, possibly with financial impact. In many, it results in increased care requirements from family members and/or other caregivers. 1.5 million days are lost from work annually in Canada by fracture patients; 400,000 days are lost by caregivers.

Everyday activities can be severely compromised. If an individual has osteoporosis affecting the spine and is at high risk of fracture, an activity as ordinary as making a bed or the act of bending forward without caution can cause a fracture. A cough or sneeze can break a rib. Intimate relations are compromised. Enjoyed activities such as golf or tennis, or picking up a grandchild, may have to be avoided because of the possibility of inducing a fracture. The knowledge that bones may break with minimal trauma results in significant fear of falling, which further limits independence and mobility.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

Four patients who had been prescribed romosozumab were interviewed.

Patient 1: A 65-year-old female who was diagnosed with osteoporosis several years ago and was intolerant of conventional therapies.

Patient 2: A 77-year-old female who continued to be at very high risk of an osteoporotic fracture despite prior exposure to other drugs.

Patient 3: A female in her mid 70s who was diagnosed with osteoporosis several years ago who has suffered osteoporotic fractures but for whom other drugs are contraindicated.

.Patient 4: A male in his early 60s who was diagnosed in May 2019.

Common themes emerge from these interviews. The patients did not have an adequate response to conventional available drugs, they continued to fracture, and they could not tolerate conventional drugs. These patients expressed the value of being offered a new treatment option that works differently from conventional options, that both build new bone and prevents bone loss. This new drug offers hope that new fractures will be prevented and quality of life, including functionality and independence, will be maintained.

Patients expressed appreciation of having another anabolic therapy option (other than teriparatide) available to choose from. They appreciated that romosozumab involves monthly injections for 12 months rather than daily injections for 24 months (as is the case with teriparatide) and therefore feel that romosozumab is more acceptable and feasible.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements?

In our published patient survey mentioned in question 2, the responders reported the outcomes of pharmacotherapy that were of most importance to them. These were:

- Preserving quality of life (for example, improved mobility and independence)
- Preventing fracture-related deaths
- Preventing admission to long-term care homes
- Preserving their ability to perform daily physical and social activities
- Preventing all fractures related to osteoporosis
- Avoiding serious side effects

Patients express the desire to have choice with alternative options to achieve these ends when unable to tolerate conventional medications, have inadequate response to other medications or

have severe osteoporosis and continue to fracture. Compared to teriparatide, romosozumab may be more acceptable and feasible to many patients due to it's less frequent injection schedule and shorter treatment course.. The patients who were interviewed expressed the feasibility and ease of the monthly injection schedule of romosozumab.. Some got the injection done by a healthcare professional, which was convenient; some learned to self inject.

Patients interviewed expressed appreciation of a novel therapy that both increases bone formation and bone resorption. It holds great promise for those patients for whom conventional therapies are contraindicated or not working.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

Patient 1. This patient had tried both a bisphosphonate and denosumab but was intolerant to both. She was prescribed romosozumab by her specialist and has completed nine months. Romosozumab has worked very well for this patient in that there have been none of the side effects experienced previously.
Key values for this patient:

- Lack of serious side effects: There has been some joint, muscle, hip and groin pain but it is tolerable.
- Accessibility: She is very pleased with the administration of the drug. She goes to the doctor's office for the injection by a nurse.

Patient 2. She was prescribed romosozumab by her specialist and has completed the full 12 months.
Key values:

- Lack of serious side effects. She has had no side effects, no pain or irritation.
- Accessibility: There has been no problem with the administration of the drug.

Patient 3. She was also prescribed romosozumab by her specialist because conventional therapies were contraindicated. She has completed six months.
Key values:

- Lack of serious side effects. On the day of and the day after the injection, she does experience some achiness and a burning at the injection site, but these are inconsequential.
- Efficacy. She is very grateful, many years since her diagnosis, to have this drug as an option after having failed on or been contraindicated to other osteoporosis medications.

Patient 4. He was prescribed romosozumab by his specialist because of the severity of his osteoporosis.
Key values:

- Efficacy: Since completing the 12 months, he has had a follow up bone mineral density test with very good results, i.e. significant increases in BMD of both the hip and spine.
- Lack of serious side effects: Side effects have been minimal: some soreness at the injection site for a couple of days, a bit of leg pain.
- Accessibility: He has found the administration very easy – the first two times the drug was administered at the clinic; the third time they taught him how to self administer and he completed the year in that way.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it. **No**

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it. **No**

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Amgen				X

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Dr. Famida Jiwa
Position: President and CEO
Patient Group: Osteoporosis Canada
Date: February 25, 2021