CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

romosozumab (Evenity)

(Amgen Canada Inc.)

Indication: The treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture.

October 28, 2021

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0676-000
Brand name (generic)	Evenity (romosozumab)
Indication(s)	The treatment of osteoporosis in postmenopausal women at high risk of fracture, defined as a history of osteoporotic fracture or multiple risk factors for fracture
Organization	Osteoporosis Canada
Contact information[a]	Dr. Famida Jiwa, President and CEO

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☐
	No	☒

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

Osteoporosis Canada Response In each case, the recommendations are supported by the evidence (or lack thereof) provided by the ARCH trial.
Re **Initiation**, while participants in the ARCH trial were predominantly treatment naïve, Health Canada approval is not limited to this group of patients, so the requirement that patients be treatment naïve is disappointing. Many family physicians initiate therapy in high risk patients, some of whom will fracture while on therapy since current treatments only reduce fracture risk by 30-50%. This means that the vast majority of those who will be offered romosozumab will have already received another therapy for osteoporosis and fractured while on therapy. A maximum duration of 12 months is supported by both ARCH and Health Canada approval.
Re **Prescribing,** there is no evidence to support concurrent treatments.
Re **Pricing,** reduction is necessary to achieve the desired ICER. If the recommended price reduction results in a reduced cost to the patient, we are in favour as cost can be prohibitive for many patients.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

If not, what aspects are missing from the draft recommendation?

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

	Yes	☒

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	No	☐
If not, please provide details regarding the information that requires clarification.		

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Dr Famida Jiwa*
Position	*President and CEO*
Date	*21/10/2021*
☒	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.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

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	☐	☐	☐	☒
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0676
Name of the drug and Indication(s)	Evenity for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X
	No requested revisions	☐

2. Change in recommendation category or conditions
Complete this section if major or minor revisions are requested

Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation
Complete this section if editorial revisions are requested for the following elements

a) Recommendation rationale

Please provide details regarding the information that requires clarification.

b) Reimbursement conditions and related reasons

Please provide details regarding the information that requires clarification.

1. Please provide further reasoning as to why patient must be treatment naïve to osteoporosis medications.

c) Implementation guidance

Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0676
Brand name (generic)	EVENITY® (romosozumab)
Indication(s)	**Indication**: The treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture **Sponsor Requested Reimbursement Population**: The treatment of osteoporosis in postmenopausal women with a history of osteoporotic fracture and who are at very high risk for future fracture
Organization	Amgen Canada Inc.
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Amgen Canada Inc. is pleased with the Committee's reimbursement recommendation for EVENITY® (romosozumab) for the treatment of osteoporosis in postmenopausal women. Amgen Canada Inc. also agrees that romosozumab aligns with patient's values for a new treatment option that reduces the risk of osteoporosis-related fractures which can have a substantial impact on patient's lives.

However, we respectfully believe that some of the assumptions in the CADTH base case analysis are not justified by the evidence and that the ICER is likely overestimated:

- CADTH's assumption that the relative treatment benefit for romosozumab followed by alendronate would cease immediately upon discontinuation is unlikely. Following treatment discontinuation, skeletal bone material would be lost over time and the reduction in the risk of fracture would diminish. A linearly declining offset time has been very well established in published economic analyses of osteoporosis therapies.
- CADTH assumed that mortality risk could last one year post hip fracture due to limited mobility during this time. However, published studies have demonstrated that the risk of death associated with hip fracture persists beyond 1 year and modelling long-term excess mortality after hip fracture is well established in published economic analyses of osteoporosis therapies.
- CADTH assumed that after one year post fracture, a patient's utility would only be 5% less than what they experienced pre-fracture in the second and subsequent years. This is a very conservative assumption, given the clinical evidence has shown that health-related quality of life following hip fracture remains substantially below pre-fracture levels in the long-term with no evidence of a return to baseline levels.

Notwithstanding, Amgen supports the conversion of the draft recommendation to a final recommendation to expedite access for patients with postmenopausal osteoporosis with a history of fracture who are at high risk for future fracture.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
Yes, the reimbursement conditions are clearly stated, however, the Canadian Association of Radiologists and Osteoporosis Canada fracture risk assessment tool (CAROC) can also be used to evaluate an individual's 10-year fracture risk. Both FRAX and CAROC tools are available and widely used in Canada, however primary care physicians tend to be more familiar with and prefer the CAROC tool. The 'Initiation' Reimbursement Condition 1 should clarify whether the CAROC tool can be used to define a patient who is at high risk for future fracture.		

[a] CADTH may contact this person if comments require clarification.