

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Selpercatinib (Retevmo)
(Eli Lilly Canada Inc.)

Indication: Thyroid cancer

May 19, 2022

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CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0264-000	
Brand name (generic)	Selpercatinib (Retevmo)	
Indication(s)	Retevmo is indicated as monotherapy for the treatment of: RET-mutant medullary thyroid cancer in adult and pediatric patients 12 years of age and older with unresectable advanced or metastatic disease.	
Organization	Ontario Health (CCO) Head, Neck and Thyroid Cancer Drug Advisory Committee	
Contact information ^a	Name: Dr. Michael Odell	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<p>Vandetanib is the SOC. It has a black box warning in the US and in Canada we need special training. There could be patients with cardiac issues, arrhythmia problems or chronic renal problems, where given Vandetanib would be dangerous.</p> <p>More explicit wording being able to apply directly where exposure to Vandetanib would be dangerous to these patients.</p>		
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

^a CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician 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.
- For conflict of interest declarations:
 - Please 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.
 - Please note that declarations are required for each clinician that contributed to the input.
 - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
Ontario Health provides secretariat functions to the DAC.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> • Dr. Michael Odell • Dr. Eric Winqvist • Dr. Stephanie Brule 		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0264-000	
Brand name (generic)	Retevmo (Selpercatinib)	
Indication(s)	Thyroid Cancer	
Organization	Pediatric Oncology Group of Ontario	
Contact information ^a	Name: Paul Gibson	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.</p> <p>We are disappointed to read that the committee did not consider the potential biologic potential of this agent in children under 12. We feel that by deferring to the Health Canada approved indication, there is inequitable disadvantage to younger children. It is extremely unlikely that future studies focusing on this rarely impacted age range will be undertaken, leaving this group without options for future funding solutions. Furthermore, we believe the decision to recognize yet not address the funding gap of front line therapy in 12-18 year old patients further fuels inequity. While noting results may be expected in late 2026, this committee is highlighting that it will be more than 5 years until we can expect suitable funded therapy for this rare group of patients.</p>		
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	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>If not, what aspects are missing from the draft recommendation?</p> <p>Despite acknowledging the input provided, the committee chose to defer only the Health Canada indication, which ignores the reality of rare populations.</p>		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p>		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p>		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p>		

^a CADTH may contact this person if comments require clarification.

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 - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> Clinician 1 Clinician 2 Add additional (as required) 		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

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
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 2

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)

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

Conflict of Interest Declaration

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
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 3

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)

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

Conflict of Interest Declaration

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
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 4				
Name	<i>Please state full name</i>			
Position	<i>Please state currently held position</i>			
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			
Conflict of Interest Declaration				
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
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 5				
Name	<i>Please state full name</i>			
Position	<i>Please state currently held position</i>			
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			
Conflict of Interest Declaration				
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
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0264
Name of the drug and Indication(s)	Selpercatinib for RET-mutant MTC
Organization Providing Feedback	PAG

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	<input type="checkbox"/>
	Minor revisions: A change in reimbursement conditions is requested	<input type="checkbox"/>
No Request for Reconsideration	Editorial revisions: Clarifications in recommendation text are requested	X
	No requested revisions	<input type="checkbox"/>

2. Change in recommendation category or conditions

Complete this section if major or minor revisions are requested

None.

3. Clarity of the recommendation

Complete this section if editorial revisions are requested for the following elements

a) Recommendation rationale

In the Economic Evidence section, Cost and Effectiveness table, Treatment row, PAG is requesting the following addition “120 mg orally twice daily (for under 50 kg) or 160 mg orally twice daily (for 50 kg and above).”

b) Reimbursement conditions and related reasons

None.

c) Implementation guidance

None.

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0264-000	
Brand name (generic)	Retevmo (Selpercatinib)	
Indication(s)	For the treatment of RET-mutant medullary thyroid cancer in adult and pediatric patients 12 years of age and older with unresectable advanced or metastatic disease.	
Organization	Canadian Cancer Society	
Contact information ^a	Name: Sasha Frost Email: [REDACTED] Phone: [REDACTED]	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.		
<ul style="list-style-type: none"> Retevmo (Selpercatinib) addresses a therapeutic need as this variant of thyroid cancer is rare and incurable. As stated in the recommendation, there are currently no funded therapies available for patients with RET-mutant MTC who progressed on or are intolerant to first line therapy. Therefore, the recommendation to reimburse with conditions would help address this need. According to our survey, thyroid cancer patients, in general, expressed the need for treatment options that will help them maintain their quality of life (QOL). Thirty-two percent of responses measuring the impact of side effects on their life fell into the moderate to significant range. If responses were limited to those with RET-mutant MTC with advanced or metastatic disease, this figure would likely have been much higher. Selpercatinib will provide an option for this rarer group of patients. According to the recommendation, clinician trial data demonstrated the majority of patients experienced either improvement in QOL or their QOL remained stable with only a smaller proportion experiencing a deterioration in QOL (page 6) which speaks to the need above. Based on the price reduction of 87% (or more) required for selpercatinib to be cost-effective, as per page 3 and 5 of the recommendation, this may result in a barrier for patients without other options if the price can not reach this figure. 		
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?		
Yes, however there was one small error on the recommendation. In the patient input section, it indicates that patients living with MTC were surveyed by the Canadian Cancer Society. However, it		

was thyroid cancer patients overall due to the rarity of MTC and challenges associated with accessing patients with MTC within the submission window.

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.

More information on the feasibility of adopting Selpercatinib is needed. Specifically, the costs associated with adding Selpercatinib to any drug formularies. Due to this uncertainty, it is noted additional price reductions beyond the suggested 87% may be necessary (page 5). More clarity may be helpful to decisionmakers.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?

Yes

No

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

^a CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.