

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Cabozantinib (Cabometyx)
Ipsen Biopharmaceuticals Canada Inc.

Indication: For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

October 21, 2022

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

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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 identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0287-000
Brand name (generic)	Cabometyx (cabozantinib)
Indication(s)	Treatment of adult and adolescent patients 12 years of age and older with differentiated thyroid carcinoma (DTC) that has progressed following prior therapy and who are radioactive iodine-refractory or ineligible.
Organization	Canadian Cancer Society
Contact information	Name: Sasha Frost [REDACTED] [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"/>
<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>Overall, the recommendation reflects the needs of the patient group as identified in the patient submission. CADTH should consider any and all limitations on patient access stemming from this draft recommendation.</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"/>
<p>If not, what aspects are missing from the draft recommendation?</p> <p>Overall, the recommendation reflected the input of the patient group. As this patient group is very rare, there was only one patient who tried cabozantinib who completed the survey for CCS. However, the details surrounding this patient's perspectives on the drug could be better reflected in the recommendation.</p> <p>Overall, the patient strongly felt the side effects were tolerable, strongly agreed that she would choose to take cabozantinib again considering the side effects, and strongly agreed that this medication was easy to use. She also agreed that cabozantinib has been effective at controlling her cancer and that the pill form allowed her to spend less time in the clinic receiving treatment. This could be better reflected on pages 6-7 of the recommendation.</p>	
Clarity of the draft recommendation	
3. Are the reasons for the recommendation clearly stated?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
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"/>
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.

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	Sasja Frost			
Position	Sr Advocacy Specialist, Public Engagement			
Date	Please add the date form was completed (20-10-2022)			
<input checked="" type="checkbox"/>	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	<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 patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
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	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
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
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"/>

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0287-000
Brand name (generic)	Cabometyx (cabozantinib)
Indication(s)	Treatment of adult and adolescent patients 12 years of age and older with differentiated thyroid carcinoma (DTC) that has progressed following prior therapy and who are radioactive iodine-refractory or ineligible.
Organization	The Medical Advisory Panel of Thyroid Cancer Canada (TCC) and other Thyroid cancer-treating physicians
Contact information ^a	Name: Dr. Brandon Meyers [REDACTED] [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.	
<p><u>Clinical Feedback</u></p> <p>We do agree generally with the reimbursement conditions laid out in Table 1 of the CADTH Reimbursement recommendation, however with respect to the comment (in discussion points on p.5 of the draft recommendation):</p> <p><i>There is no evidence on the comparative efficacy or harms of cabozantinib relative to targeted treatments recommended for reimbursement by pERC for the small proportion of patients with DTC that have RET fusions or NTRK fusions, such as selpercatinib or larotrectinib. pERC noted that these treatments, if funded, would be available only to the minority of patients with the respective targetable fusions. pERC noted that patients with DTC who do not have targetable mutations could be eligible for treatment with cabozantinib.</i></p> <p>We would like to ensure that patients, who have had a mutation (RET fusions or NTRK fusions), and had targeted therapy, which did not work or to which there was intolerance, would have access to cabozantinib.</p> <p><u>Economic Feedback</u></p> <p>Re: p. 11</p> <p>"In the CADTH reanalysis, the ICER for cabozantinib + BSC was \$664,742 per QALY compared to BSC alone. Price reductions of at least 95% would be required for cabozantinib, or for cabozantinib + BSC to be considered cost-effective at a willingness-to-pay threshold of \$50,000 per QALY threshold.</p>	

As a group of physicians with expert knowledge of the clinical factors related to the treatment of thyroid cancer, we generally do not comment on issues related to pharmacoeconomics. However, we felt it important to comment on CADTH's use of an ICER pegged at \$50,000 per QALY as the willingness-to-pay (WTP) threshold for payers.

We are aware that previous pERC recommendations (prior to 2020) included analyses to determine needed price reductions for ICERS of \$100,000 and \$50,000. We are also aware of ICERS considered that were significantly over \$100,000 in situations where there was significant unmet need or where there was considerable therapeutic improvement.

We support the work of Canadian health technology assessment agencies and the pan Canadian Pharmaceutical Alliance (pCPA) in assessing value and achieving value in prescription medications for publicly funded drug programs. However, we are concerned that CADTH arbitrarily established a new (and low) WTP threshold, with no consultation, that could ultimately result in Canadian patients with difficult-to-treat cancers being denied access to important new therapies.

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?		

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
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	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
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"/>
If not, please provide details regarding the information that requires clarification.		

^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 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 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"> • Clinician 1 • Clinician 2 • Add additional (as required) 		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0287
Name of the drug and Indication(s)	Cabozantinib for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC).
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	<input type="checkbox"/>
	No requested revisions	X

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

None.

b) Reimbursement conditions and related reasons

None.

c) Implementation guidance

None.