



Canada's Drug Agency  
L'Agence des médicaments du Canada

## CDA-AMC REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**dabrafenib trametinib**  
(non-sponsored review)

**Indication:** BRAF V600E mutant anaplastic thyroid cancer

**Apr 29, 2025**

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

By filing with CDA-AMC, the submitting organization or individual agrees to the full disclosure of the information. CDA-AMC does not edit the content of the submissions.

CDA-AMC 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.

## Feedback on Draft Recommendation

Interested party information	
Project number	PX0373-000
Brand name (generic)	Dabrafenib-Trametinib
Indication(s)	For the treatment of unresectable or metastatic BRAF V600 mutant anaplastic thyroid cancer
Organization	Ontario Health (Cancer Care Ontario)- Head & Neck Cancer Drug Advisory Committee (DAC)
Contact information <sup>a</sup>	Dr. Michael Odell, Lead, Head & Neck Cancer DAC
Interested party agreement with the draft recommendation	
1. Does the interested party agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
<p>The DAC agrees with the committee's recommendation but would like to suggest the following:</p> <ul style="list-style-type: none"> <li>- For condition no. 1 - good performance status" is required. There may be a patient with, for example, airway obstruction from their tumor who is in the hospital and it could be very appropriate to start that patient on therapy. Can there be a statement on Table 1 to reflect these situations wherein the patient may still be considered along the lines of "suitable for treatment with dabrafenib/trametinib".</li> <li>- For condition no.2 – "should be discontinued for disease progression or significant toxicity." The DAC suggests clarifying that treatment should be discontinued if the patient is no longer deriving clinical benefit or if the patient is experiencing unacceptable toxicity.</li> </ul>	
Expert committee consideration of the input	
2. Does the recommendation demonstrate that the committee has considered the input that your organization provided?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Not applicable	
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 type="checkbox"/>
	No <input checked="" type="checkbox"/>
See above.	

<sup>a</sup> CDA-AMC 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 CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for Drug Reimbursement Reviews* for further details.

A. Patient Group Information				
<b>Name</b>	Please state full name			
<b>Position</b>	Please state currently held position			
<b>Date</b>	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 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				
<b>1. Did you receive help from outside your patient group to complete your feedback?</b>			No	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
<b>2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?</b>			No	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
<b>1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the review and have those declarations remained unchanged? If no, please complete section D below.</b>			No	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
<b>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.</b>				
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"/>

## Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for 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		
2. Did you receive help from outside your clinician group to complete this submission?	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
Ontario Health (Cancer Care Ontario) provided secretariat support for this submission.		
3. 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"/>
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the 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"> <li>Clinician 1</li> <li>Clinician 2</li> <li>Add additional (as required)</li> </ul>		

### C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Dr. Eric Winquist
Position	Member, Ontario Health (Cancer Care Ontario) – Head & Neck Cancer Drug Advisory Committee
Date	16-04-2025
<input checked="" 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				
<b>Name</b>	Dr. Anna Spreafico			
<b>Position</b>	Member, Ontario Health (Cancer Care Ontario) – Head & Neck Cancer Drug Advisory Committee			
<b>Date</b>	13-04-2025			
<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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				
<b>Name</b>	Dr. Martin Smoragiewicz			
<b>Position</b>	Member, Ontario Health (Cancer Care Ontario) – Head & Neck Cancer Drug Advisory Committee			
<b>Date</b>	14-04-2025			
<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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				
<b>Name</b>	Dr. Lucy Ma			
<b>Position</b>	Member, Ontario Health (Cancer Care Ontario) – Head & Neck Cancer Drug Advisory Committee			
<b>Date</b>	14-04-2025			
<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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 5				
<b>Name</b>	Dr. Stephanie Brule			
<b>Position</b>	Member, Ontario Health (Cancer Care Ontario) – Head & Neck Cancer Drug Advisory Committee			
<b>Date</b>	15-04-2025			
<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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 6	
<b>Name</b>	Dr. Michael Odell
<b>Position</b>	Lead, Ontario Health (Cancer Care Ontario) – Head & Neck Cancer Drug Advisory Committee
<b>Date</b>	17-04-2025

<input checked="" type="checkbox"/>	<b>I hereby certify</b> 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.
-------------------------------------	---

<b>Conflict of Interest Declaration</b>
---

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"/>

# CDA-AMC Reimbursement Review

## Feedback on Draft Recommendation

Stakeholder information		
CDA-AMC project number	PX0373	
Name of the drug and Indication(s)	Dabrafenib-Trametinib for the treatment of unresectable or metastatic BRAF V600 mutant anaplastic thyroid cancer	
Organization Providing Feedback	OWG (PAG)	
<b>1. Recommendation revisions</b> Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	<b>Major revisions:</b> A change in recommendation <b>category</b> or patient <b>population</b> is requested	<input type="checkbox"/>
	<b>Minor revisions:</b> A change in reimbursement <b>conditions</b> is requested	<input type="checkbox"/>
No Request for Reconsideration	<b>Editorial revisions:</b> Clarifications in recommendation <b>text</b> are requested	X
	<b>No requested revisions</b>	<input type="checkbox"/>
<b>2. Change in recommendation category or conditions</b> 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.		
<b>3. Clarity of the recommendation</b> Complete this section if editorial revisions are requested for the following elements		
<b>a) Recommendation rationale</b>		
Please provide details regarding the information that requires clarification.		
<b>b) Reimbursement conditions and related reasons</b>		
Please provide details regarding the information that requires clarification.  In Table 1, OWG suggested adding this additional statement under Implementation guidance (Initiation): "BRAF V600 testing is required to determine if patients are eligible for treatment with dabrafenib-trametinib."		
<b>c) Implementation guidance</b>		
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 CDA-AMC 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
<b>1. Please specify sequencing questions or issues that should be addressed by CDA-AMC (oncology only)</b>
1. 2.
<b>2. Please specify other implementation questions or issues that should be addressed by CDA-AMC</b>
1. 2.
Support strategy
<b>3. Do you have any preferences or suggestions on how CDA-AMC should address these issues?</b>
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.