

## CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**pembrolizumab (Keytruda)**  
(Merck Canada Inc.)

**Indication:** In combination with gemcitabine-based chemotherapy, is indicated for the treatment of adult patients with locally advanced unresectable or metastatic biliary tract carcinoma (BTC).

June 13, 2024

**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.

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

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	PC0344-000-000
Brand name (generic)	Pembrolizumab (Keytruda)
Indication(s)	In combination with gemcitabine-based chemotherapy, indicated for the treatment of adult patients with locally advanced unresectable or metastatic biliary tract carcinoma
Organization	Colorectal Cancer Resource & Action Network (CCRAN)
Contact information <sup>a</sup>	Name: Filomena Servidio-Italiano, President & CEO [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"/>
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"/>

<sup>a</sup> 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				
<b>Name</b>	<i>Filomena Servidio-Italiano</i>			
<b>Position</b>	<i>President &amp; CEO</i>			
<b>Date</b>	<i>June 13, 2024</i>			
<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
<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	PC0344-000
Brand name (generic)	Keytruda (pembrolizumab)
Indication(s)	In combination with gemcitabine-based chemotherapy, is indicated for the treatment of adult patients with locally advanced unresectable or metastatic biliary tract carcinoma
Organization	OH (CCO) Gastrointestinal Cancer Drug Advisory Committee
Contact information <sup>a</sup>	Name: Dr. Erin Kennedy
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.	
For condition #4: Imaging should initially be completed every 3 to 4 <u>months</u> .	
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.	
For condition #4: Imaging should initially be completed every 3 to 4 <u>months</u> .	

<sup>a</sup> 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		
2. Did you receive help from outside your clinician group to complete this submission?	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please detail the help and who provided it. OH provided a secretariat function to the group.		
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"/>
If yes, please detail the help and who provided it.		
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 CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input 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>Dr. Erin Kennedy</li> </ul>		

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

New or Updated Declaration for Clinician 1	
Name	Dr. Rachel Goodwin
Position	Member, OH (CCO) GI DAC
Date	05-06-2024
<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
Merck	<input type="checkbox"/>	<input checked="" 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. Suneil Khanna
<b>Position</b>	Member, OH (CCO) GI DAC
<b>Date</b>	05-06-2024
<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
Merck	<input type="checkbox"/>	<input checked="" 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. Tim Asmis
<b>Position</b>	Member, OH (CCO) GI DAC
<b>Date</b>	05-06-2024
<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
Merck	<input type="checkbox"/>	<input checked="" 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	PC0344
Name of the drug and Indication(s)	Pembrolizumab In combination with gemcitabine-based chemotherapy, is indicated for the treatment of adult patients with locally advanced unresectable or metastatic biliary tract carcinoma (BTC).
Organization Providing Feedback	PAG
<b>1. Recommendation revisions</b>	
Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.	
<b>Request for Reconsideration</b>	<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 checked="" type="checkbox"/>
<b>No Request for Reconsideration</b>	<b>Editorial revisions:</b> Clarifications in recommendation <b>text</b> are requested <input type="checkbox"/>
	<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.	
PAG requested the 2-year fixed duration for pembrolizumab be added to Table 1 under Discontinuation.	
<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.	
<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 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
<b>1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)</b>
1. 2.
<b>2. Please specify other implementation questions or issues that should be addressed by CADTH</b>
1. 2.
Support strategy
<b>3. Do you have any preferences or suggestions on how CADTH should address these issues?</b>
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.



## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0344	
Brand name (generic)	Keytruda (pembrolizumab)	
Indication(s)	Biliary Tract Cancer	
Organization	Merck Canada Inc.	
Contact information <sup>a</sup>	[REDACTED]	
<b>Stakeholder agreement with the draft recommendation</b>		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<b>Expert committee consideration of the stakeholder input</b>		
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"/>
<b>Clarity of the draft recommendation</b>		
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"/>
<p>Merck Canada would like to highlight that in the KN-966 clinical trial, the use of gemcitabine is permitted beyond the initial 8 cycles of platinum doublet, which is aligned with Canadian practice according to Canadian experts and as such kindly requests this to be reflected in the reimbursement criteria.<sup>1</sup> This is also aligned with the KEYTRUDA product monograph.<sup>2</sup></p>		

<sup>a</sup> CADTH may contact this person if comments require clarification.

### References

1. Kelley RK, Ueno M, Yoo C, et al. Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2023;401(10391):1853-1865.
2. Health Canada. Product monograph - Keytruda. [https://pdf.hres.ca/dpd\\_pm/00075758.PDF](https://pdf.hres.ca/dpd_pm/00075758.PDF). Accessed June, 2024.