

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Pembrolizumab (Keytruda)

Merck Canada Inc.

Indication: Pembrolizumab as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

January 16, 2025

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.



Stakeholder information	Colorectal Cancer Resource & Action Network (CCRAN)			
CADTH project number	PC0377-000			
Brand name (generic)	Pembrolizumab (Keytruda®)			
Indication(s)	For the treatment of adult and pediatric patients with unresed metastatic MSI-H or dMMR solid tumours, as determined by test, that have progressed following prior treatment and who satisfactory alternative treatment options	a validated		
Organization	Colorectal Cancer Resource & Action Network (CCRAN)			
Contact information ^a	Name: Cassandra Macaulay, Chief Research Officer, CCF	RAN		
Stakeholder agreement wi	ith the draft recommendation			
CCRAN happily agrees with	gree with the committee's recommendation. the committee's recommendation, with one exception: In Table tients must not have a history of therapy with an anti-PD-1, and			
CCRAN grappled with the above-noted portion of the recommendation, particularly in respect of current patients who may have already accessed one of these therapies as a part of a clinical trial, and in the absence of funded access to pembrolizumab. To ensure equitable access and to promote consistency within the MSI-H metastatic and unresectable patient population, CCRAN believes that patients who have accessed another immunotherapeutic prior to publicly funded access to pembrolizumab being available in their respective province should be permitted to avail themselves of access to pembrolizumab.				
1	eration of the stakeholder input	1		
	on demonstrate that the committee has considered the our organization provided to CADTH?	Yes ⊠ No □		
	fully considered CCRAN's input and the positive funding recond ith the patient perspectives captured within CCRAN's submiss			
Clarity of the draft recomn	nendation			
3. Are the reasons for the I	recommendation clearly stated?	Yes ⊠ No □		
The recommendations are c	clearly stated with the exception of a clerical error in the on page 3: "only if the conditions listed in Error! Reference	No 🗆		

Overall, CCRAN finds the implementation issues to be clearly addressed and articulated, however, additional guidance is required with respect to mutational testing.

CCRAN implores this kind committee to highlight the importance of access to biomarker testing results for all metastatic and unresectable cancer patients in Canada. The difficulty or inability to access tissue biopsy in some tumour types, and subsequently, the critical role of liquid biopsy, has not been addressed within the implementation guidance. Additionally, there are significant disparities related to biomarker testing access and timeliness of reporting of the results (Snow et al., 2024), which infers a substantial threat to health equity in Canada. CCRAN seeks clarity with respect to the guidance provided by the committee to address this issue in Canada.

5. If applicable, are the reimbursement conditions clearly stated and the rationale	Yes	\boxtimes
for the conditions provided in the recommendation?	No	
Yes, with the exceptions noted above.		22

^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 <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.

A. Patient Group Information								
Name	Filomena Servidio-Italiano							
Position	President & CEO							
Date	15-01-2025							
	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. Assistan	ce with Providing Feedback							
4 5:1		4:4		fIII-O	No			
1. Dia you	1. Did you receive help from outside your patient group to complete your feedback?							
	The patient groups who collaborated on the collective patient input submission did not have any feedback to provide in respect of the recommendation.							
2. Did you	receive help from outside you	r patient grou	p to collect or a	nalyze any	No			
informa	tion used in your feedback?	. 	70	71 TO 1 TO 1	Yes			
C. Previous	ly Disclosed Conflict of Interes	it						
	onflict of interest declarations				No			
	ed at the outset of the CADTH ged? If no, please complete se			ations remaine	d Yes			
D. New or U	pdated Conflict of Interest Dec	laration						
3. List any past two	r companies or organizations t o years AND who may have dir	hat have provi ect or indirect	ded your group interest in the	with financial drug under revi	payment ew.	over the		
			Check Approp	oriate Dollar Ra	nge			
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Add compan	y name				į			
Add or remo	or remove rows as required							

Stakeholder information						
CADTH project number	PC0377					
Brand name (generic)	Keytruda (pembrolizumab)					
Indication(s)	As monotherapy for the treatment of adult and pediatric patients with					
	unresectable or metastatic microsatellite instability-high (MSI-H)					
	mismatch repair deficient (dMMR) solid tumors, as determined by a					
	validated test, that have progressed following prior treatment and who have					
	no satisfactory alternative treatment options					
Organization	Ontario Health (Cancer Care Ontario) CNS Cancer Drug Advis Committee ("DAC")	sory				
Contact informationa	Name: Dr. Sunit Das					
Stakeholder agreement wi	ith the draft recommendation					
4. Done the stakeholder of	was with the committee's vector and the	Yes	\boxtimes			
1. Does the stakeholder ag	gree with the committee's recommendation.	No				
	eholder agrees or disagrees with the draft recommendation. Wile specific text from the recommendation and rationale.		.			
Expert committee conside	eration of the stakeholder input					
2. Does the recommendati	on demonstrate that the committee has considered the	Yes	\boxtimes			
stakeholder input that y	our organization provided to CADTH?	No				
If not, what aspects are miss	sing from the draft recommendation?					
Clarity of the draft recomm	nendation					
3 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes			
3. Are the reasons for the	econiniendation cleany stated:	No				
If not, please provide details	regarding the information that requires clarification.					
4. Have the implementation	n issues been clearly articulated and adequately	Yes	\boxtimes			
addressed in the recom		No				
If not, please provide details	regarding the information that requires clarification.	×	8			
	mbursement conditions clearly stated and the rationale	Yes				
	ded in the recommendation?	No	\boxtimes			
If not, please provide details	regarding the information that requires clarification.					
	rogalang are membanen alam oquilo olam oo					
Table 1						
Re: 2.1 Active CNS metasta						

Our practitioners often encounter cases for which local therapy is not indicated (i.e. small, asymptomatic brain metastases that do not necessarily require local therapy) or possible (e.g. no more "room" for XRT), for whom immunotherapy may still be valuable. Further, there are data to suggest that pembrolizumab can be effective in treating patients with active brain metastases (https://www.nature.com/articles/s41591-023-02392-7) across diverse histologies.

Re: tumour testing

We need to ensure we can test tumors for MMR/MS status adequately where this is not already implemented. dMMR can be screened cost-effectively with the IHC- the younger patients will have NGS done reflexively in most centres (in Ontario); some patients may be missed across the province.

Another aspect is the regarding the approval of pembrolizumab in addition to other systemic treatments - specific to CNS, could we ensure that language is inclusive of concurrent use of bevacizumab which is sometimes needed without progression of disease in the context of tumor-related inflammation (and because steroids are counterproductive). There are several published trials that speak to safety of the combination in CNS and other systemic cancers.

^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		5 8
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	\boxtimes
If yes, please detail the help and who provided it.		
OH-CCO PDRP provided secretariat function to the group.		
To the second se		
2. Did you receive help from outside your clinician group to collect or analyze any	No	
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		7
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was	No	
submitted at the outset of the CADTH review and have those declarations remained	Yes	\boxtimes
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Dr. Sunit Das		
Dr. Seth Climans		
Add additional (as required)		

C. New or Updated Conflict of Interest Declarations

New or Up	New or Updated Declaration for Clinician 1			
Name	Dr. Mary Jane Lim-Fat			
Position	Member, Ontario Health (Cancer Care Ontario) CNS Cancer Drug Advisory Committee			
Date	07-01-2025			
	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.					
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Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add compa	mpany name				
Add compa	company name				
Add or rem	ove rows as required				
New or Up	dated Declaration for Clinician	2			
Name	Dr. Garth Nicholas				â
Position	Member, Ontario Health (Cance	er Care Ontario) CNS Cancer Dr	rug Advisory Com	mittee
Date	08-01-2025		-		
\boxtimes	I hereby certify that I have the	authority to dis	close all relevant	information with r	espect to any
	matter involving this clinician or				AN 50
	place this clinician or clinician g	roup in a real, _l	potential, or perce	eived conflict of inf	terest situation.
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In Excess of

\$50,000

Check Appropriate Dollar Range

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50,000

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New or Up	dated Declaration for Clinician	4			
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Conflict of	Interest Declaration				
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Add or remove rows as required

Stakeholder information						
CADTH project number	PC0377					
Brand name (generic)	Keytruda (pembrolizumab)					
Indication(s)	Indication(s) For the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumours, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options					
Organization	Ontario Health (Cancer Care Ontario) Gastrointestinal Cance Advisory Committee	r Drug				
Contact information ^a	Name: Dr. Erin Kennedy					
Stakeholder agreement wi	th the draft recommendation					
	ree with the committee's recommendation. eholder agrees or disagrees with the draft recommendation. W	Yes No heneve	⊠ □ er			
possible, please identify the	specific text from the recommendation and rationale.		north.			
Expert committee conside	ration of the stakeholder input					
and the second	on demonstrate that the committee has considered the our organization provided to CADTH?	Yes No				
If not, what aspects are miss	sing from the draft recommendation?		A 100			
NA - The GI DAC did not pro	ovide input at the onset of this review.					
Clarity of the draft recomm	nendation					
3 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes			
3. Are the reasons for the	recommendation clearly stated:	No				
If not, please provide details	regarding the information that requires clarification.					
	n issues been clearly articulated and adequately	Yes	\boxtimes			
addressed in the recom	NATION CONTROL OF THE PROPERTY	No				
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	mbursement conditions clearly stated and the rationale	Yes	\boxtimes			
A CONTRACTOR OF THE PROPERTY O	ded in the recommendation?	No				
it not, please provide details	regarding the information that requires clarification.					

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A. Patient Group Information							
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was d						
B. Assistan	ce with Providing Feedback						
4 Did von				المحملات منادع	No		
1. Did you	receive help from outside you	r patient grou	p to complete y	our reedback?	Yes		
If yes, pleas	e detail the help and who provide	d it.					
2. Did you	2. Did you receive help from outside your patient group to collect or analyze any						
informa	tion used in your feedback?			ender S ervice de la Constant	Yes		
If yes, please detail the help and who provided it.							
	ly Disclosed Conflict of Interes						
	onflict of interest declarations				No		
	ted at the outset of the CADTH ged? If no, please complete se			rations remaine	d Yes		
D. New or U	Ipdated Conflict of Interest Dec	laration					
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 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		3 8
2. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	
If yes, please detail the help and who provided it.		
OH-CCO PDRP provided secretariat function to the group.		
Did you receive help from outside your clinician group to collect or analyze any	No	
information used in this submission?	Yes	
If yes, please detail the help and who provided it.	100 100 10	
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was	No	\boxtimes
submitted at the outset of the CADTH review and have those declarations remained	Yes	
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Clinician 1		
Clinician 2		
Add additional (as required)		
Add additional (as required)		

C. New or Updated Conflict of Interest Declarations

New or Up	New or Updated Declaration for Clinician 1			
Name	Dr. Erin Kennedy			
Position	Lead, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee			
Date	10-01-2025			
	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			

			Check Appro	priate Dollar Kar	ige
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add compa	any name				
Add company name					
Add or rem	nove rows as required				
			8		_
New or Up	dated Declaration for Clinician	2			
Name	Dr. Tim Asmis				
Position	Member, Ontario Health (Cance	er Care Ontario	o) Gastrointestina	l Cancer Drug Ad	visory Committee
Date	10-01-2025				
⊠	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company	, organization, or	entity that may
Conflict of	f Interest Declaration				
	mpanies or organizations that ha who may have direct or indirect i				er the past two
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Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Merck					
Add compa	any name				
Add or rem	nove rows as required				
	dated Declaration for Clinician	3			
Name Position	Dr. Rachel Goodwin	or Cara Ontorio) Cootrointoctina	I Canaar Drug Aa	luisani Cammittaa
Date	Member, Ontario Health (Cancel 10-01-2025	er Care Onland	o) Gastrointestina	il Caricer Drug Ad	visory Committee
☐ I hereby certify that I have the authority to disclose all relevant information with res matter involving this clinician or clinician group with a company, organization, or ent place this clinician or clinician group in a real, potential, or perceived conflict of intermediate.			entity that may		
Conflict of	f Interest Declaration				
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Merck					
Add compa	any name				
Add or remove rows as required		П	п	П	

Name	Dr. Suneil Khanna
Position	Member, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Date	10-01-2025
×	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.

	Check Appropriate Dollar Range				
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Merck					
Add company name					
Add or remove rows as required					

New or Up	dated Declaration for Clinician 5
Name	Dr. Consolacion Molto Valiente
Position	Member, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee
Date	10-01-2025
⊠	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

	Check Appropriate Dollar Range				
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Merck					
Add company name					
Add or remove rows as required					

New or Updated Declaration for Clinician 6			
Name	Dr. Michael Raphael		
Position	Member, Ontario Health (Cancer Care Ontario) Gastrointestinal Cancer Drug Advisory Committee		
Date	10-01-2025		

\boxtimes	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
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Conflict of Interest Declaration

		Check Appropriate Dollar Range				
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000		
Add company name						
Add company name						
Add or remove rows as required						

Stakeholder information							
CADTH project number	PC0377						
Brand name (generic)							
Indication(s) As monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options							
Organization	Ontario Health (CCO) GU Cancers Disease Site Drug Advisor	ry					
0	Committee						
Contact informationa	Name: Dr. Girish Kulkarni						
Stakeholder agreement wi	th the draft recommendation						
1. Does the stakeholder ag	ree with the committee's recommendation.	Yes No					
	eholder agrees or disagrees with the draft recommendation. W specific text from the recommendation and rationale.	heneve	er				
Expert committee conside	ration of the stakeholder input						
	on demonstrate that the committee has considered the our organization provided to CADTH?	Yes No					
	sing from the draft recommendation?	110					
Clarity of the draft recomm	nendation						
2 A 41		Yes	\boxtimes				
3. Are the reasons for the	recommendation clearly stated?	No					
If not, please provide details	regarding the information that requires clarification.						
	n issues been clearly articulated and adequately	Yes	\boxtimes				
addressed in the recommendation?							
If not, please provide details regarding the information that requires clarification.							
	mbursement conditions clearly stated and the rationale ded 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.

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		5 6
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	
If yes, please detail the help and who provided it.		
OH-CCO PDRP provided secretariat function to the group.		
2. Did you receive help from outside your clinician group to collect or analyze any	No	
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		
B. Braviavaly Disabased Conflict of Interest		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was	No	
submitted at the outset of the CADTH review and have those declarations remained	Yes	\boxtimes
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Dr. Girish Kulkarni		
Dr. Urban Emmenegger		
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)		
	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			

Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	\$50,000		
Add compa	any name						
Add compa	any name						
Add or rem	ove rows as required						
New or Un	New or Updated Declaration for Clinician 2						
Name	Please state full name	_					
Position	Please state currently held posi-	ition					
Date	Please add the date form was d		-MM-YYYY)				
	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may		
Conflict of	Interest Declaration						
	mpanies or organizations that have who may have direct or indirect i		lrug under review	•			
120				riate Dollar Ran			
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000		
Add compa	any name						
Add compa	any name						
Add or rem	ove rows as required						
New or Up	dated Declaration for Clinician	3					
Name	Please state full name						
Position	Please state currently held posi	ition					
Date	Please add the date form was d	completed (DD-	-MM-YYYY)				
⊠							
Conflict of	Interest Declaration						
	mpanies or organizations that have who may have direct or indirect i				er the past two		
2000				riate Dollar Ran			
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000		
Add compa	any name						
Add company name							
Add or rem	Add or remove rows as required						
	<u> </u>						

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.

Check Appropriate Dollar Range

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					
	mpanies or organizations that ha who may have direct or indirect i				r the past two	
			Check Approp	riate Dollar Rang	je	
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Add compa	ny name					
Add compa	nny name					
Add or rem	ove rows as required					
2	dated Declaration for Clinician	5				
Name	Please state full name					
Position	Please state currently held posi					
Date	Please add the date form was o		,		V110	
	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.						
				riate Dollar Rang		
Company	Company \$0 to 5,000 \$5,001 to \$10,001 to In Excess o 10,000 50,000 \$50,000				In Excess of \$50,000	
Add compa	mpany name					
Add compa	ompany name					

New or Updated Declaration for Clinician 4

Please state full name

Please state currently held position

Name

Position

Feedback on Dra	aft Recommendation			
Stakeholder information				
CADTH project number	PC0377			
Brand name (generic)	Keytruda (pembrolizumab)			
Indication(s) As monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options				
Organization	Ontario Health (Cancer Care Ontario) Head and Neck Cance Advisory Committee ("DAC")	r Drug		
Contact information ^a	Name: Dr. Michael Odell			
Stakeholder agreement wit	th the draft recommendation			
	ree with the committee's recommendation.	Yes No		
one feedback point would be have no satisfactory alternat MSI high/MMR in all the difference don't have any satisfactory at data, lowish response rates a generally tolerated, an ORR tumours, there really are no Neck cancer DAC advocates undergo chemo for the sake. The DAC would also like to find the options for patient who make	eholder agrees or disagrees with the draft recommendation. We specific text from the recommendation and rationale. The regarding "that have progressed following prior treatment and ive treatment options". While there is uncertainty in the prevalence of the subtypes of HN cancers, a number of these histologies and ternative treatments options regardless of line of therapy (no to chemo), especially in comparison to how well pembrolizum of approx. 30%, and potential duration of response. In some reasonable treatment options available at all. The OH-CCO Has for some flexibility for these rare subtypes and not require part of have a previous line of therapy. The following - Re: wording "unresectable or metastatic" is nay have no metastatic spread but local recurrence who could tremely morbid and low chance of cure (example <10%) - this olems for patients with local recurrence with very low or no optical from funding.	d who ence of ctually phase ab is are ead and tients to limiting the wording	f 3 d to	
	on demonstrate that the committee has considered the	Yes		
	our organization provided to CADTH?	No]	
	provide input on this reimbursement review.			
Clarity of the draft recomm	nendation		5	
3. Are the reasons for the r	ecommendation 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	Yes	\boxtimes
addressed in the recommendation?	No	
If not, please provide details regarding the information that requires clarification.		7
5. If applicable, are the reimbursement conditions clearly stated and the rationale	Yes	
for the conditions provided in the recommendation?	No	\boxtimes
If not, please provide details regarding the information that requires clarification. Re: Table 1 Please refer to comments in #1 above.		
Re: Active CNS metastases The recommendation was for pembrolizumab only be given to patients without active brain metastases, as per the clinical trial eligibility criteria. The H&N DAC would like to reiterate world situations, pembrolizumab often is given to patients with "active" brain metastases where the urgent radiotherapy because they are clinically stable or they are being managed of this appears to be safe, and there can be response to IO in the brain.	that in ho do r	not

^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.
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 - 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		5 8
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	\boxtimes
If yes, please detail the help and who provided it.		
OH-CCO PDRP provided secretariat function to the group.		
2. Bid to be from out-ide complication and to call the complete	NI	_
2. Did you receive help from outside your clinician group to collect or analyze any	No	\boxtimes
information used in this submission?	Yes	
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	No	\boxtimes
submitted at the outset of the CADTH review and have those declarations remained	Yes	
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Clinician 1		
Clinician 2		
Add additional (as required)		

C. New or Updated Conflict of Interest Declarations

New or Up	odated Declaration for Clinician 1
Name	Dr. Michael Odell
Position	Lead, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Committee
Date	07-01-2025
	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.

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.						
	Check Appropriate Dollar Range					
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000		
Add company name						
Add company name	П	П	П	П	_	

New or Up	odated Declaration for Clinician 2
Name	Dr. Stephanie Brule
Position	Member, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Committee
Date	14-01-2025
	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

Conflict of Interest Declaration

Add or remove rows as required

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.

	Check Appropriate Dollar Range				
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000	
Merck					
Add company name					
Add or remove rows as required					

New or Up	odated Declaration for Clinician 3
Name	Dr. Martin Smoragiewicz
Position	Member, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Committee
Date	14-01-2025
	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.

	Check Appropriate Dollar Range			
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Merck				
Add company name				

New or Updated Declaration for Clinician 4 Name Dr. Anna Spreafico Position Member, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Co. Date 14-01-2025						
Position Member, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Co.						
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Dr. Anna Spreafico					
Date 14-01-2025	Member, Ontario Health (Cancer Care Ontario) Head and Neck Cancer Drug Advisory Committee					
☑ 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	1					
place this clinician or clinician group in a real, potential, or perceived conflict of interest situ	uation.					
Conflict of Interest Declaration						
List any companies or organizations that have provided your group with financial payment over the pas	t two					
years AND who may have direct or indirect interest in the drug under review.						
Check Appropriate Dollar Range	_					
	cess of 0,000					
Add company name						
Add or remove rows as required						
New or Updated Declaration for Clinician 5						
Name Please state full name						
Position Please state currently held position						
Date Please add the date form was completed (DD-MM-YYYY)	000/					
☐ I hereby certify that I have the authority to disclose all relevant information with respect to matter involving this clinician or clinician group with a company, organization, or entity that						
place this clinician or clinician group in a real, potential, or perceived conflict of interest situ	ALL DESCRIPTION OF THE PROPERTY OF THE PROPERT					
place this chilician of chilician group in a real, potential, or perceived conflict of interest site	Jation.					
Conflict of Interest Declaration						
List any companies or organizations that have provided your group with financial payment over the pas years AND who may have direct or indirect interest in the drug under review.	st two					
Check Appropriate Dollar Range						
	cess of					
	0,000					
L COLO						
Add company name	company name					
Add or remove rows as required						

Add or remove rows as required

Stakeholder information					
CADTH project number	PC0377				
Brand name (generic)	Keytruda (pembrolizumab)				
Indication(s) As monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options					
Organization	Ontario Health (Cancer Care Ontario) Skin Cancer Drug Advis Committee	sory			
Contact information ^a	Name: Dr. Nicole Look Hong				
Stakeholder agreement wi	th the draft recommendation				
	ree with the committee's recommendation.	Yes No			
	eholder agrees or disagrees with the draft recommendation. W specific text from the recommendation and rationale.	nenev	er -		
Expert committee conside	ration of the stakeholder input				
	2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH? No				
If not, what aspects are miss	sing from the draft recommendation?				
NA - Ontario Health (Cancel not provide input on this rein	r Care Ontario) Skin Cancers Disease Site Drug Advisory Com nbursement review.	mittee	did		
Clarity of the draft recomn	nendation				
		Yes	\boxtimes		
3. Are the reasons for the	recommendation clearly stated?	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?					
If not, please provide details	regarding the information that requires clarification.				
5. If applicable, are the rein	mbursement conditions clearly stated and the rationale	Yes	\boxtimes		
	ded 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 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.
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 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	
	Yes	\boxtimes
If yes, please detail the help and who provided it.		
OU CCO DDDD may ided as enstants from the may in		
OH-CCO PDRP provided secretariat function to the group.		
2. Did you receive help from outside your clinician group to collect or analyze any	No	
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		9.
B. Previously Disclosed Conflict of Interest		
Were conflict of interest declarations provided in clinician group input that was	No	X
submitted at the outset of the CADTH review and have those declarations remained	Yes	
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Clinician 1		
Clinician 2		
Add additional (as required)		

C. New or Updated Conflict of Interest Declarations

New or Up	dated Declaration for Clinician 1				
Name	Dr. Nicole Look Hong				
Position	Lead, Ontario Health (Cancer Care Ontario) Skin Cancer Drug Advisory Committee				
Date	06-01-2025				
	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	Conflict of Interest Declaration				

	Check Appropriate Dollar Range				ge
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add compa	any name				
Add compa	any name				
Add or rem	nove rows as required				
New or Up	dated Declaration for Clinician	2			
Name	Dr. Xinni Song				
Position	Member, Ontario Health (Cance	er Care Ontario) Skin Cancer Dr	rug Advisory Comi	mittee
Date	12-01-2025				
	I hereby certify that I have the matter involving this clinician or	clinician group	with a company	, organization, or e	entity that may
	place this clinician or clinician g	roup in a real,	potential, or perce	eived conflict of in	terest situation.
Conflict o	f Interest Declaration				
	mpanies or organizations that ha				er the past two
years AND	who may have direct or indirect i	interest in the d			
<u>12</u> 0				oriate Dollar Ran	
Company \$0 to 5,000 \$5,001 to 10,000			\$10,001 to 50,000	In Excess of \$50,000	
Merck					
Add compa	company name				
Add or rem	nove rows as required				
New or Up	dated Declaration for Clinician	3			
Name	Dr. Elaine McWhirter				
Position	Member, Ontario Health (Cance	er Care Ontario) Skin Cancer Dr	rug Advisory Comi	mittee
Date	13-01-2025				
	I hereby certify that I have the matter involving this clinician or	clinician group	with a company	, organization, or e	entity that may
	place this clinician or clinician g	roup in a real,	potential, or perc	eived conflict of in	terest situation.
Conflict o	f Interest Declaration				
	mpanies or organizations that ha who may have direct or indirect i				er the past two
			Check Approp	oriate Dollar Ran	ge
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Merck					
Add compa	Add company name				
Add or rem	nove rows as required				

Name	Dr. Teresa Petrella
Position	Member, Ontario Health (Cancer Care Ontario) Skin Cancer Drug Advisory Committee
Date	13-01-2025
	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.

1	Check Appropriate Dollar Range			ge
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Merck				
Add company name				
Add or remove rows as required				

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

Check Appropriate Dollar Range			ge	
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name				
Add company name				
Add or remove rows as required				

Stakeholder information						
CADTH project number	PC0377					
Brand name (generic)	Keytruda (pembrolizumab)					
Indication(s)	As monotherapy for the treatment of adult and pediatric patients	with				
	unresectable or metastatic microsatellite instability-high (MSI-H)					
	mismatch repair deficient (dMMR) solid tumors, as determined by	The state of the s				
	validated test, that have progressed following prior treatment and	l who h	nave			
	no satisfactory alternative treatment options	ARWENS				
Organization	Ontario Health (CCO) Breast Cancer Drug Advisory Committee	е				
Contact informationa	Name: Dr. Andrea Eisen					
Stakeholder agreement wi	ith the draft recommendation					
1 Does the stakeholder ac	gree with the committee's recommendation.	Yes	\boxtimes			
		No				
	ceholder agrees or disagrees with the draft recommendation. W	henev	er			
possible, please identify the	specific text from the recommendation and rationale.					
Evpert committee consider	eration of the stakeholder input					
	Automotive of control of control of the second of the seco	Yes	\boxtimes			
	stakeholder input that your organization provided to CADTH? If not, what aspects are missing from the draft recommendation?					
in not, what apposes are mist	sing iron the drait recommendation.					
Clarity of the draft recomn	nendation					
3 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes			
	₹	No				
If not, please provide details	regarding the information that requires clarification.					
4. Have the implementation	n issues been clearly articulated and adequately	Yes				
addressed in the recomi		No	\boxtimes			
If not, please provide details	regarding the information that requires clarification.	7				
	egative breast cancer (TNBC) patients who may receive neoadj		•			
	t upon relapse are not PD-L1 positive with CPS>=10. Would the prolizumab in the advanced setting if they are MSH-H/dMMR?	ese				
patients be engible for pernic	nonzamab in the advanced setting if they are Mon-rival mint:					
			53			
	mbursement conditions clearly stated and the rationale	Yes				
for the conditions provide	ded in the recommendation?	No	\boxtimes			
If not, please provide details	regarding the information that requires clarification.					
See #4.						
3ee #4.						

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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 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		5 8
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	\boxtimes
If yes, please detail the help and who provided it.		
OU CCO DDDD provided econotoxist function to the group		
OH-CCO PDRP provided secretariat function to the group.		
2. Did you receive help from outside your clinician group to collect or analyze any	No	
information used in this submission?	Yes	
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	No	
submitted at the outset of the CADTH review and have those declarations remained	Yes	\boxtimes
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Dr. Andrea Eisen		
Clinician 2		
Add additional (as required)		

C. New or Updated Conflict of Interest Declarations

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				
	mpanies or organizations that have who may have direct or indirect in				r the past two
1970			Check Approp	oriate Dollar Ran	ge
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add compa	ny name				
Add compa	ny name				
Add or rem	ove rows as required				
New or Up	dated Declaration for Clinician	2			
Name	Please state full name				
Position	Please state currently held posi	tion			
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		N. 7.		- 15 M
	place this clinician or clinician g	roup in a real,	potential, or perce	eived conflict of inf	terest situation.
Conflict of	Interest Declaration				
	mpanies or organizations that have who may have direct or indirect in				r the past two
			Check Approp	riate Dollar Rang	je
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add compa	ny name				
Add compa	ny name				
Add or rem	ove rows as required				
			**	1500	500
New or Up	dated Declaration for Clinician	3			
Name	Please state full name				
Position	Please state currently held posi	tion			
Date	Please add the date form was o	completed (DD-	MM-YYYY)		***
	I hereby certify that I have the				
	matter involving this clinician or	to the meaning of a real party and a second of the second	and the second s	Commence of the second	Contraction of Chicago Contraction Contraction
	place this clinician or clinician group in a real potential or perceived conflict of interest situation				

Conflict of Interest Declaration

		Check Approp	riate Dollar Ranç	ge
Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name				
Add company name				

201								
New or Up	dated Declaration for Clinician	4						
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	the state of the s	The state of the s					
	place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.							
Conflict of	Interest Declaration							
	mpanies or organizations that ha				r the past two			
years AND	who may have direct or indirect i	nterest in the di	rug under review.					
			Check Appropriate Dollar Range					
Company		\$0 to 5,000	\$5,001 to	information with reorganization, or entitle Dollar Range \$10,001 to 50,000	In Excess of			
Add sampa	any nama		10,000		\$50,000			
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Add or remove rows as required								
T _i								
New or Up	dated Declaration for Clinician	5						
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							
HOLLES	matter involving this clinician or clinician group with a company, organization, or entity that							
	place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.							
Conflict of	Conflict of Interest Declaration							
List any cor	mpanies or organizations that ha	ve provided you	r group with finar	ncial payment ove	r the past two			
	who may have direct or indirect i				,			
2.000	Check Appropriate Dollar Range							
Company		\$0 to 5,000	\$5,001 to		In Excess of			
100			10,000	50,000	\$50,000			
Add company name								
Add company name								
Add or remove rows as required								

Add or remove rows as required

CADTH Reimbursement Review

Feedback on Draft Recommendation

геефраск о	n Dra	aπ Recommendation					
Stakeholder inform	nation						
CADTH project number		PC0377					
Name of the drug and		Pembrolizumab					
Indication(s)							
Organization Providing		PAG					
Feedback							
Recommendat Please indicate if the recommendation.	ne stakeh	older requires the expert review committee to reconsider or clari	fy its				
Request for	Major revisions: A change in recommendation category or patient population is requested						
Reconsideration	Minor revisions: A change in reimbursement conditions is requested □						
No Request for	Editorial revisions: Clarifications in recommendation text are requested		X				
Reconsideration	No requested revisions						
Complete this secti	on if maj specific t	lation category or conditions or or minor revisions are requested ext from the recommendation and provide a rationale for request n.	ting				
Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements Recommendation rationale							
Please provide deta	ails regar	ding the information that requires clarification.					
b) Reimbursemer	nt condit	tions and related reasons					
Please provide details regarding the information that requires clarification.							
In Table 1, under Discontinuation, PAG suggested only keeping treatment duration but omitting details on dosing and dosing schedule as most jurisdictions have implemented weight-based dosing.							

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.

In Table 2, under Considerations for initiation of therapy, PAG suggested only keeping treatment duration (i.e., 1 year) but omitting the number of cycles to allow some flexibility with the dosing schedule.

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

- 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
- 1.
- 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.



Stakeholder information									
CADTH project number	PC0377								
Brand name (generic)	nd name (generic) KEYTRUDA (pembrolizumab)								
Indication(s) For the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumours, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options									
Organization	Merck Canada Inc.								
Contact information ^a	Name:,								
Stakeholder agreement wi	th the draft recommendation								
Does the stakeholder agree with the committee's recommendation.									
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.									
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?									
stakeholder input that your organization provided to CADTH? No ☐ If not, what aspects are missing from the draft recommendation?									
Clarity of the draft recomm	nendation								
3 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes						
5. Are the reasons for the	recommendation clearly stated?	No							
If not, please provide details regarding the information that requires clarification.									
	n issues been clearly articulated and adequately	Yes	\boxtimes						
addressed in the recommendation?									
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?									
If not, please provide details regarding the information that requires clarification.									

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