

### **CADTH REIMBURSEMENT REVIEW**

# Stakeholder Feedback on Draft Recommendation

nivolumab and relatlimab (Opdualag)

(Bristol Myers Squibb)

**Indication:** For the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma who have not received prior systemic therapy for unresectable or metastatic melanoma

January 18, 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**

Otalia kaldan infansatian			
Stakeholder information	D00000		
CADTH project number	PC0329		
Brand name (generic)	Opdualag (nivolumab and relatlimab)		
Indication(s)	For the treatment of adult and pediatric patients 12 years of a with unresectable or metastatic melanoma who have not recessystemic therapy for unresectable or metastatic melanoma.	_	
Organization	Ontario Health (Cancer Care Ontario) Skin Cancer Drug Adv Committee	isory	
Contact information <sup>a</sup>	Name: Dr. Frances Wright		
Stakeholder agreement w	ith the draft recommendation		
	gree with the committee's recommendation.	Yes No	
Please see below.	e specific text from the recommendation and rationale.		
Expert committee conside	eration of the stakeholder input		
	ion demonstrate that the committee has considered the our organization provided to CADTH?	Yes No	
If not, what aspects are mis	sing from the draft recommendation?		
Nivolumab-relatlimab shoul	d still be considered in subsequent lines of therapy.		
Clarity of the draft recomi	mendation		
3. Are the reasons for the	recommendation clearly stated?	Yes No	
If not, please provide details	s regarding the information that requires clarification.		
4. Have the implementatio addressed in the recom	n issues been clearly articulated and adequately mendation?	Yes No	
If not inlease provide details	s regarding the information that requires clarification		

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

The DAC strongly disagrees to exclude patients with uveal melanoma. The DAC also believe the wording to exclude <u>active</u> autoimmune disease is vague. This should be at the discretion of the clinician, weighing the risks/benefits. Patients with brain metastases should also be treated at the discretion of the medical oncologist. This should align with the criteria established for patients who receive single agent nivolumab or pembrolizumab.

If patients progress on BRAF/MEK therapy in the adjuvant setting, they should be eligible for relatlimab-nivolumab.

In the current provisional algorithm for melanoma, patients treated for BRAF/MEK first line are eligible for immunotherapy in the second line, so they should be considered for relatlimab-nivolumab as well.

There should not be a timeline for when patients progressed while "off" therapy.

Patients who started single agent therapy due to limited access to treatment options, should be allowed to switch to relatlimab-nivolumab once reimbursed.

Once relatlimab-nivolumab is reimbursed, an updated provisional algorithm should address that patients should have the same access to second line therapies that they would have access to after other first line immunotherapy.

#### 

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

If patients received nivolumab or pembrolizumab single agent and relapsed, they should have the option to receive relatlimab-nivolumab.

The DAC strongly disagrees to exclude patients with uveal melanoma. The DAC also believe the wording to exclude <u>active</u> autoimmune disease is vague. This should be at the discretion of the clinician, weighing the risks/benefits. Patients with brain metastases should also be treated at the discretion of the medical oncologist. This should align with the criteria established for patients who receive single agent nivolumab or pembrolizumab.

<sup>&</sup>lt;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 G	roup information							
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 patient gro				nay place	this		
	patient group in a real, potential	, or perceived	conflict of interes	t situation.				
B. Assistan	ce with Providing Feedback							
1 Did you	receive help from outside you	r patient grou	n to complete v	our foodback?	No			
1. Did you	receive help from outside you	r patient grou	p to complete y	our reeuback?	Yes			
If yes, please	e detail the help and who provide	d it.			•			
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?				Yes			
If yes, please	e detail the help and who provide	d it.						
	ly Disclosed Conflict of Interes							
	onflict of interest declarations p				No			
	ed at the outset of the CADTH			ations remaine	d Yes			
unchan	ged? If no, please complete se	ction D below	•					
D. New or U	pdated Conflict of Interest Dec	laration						
3. List any	companies or organizations t	hat have provi	ded your group	with financial	payment	over the		
past tw	o years AND who may have dir	ect or indirect	interest in the	drug under revi	ew.			
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	move rows as required							

#### **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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- 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	
	Yes	$\boxtimes$
If yes, please detail the help and who provided it.		
OH-CCO provided a secretariat function to the group.		
3. 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		
4. 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	
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
Dr. Marcus Butler		
Dr. Teresa Petrella		
Dr. Xinni Song		
Dr. Tara Baetz		

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

New or Up	dated Declaration for Clinician 1
Name	Dr. Frances Wright
Position	Ontario Health (Cancer Care Ontario) Skin Cancer Drug Advisory Committee lead
Date	10-01-2024
	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						
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Name	Please state full name						
Position	Please state currently held posi	ition					
Date	Please add the date form was d	completed (DD-	MM-YYYY)				
	I hereby certify that I have the	-					
	matter involving this clinician or	• .		•	•		
place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.							
Conflict of	Interest Declaration						
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List any companies or organizations that have provided your group with financial payment over the past two

\$0 to 5,000

Check Appropriate Dollar Range

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50,000

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10,000

years AND who may have direct or indirect interest in the drug under review.

Company

Add company name

Add company name

In Excess of

\$50,000

	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 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.							
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Add compa	ny name							
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New or Up	dated Declaration for Clinician	5						
Name	Please state full name							
Position	Please state currently held posi	tion						
Date	Please add the date form was d	completed (DD-	MM-YYYY)					
	I hereby certify that I have the	authority to disc	close all relevant	information with r	espect to any			
	matter involving this clinician or	clinician group	with a company,	organization, or e	ntity that may			
	place this clinician or clinician g	roup in a real, p	ootential, or perce	ived conflict of int	erest situation.			
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years AND	who may have direct or indirect i	nterest in the di	rug under review.					
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Add compa	ny name							
Add or rem	ove rows as required							

Add or remove rows as required



## **CADTH Reimbursement Review**

### **Feedback on Draft Recommendation**

Stakeholder inform	nation			
CADTH project number		PC0329		
Name of the drug and Indication(s)		Nivoluamb and relatlimab for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma who have not received prior systemic therapy for unresectable or metastatic melanoma		
Organization Provide Feedback	ding	PAG		
Recommendat     Please indicate if the recommendation.	ie stakeh	nolder requires the expert review committee to reconsider or clari	fy its	
Request for		revisions: A change in recommendation category or patient tion is requested		
Reconsideration	Minor r	revisions: A change in reimbursement conditions is requested		
No Request for	equest for Editorial revisions: Clarifications in recommendation text are requested		Х	
Reconsideration	No req	uested revisions		
	specific t	or or minor revisions are requested rext from the recommendation and provide a rationale for request in.	ting	
·	on if edit	orial revisions are requested for the following elements		
a) Recommendation rationale  Please provide details regarding the information that requires clarification.				
b) Reimbursement conditions and related reasons				
Please provide deta	ails regar	ding the information that requires clarification.		
c) Implementatio	n guidar	nce		
	nments i	etails regarding the information that requires clarification. You can n the draft recommendation found in the next section. Additional an be raised here.		



- Under Considerations for initiation of therapy – d) Eligibility to re-treatment (second question): PAG suggested changing the statement to "pERC acknowledged that commonly, progression after a 6-month break is accepted as a guideline to reinstitute treatment. However, pERC agreed with the clinical experts that re-initiation may be considered regardless of the disease-free interval provided the disease progression occurred while off therapy."

### **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)
- An update to the algorithm is needed (panel algorithm). In particular, PAG asked whether single agent ipilimumab would be a funded option following 1L treatment with nivolumab/relatlimab combination.
- 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.



### CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0329-000-000
Brand name (generic)	Opdualag - nivolumab and relatlimab
Indication(s)	unresectable or metastatic melanoma
Organization	Save Your Skin Foundation
Contact information <sup>a</sup>	Name: Kathleen Barnard

#### Stakeholder agreement with the draft recommendation

#### 1. Does the stakeholder agree with the committee's recommendation.

Yes ⊠ No ⊠

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

#### We agree with the following positive conditional recommendations:

- Unresectable stage III or stage IV (metastatic) melanoma, no prior systemic therapy for unresectable or metastatic melanoma
- Reimbursed in patients who had prior adjuvant or neoadjuvant anti-PD-1 or anti-CTLA-4 therapy if the therapy was completed at least 6 months before the date of recurrence
- May continue until progression
- -Should be prescribed by clinicians who have expertise in diagnosis and management of patients with melanoma and are familiar with the IO toxicities

#### We disagree with the following recommendation:

-Should not be reimbursed in patients with active brain metastases, uveal melanoma or active autoimmune disease

The patient experience data we obtain in our surveys, for the CADTH Reimbursement Review of Opdualag and beyond, consistently reiterates the need for as many options as can be offered to melanoma patients. In the current care landscape, patients with uveal/ocular melanoma have such limited care options; it is therefore imperative that these patients (particularly those who are not eligible for Tebentafusp) have access to as many care options as possible. Further, Opdualag for brain metastases was also specifically identified as a gap in our patient survey for this submission. In the responses to our survey for the Opdualag submission, participants reiterated the need for as many care options as possible, in the case that they either fail other options or experience a metastasis or recurrence. Several participants noted that they only had one or two treatment options available at the outset of their care, meaning that options are scarce from the beginning. One participant wrote that they failed on Keytruda and is now receiving chemotherapy, indicating that options with more aggressive side effect profiles are what currently await those who fail on immunotherapies. Overall, this data emphasizes the importance of Opdualag as an option for all melanoma patients.

#### 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	$\boxtimes$
No	

If not, what aspects are missing from the draft recommendation?			
Clarity of the draft recommendation			
3. Are the reasons for the recommendation clearly stated?			
5. Are the reasons for the recommendation clearly stateur	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?	No		
If not, please provide details regarding the information that requires clarification.			
5. If applicable, are the reimbursement conditions clearly stated and the rationale	Yes	$\boxtimes$	
for the conditions provided in the recommendation?	No		
If not, please provide details regarding the information that requires clarification.			

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

#### **Appendix 1. Conflict of Interest Declarations for Patient Groups**

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A. Patient G	roup Information					
Name	Kathleen Barnard					
Position	President					
Date	10/01/2024					
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 Did you	raasiya bala from sutaida yay	r nationt grou	n to complete v	your foodbook?	No	X
1. Did you	receive help from outside you	r patient grou	p to complete y	our reedback?	Yes	
If yes, please	e detail the help and who provide	d it.				
2. Did you	receive help from outside you	r patient grou	p to collect or a	ınalyze any	No	$\boxtimes$
informa	tion used in your feedback?				Yes	
	e detail the help and who provide					
	ly Disclosed Conflict of Interes					
	onflict of interest declarations				No	
	ed at the outset of the CADTH ged? If no, please complete se			rations remained	Yes	
D. New or U	pdated Conflict of Interest Dec	laration				
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#### 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		
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.		
3. 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		
4. 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	
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 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					

		Check Appropriate Dollar Range					
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New or Up	dated Declaration for Clinician	2					
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Date	Please add the date form was d	completed (DD-	-MM-YYYY)				
	I hereby certify that I have the	-					
	matter involving this clinician or		•	•			
	place this clinician or clinician g	roup in a real,	potential, or perce	eived conflict of in	terest situation.		
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New or Up	dated Declaration for Clinician	3					
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Position	Please state currently held posi						
Date	Please add the date form was o						
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	matter involving this clinician or			•	•		
	place this clinician or clinician g	roup in a real,	potential, or perce	eived conflict of in	terest situation.		
Conflict of	Interest Declaration						
List any co	mpanies or organizations that have	ve provided you	ur group with fina	ncial payment ove	er the past two		
years AND	who may have direct or indirect i	nterest in the d	rug under review	•			
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Add compa	any name						
Add or rem	nove 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.

	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			
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Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000			
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Add compa	any name							
Add or rem	ove rows as required							
New or Up	dated Declaration for Clinician	5						
Position	Please state currently held pos	ition						
Date	Please add the date form was d		•					
	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							
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.								
		40.1.5000		riate Dollar Rang				
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000			
Add company name								
Add compa	any name							
Add or remove rows as required								

New or Updated Declaration for Clinician 4

Please state full name

Please state currently held position

Please add the date form was completed (DD-MM-YYYY)

Name

Date

Position



## **CADTH Reimbursement Review Feedback on Draft Recommendation**

Stakeholder information									
CADTH project number	PC0329-000-000								
Brand name (generic)	me (generic) Opdualag (nivolumab and relatlimab)								
Indication(s)	unresectable or metastatic melanoma								
Organization	tion Melanoma Canada								
Contact information <sup>a</sup> Name: Annette Cyr									
Stakeholder agreement wi	th the draft recommendation								
1. Does the stakeholder ag	gree with the committee's recommendation.	Yes No	$\square$						
Subject to price negotiations, the committee has recommended approval of this combination therapy, based on scientific evidence and stakeholder input. We support approval of this valuable combination therapy as another valuable option for treatment of advanced melanoma.									
Expert committee conside	eration of the stakeholder input								
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?									
	ne work of the committee and that they have taken the time and aback to approve and accept the recommendations of stakehold								
Clarity of the draft recomm	nendation								
2 Are the reasons for the I	rocommondation clearly stated?	Yes	$\boxtimes$						
3. Are the reasons for the r	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.								

<sup>&</sup>lt;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									
Name	Melanoma Canada								
Position	Volunteer – Former chair and founder								
Date	18/01/2024								
B. Assistan	ce with Providing Feedback								
1. Did vou	receive help from outside you	r nationt grou	n to complete v	our foodback?	No	$\boxtimes$			
i. Dia you	receive help from outside you	r patient grou	p to complete y	our reeuback?	Yes				
If yes, please	e detail the help and who provide	d it.							
2. Did you	receive help from outside you	r patient grou	p to collect or a	ınalyze any	No	$\boxtimes$			
informa	tion used in your feedback?				Yes				
	e detail the help and who provide								
	ly Disclosed Conflict of Interes								
	onflict of interest declarations				No				
	ed at the outset of the CADTH ged? If no, please complete se			rations remained	Yes	$\boxtimes$			
D. New or U	pdated Conflict of Interest Dec	laration							
<ol><li>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.</li></ol>									
			Check Appro	priate Dollar Raı	nge				
Company	Company \$0 to 5,000 \$5,001 to \$10,001 to In Excess of \$5,000 \$50,000					s of			
Bristol Myers	Bristol Myers Squibb Canada □ □ □ □					×			
Add company name									
Add or remove rows as required									



## **CADTH Reimbursement Review Feedback on Draft Recommendation**

Stakeholder information								
CADTH project number	PC0329							
Brand name (generic)	OPDUALAG (nivolumab and relatlimab)	OPDUALAG (nivolumab and relatlimab)						
Indication(s)	For the treatment of adult and pediatric patients 12 years of age or older							
	with unresectable or metastatic melanoma who have not rece	eived pr	ior					
	systemic therapy for unresectable or metastatic melanoma							
Organization	Bristol Myers Squibb Canada	Bristol Myers Squibb Canada						
Contact information <sup>a</sup>								
Stakeholder agreement w	ith the draft recommendation							
1. Does the stakeholder ag	gree with the committee's recommendation.	Yes No						
	seholder agrees or disagrees with the draft recommendation. We specific text from the recommendation and rationale.	/heneve	er:					
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 mis-	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	recommendation clearly stated:	No						
If not, please provide details	regarding the information that requires clarification.							
4. Have the implementatio	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 rei	mbursement conditions clearly stated and the rationale	Yes	$\boxtimes$					
	for the conditions provided in the recommendation?							
_	regarding the information that requires clarification.							

<sup>&</sup>lt;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 <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.

A. Patient Group Information								
Name	Please state full name							
Position	Please state currently held position							
Date	Please add the date form was c	ompleted (DD-	MM-YYYY)					
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							
1. Did you	1. Did you receive help from outside your patient group to complete your feedback?							
If yes, please	e detail the help and who provide	d it.						
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?				Yes			
If yes, please	If yes, please detail the help and who provided it.							
C. Previous	ly Disclosed Conflict of Interes	t						
	onflict of interest declarations p				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 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 Approp	priate Dollar Ra	nge			
Company \$0 to 5,000 \$5,001 to \$10,001 to In Excess of 10,000 50,000 \$50,000					s of			
Add compan	ny name							
Add compan	ny name				[			

#### **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	
	Yes	
If yes, please detail the help and who provided it.		
3. 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		
4. 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	
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	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	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 d	completed (DD-	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		rug under review.		•		
				riate Dollar Ranç			
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	3					
Name	Please state full name						
Position	Please state currently held posi	tion					
Date	Please add the date form was d	completed (DD-	MM-YYYY)				
⊠	· · · · · · · · · · · · · · · · · · · ·						
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.						
		\$0 to 5,000		riate Dollar Ranç			
Company	Company		\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000		
Add compa	ny name						
Add compa	ny name						
		i	·				
Add or rem	ove 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** 

	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			
				riate Dollar Ranç	је			
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	5						
Position	Please state currently held pos	ition						
Date	Please add the date form was d		•					
	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							
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.								
		40.1.5000		riate Dollar Rang				
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000			
Add company name								
Add compa	any name							
Add or remove rows as required								

New or Updated Declaration for Clinician 4

Please state full name

Please state currently held position

Please add the date form was completed (DD-MM-YYYY)

Name

Date

Position