

## CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**NIVOLUMAB (Opdivo)  
(Bristol Myers Squibb Canada)**

**Indication:** as monotherapy, for the adjuvant treatment of adult patients with Stage IIB or IIC melanoma following complete resection

**May 16, 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

## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0339-000
Brand name (generic)	Opdivo (nivolumab)
Indication(s)	Monotherapy, for the adjuvant treatment of adult patients with Stage IIB or IIC melanoma following complete resection.
Organization	Melanoma Canada
Contact information <sup>a</sup>	Name: Annette Cyr
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
The monotherapy will provide important access to this patient group that has a high-risk profile for recurrence but has had little in the way of options for treatment to prevent recurrence. We are pleased to see this recommendation.	
Expert committee consideration of the stakeholder input	
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
It is sufficient, thanks.	
Clarity of the draft recommendation	
3. Are the reasons for the recommendation clearly stated?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	

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

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

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
<b>Name</b>	<i>Annette Cyr</i>			
<b>Position</b>	<i>Volunteer – former Board Chair</i>			
<b>Date</b>	<i>09/05/2024</i>			
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## CADTH Reimbursement Review Feedback on Draft Recommendation

### Instructions for Stakeholders

This template is for eligible stakeholders to provide feedback and comments on draft reimbursement recommendations. Draft recommendations are available for feedback for 10 business days.

CADTH will only consider feedback received from eligible stakeholders, including the sponsor, patient groups, clinician groups, and the participating drug programs. Individuals interested in providing feedback should contact the relevant patient and clinician organizations. This template may also be used by eligible industry stakeholders to provide feedback on draft recommendations from the non-sponsored review process (i.e., any current or future Drug Identification Number [DIN] holders for the drug under review).

The sponsor may use this form to provide general feedback on the draft recommendation if they are not filing a request for reconsideration. If the sponsor is filing a request for reconsideration, they must complete the [reconsideration template](#) and should not complete this template.

All submitted feedback must be disclosable and will be posted on the CADTH website.

If you have questions, please email [requests@cadth.ca](mailto:requests@cadth.ca) with the complete details of your question(s).

### Before Completing the Template:

Please review the following documents to ensure an understanding of CADTH's procedures:

- [Procedures for CADTH Reimbursement Reviews](#)
- [Procedures for Non-sponsored Reimbursement Reviews](#)
- CADTH Pharmaceutical Review Updates for any applicable information.

### Completing the Template:

Feedback should be presented clearly and succinctly in point form, whenever possible. The issue(s) should be clearly stated and specific reference must be made to the section of the recommendation document under discussion (i.e., page number, section title, and paragraph).

Comments should be restricted to the content of the draft recommendation and should not contain any language that could be considered disrespectful, inflammatory or could be found to violate applicable defamation law.

Feedback must be based on the information that was considered by the expert committee in making the draft recommendation. No new evidence will be considered at this part of the review process.

Feedback must not exceed 3 pages in length, using a minimum 11-point font on 8.5" by 11" paper. If comments exceed 3 pages, the feedback will not be accepted by CADTH. References may be provided separately; however, these cannot be related to new evidence.

**Patient groups must complete Appendix 1.**

**Clinician groups must complete Appendix 2.**

**Filing the Completed Template:**

The feedback must be provided in Microsoft Word format by using the *Submit* link next to the drug on the [Open Calls](#) page. In order to ensure fairness in CADTH's procedures, all stakeholder feedback must be received by the deadline posted on the CADTH website.

# CADTH Reimbursement Review

## Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	PC0339-000	
Brand name (generic)	Opdivo	
Indication(s)	Stage IIB and IIC melanoma, adjuvant	
Organization	Save Your Skin Foundation	
Contact information <sup>a</sup>	Name: Kathy Barnard	
Stakeholder agreement with the draft recommendation		
<b>1. Does the stakeholder agree with the committee's recommendation.</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.		
Expert committee consideration of the stakeholder input		
<b>2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?		
Clarity of the draft recommendation		
<b>3. Are the reasons for the recommendation clearly stated?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
<b>4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
<b>5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?</b>	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		

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

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

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
<b>Name</b>	Save Your Skin Foundation			
<b>Position</b>	Founder/President			
<b>Date</b>	Please add the date form was completed (DD-MM-YYYY)			
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>
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 information used in this submission?	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> <li>Clinician 1</li> <li>Clinician 2</li> <li>Add additional (as required)</li> </ul>		

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

New or Updated Declaration for Clinician 1	
Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	



List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### New or Updated Declaration for Clinician 2

<b>Name</b>	Please state full name
<b>Position</b>	Please state currently held position
<b>Date</b>	Please add the date form was completed (DD-MM-YYYY)
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

### Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### New or Updated Declaration for Clinician 3

<b>Name</b>	Please state full name
<b>Position</b>	Please state currently held position
<b>Date</b>	Please add the date form was completed (DD-MM-YYYY)
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

### Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 4				
<b>Name</b>	<i>Please state full name</i>			
<b>Position</b>	<i>Please state currently held position</i>			
<b>Date</b>	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	<b>I hereby certify</b> that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			
Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 5				
<b>Name</b>	<i>Please state full name</i>			
<b>Position</b>	<i>Please state currently held position</i>			
<b>Date</b>	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	<b>I hereby certify</b> that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			
Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0339
Brand name (generic)	Opdivo (nivolumab)
Indication(s)	For the adjuvant treatment of adult patients with Stage IIB or IIC melanoma following complete resection
Organization	OH (CCO) Skin Cancer Drug Advisory Committee
Contact information <sup>a</sup>	Name: Dr. Frances Wright
Stakeholder agreement with the draft recommendation	
<b>1. Does the stakeholder agree with the committee's recommendation.</b>	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
<p>Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.</p> <p>For condition #1, there is no difference in the reimbursement criteria between nivolumab and pembrolizumab, and mucosal patients should be included.</p> <p>Condition #5 should be reworded to "Patients should complete a maximum of 12 months (or 26 doses if given every 2 weeks, or 13 doses if given every 4 weeks) of adjuvant nivolumab."</p> <p>If patients are found to have clinical or radiological disease recurrence within 3 months, they should still be eligible for ipilimumab-nivolumab, once approved.</p> <p>For condition #7, there should be an allowance to use nivolumab in combination with other anticancer drugs, in the context of clinical trials.</p>	
Expert committee consideration of the stakeholder input	
<b>2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?</b>	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?	
Clarity of the draft recommendation	
<b>3. Are the reasons for the recommendation clearly stated?</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
<b>4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?</b>	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
	Yes <input checked="" type="checkbox"/>

<b>5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?</b>	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification. Please see comments above.		

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

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

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
<b>Name</b>	<i>Please state full name</i>			
<b>Position</b>	<i>Please state currently held position</i>			
<b>Date</b>	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input type="checkbox"/>
			Yes	<input type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please detail the help and who provided it. OH (CCO) provided a secretariat function to the group.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> <li>Dr. Frances Wright</li> <li>Dr. Teresa Petrella</li> <li>Dr. Marcus Butler</li> <li>Dr. Xinni Song</li> <li>Dr. Tara Baetz</li> <li>Dr. Elaine McWhirter</li> </ul>		

### 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)

<input type="checkbox"/>	<b>I hereby certify</b> that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
--------------------------	---

**Conflict of Interest Declaration**

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Review**

**Feedback on Draft Recommendation**

Stakeholder information	
CADTH project number	PC0339
Name of the drug and Indication(s)	Nivolumab as monotherapy, for the adjuvant treatment of adult patients with Stage IIB or IIC melanoma following complete resection
Organization Providing Feedback	PAG

**1. Recommendation revisions**  
Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.

<b>Request for Reconsideration</b>	<b>Major revisions:</b> A change in recommendation <b>category</b> or patient <b>population</b> is requested	<input type="checkbox"/>
	<b>Minor revisions:</b> A change in reimbursement <b>conditions</b> is requested	<input type="checkbox"/>
<b>No Request for Reconsideration</b>	<b>Editorial revisions:</b> Clarifications in recommendation <b>text</b> are requested	<input type="checkbox"/>
	<b>No requested revisions</b>	x

**2. Change in recommendation category or conditions**  
Complete this section if major or minor revisions are requested

Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

**3. Clarity of the recommendation**  
Complete this section if editorial 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 details regarding the information that requires clarification.

Version: 1.0  
 Publication Date: TBC  
 Report Length: 2 Pages

**Single**

**Technology**





<b>c) Implementation guidance</b>
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

## Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

<b>Algorithm and implementation questions</b>
<b>1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)</b>
1. An update to the algorithm is needed (rapid algorithm). 2.
<b>2. Please specify other implementation questions or issues that should be addressed by CADTH</b>
1. 2.
<b>Support strategy</b>
<b>3. Do you have any preferences or suggestions on how CADTH should address these issues?</b>
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.

## CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0339
Brand name (generic)	OPDIVO (nivolumab)
Indication(s)	As monotherapy, for the adjuvant treatment of adult patients with Stage IIB or IIC melanoma following complete resection
Organization	Bristol Myers Squibb (BMS)
Contact information <sup>a</sup>	[REDACTED]
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
<p>BMS Canada agrees with the pERC draft recommendation for nivolumab as monotherapy, for the adjuvant treatment of adult patients with Stage IIB or IIC melanoma following complete resection. The pERC acknowledged that treatment with nivolumab resulted in a statistically significant improvement in RFS over placebo in patients with Stage IIB or IIC melanoma following complete resection. Furthermore, pERC agreed with both patients and clinicians that it is important to have an additional drug as an alternative option for this patient population. BMS Canada is committed to working with the provinces to facilitate access to nivolumab by Canadian adult patients with Stage IIB or IIC melanoma following complete resection.</p>	
Expert committee consideration of the stakeholder input	
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?	
Clarity of the draft recommendation	
3. Are the reasons for the recommendation clearly stated?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.	

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