CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

NIVOLUMAB (OPDIVO)

(Bristol-Myers Squibb)

Indication: in combination with platinum-doublet chemotherapy for the neoadjuvant treatment of adult patients with resectable NSCLC (tumours ≥ 4 cm or node positive)

March 16, 2023

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0303-000
Brand name (generic)	Nivolumab (Opdivo)
Indication(s)	Neoadjuvant treatment of adult patients with resectable NSCLC (tumours 4cm or node positive) when used in combination with platinum-doublet chemotherapy.
Organization	Lung Cancer Canada - Medical Advisory Committee
Contact information[a]	Name: Shem Singh [redacted]

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.		

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	☒
	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?	Yes	☒
	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?	Yes	☐
	No	☒

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

The lung cancer physician community (both medical and radiation oncology) have concerns around the implementation issues as stated in the recommendation – specifically around not allowing further immunotherapy for 6 months after this treatment is given. While this was a reasonable recommendation after the 1 year of curative intent treatment from the PACIFIC trial – discontinuing therapy based on just 3 doses in the neoadjuvant setting is potentially a premature assessment of the benefit of immune based treatment.

In the Checkmate 816 trial, 17% of patients who received neoadjuvant therapy did NOT go on to have surgery. In discussion with physicians who were investigators on this trial, many of those patients, while no longer considered resectable, were still candidates for curative concurrent chemotherapy and radiation. The global standard of care for patients treated with concurrent chemotherapy and radiation is to give consolidation durvalumab for 12 months. The addition of durvalumab provides an 18 month improvement in medial overall survival.

As resectability is not something that was defined in the trial and is quite subjective based on the skill set of the surgeon, and with variability between different Canadian thoracic surgery centres, we have concerns about patients starting down the path of neoadjuvant chemotherapy and nivolumab and then being denied access to our best standard for what may still be curative but not resectable lung cancer. This is a brand new paradigm in lung cancer and our multidisciplinary physician teams are going to be learning about how to select the best patients for this approach.

Three doses of chemotherapy and immunotherapy is not enough time to truly determine if a patient has benefitted from treatment. As you will see in the trial – there is significant discordance between what was determined as an imaging response and the pathologic responses. As new teams begin treating these patients, there is risk of an even higher proportion of patients not proceeding with surgery and then losing out on the potential benefits of chemoradiation followed by immunotherapy.

Even in the metastatic setting, given the complexity of interpreting imaging, physicians can treat beyond progression as pseudoprogression (often representing enlarging lymph nodes that may potentially suggest a response to immune therapy) is a well described phenomenon. It is also possible for metastatic disease to become apparent during these 3 cycles of therapy that may not represent lack of response – but rather occult disease. This happens most commonly with bone metastases that were obscured on staging imaging but then become apparent as the sclerosis of healing bone metastases on subsequent scans. These patients would benefit from continued systemic therapy: either single agent pembrolizumab or the combination of pembrolizumab + platinum doublet as per Keynote 189 and 407.

Our group feels that the decision to a) not proceed with surgery and b) allow either consolidation immunotherapy after a pivot from surgery to chemoradiation or continued palliative immunotherapy either alone or in combination should be left in the hands of the multi-disciplinary team caring for the patients. Just three doses of treatment, especially with immunotherapy, is too short to make a final decision on its benefit. The recommendation from The National Institute for Health and Care Excellence in the UK has taken this approach which we feel is a patient centered approach.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided 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		
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.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	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 submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒

If yes, please list the clinicians who contributed input and whose declarations have not changed:

- Dr. Rosalyn Juergens (lead)
- Dr. Normand Blais (lead)
- Dr. Geoffrey Liu
- Dr. Paul Wheatley-Price
- Dr. Barbara Meolsky
- Dr. Quincy Chu
- Dr. Jeffery Rothenstein
- Dr. Kevin Jao
- Dr. Silvana Spadafora
- Dr. Ron Burkes

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

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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2

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

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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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3

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

List any companies or organizations that have provided your group with financial payment over the past two

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0303-000
Brand name (generic)	Opdivo (nivolumab)
Indication(s)	Neoadjuvant treatment of adult patients with resectable NSCLC (tumours ≥4cm or node positive) when used in combination with platinum-doublet chemotherapy.
Organization	Ontario Health (Cancer Care Ontario) Lung and Thoracic Cancer Drug Advisory Committee
Contact information[a]	Name: Dr. Donna Maziak

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.		

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	☒
	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?	Yes	☒
	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?	Yes	☐
	No	☒

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

(Re: Table 2)

Re: neo-adjuvant chemotherapy regimen options
THE OH-CCO Lung DAC advocates to allow for flexibility in platinum-based regimen used with nivolumab based on patient-related reasons.

Re: Consideration for initiation of therapy
The Lung DAC strongly supports that EGFR or ALK testing at diagnosis is recommended, such as rapid EGFR testing in the early stage setting.

The Lung DAC would like to highlight the potential safety issues with giving an EGFR mutant lung cancer patients pre-operative chemo-immunotherapy. For EGFR mutant patients, adjuvant osimertinib is a funded treatment after. There is potential increased risk of death from immune-mediated pneumonitis, hepatitis, toxic epidermal necrolysis when checkpoint inhibition and targeted

therapy are overlapped (i.e., if a patient with EGFR mutation lung cancer is given chemoimmunotherapy induction and then after surgery, before adjuvant osimertinib is offered, will need be very thoughtful about the potential fatal interaction between checkpoint inhibition and targeted therapy).

Re: Implementation Issues

The Lung DAC comments that additional consideration is needed to decide on downstream PD1/PDL-1 inhibitor in these patients for different scenarios, where the “6 months” period may not make sense:

- Patients who completed 3 cycles of neoadjuvant nivolumab-chemo but are no longer surgical candidates and are receiving chemorads – will durvalumab be funded and for how long?
- Patients who completed 3 cycles of neoadjuvant nivolumab-chemo but are found to have metastatic disease during pre/perioperative therapy.
- Patients whose disease recurs within 6 months. Is this the same as other scenarios where the “6 months” period applies for immunotherapy? (The rationale for the 6 months was long half-life of IO.) Neoadjuvant nivolumab-chemotherapy for the current indication is only for 3 cycles and major surgery (which likely would shorten IO half-life etc.).

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided 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.
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  - 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	☒
Ontario Health provided secretariat function to the DAC.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
B. Previously Disclosed Conflict of Interest		
3. 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	☐
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. Donna Maziak • Dr. Sara Kuruvilla		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr Natasha Leighl*
Position	Member, Ontario Health (Cancer Care Ontario) Lung Cancer Drug Advisory Committee
Date	07-03-2023
☒	**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	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	Dr Andrew Robinson
Position	Member, Ontario Health (Cancer Care Ontario) Lung Cancer Drug Advisory Committee
Date	07-03-2023
☒	**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	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0303
Brand name (generic)	Opdivo (Nivolumab)
Indication(s)	Resectable Non-Small Cell Lung Cancer
Organization	Canadian Pulmonary Radiotherapy Investigators Group (CAPRI)
Contact information[a]	Chair: Dr. David Palma, MD, PhD, FRCPC [redacted] On behalf of the CAPRI executive committee

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☐
	No	☒

We thank the CADTH pCODR Expert Review Committee for their efforts to evaluate the use of nivolumab as part of neoadjuvant systemic therapy for patients with resectable NSCLC. This treatment is a major advance for patients, and embrace this is an outstanding treatment option for Canadians with lung cancer.

Our disagreement pertains to the inclusion criteria in the Checkmate 816 (CM816) trial, vs. the approved indications in the draft recommendation. CM816 included patients with stages up to IIIA (using the AJCC 7th edition), and therefore patients with stage IIIB disease were not included in Checkmate 816. Specifically, in the 7th edition, any patients with T4N2 or any N3 disease were classified as stage IIIB and not eligible for CM816.

The staging system has now changed to the 8th edition. In the 8th edition, stage IIIB now includes some patients who were eligible for CM816 and some who were not. The draft recommendation acknowledges this in the fine print on page 9: "*Checkmate 816 inclusion criteria were Stage IB (≥ 4 cm)-IIIA (per AJCC7th edition) which corresponds to Stage IB – IIIB non N3; non N2-T4 per 8th edition]"* (colored emphasis added). However, in Table 1, patients with N3 or T4N2 disease are not excluded from eligibility.

It is unclear from the recommendation as to whether:

1. The committee was aware of these exclusion criteria and intended to add these exclusions to Table 1, but they were not added.
2. The committee was aware of these exclusion criteria and elected to expand the eligibility of nivolumab to patients with T4N2 and N3 cancers.

If #1 is correct, we ask that Table 1 be updated to reflect these exclusions.

If #2 is correct, then we submit to the committee that extrapolation of this paradigm to T4N2 and N3 disease is risky, for the following reasons:

1. Risk of progression or unresectability after chemoimmunotherapy, with subsequent inability to deliver standard curative-intent treatment
In CM 816, 15.6% of patients could not proceed to surgical resection after neoadjuvant chemo-immunotherapy, for reasons including progression and unresectability. This risk will be higher in patients with more advanced disease (i.e. T4N2 and N3). Patients who do not proceed to resection after chemotherapy + nivolumab would then be offered chemoradiation as their curative-intent treatment option. However, in such patients, the standard-of-care treatment is chemoradiation followed by durvalumab, based on the results PACIFIC trial. The safety of a PACIFIC-type approach after neoadjuvant chemoimmunotherapy is unknown, and whether the adjuvant durvalumab would be funded by provincial payers is unclear. If these patients are denied durvalumab after chemoradiotherapy, this would lead to real harm, given the large survival benefit evident with adjuvant durvalumab in the PACIFIC trial.

2. Risk of treatment intensification (with resultant increased morbidity) after surgery with incomplete resections.
Even in T4N2 and N3 patients who can proceed to surgery after induction chemoimmunotherapy, given their more advanced disease status, there is a higher risk of incomplete resections (i.e. positive margins or gross residual disease). In such a situation, after receipt of the CM816 regimen including chemoimmunotherapy and surgery, patients with R1 or R2 resections would then likely proceed to chemoradiation (concurrent or sequential), and there would still be a question of requiring adjuvant durvalumab if there is gross residual disease. This would be a major escalation in treatment, with an elevated risk of toxicity for no known benefit, compared to a PACIFIC-type approach upfront.

3. Imprecision of the current criteria of "resectable". The current CADTH wording of "resectable" without an upper limit on stage is ambiguous, since there is disagreement within the surgical community about what constitutes resectability in the realm of stage IIIB disease.

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	☐
	No	☐
N/A: no prior input provided		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☐
	No	☒
As noted above, it is unclear whether the committee deliberately extended the CM816 paradigm to T4N2 and N3 disease.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☒

If this paradigm is implemented for T4N2 and N3 disease, it is unclear if curative-intent treatment would be fully funded for patients with unresected or partially resected disease (i.e. adjuvant durvalumab)		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☒
Please clarify if T4N2 and N3 disease was meant to be included in this recommendation as a patient group eligible for funding.		

[a] CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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  - 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	☒
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☐
	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 submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☒
	Yes	☐
• *No prior submission*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. David Palma*
Position	*Radiation Oncologist, London Health Sciences Centre* *Chair, Canadian Pulmonary Radiotherapy Investigators (CAPRI) Group*
Date	*10-03-2023*
☒	**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	

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0303
Name of the drug and Indication(s)	Nivolumab in combination with platinum-doublet chemotherapy for neoadjuvant treatment of resectable NSCLC
Organization Providing Feedback	PAG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	x
	No requested revisions	☐

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.
c) Implementation guidance

CADTH

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. PAG is requesting the following editorial revision. In Table 2: under implementation issues for considerations of initiation of therapy (last comment in the table), PAG would like to apply the consistent wording of "6 months and more" in place of "more than 6 months" when discussing the eligibility for downstream PD-1/PDL-1 inhibitor.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0303-000
Brand name (generic)	Nivolumab (Opdivo)
Indication(s)	Neoadjuvant treatment of adult patients with resectable NSCLC (tumours 4cm or node positive) when used in combination with platinum-doublet chemotherapy.
Organization	Lung Cancer Canada – Patient Group
Contact information[a]	Name: Shem Singh

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

LCC thanks pERC for the positive recommendation of nivolumab for resectable non-small cell lung cancer patients and for addressing the unmet need in the neoadjuvant treatment paradigm. This positive step will undoubtably broaden the treatments available for this population and improve their chance at survival and potential cure. Cure is the primary treatment goal for those with resectable NSCLC and neoadjuvant treatment, although seldom used in the Canadian setting, has shown to provide advantages to patients, including improving success of complete resection, increase their chance at survival, and reducing the risk of recurrence. These are values that many patients ultimately wish for in their treatments, as outlined in our initial submission. The reimbursement of nivolumab will be instrumental in allowing these patients and their families to focus on life outside their disease.

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	☒
	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?	Yes	☒
	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?	Yes	☒
	No	☐

From a patient group perspective, the implementation issues in the recommendation are adequately addressed; however, the clinician community and LCC Medical Advisory Group (MAC) have concerns regarding some of the implementation guidelines as outlined.

Given that neoadjuvant treatment is not used as often in the Canadian setting, and with nivolumab being the first immunotherapy agent reviewed in this indication, having the multidisciplinary clinician teams take a patient-centered approach and considering each individual patient's unique case will be

required to ensure treatment options beyond neoadjuvant nivolumab/chemotherapy are accessible, whether surgical resection follows treatment or not. Please refer to the LCC MAC's feedback submission for details.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided 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 1. Conflict of Interest Declarations for Patient Groups

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- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Shem Singh*
Position	*Executive Director, Lung Cancer Canada*
Date	*March 15, 2023*
☒	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	☒
	Yes	☐
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	☒
	Yes	☐
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	☐
	Yes	☒

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	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐