

CADTH REIMBURSEMENT REVIEW

Clinician Input

NIVOLUMAB-IPILIMUMAB (Opdivo-Yervoy)
(Bristol-Myers Squibb)

Indication: OPDIVO, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

November 19, 2020

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Clinician Input Template for CADTH pan-Canadian Oncology Drug Review Program

Before completing this template, be sure to register with the pCODR program. Please visit www.cadth.ca/pcodr/registration for information about the registration process.

1. About the Registered Clinician

Name of Registered Clinician	Dr. Quincy Chu
Title	Medical Oncologist
Disease Specialty (if applicable)	Thoracic Malignancy
Province	Alberta
Organization Membership (if applicable, national or provincial)	Lung Cancer Canada
Email	[REDACTED]
Telephone Number	[REDACTED]

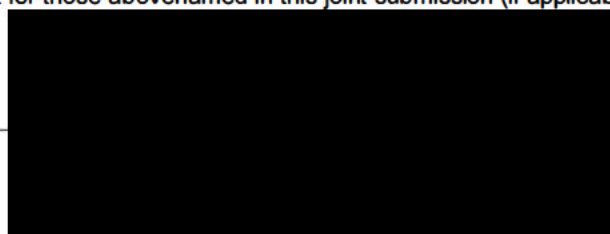
If this is a joint clinician input submission, please indicate the organization this submission is on behalf of, as well as list the names of the other clinicians and disease site specialty (if applicable). Please note that all clinicians listed must also register with CADTH and complete conflict of interest declaration forms.

Dr Geoffrey Liu Dr Barbara Melosky Dr Paul Wheatley Price Dr Rosalyn Juergens Dr Jeffrey Rothenstein Dr Ronald Burkes Dr Nicole Bouchard Dr Normand Blais Dr Kevin Jao Dr David Dawe Dr Stephanie Snow Dr Catherine Labbé
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Confirmation of Authorship

I declare that I am the author of this submission and I confirm that no other parties have written or participated in the writing of the submission, except for those abovenamed in this joint submission (if applicable).

Signature



2020/11/11
Date (YYYY/MM/DD)

2. About the Drug and Indication Under Review

CADTH pCODR Project Number	pCODR 10229
Generic Drug Name (Brand Name)	Nivolumab (Opdivo) and Ipilimumab (Yervoy)
Indication	Nivolumab in combination with ipilimumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.
Funding Request	Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.
Trial(s) Being Submitted to pCODR^a	CheckMate743 (NCT02899299)
Health Canada Status	Pending
FDA	Not applicable
European Medicines Agency Status	Not applicable
Practice Guidelines^a	<u>NCCN</u>
Provincial Funding of Current Treatments or Funding Algorithm	The standard of care for first line treatment in patients with malignant pleural mesothelioma in Canada is pemetrexed plus platinum chemotherapy (either cisplatin or carboplatin).

^a Please note that access to some online publications require subscription.

3. Key Questions for Clinician Input

3.1 Current Treatment(s) for the Indication Under Review:

- If this is different than what is listed in the Provincial Funding of Current Treatments or Funding Algorithm on the previous page, identify the treatment(s) you would use.
- If more than one treatment is funded in your province, identify the treatment(s) that would be the most appropriate comparator for the drug under review.

The current standard of care palliative systemic therapy for incurable, treatment-naïve mesothelioma with ECOG performance status of 0-2 is platinum/pemetrexed in Canada. This standard is established by the phase III study by Vogelzang et al. (JCO 2005;21:2636-2641) that demonstrated clinically and statistically significant improvement in median overall survival (12.1 months versus 9.3 months; HR=0.77, p=0.02), median progression-free survival (5.7 months versus 3.9 months, p=0.001), overall response rate (41.3% versus 16.7%, p<0.0001), and health-related quality-of-life. The MAPS trial by IFCT (Zalcman et al. Lancet 2016;387:1405-1414) showed the additional of bevacizumab to cisplatin/pemetrexed in this patient population improved the median overall survival (18.8 versus 16.1 months; HR=0.77, p=0.0167) and median progression-free survival (9.2 versus 7.3 months; HR=0.61, p<0.0001). However, the overall QoL were not significantly different between the two arms, but patients treated with bevacizumab and chemotherapy had a delayed in symptoms deterioration (37% versus 52%, p=0.015) and general condition (36% versus 48%, p=0.04). The addition of bevacizumab did lead to increase in both hematological and non-hematological toxicity. Unfortunately, the reimbursement of this combination was withdrawn from pCODR approval, according to the CADTH website.

The SEER data showed a small improvement of 0.5% per year in pleural mesothelioma from 1973-2011 such that the 1- and 5-year survival for localized, regional and metastatic disease were 41% and 6%, 40% and 4% and 32% and 3%, respectively (Shavelle et al. Lung Cancer Int 2017:2782590). Thus, there is a high unmet need for more efficacious and less toxic systemic therapy in this patient population, who are often older than 70 and have significant cardiac, pulmonary and other co-morbidity.

3.2 Eligible Patient Population

Describe the patients for whom you would use the new treatment. Examples can include, but are not limited to, the following questions:

- Does the patient population in the reimbursement request align with the need identified in your clinical practice? Is there an unmet need?
- Can the inclusion and exclusion criteria of the clinical trial be applied in clinical practice?
- Is there a subgroup of patients beyond the study population that you would like to use the new treatment in? Is there a subgroup of patients within the study population that the new treatment should be limited to?

Except selected mesothelioma patients who are young, clinical stage I-II or selected stage IIIA, ECOG 0-2, FEV1>40% predicted, DLCO >45% predicted, good cardiac function and epithelioid subtype mesothelioma can be considered for aggressive extrapleural pneumonectomy/extensive pleurectomy, hemithoracic radiation and/or chemotherapy, over 85% of the patients will be deemed unresectable who have a median survival of 12 months (Bibby et al. Eur Respir Rev 2014;25:472-486). According to the SEER data from 1973-2011, over 50% of pleural mesothelioma patients were over 70. With co-morbidity, history of smoking and other asbestos related pulmonary diseases, these patients are rarely surgical candidates (Shavelle et al. Lung Cancer Int 2017:2782590). For those who can undergo aggressive resection, the median survival is up to 29 months (Krug et al. JCO 2009;27:3007-3013, Cao et al. Cardiothorac Surg 2012;1:428-437, van Schil et

al. *Eur Respir J* 2010;36:1362-1369). Cho et al. reported a 3-year overall survival rate of 58% in a highly selective group of clinical T1-3N0M0, good performance, lung and cardiac function mesothelioma patients (*J Thorac Oncol* 2014;9:397-402) who underwent pre-operative radiation and extrapleural pneumonectomy. Those with non-epithelioid histology had a 3-year overall survival rate of 18% as compared to 58% in those who had epithelioid subtype. At the time of recurrence in these surgically resected patients, palliative systemic therapy will be offered.

Patients enrolled in the CHECKMATE 743 study were treatment-naïve, unresectable mesothelioma who had an ECOG performance status of 0-1, which represented the majority of the incurable mesothelioma patients who are seen in the Canadian cancer centres. Like other immunotherapy trials in various disease sites, ECOG performance status of 2 patients were excluded. Although there was no study of this combination in ECOG 2 mesothelioma patients, CHECKMATE 817 study reported treatment-naïve, metastatic non-small cell lung cancer patients with ECOG 2 treated with nivolumab and ipilimumab had inferior median overall survival (9.9 months versus 17 months), median progression-free survival than those who were ECOG 0-1 (3.6 versus 5.9 months) or 1-year progression-free rate (25% versus 35%) but similar 1-year duration of response and toxicity (Barlesi et al. *WCLC* 2019:OA04.02 and Barlesi et al. *ESMO IO* 2019:A920). It is unclear if treatment-naïve, incurable mesothelioma patients with ECOG 2 will benefit from nivolumab and ipilimumab combination due to the lack thereof any data. But this patient population may experience significant toxicity or be reluctant to undergo platinum/pemetrexed and so this combination may be made available as an option to this subpopulation of mesothelioma patients, especially those with non-epithelioid mesothelioma given the significant benefit reported in CHECKMATE 743 (18.8 versus 9.9 months) who do not derive benefit from standard platinum/pemetrexed chemotherapy.

IMPLEMENTATION QUESTIONS

- **Is there evidence to inform whether nivolumab and ipilimumab may be used to treat unresectable malignant peritoneal mesothelioma if no local treatment options (e.g., intraperitoneal chemotherapy) are appropriate?**

Given the rarity of peritoneal mesothelioma, clinical data for PD(L)1 alone or in combination with CTLA4 antibody or other agents are very limited. Hassan et al. reported the clinical activity of avelumab (an PD1 antibody) in both pleural and peritoneal mesothelioma but the number of peritoneal mesothelioma and their response were not reported separately (Hassan et al. *JAMA Oncol* 2019;5:351-357). But the conclusion stated clinical activity was observed in both pleural and peritoneal mesothelioma. The NIBIT-MESO-1 study (Calabro et al. *Lancet Respir Med* 2018;6:451-460) and a retrospective series by Ahmadzadea et al (JTOCRR Epub) included 2 and 3 peritoneal mesothelioma patients respectively, but again no specific efficacy data were reported. The Phase II study by Raghav et al. (PASCO 2020:A9013) reported a response rate of 35%, median progression-free survival of 17.6 month and 1-year overall survival rate of 75% in 20 peritoneal mesothelioma who were treated with atezolizumab (PDL-1 antibody) and bevacizumab. Both bevacizumab or multi-targeted VEGFR tyrosine kinase inhibitor has no significant single agent activity in mesothelioma (Nowak et al. *Front Oncol* 2020;10:126). Peritoneal mesothelioma occurs more commonly in younger patients, female and are common to be epithelioid subtype and asbestos related. The benefit to platinum/pemetrexed (Nakano et al. *Anticancer Res* 2014;34:215-220; Fujimoto et al. *Expert Rev Anticancer Ther* 2017;17:865-872) and overall prognosis was better than that of pleural mesothelioma (Shavelle et al. *Lung Cancer Int* 2017:2782590). Despite the paucity of data of PD(L)1 therapy in peritoneal mesothelioma, with similar biology and being asbestos related, it is highly likely nivolumab and ipilimumab will benefit this patient population. As this population often can undergo peritoneal stripping if there is a good response after pre-operative chemotherapy of platinum/pemetrexed, it is unclear if nivolumab and ipilimumab

combination is better in efficacy and/or toxicity and this combination can potentially increase fibrosis in the peritoneum which can lead to increase risk from surgery. Due to the rarity of peritoneal mesothelioma, this remains an unanswered question.

3.3 Relevance to Clinical Practice

Do you have experience with using the treatment (through clinical trials, manufacturer's access program, private drug insurance) under review?

Yes No

- How or when would you use the new treatment? Is there any population/subpopulation where you particularly want to use this drug?
- How is the new treatment different than currently available treatments with respect to efficacy, safety, and tolerability?
- Are there contraindications to using the new treatment? Are there contraindications to current treatments that would make the new treatment favourable?

Please note: Scientific published references are not required, as pCODR has access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search.

All incurable, treatment-naïve, pleural and peritoneal mesothelioma who have ECOG 0-2 and no active autoimmune disease should be offered nivolumab and ipilimumab as first-line therapy. For patients who have recurrence of mesothelioma after initial curative surgery +/- (neo)adjuvant chemotherapy should also be allowed to use this combination. Based on the forest plot, all subgroups benefited from the combination but the benefit was especially clinically significant in those with non-epithelioid subtypes.

The incidences of treatment-related adverse events were similar between nivolumab/ipilimumab and chemotherapy, but those treated with the nivolumab/ipilimumab were more likely to discontinuation therapy due to adverse events (23% versus 16%) and to experience serious adverse events (21% versus 8%). The latter 2 observations may be related to the median duration of therapy of nivolumab and ipilimumab was longer (5.6 versus 3.5 months) and the duration of therapy was up to 2 years, and thus the chances of developing treatment-related adverse events will be higher for the immunotherapy arm. It will be of interest to have the median time to treatment-related adverse events, median time-to-prednisone or other immune suppressant use and median time to discontinuation of therapy due to treatment-related adverse events to help answer the above 2 questions. There were higher incidences of diarrhea and pruritis in the nivolumab and ipilimumab-treated patients while the incidences of nausea, anemia, neutropenia, fatigue anorexia and asthenia were more commonly reported in the chemotherapy-treated patients. Thoracic oncologists are familiar with the toxicity management from immunotherapy of PD(L)1 +/- CTLA4 antibody from their clinical practice or clinical trials.

Patients who have active autoimmune disease requiring steroid of >10 mg daily or other immunosuppressants may not be considered for this combination.

3.4 Sequencing and Priority of Treatments

- Please describe how the new treatment could be sequenced with current treatment(s), if appropriate.
- In your opinion, in the event that the drug under review becomes available for funding in your jurisdiction, would the new treatment be a replacement of current treatment(s) or another option?

For any newly diagnosed pleural and peritoneal mesothelioma who have no contraindication stated in section 3.3, should be offered this combination. Upon progression, platinum/pemetrexed will be given as second-line therapy although there is no clinical data available to date. The long-term data from CHECKMATE 743, such as PFS2, a recognized clinical endpoint by EMA, and post-study therapy will be informative of the benefit of chemotherapy in the nivolumab/ipilimumab treated patients.

For those who have received prior palliative chemotherapy and now experiences disease progression should be allowed to use this combination as second line therapy based on the MAPS2 trial (Scherpereel et al. Lancet Oncol 2019;20:239-253) based on a response rate of 25.9%, median progression-free survival of 5.6 months, and median overall survival of 15.9 months. Limited by the non-comparative randomized phase II design to the nivolumab and cross trial comparison to the pembrolizumab or vinorelbine- or gemcitabine-treated patients in the PROMISE trial (Popat et al. ESMO 2019:LBA91_PR).

	MAPS-2		PROMISE	
	Nivolumab	Nivolumb/Ipilimumab	Pembrolizumab	Chemotherapy
Response rate	19%	28%	22%	15%
Median Progression-free survival	4 months	5.6 months	2.5 months	3.4 months
1-year progression-free rate	15.9%	22.6%	15%	15%
Median overall survival	11.9 months	15.9 months	10.7 months	10.7 months

IMPLEMENTATION QUESTIONS

- In what circumstances would nivolumab and ipilimumab be preferred over first line chemotherapy?

In the forest plot, all subgroups benefited from the combination, particularly the non-epithelioid subtypes.

- **What evidence is available to support re-treatment with nivolumab and ipilimumab? What is the appropriate timing of re-treatment with nivolumab and ipilimumab after relapse?**

Currently, there is no clinical data on re-treatment of patients who have disease progression after the 2-year of therapy. At this time, the number of patients in CHECKMATE 743 who have received 2 years of therapy is still unknown and longer term data are needed to address this question fully. We should adopt the same criterion for retreatment as in treatment-naïve, advanced non-small cell lung cancer who have received pembrolizumab or pembrolizumab + platinum-based chemotherapy that patients who have stopped therapy due to toxicity should be allowed to restart upon resolution of toxicity and termination of systemic steroid. Similarly, patients who have finished 2 years of therapy and then experience progression should be allowed to be retreated regardless of time to relapse until more data are available to answer this question.

- **What evidence is there to inform options following treatment failure on nivolumab and ipilimumab?**

There is no level 1 evidence to guide the optimal subsequent lines of therapy. In the oral presentation in August 2020 by Baas et al., no data on the number of patients who have received subsequent line(s) of systemic therapy and the efficacy such as PFS-2.

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Quincy Chu

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance

of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

1. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

2. What form of payment did you receive? (Check all that apply.)

- Advisory role (e.g., advisory boards, health technology assessment submission advice) Program or Operating Funding (e.g., website)
 Conference attendance Research/educational grants
 Royalties Travel grants
 Gifts Sponsorship of events
 Honoraria Other, please specify: _____

3. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Amgen	Advisory board and honorarium	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abbvie	Advisory board and honorarium	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Astra Zeneca	Advisory board and honorarium	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BMS	Advisory board and honorarium		X		
Boehringer Ingelheim	Advisory board and honorarium	X			
Novartis	Advisory board and honorarium	X			
Merck	Advisory board and honorarium	X			
Pfizer	Advisory board and honorarium		X		
Roche	Advisory board and honorarium	X			
Takeda	Advisory board and honorarium	X			
Astra Zeneca	Research grants			X	
Exactis	Research grants				X

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

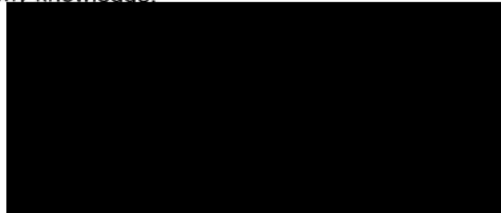
No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician:

Geoffrey Liu

Name of drug and indication under review:

Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

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Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

1. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

2. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input checked="" type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

3. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Takeda Canada	Advisory Board, Health Technology Assessment Submissions on Advice, Speaker's Bureau, past 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Takeda Canada	(To nst tut on, not nd v dua) Observat ona Study fund ng, past 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hoffman La Roche	Adv sory Board, Hea th Techno ogy Assessment Subm ss on Adv ce, past 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Pf zer	Adv sory Board, Hea th Techno ogy Assessment Subm ss on Adv ce, part 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
AstraZeneca	Adv sory Board, Hea th Techno ogy Assessment Subm ss on Adv ce, Speaker s Bureau, past 10 years,	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
AstraZeneca	(To nst tut on, not nd v dua) Observat ona Study fund ng, past 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Br sto Myers Squ bb	Adv sory Board	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Boehr nger Ingerhe m	(To nst tut on, not nd v dua) Observat ona Study fund ng, past 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Abbv e	Adv sory Board, past 10 years	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Merck	Adv sory Board, Hea th Techno ogy Assessment Subm ss on Adv ce, past 10 years	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EMD Serono	Speaker s Bureau, past 10 years	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Novart s	Adv sory Board,past 10 years	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
G axo Sm th K ne	Adv sory Board, past 10 years	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you rece ved or are n possess on of stocks or opt ons of more than \$10,000 (exc ud ng mutua funds) for organ zat ons that may have a d rect or nd rect nterest n the drug under rev ew? If yes, p ease st them n the fo ow ng box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have persona or commerc a re at onsh ps e ther w th a drug or hea th techno ogy manufacturer (nc ud ng the manufacturer s parent corporat on, subs d ar es, aff ates, and assoc ated corporat ons) or other nterest groups? If yes, p ease prov de the names of the compan es and organ zat ons, and out ne the nature of these re at onsh ps, n the fo ow ng box.

No

By check ng th s box, I hereby cert fy that the nformat on that I have presented here s accurate and comp ete to the best of my know edge.



11 November, 2020
Date

Geoffrey Liu
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Barbara Melosky

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

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Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

4. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

5. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
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| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

6. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

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		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Novartis	Advisory Board	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Roche	Advisory Board	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Merck	Advisory Board	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No, I do not have holdings or other interests in organizations that may have a direct or indirect interest in the drug under review.

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No, I do not have personal or commercial relationships either with a drug or health technology manufacturer or other interest groups.

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



November 10th 2020
Date

Barbara Melosky
Name

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Name of registered clinician:

Dr Paul Wheatley-Price

Name of drug and indication under review:

Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma."

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- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

1. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

2. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

3. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Astra Zeneca	Advisory Role	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Boehringer Ingeiheim	Advisory Role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bristol-Myers Squibb	Advisory Role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Merck	Advisory Role	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Novartis	Advisory Role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bayer	Advisory Role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



November 19th 2020
Date

Paul Wheatley-Price
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Rosalyn Juergens

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

10. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

11. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input checked="" type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

12. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Brysto-Myers Squibb	Advisory role and honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AstraZeneca	Advisory role and honoraria	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Merck Sharp and Dohme	Advisory role and honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Roche	Advisory role and honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



November 12th, 2020
Date

Rosalyn Juergens, MD PhD
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Jeffrey Rothenstein

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

13. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

14. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input checked="" type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

15. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Roche	Advisory Role and Honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



November 12th, 2020
Date

Jeffrey Rothenstein
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Ronald Burkes

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

16. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

17. What form of payment did you receive? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

18. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



November 12th, 2020

Date

Ronald Burkes

Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Nicole Bouchard

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

19. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

20. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input checked="" type="checkbox"/> Conference attendance | <input checked="" type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

21. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Astra Zeneca	Advisory Role/Conference	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bristol-Myers Squibb	Advisory Role/Research	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Merck	Adv sory Ro e /Research/Conference	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bayer	Adv sory Ro e	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pf zer	Conference/Research	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Roche	Adv sory Ro e	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you rece ved or are n possess on of stocks or opt ons of more than \$10,000 (exc ud ng mutua funds) for organ zat ons that may have a d rect or nd rect nterest n the drug under rev ew? If yes, p ease st them n the fo ow ng box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have persona or commerc a re at onsh ps e ther w th a drug or hea th techno gy manufacturer (nc ud ng the manufacturer s parent corporat on, subs d ar es, aff ates, and assoc ated corporat ons) or other nterest groups? If yes, p ease prov de the names of the compan es and organ zat ons, and out ne the nature of these re at onsh ps, n the fo ow ng box.

Expert for INESSS (d agnos s and treatment for Lung Cancer n Quebec)

By check ng th s box, I hereby cert fy that the nformat on that I have presented here s accurate and comp ete to the best of my know edge.



November 12th, 2020
Date

Nicole Bouchard
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Normand Blais

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

22. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

23. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

24. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Novartis	Medical advisor	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

N/A

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

N/A

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 11 2020

Normand B a s

Date

Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Kevin Jao

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

25. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

26. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

27. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Brysto-Myers Squibb	Advisory Role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



November 12th, 2020

Date

Kevin Jao

Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr David Dawe

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

28. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

29. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input checked="" type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input checked="" type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

30. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Name of Organization	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AstraZeneca	Advisory boards	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Merck	Advisory Boards	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AstraZeneca	Research Grant	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Boehringer-Ingelheim	Honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 13, 2020

Date

David Dawe _____
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr Stephanie Snow

Name of drug and indication under review: Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

31. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

32. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submissions on advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input checked="" type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

33. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Bristol-Myers Squibb	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Amgen	Advisory Role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Astra Zeneca	Advisory Role	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Astra Zeneca	Research Grant	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bayer	Adv sory Ro e	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Br sto -Myers Squ bb	Adv sory Ro e	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E sa	Adv sory Ro e	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Merck	Adv sory Ro e	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Novartis	Adv sory Ro e	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pfizer	Adv sory Ro e	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Purdue	Adv sory Ro e	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Roche	Adv sory Ro e	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Taiho	Adv sory Ro e	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Takeda	Adv sory Ro e	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you rece ved or are n possess on of stocks or opt ons of more than \$10,000 (exc ud ng mutua funds) for organ zat ons that may have a d rect or nd rect nterest n the drug under rev ew? If yes, p ease st them n the fo ow ng box.

No

Section C: Affiliations, Personal or Commercial Relationships

Do you have persona or commerc a re at onsh ps e ther w th a drug or hea th techno gy manufacturer (nc ud ng the manufacturer s parent corporat on, subs d ar es, aff ates, and assoc ated corporat ons) or other nterest groups? If yes, p ease prov de the names of the compan es and organ zat ons, and out ne the nature of these re at onsh ps, n the fo ow ng box.

No

By check ng th s box, I hereby cert fy that the nformat on that I have presented here s accurate and comp ete to the best of my know edge.



November 12th 2020
Date

Stephanie Snow
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician:

Dr Catherine Labbé

Name of drug and indication under review:

Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

1. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

2. What form of payment did you receive? (Check all that apply.)

- Advisory role (e.g., advisory boards, health technology assessment submission advice) Program or Operating Funding (e.g., website)
- Conference attendance Research/educational grants
- Royalties Travel grants
- Gifts Sponsorship of events
- Honoraria Other, please specify: _____

3. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
BMS	Ad boards and clinical trials	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Astra Zeneca	Ad boards, clinical trials honoraria for conferences	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Meet + Prizes	Ad boards + conferences	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

No.

Section C: Affiliations, Personal or Commercial Relationships

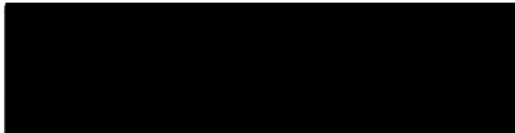
Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

No.

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



2020-11-18
Date



Clinician Input Template for CADTH pan-Canadian Oncology Drug Review Program

Before completing this template, be sure to [register](#) with the pCODR program. Please visit www.cadth.ca/pcodr/registration for information about the registration process.

1. About the Registered Clinician

Name of Registered Clinician	Dr. Gail Darling
Title	Thoracic Surgeon; Thoracic Cancers Lead, Ontario Health (Cancer Care Ontario)
Disease Specialty (if applicable)	Surgical Oncology
Province	Ontario
Organization Membership (if applicable, national or provincial)	Ontario Health (Cancer Care Ontario) Lung Cancer Drug Advisory Committee (DAC)
Email	[REDACTED]
Telephone Number	NA

If this is a joint clinician input submission, please indicate the organization this submission is on behalf of, as well as list the names of the other clinicians and disease site specialty (if applicable). Please note that all clinicians listed must also register with CADTH and complete conflict of interest declaration forms.

Dr. Natasha Leigh
 Dr. Stacey Hubay
 Dr. Andrew Robinson
 Dr. Mohammad Rassouli
 Pamela Ng (pharmacist)
 members of OH-CCO Lung DAC.

Confirmation of Authorship

I declare that I am the author of this submission and I confirm that no other parties have written or participated in the writing of the submission, except for those abovenamed in this joint submission (if applicable).

[REDACTED]

2020/11/19

Date (YYYY/MM/DD)

2. About the Drug and Indication Under Review

CADTH pCODR Project Number	pCODR 10229
Generic Drug Name (Brand Name)	Nivolumab (Opdivo) and Ipilimumab (Yervoy)
Indication	Nivolumab in combination with ipilimumab for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.
Funding Request	Nivolumab in combination with ipilimumab for the first-line treatment of patients with unresectable malignant pleural mesothelioma.
Trial(s) Being Submitted to pCODR^a	CheckMate743 (NCT02899299)
Health Canada Status	Pending
FDA	Not applicable
European Medicines Agency Status	Not applicable
Practice Guidelines^a	<u>NCCN</u>
Provincial Funding of Current Treatments or Funding Algorithm	The standard of care for first line treatment in patients with malignant pleural mesothelioma in Canada is pemetrexed plus platinum chemotherapy (either cisplatin or carboplatin).

^a Please note that access to some online publications require subscription.

3. Key Questions for Clinician Input

3.1 Current Treatment(s) for the Indication Under Review:

- If this is different than what is listed in the Provincial Funding of Current Treatments or Funding Algorithm on the previous page, identify the treatment(s) you would use.
- If more than one treatment is funded in your province, identify the treatment(s) that would be the most appropriate comparator for the drug under review.

As noted in the previous page, only pemetrexed-platinum is currently funded for this patient population

3.2 Eligible Patient Population

Describe the patients for whom you would use the new treatment. Examples can include, but are not limited to, the following questions:

- Does the patient population in the reimbursement request align with the need identified in your clinical practice? Is there an unmet need?
- Can the inclusion and exclusion criteria of the clinical trial be applied in clinical practice?
- Is there a subgroup of patients beyond the study population that you would like to use the new treatment in? Is there a subgroup of patients within the study population that the new treatment should be limited to?

The reimbursement request aligns with need. There is a huge unmet need. The trial criteria is appropriate for practice (based on information available at the time of this input – abstract and presentation from WCLC 2020).

This is appropriate for all MPM patients. There is no subgroup of patients within the study population that the new treatment should be limited to regardless of histology.

IMPLEMENTATION QUESTIONS

- Is there evidence to inform whether nivolumab and ipilimumab may be used to treat unresectable malignant peritoneal mesothelioma if no local treatment options (e.g., intraperitoneal chemotherapy) are appropriate?

Peritoneal (and scrotal) mesothelioma is rare and have been treated the same as pleural mesothelioma and there's no reason to expect nivo-ipi will not work for peritoneal mesothelioma (i.e., it is reasonable to extend treatment with nivo-ipi to peritoneal population).

There are slight differences with peritoneal mesothelioma as those patients may be considered for HIPEC and debulking therapy, often go for debulking and HIPEC but often end up with palliative therapy.

3.3 Relevance to Clinical Practice

Do you have experience with using the treatment (through clinical trials, manufacturer's access program, private drug insurance) under review?

Yes No

- How or when would you use the new treatment? Is there any population/subpopulation where you particularly want to use this drug?
- How is the new treatment different than currently available treatments with respect to efficacy, safety, and tolerability?
- Are there contraindications to using the new treatment? Are there contraindications to current treatments that would make the new treatment favourable?

Please note: Scientific published references are not required, as pCODR has access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search.

The Lung DAC anticipates that nivo-ipi will replace pem-platinum as first-line therapy and the preferred first choice for most patients (70-80%). Additionally, patients who don't benefit from nivo-ipi will get pemetrexed-platinum (chemotherapy) after immunotherapy failure as subsequent systemic therapy.

However, not all patients will be candidates for first-line nivo-ipi and pem-platinum or vice versa so it's important to have treatment options for these patients.

As the published paper was not yet available at the time of the clinician input, nivo-ipi in other context does have toxicities and likely more than pem-platinum in a lot of cases.

3.4 Sequencing and Priority of Treatments

- Please describe how the new treatment could be sequenced with current treatment(s), if appropriate.
- In your opinion, in the event that the drug under review becomes available for funding in your jurisdiction, would the new treatment be a replacement of current treatment(s) or another option?

As noted in 3.3, the Lung DAC anticipates that most patients will be treated with nivo-ipi first, followed by chemo. Nivo-ipi will become the new standard first-line treatment unless there are reasons not to use in patients.

IMPLEMENTATION QUESTIONS

- In what circumstances would nivolumab and ipilimumab be preferred over first line chemotherapy?

As noted above.

All situations except where immunotherapy is contra-indicated.

- What evidence is available to support re-treatment with nivolumab and ipilimumab? What is the appropriate timing of re-treatment with nivolumab and ipilimumab after relapse?

With respect to re-treatment with nivo-ipi, follow what's done in the pivotal trial.

- What evidence is there to inform options following treatment failure on nivolumab and ipilimumab?

In the pivotal trial, a large number of these patients received chemotherapy as subsequent systemic therapy (i.e., nivo-ipi patients went on to chemo). Randomized discontinuation trial will not happen.

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr. Gail Darling

Name of drug and indication under review: Nivo-ipi/MPM

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

1. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

2. What form of payment did you receive? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |

- Gifts
 Sponsorship of events
 Honoraria
 Other, please specify: _____

3. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

None

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

None

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 12, 2020
Date

Dr. Gail Darling
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr. Stacey Hubay

Name of drug and indication under review: Nivo-ipi/MPM

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

4. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

5. What form of payment did you receive? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

6. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

None

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

None

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 12, 2020
Date

Dr. Stacey Hubay
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr. Natasha Leighl

Name of drug and indication under review: Nivo-ipi/MPM

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

7. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

8. What form of payment did you receive? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

9. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

None

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

None

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 12, 2020
Date

Dr. Natasha Leigh
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr. Andrew Robinson

Name of drug and indication under review: Nivo-ipi/MPM

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

10. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

11. What form of payment did you receive? (Check all that apply.)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

12. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Merck	Advisory role	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

None

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

None

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 12, 2020
Date

Dr. Andrew Robinson
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Dr. Mohammad Rassouli

Name of drug and indication under review: Nivo-ipi/MPM

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

13. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

14. What form of payment did you receive? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

15. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

None

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

None

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 12, 2020
Date

Dr. Mohammad Rassouli
Name

Appendix A: pCODR Clinician Conflict of Interest Declarations

Please note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.

Name of registered clinician: Pamela Ng (pharmacist)

Name of drug and indication under review: Nivo-ipi/MPM

Conflict of Interest Declaration

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. A conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

- financial support from the pharmaceutical industry or other entities (e.g., educational or research grants, honoraria, gifts, and salary)
- affiliations, or personal or commercial relationships with drug manufacturers or other interest groups.

Section A: Payment Received

16. Have you received any payments over the previous two years from any company or organization that may have a direct or indirect interest in the drug under review?

- Yes
 No

If no, please go to Section B.

17. What form of payment did you receive? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Advisory role (e.g., advisory boards, health technology assessment submission advice) | <input type="checkbox"/> Program or Operating Funding (e.g., website) |
| <input type="checkbox"/> Conference attendance | <input type="checkbox"/> Research/educational grants |
| <input type="checkbox"/> Royalties | <input type="checkbox"/> Travel grants |
| <input type="checkbox"/> Gifts | <input type="checkbox"/> Sponsorship of events |
| <input type="checkbox"/> Honoraria | <input type="checkbox"/> Other, please specify: _____ |

18. Please provide the names of companies and organizations, and the amounts of the payments, in the following table.

Company	Nature or description of activities or interests	Check Appropriate Dollar Range			
		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B: Holdings or Other Interests

Have you received or are in possession of stocks or options of more than \$10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list them in the following box.

None

Section C: Affiliations, Personal or Commercial Relationships

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including the manufacturer's parent corporation, subsidiaries, affiliates, and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations, and outline the nature of these relationships, in the following box.

None

By checking this box, I hereby certify that the information that I have presented here is accurate and complete to the best of my knowledge.



Nov 12, 2020
Date

Pamela Ng
Name