Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

pembrolizumab (Keytruda)

(Merck Canada Inc.)

Indication: Keytruda in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult and pediatric (12 years and older) patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

December 6, 2024

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings. **If your group has submitted input that is not reflected within this document, please contact Formulary-Support@cda-amc.ca.**

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CDA-AMC and do not necessarily represent or reflect the views of CDA-AMC. No endorsement by CDA-AMC is intended or should be inferred.

By filing with CDA-AMC, the submitting organization or individual agrees to the full disclosure of the information. CDA-AMC does not edit the content of the submissions received.

CDA-AMC does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting group and all conflicts of interest information from individuals who contributed to the

CADTH

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: Pembrolizumab (Keytruda)

Indication: Keytruda in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult and pediatric (12 years and older) patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

Name of Patient Group: Joint Submission by Lung Health Foundation, Lung Cancer Canada and the Canadian Cancer Survivor Network

Author of Submission: Riley Sanders - Lung Health Foundation, Winky Yau – Lung Cancer Canada, Lindsay Timm - Canadian Cancer Survivor Network

1. About Your Patient Group

This patient input submission is jointly submitted by Lung Health Foundation (LHF), Lung Cancer Canada (LCC), and the Canadian Cancer Survivor Network (CCSN).

The Lung Health Foundation (www.lunghealth.ca) legally known as the Ontario Lung Association, is registered with the CADTH and pCODR, and stands as a cornerstone of trust and reliability in the Canadian healthcare and public health systems. Lung Health Foundation is a registered charity that assists and empowers people living with or caring for others with lung disease. It is a recognized leader, voice and primary resource in the prevention and control of respiratory illness, tobacco cessation and prevention, and its effects on lung health. We are governed by a dedicated board of directors and supported by a team of approximately 40 employees alongside thousands of passionate volunteers. Together, we work tirelessly to improve the lung health of Canadians, driving positive change and fostering a brighter, healthier future for all.

Lung Cancer Canada is a registered national charitable organization that serves as Canada's leading resource for lung cancer education, patient support, research and advocacy. Lung Cancer Canada is a member of the Global Lung Cancer Coalition and is the only national organization in Canada focused exclusively on lung cancer. Lung Cancer Canada is registered with CADTH. https://www.lungcancercanada.ca/

The Canadian Cancer Survivor Network (CCSN) is a national network of patients, families, survivors, friends, community partners, funders, and sponsors who have come together to take action to promote the very best standard of care, whether it be early diagnosis, timely treatment and follow-up care, support for cancer patients, or issues related to survivorship or quality of end-of-life care. https://survivornet.ca/

2. Information Gathering

The information provided by the Lung Health Foundation in this submission builds from our robust experience working directly with people living with lung cancer through our patient and caregiver support programs, lung cancer patient advisory group, our lung cancer patient advocates as well as information obtained from an online survey completed by 70 people who identified as living with lung cancer or caring for someone living with lung cancer. Out of these 70 people, 6 indicated they had experience with the drug under review, Pembrolizumab.

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From this respondent group, 59 are people living with lung cancer and 11 are caregivers for people living with lung cancer. Respondents were identified at all stages of diagnosis, from just being diagnosed through to stage 4 metastatic. Most of the respondents (61) were diagnosed with non-small cell lung cancer, 6 were diagnosed with small cell lung cancer and 3 self-identified as non-small lung cancer and ALK-positive.

All 70 online respondents to the survey were from Canada with the provincial breakdown as follows: 8 from British Columbia; 9 from Alberta; 2 from Saskatchewan; 4 from Manitoba; 38 from Ontario; 4 from Quebec; 3 from New Brunswick; and 2 from Nova Scotia. Age and gender were not captured on this survey tool. These respondents completed the survey between June 2023 - November 2024. Alchemer was the online survey tool utilized for the collection of this data.

In Section 6, *Experience with Drug under Review*, information was gathered from 3 patients who were interviewed for previous submissions who had experience with pembrolizumab, mainly in the advanced/metastatic NSCLC setting. 2 patients, JG and DH are female, and TM identifies as male. All 3 are Canadian.

Information was also gathered from a previous submission completed in 2020 that included patients who were living with pleural mesothelioma. 2 patients, CH and HO are male, and both are Canadian.

3. Disease Experience

The respondents had varying experiences with their lung cancer diagnosis, but several consistent themes did arise.

First, the theme of it being difficult to get an accurate and timely diagnosis was evident among this group, “It's hard to get a diagnosis at an early stage.” One of the interviewees reported that what led him to the emergency department, and eventual lung cancer diagnosis, was severe numbness in his right hand. While there, he mentioned his cough that wouldn’t go away. It was discovered he had a brain tumor (secondary), and then the primary source was discovered, lung cancer. Another interviewee stated, “It's hard to get a diagnosis at an early age. I wish, at least after the brutal news, we could have easy access to affordable medications. Maybe it's too late for me, but not too late for others.” A third respondent shared, “During the few months before my lung cancer diagnosis, I had a poor quality of life. I was unable to have full conversations without being abruptly interrupted by coughing fits. During remote work virtual meetings, I often had to be on mute and found it difficult to speak. I had to ask other teammates to carry on conversations for me. In the evenings, my cough would be worse, and I could only communicate with my partner via writing at times. The symptoms did not allow me to work, exercise and socialize like I had before. Once diagnosed, on the right therapy and on the right dosage, I have been able to resume my regular life activities such as working, exercise, traveling, sleeping, and spending time with family and friends. My treatment is taken orally which offers me a convenient way to receive treatment that I can take anywhere. Living with lung cancer is difficult in many ways. What truly makes it a manageable disease is having access to effective, convenient and affordable/covered therapies.”

A second theme was the symptoms and challenges these patients experienced because of their lung cancer. At the top of the list was fatigue (67%), and shortness of breath (67%), followed by cough (23%) nausea (23%), and pain (20%). Chest tightness, wheezing, weight loss, diminished appetite, low mood / depressive periods and challenges with physical and emotional intimacy were also noted by some respondents.
A third theme was how lung cancer negatively affected their day-to-day life. The inability to work was at the top of this list (48%), followed by the inability to participate in physical activities (33%), do housework (21%), use stairs (22%), or partake in hobbies (21%).

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As a result of living with lung cancer, almost all respondents indicated it had negative impacts on their emotional well-being. Some (44%) feel isolated and struggle to manage their symptoms. Others indicated they feel guilty for the burden they are putting on their family members / friends. One respondent stated his daughter attends all medical appointments with him so that is time-consuming for her and causes her to miss work. Another respondent stated the real-life impact of living with lung cancer is hard. “I used to be extremely outgoing. Now with my shortness of breath, I never know how I am going to be feeling from one day to the next. I don't make long term plans as my breathing is unpredictable.”

When asked if there was an aspect of their disease that is most important to them to control, the respondents gave these responses:

- “Improved energy levels and less fatigue”
- “Shortness of breath”
- “Managing pain and side effects from treatments”
- “Simply maintaining a quality of life”
- “More resources and support”

4. Experiences With Currently Available Treatments

The treatments tried by the respondents included surgery, radiation, chemotherapy, targeted therapy and immunotherapy. The medications tried included Alectinib, Lorlatinib, Maxolone, Gefitinib, Entrectnib, Tagrisso, Alunbrig and Pembrolizumab. Some patients are participating in clinical trials. The benefits experienced with the treatments were: reduced cough, reduced shortness of breath, increased participation in daily activities, ability to exercise, prolonged life, delayed disease progression and a reduction in the severity of other disease-related symptoms. Patients on oral drugs also value the flexibility the drugs provide in allowing them to work and travel without restrictions. “These drugs are expensive but do work. I have a life and, when metastasis develops, I hope the next treatment option is approved and funded. What lung cancer needs is more public education to promote awareness and to reduce the association with smoking. This will help to lead to more funding and support for the development of a broad-based screening test to catch it early, in stage 1 not 4. Anyone with lungs can get lung cancer.” Another respondent stated, “Each time meds are changed there is a fear that I will not be able to get the new drug. All have been via compassionate care programs. Cost is prohibitive in most cases. Provincial and or federal coverage is a must.”

Some patients reported struggling with lingering side effects. Respondents who received surgery reported deconditioning and chronic fatigue. Some of the side effects reported from radiation were fatigue, skin changes, hair loss and tissue scarring. With medications, the side effects reported included extreme itching that affects sleep, brain fog, fatigue, nausea, vomiting, mood changes, diminished appetite, weight loss, hair loss, anemia, and neuropathy. Side effects from chemotherapy severely impacted the patients’ quality of life, ability to work and in some cases, the ability to perform activities of daily living.

When asked about challenges with access to treatment, the respondents reported that they struggled with the cost associated with some treatments. They also found it challenging to navigate the healthcare system and, in some cases, they were not clear where to go for information and support. Patients on targeted therapy also worry about access to the next line of treatment if or when their current treatment stops working. One said, “I have ALK+ NSCLC diagnosed in 2021. I am a non-smoker. I have been through chemo and radiation but only saw real

improvement in my cancer with Alectinib. However, no medication lasts forever, and I don't know what will happen when I have progression as the next drug, Lorlatinib, is not readily available in all provinces."

5. Improved Outcomes

Key treatment outcomes for this group of lung cancer patients included stopping or slowing the progression of the disease with minimal side effects. Regarding side effects, one respondent stated, "I hope for little to no side effects, particularly when it comes to energy levels, and ability to focus. Being able to work, contribute to my community and be with friends & family is important to me. This requires the right energy levels and focus."

Patients would also like to see medications that are effective for advanced disease. Due to the poor outcomes associated with advanced disease, patients describe feeling very anxious about any sign or prospect of disease progression.

When choosing therapy, patients are also interested in the efficacy of the medication. One respondent commented that they would be more receptive to side effects if there was strong evidence that the medication would stop or slow down the progression of their lung cancer.

There is a need for increased treatment options that not only treat their disease successfully but also delay its progression.

6. Experience With Drug Under Review

Pembrolizumab has been available in Canada for a number of years now for the treatment of NSCLC in addition to other cancer types, and expanding its accessibility for this indication in early-stage lung cancer is a key step moving forward in the treatment paradigm. Currently for resected Stage IB-IIIA NSCLC patients with PDL1 < 50%, there is no indication for adjuvant immunotherapy, which defines an unmet need that the approval of pembrolizumab can address. Currently available treatments are also inadequate in achieving high rates of cure and also preventing recurrence in the early-stage resected NSCLC patient population.

In previous CADTH submissions for pembrolizumab, it has been presented that patients on treatment are able to maintain a high quality of life level. Pembrolizumab has been seen to be effective at reducing tumour size and controlling symptoms, Patients are able to be independent as side effects are highly manageable and patients are able to engage in life, perform tasks and even work without caregiver assistance. This means that caregivers do not have to take time off work to care for their loved one or take them to treatments, thus minimizing the financial impact of the treatment. Patients are able to maintain a high level of functionality, and this positively impacts the mental health of patients and their families.

JG had always been very active throughout her life, played numerous different sports each week and worked out nearly every day. One day in April 2022, the sudden onset of severe back and chest pain brought her to the hospital as she thought she'd been having a heart attack, but instead, was shocked to hear she had lung cancer. She had no symptoms of the disease or any indication she'd been unwell, so when doctors initially thought the disease was localized, she had surgery to remove the tumour but were shocked to see she had numerous tiny lesions in her chest across both lungs, meaning she had stage 4 lung cancer and was positive for the EGFR Exon 20 mutation.

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JG started first-line treatment after surgery with pembrolizumab in combination with chemotherapy for 19 months from June 2022 to January 2024. She recalls that although constipation and nausea were the only consistent side effects during this treatment, it didn't stop her from being able to carry on with her activities of daily living, while also staying active and exercising nearly as often as she did prior to her diagnosis. JG says with pembrolizumab, she felt she was in this *"weird middle ground where I'd never felt 100% myself any day, but still strong enough to push it all down and carry on with my activities*". When she progressed at the beginning of 2024, she then started second-line amivantamab in February 2024, which she is still on currently. JG says that she has been "incredibly grateful" that her treatments like pembrolizumab have allowed her to maintain an excellent quality of life, and even continues to play tennis and pickleball each week throughout treatment.

TM was first diagnosed with lung cancer in the spring of 2016 at stage 1, which was successfully removed with surgery and remained disease-free for 3 years without active treatments, going back to work as a school superintendent. In May 2018 shortly after retiring, his routine scans showed there were now 11 new nodules in his lungs. He had a wedge resection which confirmed his disease had metastasized into both lungs and was now stage 4 NSCLC. Further biomarker testing showed he had a high PDL1 expression, so he started immunotherapy treatment with pembrolizumab in March 2021, which he was on formerly 3 years until the start of 2024.
TM recalls he had minimal side effects from pembrolizumab, all of which were manageable. He experienced some diarrhea, had sore muscles, felt tired, and his eczema, diabetes, and liver enzymes got worse. He had to see a dermatologist and endocrinologist to manage the liver and skin issues (and continues to do so today in mid-2024), but he says all the side effects were managed well and did not impede his ability to go about his day-to-day life. He even started an annual fundraising walk/run for lung cancer in the midst of treatment, which has been incredibly fulfilling for him and says he is grateful to have maintained a great quality of life thanks to pembrolizumab.

DH was diagnosed with stage 4 NSCLC in August 2017, and testing showed she had PDL-1 expression and KRAS mutation as well. She had 2 large brain tumours which were removed surgically and then treated with whole brain radiation, She was then treated with pembrolizumab in November, which was effective in shrinking the tumours, and DH remained on it for 3 years until being taken off in October 2020, as the tumours were considered inactive. Unfortunately, by December 2020, the tumours became active in the lymph nodes, abdominal area and chest, and she was put back on Keytruda on a double dose, which were successful again as some new tumours have disappeared and some others shrunk, and after just two months one of her tumours have shrunk from 3.5 to 1.1cm. She recalls minimal side effects from the therapy as well. DH says, "My healthcare team is happy with how Keytruda has worked for me. I hope it treats all my tumours and I never have to go on treatment again. I look forward to being told by my doctors that I am NED."

A few direct quotes taken from the online survey group include:

- "Even though my father developed colitis at 21 months of use, Keytruda saved his life. He was able to go back to work and do all the things he loved."
- "This is the only ongoing treatment that I have received. It seems to be working well with fairly manageable side effects."
- "This is easier than chemo but harder than targeted therapy."

Input gathered from the submission made in 2020, offered these insights:

CH was diagnosed with pleural mesothelioma in February 2020, following treatment for a deflated right lung. He was initially placed on chemotherapy, but when tests showed he would be a good candidate for immunotherapy

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he was switched to Nivolumab and Ipilimumab. He started in September and within two months his tumours had shrunk by 50%. He says this treatment has been a game-changer for him.

HO was diagnosed with pleural mesothelioma in 2016. Prior to his diagnosis, he was typically able to work 12 hrs a day, working on the house and in the yard but since diagnosis, after about 2 hours he would become very tired. His tumour had spread to the diaphragm, liver and heart (wrapped around his aorta), and was deemed too large to operate on. He was given 3 months to live.

His spouse called around to get him into different clinical trial sites, but no one would take him. A physician finally got him on a clinical trial. At 2.5 month after diagnosis, HO could barely dress himself, had lost about 50 pounds, could not drive and was unable to care for himself. He went from being able to work 12 hours a day to 2 hours a day in 8-10 months.

He was initially enrolled in a clinical trial for Keytruda and after 10 hours of being on the treatment he started feeling better. He said “I was alive. It was like a light switch had been flipped. I felt better and my appetite was back.” Two years after the trial it was discovered his tumor started growing again. Keytruda was tried again but did not work. He was then placed on nivolumab and ipilimumab and had been on that treatment for a year. His tumours were shrinking, his quality of life was much better, and his health was good.

7. Companion Diagnostic Test

N/A

8. Anything Else?

There is an unmet need for lung cancer therapies that will prolong progression-free survival and improve health-related quality of life for patients. Our patients consistently raise their quality of life as a critical consideration when balancing benefits and risks when they are working with their physicians to select their treatment options. Lung Health Foundation, Lung Cancer Canada and the Canadian Cancer Survivor Network all strongly urge the Canada Drug Agency to recognize the gap and barrier in adequate treatment options that are specific to these patients who deserve treatments that will work and increase the accessibility of these treatments for patients across Canada.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.
   No
2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.
   No

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3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have a direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Merck Canada (LHF)				X
Merck Canada (LCC)				X
Merck Canada (CCSN)				X

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Riley Sanders

Position: Senior Manager, Public Affairs

Patient Group: Lung Health Foundation (Legal name: Ontario Lung Association)

Date: December 6, 2024

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CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0387-000
Generic Drug Name (Brand Name): pembrolizumab (Keytruda)
Indication: pembrolizumab in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult and pediatric (12 years and older) patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM)
Name of Clinician Group: OH (CCO) Lung Cancer Drug Advisory Committee
Author of Submission: Dr. Donna Maziak and members of OH (CCO) Lung Cancer Drug Advisory Committee

1. About Your Clinician Group

OH(CCO)'s Drug Advisory Committees provide timely evidence-based clinical and health system guidance on drug-related issues in support of CCO's mandate, including the Provincial Drug Reimbursement Programs (PDRP) and the Systemic Treatment Program.

2. Information Gathering

Information was gathered by email.

3. Current Treatments and Treatment Goals

The immunotherapy combination of ipilimumab with nivolumab is the standard first line treatment based on the results of the checkmate 743 trial that compared first line treatment with ipilimumab and nivolumab to platinum pemetrexed chemotherapy in patients with unresectable MPM and demonstrated an improvement in median overall survival(OS) (18·1 months vs 14·1 months; hazard ratio(HR) 0·74 p=0·0020) and 2-year OS rates (41% vs. 27%) favoring the immunotherapy doublet.

Platinum pemetrexed chemotherapy remains the preferred treatment option in patients with contraindications to the immunotherapy doublet such as patients with active or suspected autoimmune disease or those on long-term immunosuppressive therapy.

Platinum pemetrexed chemotherapy in the first line setting is generally administered for 4-6 cycles. The immunotherapy combination in the first line setting is administered for up to 2 years or till disease progression or unacceptable toxicity.

The addition of bevacizumab to platinum pemetrexed chemotherapy improves survival in select patients, but its use has been limited by difficulty with access and toxicity concerns in this population.

Patients with poor PS who cannot tolerate doublet chemotherapy or immunotherapy treatment may be managed either with single agent chemotherapy or with best supportive care.

Current goals of treatment remain improving overall survival, progression free survival, improving responses rates to alleviate symptoms and improving quality of life.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

Despite the current treatment options available, median overall survival in patients with unresectable advanced MPM remains poor. Symptom burden and morbidity remain high, There is need for improved and better tolerated treatments. All patients eventually progress and die of their disease.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Pembrolizumab is an inhibitor of programmed cell death protein 1 (PD-1). In the three arm, randomized phase 2 portion of the IND227 trial, pembrolizumab in combination with platinum-pemetrexed improved response rates when compared to platinum pemetrexed chemotherapy alone (47% vs. 19%) and improved survival (19.8 months vs. 8.9 months) in this population. The phase 3 portion of this trial demonstrated a 21% reduction in the risk of death favoring the pembrolizumab arm. This benefit was evident in many of the a priori determined subgroups and was evident regardless of PD-L status. Despite a higher incidence of grade 3 or higher adverse events, there was no detrimental effect on the patient-reported quality of life and the tolerability of the pembrolizumab combination with platinum chemotherapy was noted to be similar that what waws observed in the treatment of advanced non-small-cell lung cancer.

Based on the results of this study, pembrolizumab would be used in combination with platinum and anti-folate chemotherapy doublet as a first line alternative to ipilimumab-nivolumab in the treatment of patients with advanced unresectable MPM. There is no direct comparative data between these two regimens, and so the decision will be based on patient and physician choice. The DAC also supports keeping platinum-based chemotherapy as a second line option given there is no clear superiority between pembrolizumab versus ipilimumab-nivolumab.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Adult patients with a diagnosis of MPM who are deemed unsuitable for surgery and have had no previous systemic therapy in the setting of unresectable advanced disease would be suitable for this treatment. Patients without untreated CNS metastases significant pneumonitis would also be well suited to receive this treatment. Patients with poor disease related performance status or those with uncontrolled autoimmune disease or who have significant contraindication to platinum or anti-folate chemotherapy would be least suitable for this treatment. Benefit was seen regardless of PD-L1 status and hence a companion diagnostic biomarker is not likely to identify patients who may preferentially benefit from treatment.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Patients would be assessed clinically and radiologically to ascertain whether they are benefiting from treatment. Clinical assessments to assess cancer-related symptom burden and tolerability of treatment would occur before each cycle of systemic treatment. Radiologic assessments using imaging modalities such as CT scans and/or chest Xrays would occur approximately every three months while on treatment. Clinically meaningful outcomes would include tumor responses (or stability) to help alleviate (or delay progression of) cancer related symptoms, improve quality of life, delay progression and improve overall survival

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Development of serious/unacceptable and/or life-threatening adverse events, unambiguous evidence of disease progression or completion of therapy would be factors that influence the decision to discontinue treatment with the drug.

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

This is an outpatient treatment to be administered under the supervision of a medical oncologist.

6. Additional Information

Pembrolizumab in combination with chemotherapy offers a clinically meaningful treatment option especially in patients with significant/symptomatic burden of disease who would benefit from improved tumor responses in this palliative treatment setting.

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

1. Did you receive help from outside your clinician group to complete this submission? If yes, please detail the help and who provided it.

   OH (CCO) provided a secretariat function to the group.

2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission? If yes, please detail the help and who provided it.

   No.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Dr. Donna Maziak
Position: Lead, OH (CCO) Lung Cancer Drug Advisory Committee
Date: 19-11-2024

☒ **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for Clinician 1

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Dr. Sara Kuruvilla
Position: Member, OH (CCO) Lung Cancer Drug Advisory Committee
Date: 15-November-2024

☒ **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 2: Conflict of Interest Declaration for Clinician 2

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Merck				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Dr. Peter Ellis
Position: Member, OH (CCO) Lung Cancer Drug Advisory Committee
Date: 18-11-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 3: Conflict of Interest Declaration for Clinician 3

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Merck	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: Dr. Andrew Robinson
Position: Member, OH (CCO) Lung Cancer Drug Advisory Committee
Date:

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
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* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: Dr. Stephanie Brule
Position: Member, OH (CCO) Lung Cancer Drug Advisory Committee
Date: 19-Nov-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 5: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
	$0 to $5,000	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Merck	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 6

Name: Dr. Mihaela Mates
Position: Member, OH (CCO) Lung Cancer Drug Advisory Committee
Date: 19-Nov-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 6: Conflict of Interest Declaration for Clinician 6

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Merck	x			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 7

Name: Dr. Michela Febbraro
Position: Member, OH (CCO) Lung Cancer Drug Advisory Committee
Date: 24-Nov-2024

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 7: Conflict of Interest Declaration for Clinician 7

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Merck	X			

* Place an X in the appropriate dollar range cells for each company.