

CADTH REIMBURSEMENT REVIEW

Patient Input

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

Indication: Malignant Pleural Mesothelioma (MPM)

CADTH received patient input from:

Lung Cancer Canada and Canadian Mesothelioma Foundation (Joint Submission)

November 19, 2020

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Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Nivolumab-ipilimumab (Opdivo-Yervoy) Opdivo, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma
Name of the Patient Group	Lung Cancer Canada
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	██
Telephone Number	██████████

1. About Your Patient Group

This submission is a joint collaboration from Lung Cancer Canada and the Canadian Mesothelioma foundation. Both organizations are registered with CADTH.

Lung Cancer Canada is a registered national charity and is the only organization in Canada focused exclusively on lung cancer. The Canadian Mesothelioma Foundation is a registered charity, dedicated to raising awareness and understanding about mesothelioma in Canada.

2. Information Gathering

- **Data collection:** This information was collected by conducting surveys, interviews and environmental scans. Surveys of mesothelioma patients and their caregivers were undertaken to glean insights into their experiences with currently available treatments. The thoughts and experiences from these collection methods have been included in this submission. The data was accessed October – November, 2020.
- **Demographic data:**
 - Malignant pleural mesothelioma is more common in older men with a blue-collar background.
 - Input was collected through interviews from 4 patients and 1 caregiver. An environmental scan provided input from one patient and one caregiver. Their thoughts and experiences are captured in the drug treatment section. See table below.

Gender	Age	Patient/Caregiver	Year of Diagnosis	Source of Input	Location	Type
Male	72	Patient (HO)	2016	Interview	USA	Pleural
Male	70	Patient (CH)	2020	Interview	USA	Pleural
Female	80	Patient (TA)	2017	Environ Scan	Online	Pleural
Male	48	Patient (AT)	2014	Interview	USA	Peritoneal
Male	78	Patient (JM)	2020	Interview	Canada	Pleural
Female	N/A	Caregiver (JM's daughter)	2020	Interview	Canada	Pleural
Female	41	Caregiver (DD)	2014	Environ Scan	Online	Pleural

- Demographics from the survey that was carried are below:

Patient survey demographics:

- 11 began the survey, 10 completed
- 45% from British Columbia, 18% from Ontario; remaining 37% split evenly between Alberta, New Brunswick, Newfoundland and Labrador, Saskatchewan
- Approximately half were greater than 65 years of age; 36% were 55-64 years of age; 18% were 45-54 years of age
- Nearly two-thirds were currently living with mesothelioma; one-third had been diagnosed with mesothelioma in the past and were currently cancer free
- 20% had been living with mesothelioma for less than a year, 40% had been living with it for 1-2 years, 30% had been living with it for 3-5 years, and 10% for more than 5 years
- 90% of respondents had been diagnosed with pleural mesothelioma, 10% with peritoneal mesothelioma
- 30% reported having metastatic or advanced disease, 40% reported that their disease was not metastatic or advanced, and 30% were not sure

Caregiver survey demographics:

- 43% were greater than 65 years of age; 4% were 55-64 years of age; 30% were 45-54 years of age; 22% were 35-44 years of age (total responses: 23)
- 48% were currently caring for someone living with mesothelioma; 52% had previously cared for someone living with mesothelioma (total responses: 23)
- 53% have or had spent less than a year providing care; 26% have or had spent 1-2 years providing care; 16% have or had spent 3-5 years providing care; and 5% have or had spent more than 5 years providing care (total responses: 19)

3. Disease Experience

In 2016, HO, a patient who was interviewed for this submission, was diagnosed with malignant pleural mesothelioma. He was told there was nothing that could be done for him and was given 3 months to live. Today, he is alive as a result of treatments that he says changed his life completely, because they not only worked but also have given him hope. It has been 4 years compared to the 3 months he was given to live.

Mesothelioma is a rare, aggressive and highly fatal cancer that starts in the cells of the mesothelium, the lining that protects the body's internal organs (Canadian Cancer Society, 2020; Canadian Mesothelioma Foundation, 2020). Mesothelioma of the pleural cavity (which surrounds the lungs) is the most common form, accounting for between 70% and 80% of reported cases. Mesothelioma of the peritoneal cavity (which surrounds the abdomen and pelvis) accounts for approximately 25% of reported cases. Mesothelioma is almost exclusively caused by exposure to asbestos.

The number of cases diagnosed each year in Canada has been steadily increasing for many decades (Demers, 2020). In 1992, there were approximately 175 new cases diagnosed in Canada (excluding Quebec¹), and in 2017, the most recent year available online, that number was 445 (Demers, 2020). Based on historical data showing that Quebec had approximately 32% of all Canadian cases, the number of newly diagnosed cases in Canada is more likely closer to 640 (Demers, 2020). However, because diagnosis of mesothelioma is often difficult², these numbers are likely an under-estimate of the actual number of diagnosed cases (Canadian Mesothelioma Foundation, 2020; Mesothelioma Applied Research Foundation, 2020).

¹ Quebec stopped submitting data to the Canadian Cancer Registry and to CANSIM in 2010.

² For example, pleural mesothelioma presents symptoms similar to lung cancer and peritoneal mesothelioma is often mistaken for other tumours that arise in the abdomen (e.g., bowel or liver cancer).

There is no cure for mesothelioma and because it is often not found until it is at an advanced stage, treatment options are limited (Canadian Cancer Society, 2020). Current treatment options include: surgery, chemotherapy, radiation therapy, or some combination thereof (Canadian Mesothelioma Foundation, 2020). Mesothelioma is one of the few cancers in which no consensus standard of care exists (Canadian Mesothelioma Foundation, 2020). Patients with stage 1 or 2 mesothelioma tend to be surgical candidates, while patients with stage 3 or 4 mesothelioma are generally offered chemotherapy in combination therapies (Mesothelioma Applied Research Foundation, 2020). Radiation is rarely offered as a primary treatment since it has little effect on its own (Mesothelioma Applied Research Foundation, 2020).

Because it is an aggressive disease and because it is often diagnosed at an advanced stage, mesothelioma is generally associated with a poor prognosis (Canadian Cancer Society, 2020). Survival varies with location, stage and particular cell subtype of mesothelioma. According to the Canadian Cancer Society, epithelioid mesotheliomas have a better prognosis than other cell subtypes; sarcomatoid mesotheliomas have the worst prognosis because this cell type spreads quickly and does not respond well to treatment (Canadian Cancer Society, 2020). The 5-year net survival for mesothelioma in Canada is 7% (Canadian Cancer Society, 2020). Although available treatments have had some impact on individual cases, there has been an overall lack of progress in successful treatment of mesothelioma. The findings of a recent Canadian study examining mesothelioma trends over a 25-year period found that survival has not appreciably improved over the past 25 years. In that study, median survival was approximately 8 months, with approximately 39% survival at 1 year, and 3-8% survival at 5 years³ (Demers, 2020).

A diagnosis of mesothelioma can be quite devastating. Not only is this an aggressive disease, it has a poor prognosis with no known cure, and there are limited treatment options. Many of the patients diagnosed were exposed to asbestos when simply performing their duties or carrying out their jobs as electricians, plumbers, builders in various sectors such as shipyards, factories and the construction industry, and in some cases washing the clothes of a loved one who worked in one of these industries. They built the homes we live in, and they mined the elements that helped build many economies. And now they are sick! With few available treatment options for this group of patients, there is an unmet need to provide treatments that work, prolong survival, delay progression while allowing patients have a good quality of life.

For most patients, the cost of treatment is covered by the workers' compensation system. However, for others who were unknowingly exposed to asbestos because they simply shared a house with an asbestos-exposed worker, the cost of treatment is covered by the public health care system. These patients are not entitled to benefits under the workers' compensation system because they were not workers at the time of their exposure.

Canadian patients especially those not covered by workers compensation cannot afford to wait and need these treatments now. They need treatments that work and give them the opportunity to spend time with loved ones, to continue working and to live longer.

CH, another patient who was interviewed, resides in the United States, was diagnosed February 2020. He was in the Vietnam war and also worked in the steel mills after leaving the army. The diagnosis was a huge shock and difficult for his family. For him, since starting nivolumab in combination with ipilimumab, it has been a game changer. In his words, "it is just a home run, and my hair didn't fall out."

Canadian patients too deserve treatment options that allow them to live and live well. Treatments that allow them to be independent and active, and less of a burden on their loved ones. Treatments that give them a good quality of life.

Nivolumab in combination with ipilimumab is a treatment option that has the potential to improve patient's outcomes, and should be considered for recommendation.

³ There was a geographic variation in mesothelioma rates and in survival across the country and within individual provinces.

4. Experiences With Currently Available Treatments

The current standard of care for the first line treatment of patients with malignant pleural mesothelioma (MPM) is chemotherapy.

Chemotherapy worked to treat the cancer

Chemotherapy is a well known form of treatment given via the intravenous route. The use of chemotherapy for the treatment of mesothelioma has helped patients alleviate symptoms such as chest pain and difficulty breathing. It also helps to shrink tumors, control tumor growth and prolong survival. This form of treatment can also be used in combination with surgery, radiation therapy or immunotherapy.

Unfortunately, patients subsequently progressed on this form of treatment. Take TA (enviro scan) who was diagnosed with MPM in 2017. She had 13 sessions of chemotherapy but progressed after the 12th session and was switched to immunotherapy. DD's dad (enviro scan) also progressed on chemotherapy after treatment for about a year.

AT, a patient who was interviewed for this submission, was diagnosed with peritoneal mesothelioma in 2014, had 3 months of chemotherapy prior to a successful HIPEC surgery but eventually progressed.

Chemotherapy is also known for its toxic side effects including extreme fatigue, nausea, vomiting, diarrhea and low blood count.

One survey respondent treated with chemotherapy complained of weight loss, loss of appetite, nausea, vomiting, and another respondent also experienced nausea and vomiting but also developed neutropenia. One patient developed sores in the mouth, extreme fatigue and weakness, was not able to be as functional and active as before and did not feel good. Another patient experienced fatigue and nausea for a few days after starting chemotherapy, Zofran helped and food tasted a bit bland but his taste buds improved with time.

Impact on Patients

Just over half the patients who completed the survey were working full-time outside the home at diagnosis; the remainder were either retired or had left the workforce prior to their diagnosis. Of the 5 patients who were working full-time, 3 reported they had often had to reduce the number of hours they worked because of their illness, while 2 reported they had quit their job. More than half of the respondents reported that their experience of mesothelioma had negatively impacted on their financial situation and nearly all reported that their experience of mesothelioma had been stressful (20% reported it was moderately stressful, 70% reported it was extremely stressful).

Ninety percent of patients responding to the survey reported that they had received some form of treatment. Radiation alone or in combination with other treatments was most frequently mentioned (n=7 patients), with nearly half of these (n=3) reporting that they had received a combination of radiation, chemotherapy and immunotherapy. The top three most difficult aspects of treatment reported by those who had received treatment were: the side effects of treatment (100% of respondents), the fear of the unknown⁴ (90% of respondents) and having to travel or commute to the hospital (44% of respondents). The most difficult side effects of treatment reported were fatigue or a lack of energy (67% of respondents), followed by pain (44% of respondents), breathing issues caused by or worsened by treatment (44% of respondents), nausea and vomiting (44% of respondents).

All patients reported that their mesothelioma had affected their quality of life.

- **Functionality:** 80% reported having reduced functionality that did not yet require assistance; the remaining 20% reported that they were not quite functional and required assistance.
- **Activity level:** 70% reported they were less active than before their diagnosis; 20% reported they can manage with some modifications; 10% reported they were now sedentary.
- **Independence:** 20% reported their mesothelioma had had a large effect on their independence and that they now required assistance; 70% reported their disease had had some effect (i.e.,

⁴ Examples included: will my mesothelioma respond to treatment? what side effects will I experience?

they were not as independent) but that they didn't yet require assistance; 10% reported no impact on their independence.

Impact on Caregivers

Nearly 60% of caregivers who completed the survey were working outside the home at the time their loved one was first diagnosed: 53% (n=10 respondents) were employed full-time and 5% (n=1 respondent) was employed part-time. The remainder were either not working outside of the home (n=3, 16%), were retired or had left the workforce prior to the diagnosis (n=5, 26%). Of the 11 caregivers who were working at the time of diagnosis, 7 reported they sometimes had to reduce the number of hours they worked because of their loved one's illness, while 4 reported they had quit their job. One caregiver told us *"The whole course of our lives changed from both of us being self-employed at home and gradually heading into retirement to suddenly stopping"*.

Nearly 80% of the caregivers who responded to the survey reported that caring for someone with mesothelioma had had an impact on their ability to perform their usual tasks. More than 60% reported they had less time to spend with friends (n=12, 67%) and/or less time to relax or spend time on their own (n=11, 61%). Ten respondents (56%) reported they had less time to participate in hobbies, less time to exercise or play sports, and/or less time to complete household chores and activities. Nearly 30% reported they were no longer able to work and 22% reported they had less time to spend with family.

When asked about the top three aspects of mesothelioma treatment that were the most difficult for them to manage, the most frequent response was 'managing the symptoms of mesothelioma' (n=13, 68%), followed by 'managing the side effects of treatment' (n=9, 47%). 'Frequent medical tests or blood work' and 'time away from work' tied for third with 7 responses (37%). The most difficult side effects of treatment reported were loss of appetite or weight loss (83% of respondents), followed by fatigue or a lack of energy (72% of respondents), and pain (50% of respondents). One caregiver told us *"It is early days yet so my spouse is dealing quite well with treatment and symptoms. My biggest challenge is the emotional toll of knowing that the treatment is not a cure and our time together is shortened"*.

Nearly 70% of the respondents reported that their experience of mesothelioma had negatively impacted on their financial situation and nearly all reported that their experience of mesothelioma had been stressful (26% reported it was somewhat stressful, 32% reported it was very stressful, and 42% reported it was extremely stressful). One woman told us *"Initially my husband was able to manage most of the risks, side effects, and travel requirements on his own. But as the tumor growth has increased, I have had step in and assist him. The emotional toll his disease has taken on myself and our children is immeasurable"*. Another caregiver who lost their father to mesothelioma shared this experience: *"It was horrible for all, but especially my dad who suffered greatly. Watching that was the absolute worst part of it"*.

5. Improved Outcomes

Improved outcomes for patients would include:

- Alleviate symptoms
- Prolonged survival
- A good quality of life
- Manageable side effects
- Durable treatment
- Delayed progression

6. Experience With Drug Under Review

The requested treatment is currently not available in Canada. The experiences gathered from patients and caregivers are detailed below.

Nivolumab and ipilimumab combination treatment worked to treat the cancer

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, he was switched to the requested treatment. He started in September, and since starting 2 months ago his tumors have shrunk by 50%. He says this treatment been a game changer for him.

AT was diagnosed with peritoneal mesothelioma in 2014. He initially received chemotherapy followed by surgery but eventually progressed. He was then enrolled in a clinical trial but progressed after 3 years. He was placed on the requested treatment in July, 2020. Since starting treatment, scans have shown significant tumour shrinkage.

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 hrs became very tired. His tumour had spread to the diaphragm, liver and his heart (wrapped around his aorta), and was deemed to large to operate, and he was given 3 months to live. He had worked as an electrical technician in a steel mill for about 31 years.

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 this point 2 ½ months 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 for 12 hrs to about 2 hrs in a matter of 8 to 10 months.

He was initially enrolled in a clinical trial for Keytruda. 10 hours after taking the treatment he started feeling better, he was feeling good, almost normal but still tired, but as 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 the tumor started growing again. Keytruda was tried again but this time it didn't work. He was then placed on nivolumab and ipilimumab combination treatment and has been on this treatment for about a year. His tumors are shrinking, his quality of life much better and his health is good.

Since then, he developed colon cancer about a year ago and same treatment has helped keep the colon cancer in check.

Improved Symptoms

HO had a cough and congestion, which has improved with the treatment. He has also gained weight and feels great. Another patient, CH experienced fatigue prior to his treatment and even on chemotherapy, but with nivolumab and ipilimumab, he says he has his energy back.

Functionality and Independence

For CH, the treatment has changed his life completely. "I see and feel improvements," he says. Prior to the treatment and while on chemotherapy he spent a lot of time napping or sitting in the chair watching TV. Since starting the treatment, he says it's as though there was nothing wrong with him. For him, it is unbelievable how the treatment has allowed him to feel.

On AT's previous treatment he had taken leave of absence from work as he was unable to work, but with the current treatment his is back to work.

When HO was initially diagnosed, his spouse had to drive him for his treatments. Currently, he is able to drive 400 miles to Chicago to get his treatment. He is able to get up to cut grass, and even helped his wife get xmas decorations from the attic, they are starting to decorate the house for the holidays, and he will be cooking for about 20 people for thanksgiving.

Patient input shows this form of treatment allows them to be functional, active and independent.

Side Effects

CH had to stop his treatment temporarily due to elevated liver enzymes. His enzymes are currently back to normal and he is back to the treatments with no dosage reductions. Apart from the effect on his liver enzymes, he has had no other side effects.

When AT was on chemotherapy, he experienced nausea and vomiting. He says his current treatment is much easier than chemotherapy and the side effects have been quite manageable though his energy levels are not as before. It should be noted that with his previous surgeries he developed severe side effects including total abdominal blockage and peripheral neuropathy.

For HO, side effects were minimal apart from his adrenal gland, which stopped working. He currently takes steroids to treat this.

7. Companion Diagnostic Test

A CT scan and biopsy are the gold standard diagnostic tests to confirm malignant pleural mesothelioma. These tests are available across the Canadian provinces.

8. Anything Else?

JM, a patient who was interviewed for this submission, was initially thought to have developed a heart condition, but upon further testing he was diagnosed with malignant pleural mesothelioma in October 2020. He has been told he is not a candidate for chemotherapy. The recommended treatment has been discussed as a possibility if they can get access to it, but unfortunately it is currently not available in Canada. Over 60 years ago, JM worked as an apprentice electrician and handled renovation jobs that involved older buildings with insulating heating systems taped with asbestos. Now he has been diagnosed with malignant pleural mesothelioma. This diagnosis was a surprise, his family was quite shocked, and for his daughter it was devastating news. His family like many others is worried and anxious, hoping for a treatment that would treat the cancer, extend his quality of life, allowing him to live his life as best he can, still able to be active and functional.

There haven't been many new treatment options for malignant pleural mesothelioma over the last few years. Options that can allow patients like JM live longer with a good quality of life are needed, as many of these patients do not have the time to wait due to the aggressiveness of the disease and late stage of diagnosis.

As noted above in Section 3 (Disease Experience), mesothelioma is almost exclusively caused by exposure to asbestos or related minerals. Because asbestos-related cancers have a long latency period, many of the mesotheliomas diagnosed today are the result of exposures that occurred 30 to 50 years ago (Kirkham, 2011; Occupational Cancer Research Centre, 2019). More than 80% of the mesothelioma cases diagnosed in Canada each year are caused by occupational or para-occupational exposure to asbestos; the remaining cases are likely due to environmental exposures. Para-occupational exposures are defined as those that occur as an indirect effect of work. Historically, women and children were indirectly exposed to asbestos in the home via the clothing of asbestos-exposed workers. Of the 430 mesotheliomas caused by workplace exposure to asbestos each year, approximately 20 are attributed to para-occupational exposure (Occupational Cancer Research Centre, 2019).

There is a well-established causal relationship between workplace exposure to asbestos and mesothelioma. As a result, mesothelioma is recognized as a compensable occupational disease in all jurisdictions in Canada. What this means is that under the provincial workers' compensation laws, a worker who is diagnosed with mesothelioma is eligible for benefits and services, which include compensation for lost wages, coverage of health care costs, support with rehabilitation, and a permanent disability award. Across Canada, the workers' compensation system, which is established by provincial legislation, has the mandate to oversee a no-fault insurance system for the workplace. This system is funded by premiums paid by employers. What this means is that once a worker's claim

for mesothelioma is accepted, the costs of treating mesothelioma are borne by the workers' compensation system and not by the public health care system. Therefore, if the system is working as it should (i.e., a worker with mesothelioma files a claim and that claim is accepted for compensation), the system should cover the costs of treating all mesothelioma cases in Canada that are caused by workplace exposure to asbestos. However, because the system only applies to workers and employers, it does not cover the costs of treating mesotheliomas that are caused by para-occupational or environmental exposures. These are covered by the public health care system.

Administrative records for workers' compensation boards across Canada indicate that mesothelioma continues to be the driver of occupational disease fatalities. In British Columbia, for example, mesothelioma accounted for 67% (or 723) of the 1,081 work-related deaths due to asbestos exposure that were accepted between 2000 and 2019. The Occupational Cancer Research Centre recently reported that the total annual cost to Canadian society of asbestos-related cancers (lung cancer and mesothelioma) in 2011 was 2.35 billion dollars (Tomba, 2017). The direct and indirect societal cost of mesothelioma was \$482 million, with an average cost of 1.13 million dollars, *per person diagnosed*. Approximately 152,000 Canadian workers are estimated to have continued exposure to asbestos. Therefore, the human toll of this disease – and the economic burden to society at large – is not likely to be diminished for some years to come.

Many of these patients have very little choice, they have been afflicted by a disease through no fault of their own and are quite sick, and many do not even know how they were exposed. Many patients do not realize they are covered and eligible for compensation because most of them are retired when they are diagnosed. Some are afflicted through secondary exposure and are not covered by workers compensation and therefore cannot access these treatments. Take for example, the child who hugs their dad when he gets back from work or the mother who launders her spouse's clothes after a day at work. They all deserve to have access to a drug that works, they all deserve to live, and live with a good quality of life.

Better protection on the job for workers currently exposed to asbestos is important, but right now there are patients who are really sick with this disease condition with no recourse in terms of viable treatment options. We ask that CADTH provide a positive recommendation for this combination treatment option.

References

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Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, 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.

Yes. Joint collaboration with the Canadian Mesothelioma Foundation

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.

Yes. Joint collaboration with the Canadian Mesothelioma Foundation

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

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Bristol Myers Squibb				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: Christina Sit
Position: Programs Manager
Patient Group: Lung Cancer Canada
Date: 18 November 2020

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Yes. Joint collaboration with Lung Cancer Canada

- 5. 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.

Yes, Joint collaboration with Lung Cancer Canada

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Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

No conflicts of interest to declare.

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: Eudice Goldberg, M.D. FRCPC
Position: Chair, Board of Directors, Canadian Mesothelioma Foundation
Patient Group: Canadian Mesothelioma Foundation
Date: November 18, 2020