

CADTH REIMBURSEMENT REVIEW

Patient Input

DURVALUMAB (Imfinzi)
(AstraZeneca Canada Inc.)

Indication: Extensive-Stage Small Cell Lung Cancer

CADTH received patient input from:

Lung Cancer Canada
Lung Health Foundation

December 24, 2020

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Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Durvalumab (Imfinzi) in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
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

Lung Cancer Canada is a registered national charity and is the only organization in Canada focused exclusively on lung cancer.

Lung Cancer Canada is registered with CADTH.

2. Information Gathering

- Data collection: The information was collected through environmental scans. The thoughts and experiences of the patients have been included in the submission. The information was accessed November – December 2020.
- Demographic data:
 - The requested treatment is currently not available in Canada. Input collected from environmental scans of patients and caregivers on currently available treatments is discussed in the treatment sections.
 - Small cell lung cancer (SCLC) is found to be more common in smokers and older adults.

Gender	Age	Patient/Caregiver	Source	Location
Female (TD)	54	Patient	Interview	Canada
Female (JB)	70	Patient	Environ Scan	Online
Female (DS)	67	Caregiver	Environ Scan	Online
Female (CH)	40	Caregiver	Environ Scan	Online
Male (SM)	N/A	Patient	Environ Scan	Online
Female (SC)	N/A	Caregiver	Environ Scan	Online
Female (AS)	N/A	Patient	Environ Scan	Online

3. Disease Experience

TD, a 54-year-old non-smoker was diagnosed in May 2020 with extensive small cell lung cancer (ES-SCLC), a disease typically seen in older adults with a history of smoking. She found out about a promising treatment, immunotherapy that could extend her life, but it was not publicly covered. She was unable to secure coverage for atezolizumab, the immunotherapy recommended to her and approved by Health Canada, as it is not covered in Canada.

Due to the cost of the treatment, TD was unable to afford the treatment. Her friends launched a GoFundMe page to raise funds to help and she was able to begin treatment with atezolizumab in combination with chemotherapy. Within a few weeks, a CT scan revealed that the tumours in her lungs and pelvis had reduced by nearly half, and the tumours in her breast and pancreas were gone. She could breathe much better too. TD went from needing a wheelchair before treatment to running nearly five kilometres. In fact, she even ran a marathon to raise money for cancer research in October 2020. The treatment gave TD hope. She says, “my son is 14, and even adding a few months to my life is worth fighting for as it could mean celebrating a birthday, or Christmas.” This form of treatment for SCLC is currently not approved in Canada.

Lung cancer is the most commonly diagnosed and leading killer of all cancers in Canada, accounting for 25% of all cancer deaths, and the 5-year survival rate is just 19% (Canadian Cancer Statistics, 2020), with lower rates for advanced cases. Small cell lung cancer (SCLC), which occurs in 15% of lung cancer cases is a more aggressive form of lung cancer, and is strongly associated with a history of smoking. SCLC has a median survival of 7 to 11 months with treatment, and is usually diagnosed in the later stages with a high tumour burden, with many patients highly symptomatic at diagnosis. This condition is seen mainly in the older population with the median age at diagnosis of 70 years.

A diagnosis of lung cancer can be quite devastating, leaving patients and their families worried about survival. A diagnosis of SCLC can add more worry especially with the poorer outcomes, current survival rates and very few treatment options, that patients like TD need to live longer and better. There is a huge unmet need for this group of patients. This type of cancer should not be confused with non-small cell lung cancer (NSCLC) which occurs in about 85% of cases and has more viable treatment options.

Unlike NSCLC, SCLC is a more aggressive disease with fewer treatment options, and the standard of care, which is chemotherapy, has not changed in the last 30 years. This puts this group of patients at a disadvantage especially considering how aggressive the disease is. These patients deserve a treatment that treats the cancer, improves symptoms, delays progression and gives them a good quality of life.

These patients are an underserved group that need new treatment options now. Treatments that give them hope, like TD to spend more time with her teenage son, hope for something new that can allow them live longer and spend time with loved ones.

With this in mind, it is crucial to consider the high unmet need in this group of patients. Though chemotherapy and immunotherapy represent the current standard for these patients, more viable options are needed. Patients already have a huge burden coping with their lung cancer diagnosis; the battle to survive this disease should be made easier by ensuring the availability of treatments that work.

The median survival for a patient with extensive small-cell lung cancer is less than one year. This needs to change. Durvalumab in combination with chemotherapy for the treatment of patients with SCLC is a treatment option that should be considered for this group of patients. This treatment option can provide patients with a better chance at survival and a chance at a better and longer life.

4. Experiences With Currently Available Treatments

Patient Experience with Current Therapy

The current therapy for extensive stage small cell lung cancer is chemotherapy or immunotherapy. Patient experiences with these two treatments have been summarized below.

Chemotherapy

4.1a. Chemotherapy worked to treat the cancer

Chemotherapy continues to be a viable form of treatment for this type of cancer. This treatment has been shown to work well in this group of patients resulting in improved symptoms and increasing patients' quality of life.

This form of treatment has helped patients like JB, who was diagnosed with SCLC in 2019. She was treated with chemotherapy and her first scan showed significant improvement and shrinkage of the tumour in her lungs and lymph nodes. A follow up scan also showed minimal shrinkage.

SCLC patients are known to respond well to this treatment, and while this form of treatment helps to shrink tumours and improves patient's symptoms, patients eventually progress or relapse.

Take DS's sister who was treated with 4 different types of chemotherapy. Unfortunately, the treatments stopped working.

4.1b. Side effects of chemotherapy

Chemotherapy has been a long-standing standard of care and is still a viable option for patients with lung cancer. It may be used as a single agent, as a double combination or in conjunction with immunotherapy or radiation therapy. The side effects are well known and documented. Some patient's experience minimal symptoms, while others report side effects consistent with those of those on chemotherapy such as nausea, vomiting and fatigue.

J experienced fatigue and irregular heart rates. CH's mom experienced nausea and weakness with chemotherapy. She also developed metallic taste in her mouth and had a hard time eating.

SM had 6 rounds of chemotherapy for SCLC and says with each round he felt progressively worse. He says, " I experienced tiredness, a feeling of general unwellness and some confusion thrown in for good measure! I'm not sure if I will ever feel normal again."

4.1c. Chemotherapy weakened patients' immune system

Chemotherapy can lower patient's immunity and in some cases, the treatment has wiped out patients white and red blood cells and may result in an inability to go out, return to work, have visitors and even spend quality time with family and loved one.

4.2. Immunotherapy

Immunotherapy is a form of treatment that has allowed many patients to hope for improved outcomes and has been shown to improve quality of life with more manageable side effects.

Many of the patients mentioned in the previous submissions said that they went from feeling quite sick before treatment, to feeling better within days of their first treatment up to their first few treatments. One patient had a severe cough and had also lost weight, after his treatment his cough slowly went away and it had allowed him to have a more normal family life. Since lung cancer patients, and SCLC patients in particular have a high symptom burden, this is an important aspect of this form of treatment.

Patients also reported side effects that were mild and easily managed. In a few cases there have been stronger side effects that had to be managed either by OTC or prescription drugs. Most found that the treatment was tolerable and did not interfere with day-to-day life.

It should be noted, no form of immunotherapy has currently been approved for SCLC patients in Canada.

4.3. Impact on Caregivers

A diagnosis of lung cancer and the subsequent treatment has a major impact on the life of the patient and their loved ones. Many caregivers are involved in the care, well-being and management of their loved ones, including helping them cope with the symptoms of the disease and the side effects of treatment. With certain treatments such as chemotherapy and immunotherapy, which are given via the intravenous routes, caregivers may have to take their loved ones for their treatments and care for them afterward. In some cases, caregivers may need to take time off work to provide this care, which could lead to a reduction in productivity and sometimes financial and even mental stress, which in turn could affect their ability to care for their loved one. The emotional and physical toll during and after treatment may affect caregivers' ability to fulfill their role in the family, at work and even to participate in activities they enjoy.

Chemotherapy and immunotherapy are given via the intravenous route. This form of dosage require patients to receive treatment in hospital, and may result in long stays at the hospital and also put a burden on their loved ones or caregivers who may have to take and stay with them during their treatment.

5. Improved Outcomes

LCC had difficulties sourcing for data from this group of patients. However, improved outcomes for patients would include:

- Control the cancer
- Improve symptoms and delay deterioration
- Manageable side effects
- Effective on the CNS
- Delay progression
- Extend survival with a good quality of life
- Provide longer lasting and durable treatment

All of these align with patients' values.

6. Experience With Drug Under Review

Due to a lack of patient data/input, LCC has been unable to include patient experience on the requested treatment. As mentioned earlier, the treatment is currently not available in Canada, and there were no Canadian trial sites for the requested treatment.

As part of the research for this submission, LCC also looked at the outcomes of SCLC patients on atezolizumab in combination with chemotherapy, a submission that was given a negative recommendation.

Here are some the experiences of SCLC patients treated with chemotherapy in combination with immunotherapy (atezolizumab). The input is to highlight patient experiences on the combination treatment, which may be similar to durvalumab, in combination with chemotherapy.

Treatment of patients with this combination has been shown to work and work well. This treatment was denied to Canadian patients who are really sick and need this treatment. These delays can result in patients deteriorating rapidly and even death. Extensive SCLC has a 2 year survival rate of <5%, and a 5-year survival of <2%, these are very poor numbers. There really is no reason to delay SCLC patient's access to this treatment.

SC's spouse was diagnosed with extensive SCLC in 2018 with multiple brain metastases and was treated with chemotherapy in combination with immunotherapy. He subsequently developed MAC disease, but was able to have surgery to remove it. He was given a year to live and as she says, " Here we are almost at two years. My husband is at 14 months, and I am grateful for everyday.

AS was diagnosed September 2019 with SCLC and was also placed on the combination treatment. Three follow-up scans have all been good. She did experience constipation with the treatment. She is currently on just immunotherapy and has not experienced any other side effects.

The input shows the patients like TD who went from needing a wheelchair before treatment to running a marathon, are doing well on this treatment.

7. Companion Diagnostic Test

Not applicable.

8. Anything Else?

Small cell lung cancer (SCLC) is not non-small cell cancer (NSCLC). SCLC is a more devastating disease with very few treatment options. In fact, treatment for SCLC has not changed in the last 30 years and this puts this group of patients at a huge disadvantage. There is a high-unmet need unlike NSCLC patients who have a larger range of treatment options available to them. This needs to change. With the current standard of care, which has helped many patients by improving the high symptom burden and improving their quality of life, many will still progress thus, new treatments that will give patients the opportunity to live longer are needed now.

The results of the phase 3 CASPIAN trial, which were presented at ASCO 2020, have shown an improvement in patient survival and overall response rate. The study, which had a long follow up, with mature data showed more participants were alive at the 2-year mark, this is huge improvement compared to the current form of treatment. 10% of patients on durvalumab in combination with chemotherapy had not progressed and remained on treatment at two years vs. 2.9% on chemotherapy alone. Durvalumab plus chemotherapy also showed a median OS of 13.0 months compared to 10.3 months in patients on chemotherapy alone. For many patients like TD, this allows them have better survival rates, and this is time they get to spend with their loved ones and make new memories.

pERC provided a negative recommendation for the submission for atezolizumab in combination with chemotherapy, also a phase 3 trial study, as it was unable to conclude there was a clinically meaningful benefit with the treatment compared to chemotherapy alone. That submission had a median follow-up of 13.9 months. The requested submission has a longer median follow-up of 25.1 months, with the data showing improvement in overall survival and response rates, as such LCC believes pERC can find that the treatment is not just clinically beneficial for these patients, it also addresses the unmet needs of this patient population, giving them not just a better quality but also quantity of life.

For this group of patients, this improvement is quite a significant achievement especially considering the known poorer outcomes. Due to the aggressive nature of the disease many patients on the current standard will eventually progress, but with the requested treatment, patients have a better chance at living longer, delaying deterioration in symptoms (this is particularly significant because many SCLC are highly symptomatic and ill due to the tumour burden) and delaying progression. A treatment that can provide significant symptom relief and increase patients' quantity of life is extremely important. For patients with such an aggressive cancer, who have been told they may have less than a year to live, those extra months are quite meaningful.

The treatment is also beneficial in treating CNS involvement, as this spares patients from receiving whole brain radiation, which comes with known cognitive side effects. It should be noted the trial results showed the treatment did not cause an increase in serious side effects, and this is also clinically meaningful.

In terms of cost, LCC understands that pERC may not deem this treatment economically beneficial, and that is why we would recommend allowing the treatment go to the negotiating table and let the manufacturer and PCPA determine an agreeable price for the treatment. CADTH can also provide a conditional recommendation for this treatment, and this can give patients access to the treatment while allowing the collection of RWE for this treatment.

For too long Canadians have been denied necessary treatments. SCLC patients in other countries have access to immunotherapy, and this is unfair. With immunotherapy approvals in other countries, LCC was able to source and document some of the patient experiences in the treatment sections, which showed these patients are alive and doing well on immunotherapy, and this helps provide RWE. The SCLC population is a very sick population and making them wait for treatments that have been shown to work does not align with patient's values.

Longer survival is possible with this treatment, and it is a chance that every SCLC patient deserves. They deserve a chance at a good quality of life, time to spend with loved ones, and to be able to maintain a new "normal". The standard of care for this group of patients has not changed in the last 30 years and another possible treatment option, atezolizumab, was recently not approved. SCLC is a highly aggressive cancer and these patients are an underserved group. We hope CADTH provides a positive recommendation for this treatment, this would give these patients hope, hope for something new, hope for a chance to live longer. This is a treatment that provides the potential for survivorship, and this is a chance that every SCLC patient deserves.

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.

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

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
Astra Zeneca				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: Program Manager

Patient Group: Lung Cancer Canada

Date: December 23, 2020

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Durvalumab / Imfinzi Extensive-stage small-cell Lung Cancer
Name of the Patient Group	Lung Health Foundation / The Ontario Lung Association
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

The Ontario Lung Association (newly named Lung Health Foundation) is registered with the CADTH and pCODR (www.lunghealth.ca).

The Lung Health Foundation (Ontario Lung Association) 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. The Foundation provides programs and services to patients and health-care providers, invests in lung research and advocates for improved policies on lung health. It is run by a board of directors and has approximately 35 employees, supported by thousands of dedicated volunteers.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered in **Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

The information provided from the Lung Health Foundation (Ontario Lung Association) in this submission was obtained from twelve on-line surveys completed by people living with Lung Cancer and one caregiver to a family member living with Lung Cancer (all online input was received in December 2020). A one-on-one phone interview with a 56 year old female living with lung cancer was also completed in December 2020 and contributed to this submission. All respondents live in Ontario. Information on age and gender was not collected within the online survey respondents. Input from a certified respiratory educator, whose role at the Lung Health Foundation includes answering the Lung Health Line and educating people living with lung disease, was also obtained for this submission. That individual reviewed sections related to disease experience, experiences with available treatments and outcomes.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

All 14 people responded to our questions focused on disease experience, and in order of significance, the symptoms and challenges that people experience as a result of their lung cancer are fatigue (62%), shortness of breath (62%), cough (29%), difficulty fighting infection (29%) and pain (21%). A few other responses included: chest tightness, reduced appetite, weight loss, anxiety and sadness.

When asked whether this condition affected their day-to-day life, respondents indicated that it did indeed impact greatly their ability to work (50%), do household work / chores (36%), play sports / exercise (36%), participate in hobbies and leisure activities (36%), and socialize (21%). A few other responses included: use stairs, cook / meal preparation, take day trips and be optimistic / positive about the future.

And when asked to respond to any negative impacts on their life overall as a result of living with lung cancer, their replies included; feeling isolated, experiencing poor emotional well-being, being short-tempered / impatient with others, feeling cold much of the time, waking up in the night or very early in the morning and diminishing meaningful relationships with friends.

Some direct patient quotes are:

- “My work was demanding and it would be too stressful to continue with an incurable diagnosis over my head.”
- “I am less than 95 lbs now and am easily fatigued.”
- “It takes longer to do everything – getting dressed, doing my personal hygiene, and completing ‘normal’ daily tasks.”

- “I drink Ensure twice daily to help with my nutrition and energy level.”
- “Exercise can be difficult for me and I am unable to lead an active or social life.”
- “This condition negatively effects my emotional and social life.”
- “I have a lot of anxiety and sadness now.”
- “I cannot walk quickly or long distances anymore.”
- “My social circle has all but disappeared.”

The female patient who was interviewed by phone indicated that it took far longer than she would have liked to receive an accurate diagnosis and develop a suitable course of treatment. She was first diagnosed with adult onset asthma and given inhalers to use. After no improvement, significant worsening of her symptoms, unsuccessful phone consultations with her family doctor, she took herself to the emergency department where she finally received the appropriate tests to reveal her lung cancer diagnosis.

She shared the experience was stressful and the uncertainty of “not knowing” during this time was “anxiety-producing.” “Family physicians should be more informed of possible signs and symptoms of lung cancer.” This patient was given little information about her condition and no community resources. She and her husband and two teenage daughters have researched themselves to find resources and supports to help them through this difficult time.

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

Treatments tried by those who completed the on-line survey as well as the phone interview include: Tagrisso, Gefitinib, Entrectnib, Anora Ellipta, Ventolin, Trelegy, Onbrez, Alvesco, Besylate, Amlodipine, Lyrica, Breo and one respondent indicated the use of Cannabis.

These treatment have some side effects such as: fatigue, low energy, diarrhea, nausea, appetite loss, weight loss, heart palpitations and face blistering / rash. Two other side effects noted by patients were headaches and difficulty sleeping.

Quality of life, reduction in symptoms, improved symptom management and improved energy were the top four things mentioned when asked about what the most important benefits were when considering a new medication or treatment for their lung cancer.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

Key treatment outcomes for this group of lung cancer patients include: stopping or slowing the progression of the disease, reducing pain, fatigue, and shortness of breath, and to improve appetite. All but one person mentioned a desire for more energy.

Quality of life, not just extension of life, was a theme that consistently emerged in the responses. More information about lung cancer that is readily available was mentioned as was more community based supports.

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

No patients within this evidence group submission has experience with the medication under review.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.

- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

Not applicable

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

Not applicable

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	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AstraZeneca				X

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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: Peter Glazier
Position: Executive Vice President
Patient Group: Lung Health Foundation / Ontario Lung Association
Date: December 21, 2020