

CADTH REIMBURSEMENT REVIEW

Patient Input

budesonide/ glycopyrronium / formoterol fumarate (TBC)
(AstraZeneca Canada Inc.)

Indication: chronic obstructive pulmonary disease (COPD)

CADTH received patient input from:

British Columbia Lung Groups
Chronic Obstructive Pulmonary Disease Association (COPD Canada)
Lung Health Foundation / The Ontario Lung Association

February 22, 2021

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

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

CADTH 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 patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

CADTH Reimbursement Review Patient Input Template

Name of the Drug and Indication	Budesonide/Glycopyrrolate/Formoterol
Name of the Patient Group	British Columbia Lung Groups
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

The Mission of the British Columbia Lung Association(BCLA) is to improve lung health and to lead lung health initiatives. Our Vision is healthy lungs for everyone. Our role is to improve respiratory health and overall quality of life through programs, education, research, training, treatment, advocacy and prevention of lung disease.

The BCLA is a major Canadian Charitable Organization with more than a century of experience and leadership in lung disease prevention, treatment and management. Today its areas of interest and expertise include the entire scope of respiratory diseases including COPD, asthma, lung cancer, sleep apnea, idiopathic pulmonary fibrosis, ILD, alpha1antyttripsin, and tuberculosis. We work together with the Canadian Thoracic Society, Canadian Lung Association, Lung Health Foundation and other partners to help the one in five Canadians who have breathing problems.

Our staff and volunteers, include our Board Members, health professionals and interested individuals and patients with a broad range of training & experience in lung disease and lung health, that enables our organization to develop and lead programs of education, and health promotion at the highest standard. The BCLA provides approximately \$1.2 million each year to internationally recognized physicians and scientist doing research in BC on lung diseases. All funding proposals go through a rigorous National Peer Review system so that the most promising research can be explored. The world class research is discovering the causes of lung diseases, finding new treatments and giving hope for a future free of lung disease.

February 21, 2021

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.

Telephone interview from BCLA group members who were on the Triple therapy prescribed by their own Respiriologist, there were 5 patients & five caregivers

2. 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?

Patients were interested in the timely access for the diagnosis and assessment of their COPD, they are interested to understand what having COPD means for them and how the disease may progress, they are interested and deserve access to the best available evidenced-based, personalized treatment, to ensure that they can live as well as long as possible, they want an urgent review of the current management plan when they experience "exacerbation," flare –up to prevent further exacerbations and disease getting worse or progressing, and they are asking to be able to freely live with COPD while maximising quality of life without stigma or guilt.

COPD is the third leading cause of death worldwide, there are 2 million diagnosed with COPD in Canada. The majority of COPD cost are attributed to exacerbations(flare-up) Symptoms are dyspnea, cough, wheeze and a lot of sputum by volume & purulence. The GOLD report defines a COPD exacerbation as an "acute worsening of respiratory symptoms that requires additional therapy. Exacerbations negatively impact patient quality of life.

3. Experiences With Currently Available Treatments

Patients who have mild symptoms are on SABA,(short acting beta agonist)or SAMA, for moderate symptoms, they are on SABA or SAMA and antibiotics and or OCS(oral corticosteroid), for severe,

Hospitalization or ER visit, maybe associated with acute respiratory failure. Patients would have been on these medications for quite a long time and their symptoms continue.

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).

4. 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?

When they were put on the Triple therapy medications, symptoms disappear, thereby patients were able to do the things or activities that they were not able to do such walking in the park without being breathless, doing household chores and with that they are able to have a much improved quality of life

5. 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.

Patients, were able to access the medication by private insurance, and some paid from their own savings. The improvement of their symptoms were significant, , it decreased the number of severe COPD flare-ups that resulted in less number of hospital or ER visits. It provided patients with better quality of life for them, it also increased greater FEV1(breathing test results)lung improvements, it also eliminated their risk of side-effects such as pneumonia. Pharmacotherapy plays a role in the management of COPD

6. 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.

Our patients did not have any problems with the testing, travel to the central clinics and they were able to access the Lung Health team, the clinic without difficulty.

They found that delaying the maintenance therapy were associated with an increase future exacerbation risk the following year.

The choice of inhaler device was important and significant for COPD patients, it has been shown that the medication reached both the large & small airways, the triple therapy medication was delivered by a

device called [REDACTED] this device enabled the inhaler to achieve improved stability and homogeneity vs drug crystal only suspensions. It was easy for the patients to use with their own spacers.

7. Anything Else?

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

Please make it available for COPD patients as another choice or as an added medication to prevent future COPD exacerbations.

The Lung Association believes that patients must be empowered to live freely with COPD without symptoms, and exacerbations, reducing their interaction with hospitals and extending their life and improving their Quality of Life!

Thank you very much for your kind considerations

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

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.

GSK, \$50, 000 For our Health Initiatives Sanofi, \$ 8,000 for Influenza Campaign Novartis, \$15,000 Asthma Education Boehringer-Ingelheim, \$5,000 Patient Education	AsthmaCheck Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
No money received for this drug under review				

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: Kelly Ablog marrant
 Position: Vice President, Advocacy & Partnerships
 Patient Group: British Columbia Lung Groups
 Date: February 21, 2021

CADTH Reimbursement Review Patient Input Template

Name of the Drug and Indication	Budesonide/glycopyrronium/formoterol fumarate ██████████ Chronic Obstructive Pulmonary Disease (COPD)
Name of the Patient Group	Chronic Obstructive Pulmonary Disease Association (COPD Canada)
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	████████████████████
Telephone Number	██████████

1. About Your Patient Group

COPD Canada is an independently registered non-profit association that was established in 2005. The association’s primary mandate is to inform, educate and support Canadians who live with the burden of Chronic Obstructive Pulmonary Disease (COPD).

At its core, COPD Canada is an educational association and patient advocacy group. The organization is involved in providing patient education materials and services, in a variety of formats, using different delivery methodologies. We also develop, sponsor and produce quality-of-life seminars for patients and their families. COPD Canada strives to heighten visibility and awareness of COPD to the Canadian public. The group advocates for an expanded use of diagnostic testing for all Canadians who currently smoke or have smoked.

With a focus on emphysema and chronic bronchitis COPD Canada reviews and interprets the latest scientific and medical advances from worldwide sources. This information is then made available in easy-to-understand language to our members through our newsletter “Living with COPD”. All published information is archived and available through the COPD Canada website.

Membership in COPD Canada is free-of-charge but is restricted to COPD patients and their caregivers. Individuals can join through our website www.copdcanada.info Members are invited to participate in all COPD Canada events. They also receive complimentary copies of our bi-annual newsletter, “Living with COPD”. Members are invited to add their pulmonary rehab clinic to our complimentary list to receive bulk copies of the newsletter, for distribution to attending patients.

2. Information Gathering

For the purposes of illustrating the condition-related symptoms and problems that impact COPD patients' day-to-day activities and quality of life, we are relying primarily on the personal experiences of our members and published scientific papers related to the disease. The experiences that are described are common to most of our members and much of the Canadian population who suffer from chronic obstructive pulmonary disease. Additionally, we have extensive interactions with many other COPD patients. These interactions and conversations occur in group pulmonary rehabilitation settings, lung issue support groups, as well as in direct one-on-one consultations. The common experience of COPD sufferers will be reflected in much of the information presented in this submission.

In January 2021, COPD Canada sent an e-mail survey to an nth name group of members from our national membership database and received written responses from sixty-four (64) members. None of the respondents have had experience with this specific drug combination. The survey explicitly stated that [REDACTED], manufactured by AstraZeneca was the new drug combination under review by CADTH. We have used relevant quotes from our members and have included sex, age, province, and year of COPD diagnosis - if that information was provided by the respondent.

3. Disease Experience

“Stairs are difficult. Have difficulty breathing when exerting myself on treadmill, walking, etc. Breathe better at night if I sit upright. Less energy. Exasperations are increasing.” Female, 68, Alberta, diagnosed October 2019

With worsening disease, a COPD patient will progressively become less physically active and will have reduced social contacts. COPD is associated with a considerable burden of disease, affecting many things that are fundamental to everyday life, such as the ability to breath, talk, sleep, work, and socialize. COPD also has significant extra-pulmonary effects that may contribute to its severity in individual patients.

It has been demonstrated that reduced physical activity in patients with COPD is associated not only with clinical stages of COPD severity but also with systemic inflammation and heart dysfunction. Patients with COPD have limitations in their occupational activities as well as in household and leisure time activities. Many patients with COPD are of working age, so even in the early stages of the disease, the breathlessness and fatigue caused by COPD reduces the ability of the patient to go to work or carry out their normal work activities.

Studies have demonstrated that exacerbations are associated with short and long-term consequences on health status. The downward spiral of more frequent exacerbations leads to decline in lung function; greater anxiety; worsening quality of life; social withdrawal; more exacerbations; and increased risk of hospitalization and mortality. ¹

As symptoms worsen, one is usually forced to take early retirement. COPD has an increasingly profound effect on all aspects of one's life, severely impeding the ability to do even the most basic daily tasks, limiting social interactions and causing depression. In addition to the social stigma and isolation that COPD causes, the disease forces one to adapt their lifestyles dramatically. A typical week for a COPD patient consists of reading, spending most of their time indoors, with infrequent outings to attend pulmonary rehabilitation classes. Those classes and personal interactions with other patients have been cancelled due to the COVID-19 pandemic, increasing the isolation of people struggling with chronic obstructive pulmonary disease.

Many of the day-to-day activities most take for granted are virtually impossible or extremely difficult for people with severe COPD. These activities include:

- Changing bed sheets
- Bathing and dressing
- Shopping and carrying bags/groceries
- Climbing stairs
- Walking at a very slow pace and talking at the same time.

While being forced to adapt one's lifestyle in many ways:

- Avoiding restaurants that have stairs or washrooms that are not located on the ground floor.
- Using supplemental oxygen when walking, on an aircraft or during pulmonary rehab (when those activities were available)
- Being extra vigilant of weather conditions to assess wind conditions, humidity and temperature before venturing outside
- Avoiding any exertion outdoors particularly during cold weather or hot humid weather

“It has seriously slowed activity including ruling out some of my favorites such as, hiking, walking in the woods, climbing hills, keeping up with anyone even on flat ground and I am totally unable to walk up hills. Sexual activity is very impacted. Can't do even simple jobs around the home such as mowing the grass, lifting things or even carrying groceries and other items. The deterioration is so fast that now I could never do the renovation work I did on my house only eight years ago.”
Male, 75, British Columbia

4. Experiences With Currently Available Treatments

“Have used Spiriva and Advair. Got thrush in my mouth a couple of times. Advair leaves too much powder behind inside my mouth and I wonder if any meds even get to my lungs. Trelegy does the same. They both seem to waste a lot of the medicine. Spiriva dispenser is much easier to use and its design seems to target the back of my mouth and throat much better.” Male, 71, Ontario

There is no cure for COPD, and there are no medications that reverse the loss of lung function caused by COPD. No drug has demonstrated effectiveness in halting the progression of the disease. Currently the goal of medications for COPD is to maintain control of symptoms and prevent or minimize the frequency and duration of exacerbations (which can also be referred to as flare-ups or lung attacks).

As the disease progresses, medications are typically added on. Existing COPD management relies on medicines to open the airways and reduce inflammation. The main non-medicinal interventions include pulmonary rehabilitation exercises including breathing lessons and the use of supplemental oxygen. Surgical options include lung transplantation or lung reduction surgery, which are extremely invasive procedures that are only available to a small group of COPD patients who qualify as candidates.

Typical maintenance therapy usually includes the use of Spiriva once per day with Advair or Symbicort twice per day. Rescue medications vary from patient to patient although Ventolin is used quite extensively. These medications are to control the symptoms, but they do not improve long-term lung function. When one experiences an exacerbation Prednisone and antibiotics are often prescribed. Prednisone works quickly but has very dangerous side effects. The over-use of antibiotics (particularly in long-term care facilities) has become a national and international concern due to increasing antibiotic resistance. 2

5. Improved Outcomes

“Spiriva was great but for the memory loss noted. After I stopped Spiriva my short-term memory improved. Better quality of life generally would be good. The ability to exercise more, fewer hospital visits. Lives are improved when people can accomplish activities they’ve done in previous years, like maintaining their own home, doing housework etc.” Female, 73, Ontario

COPD patients need additional therapies that work to improve breathing and lung function, are easy to use, and do not just offer symptomatic or emergency relief. Because chronic obstructive pulmonary disease is treated in a stepwise manner, where treatments are layered on as the disease progresses, additional treatment options are often needed to address continual disease progression, particularly as the disease progresses in severity. As well, long term use of some of these compounds results in a diminishing of the drug’s effectiveness. Therefore, availability to alternative but equivalent drugs should be encouraged and supported.

Our association is cognizant of access issues throughout Canada, particularly for economically disadvantaged patients and those completely reliant on provincial drug plans. The reimbursement of approved medicines for the treatment of COPD varies dramatically by province. In Alberta, there is generally favourable access to treatments for patients reliant on the provincial drug plan. However, in Atlantic Canada there is generally poor drug access and in Ontario there is moderate coverage of approved COPD drugs. Most of our members are over 65 years of age and for many it is a financial imperative that COPD medications be covered by provincial drug plans.

██████████ would be a welcome addition to provincial formularies across the country. The ease-of-use of this triple therapy should increase compliance. And, the effectiveness of the ██████████ pressurized metered-dose inhaler would ensure that this triple drug combination is reaching the lungs without relying on a COPD patient’s ability or strength to properly inhale. 3

“I need the Symbicort but it doesn’t work like it used to. I’m not sure if the Incruse is working. I need a rescue inhaler because Ventolin doesn’t work for me but the doctor (pulmonologist) gave me nothing to replace it. I really do need something if I have a breathing attack.” Female, 70, Ontario

6. Experience With Drug Under Review

COPD Canada members surveyed have no experience with the drug under review.

7. Companion Diagnostic Test

COPD Canada members have no diagnostic testing experience with the drug under review.

8. Additional information – Comments

“I can barely do anything, walking, housecleaning, cooking, bathing. Everything takes my breath away. I take Ventolin, Spiriva, Advair. When needed for flareup, prednisone, antibiotics.” Female, 69, Quebec, diagnosed in 2010

Caregivers of COPD patients are impacted to a significant extent and are frequently the spouse or child of the patient. The disease causes serious age-related difficulties, and this is especially true with COPD which is more prevalent and pronounced in older Canadians. While each caregiver certainly has their own unique experiences and challenges, family caregivers frequently encounter the following burdens:

- limited time for managing their own health and wellbeing
- feelings of depression and isolation
- anxiety, stress, fatigue, unending days
- increased requirements for social support
- in the case of grown children who become their parent’s caregivers, they are often torn between the needs of their young families and the needs of their elderly parent with COPD.

Despite the availability of national and international guidelines, and effective, well-tolerated pharmacological treatments, COPD remains substantially under-diagnosed and under-treated within primary care. **4** Increasing evidence suggests that initiation of anti-inflammatory agents and long-acting bronchodilators at an early stage can significantly improve the patient’s long-term health and quality of life. Recent large-scale trials in COPD have confirmed the long-term benefits of the early initiation of maintenance treatments.

Although there are medications for COPD, patients still complain of symptoms. This brings forth the need for alternative bronchodilators and anti-inflammatory agents that can improve lung function, quality of life, reduce exacerbations and delay disease progression. And, over the long term, improve survival. **5**

It seems apparent to us that any new therapy to manage chronic obstructive pulmonary disease, like XXXXXXXXXX, that encourages compliance by being simpler to use with three medications in one dosage while decelerating or limiting the need for rescue inhalers is worthwhile.

The benefits to society and the healthcare system of this combination therapy accrue through fewer exacerbations resulting in less use of emergency department services while improving a patient’s quality of life. The costs associated with COPD affect the family, the healthcare system, and the community as a whole with loss of productivity and the need for additional healthcare services. **6**

As a national patient advocacy group, we encourage and support additional therapeutic choices in managing this debilitating condition.

“Breo, spiriva, alvesco, combivent, ventolin, as needed. Prednisone when required. Headaches, fast heart rate, when on prednisone faster heart rate, blood pressure elevated, lack of sleep, long term side effect of water retention. Fewer hospital visits. Less prednisone use and hospital visits. Decrease symptoms so we can function better on a daily basis.” Female 72, Manitoba

1 Activities of Life - The COPD Patient

Journal of COPD, 6:192-200 ISSN: 1541-2555 print / 1541-2563 online

2 Prevalence of multidrug-resistant gram-negative bacteria among nursing home residents: A systematic review and meta-analysis Sainfer Aliyu, Arlene Smaldone, Elaine Larson

American Journal of Infection Control, Vol. 45, Issue 5, p512–518 Published in issue: May 01, 2017

3 Consistent Pulmonary Drug Delivery with Whole Lung Deposition Using the Aerosphere Inhaler:

A Review of the Evidence <https://doi.org/10.2147/COPD.S274846>

4 Epidemiology and burden of COPD – CTS position statement Pharmacology in patients with COPD

Canadian Journal of Respiratory, Critical Care, and Sleep Medicine – 2017, VOL 1, NO. 4, 222-241

5 Optimising pharmacological maintenance treatment for COPD in primary care

Prim Care Respir J 2011; 21(1): 33-45

6 Public Health Agency of Canada. Centre for Chronic Disease Prevention and Control Chronic Respiratory Diseases. COPD. http://www.phac-aspc.gc.ca/ccdpc-cpcmc/crd-mrc/copd_e.htm

9. Appendix: Patient Group Conflict of Interest Declaration

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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**
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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
AstraZeneca Canada			X	
Boehringer Ingelheim Canada			X	
GlaxoSmithKline Canada			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: Henry Roberts

Position: Member – Executive Committee

Patient Group: Chronic Obstructive Pulmonary Disease Association (COPD Canada)

Date: February 17, 2021

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	budesonide/ glycopyrronium/ formoterol fumarate Chronic Obstructive Pulmonary Disease (COPD)
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 57 on-line surveys completed by people living with COPD (39), Emphysema (12), Chronic Bronchitis (2), and Bronchiectasis (4) as well as 18 caregivers to a family member living with COPD. (All online input was received in December 2020.) Two phone interviews with female patients living with COPD were also completed in January 2021 and contributed to this submission. All respondents live in Ontario. Information on age and gender was not collected within these 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 59 patients 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 COPD are shortness of breath (70%), fatigue (60%), cough (43%), chest tightness (33%), excessive mucus (30%), wheezing (28%) and difficulty fighting infection (25%). A few other responses included: reduced appetite, weight loss, pain and nausea.

When asked whether this condition affected their day-to-day life, respondents indicated that it did indeed impact greatly their ability to be physically active / exercise (44%), use stairs (42%), do housework (38%), work (33%), travel (24%) and participate in hobbies and leisure activities (24%). A few other responses included: cook / meal preparation, shopping, self-care and personal hygiene and taking day trips.

And when asked to respond to any negative impacts on their life overall as a result of living with lung disease, their replies included; being unable to do daily activities because of shortness of breath and fatigue, experiencing poor emotional well-being, feeling isolated, managing symptoms, being short-tempered / impatient with others, financial cost burden, feeling cold much of the time, waking up in the night or very early in the morning and diminishing meaningful relationships with friends.

Both patients who were interviewed on the phone identified anxiety, mild depression from time to time and some sense of "loss of self-worth" as a result of their COPD and inability to do the things they used to be able to do. They also indicated more difficulty fighting infections and that exacerbations seem to lead to worsening of lung

function. Tasks like taking out the recycling, getting the mail or walking upstairs causes shortness of breath and fatigue. Carrying groceries into the house must be done in several trips with resting periods in between. All day to day tasks take much longer.

Some direct patient quotes are:

- “I need to take frequent rests to regain my breath, many heavier jobs I can no longer do, such as vacuuming.”
- “It makes it very hard to do day to day activities such as house cleaning, cooking or exercising.”
- “I am unable to do things like I used to do, such as: gardening, cooking or housework. Physical exertion causes my breathing to get worse.”
- “It feels like my independence is slipping away.”

The aspects of the condition that are most important to control to patients are shortness of breath, coughing and fatigue – they all clearly indicate they would like these symptoms reduced. Caregivers identified these same three things as the most important aspects of COPD to be managed and controlled for their loved one. Caregivers also identified increased energy and an increased ability to fight infections as being important.

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 interviewed included: Spiriva, Advair, Symbicort, Daxas, Prednisone, Ventolin, Atrovent, Serevent, Seebri, Onbrez, Alvesco, Trelegy, Singulair, and Zenhale.

Current treatments do provide some relief for: fatigue, shortness of breath, cough, low energy, and the inability to fight infection, but clearly patients want to experience greater assistance with managing these symptoms. The side effects indicated from using the above-mentioned drugs include: voice hoarseness, dry mouth, mouth sores, difficulty sleeping, nausea, heart palpitations, and impact on mood. One patient stated: “it is difficult to tell which medication is responsible for what when you take multiple ones.”

Choice, ease of use and dosage were three themes that came through clearly in the respondents and caregivers responses when speaking about treatment. 40% of the respondents indicated they were living with other chronic health conditions. These co-morbidities result in additional medications, so greater choice in treatment options and in dosing are important for these patients. One patient interviewed on the phone indicated that her arthritis made it difficult to use some inhaled medications because of the strength and dexterity required, so “ease of use” was high on her priority list.

Fewer medical appointments was also mentioned several times as these require time to travel and changes to their daily routine. There is also a wish for less cost burden as many medications are not covered by the patients’ drug plan.

Overall, patients would like their treatments to provide enough help that they will experience improved independence and require less assistance from others. It is worth noting that exercise was mentioned several times in this survey as a “therapy” being used by patients to help manage their COPD.

Caregivers of those living with COPD experience many of the same negative impacts on their lives. They too indicate that caring for people with COPD has affected their work, their relationships with family and friends, and their physical and leisure activities. As well, their independence and the ability to travel and socialize were impacted. Having to take time off work to drive those they are caring for to get groceries, run errands or make medical appointments was cited as problematic for caregivers.

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 of COPD that patients and their caregivers would most like addressed are: improved quality of life (74%), reduction in symptoms (74%), improved symptom management (47%), improved energy (39%), reduced cost (17%). They would like an increased ability to fight infections and have to a higher energy level. Ideally, patients would experience an improved quality of life, improved lung function and reduced hospital admissions.

Patients indicated that they would be able to live with some side effects, but nothing worse than what they are already experiencing and nothing that was irreversible. One patient said: “most side effects would be bearable if I could just breathe a bit better and could wake up with enough energy to get through the day.”

Patients do not want to travel to a health-care setting to receive new treatments. They do not want to have to make additional changes to daily routines for themselves

or their caregivers and do not want anyone to have to take time off work to accommodate treatments. Patients want to improve enough so that they would be less of a burden to their family.

Finally, patients would like there to be less or no cost burden associated with new treatments.

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

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 – not applicable

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 – not applicable

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
AstraZeneca				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: Peter Glazier

Position: Executive Vice President

Patient Group: Lung Health Foundation / Ontario Lung Association

Date: February 22, 2021