CADTH

CADTH COMMON DRUG REVIEW

Patient Input

indacaterol/glycopyrronium bromide/mometasone furoate (TBC)
Novartis Pharmaceuticals Canada Inc.
Indication: Asthma maintenance, adults

CADTH received patient input from:

Asthma Canada

Lung Health Foundation

May 21, 2020

CADTH

Patient Input for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Indacaterol acetate/glycopyrronium bromide/mometasone furoate
Name of the Patient Group	Asthma Canada
Author of the Submission	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

About Our Patient Group

Asthma Canada is a registered charitable organization. Our vision is a world without asthma, and our mission is to help Canadians with asthma lead healthy lives through education, advocacy and research. Based in Toronto, Ontario, we operate under the direction of a volunteer Board of Directors and provide programs and services to people living with asthma and their caregivers through our website, e-newsletters, social media channels, and the Asthma & Allergy HelpLine. We also support the Asthma Canada Member Alliance, Asthma Canada's grassroots group providing asthma support to people with lived experience. The Asthma Canada Member Alliance reaches more than 7000 people living with asthma and allergies, caregivers, healthcare providers, and other interested participants from all regions of Canada.

Information Gathering

The majority of the patient impact information gathered in this section was from a study conducted by Asthma Canada (formerly the Asthma Society of Canada) in 2014, entitled "Severe Asthma: The Canadian Patient Journey." This study included Canadian adults 18 years or older who live with Severe Asthma as defined by their symptoms, their level of asthma control, and a review of their clinical profiles by a team of expert advisors. A total of 24 patients participated in in-depth personal interviews about their condition and its impact on their personal, social, medical, and economic circumstances. A complimentary online quantitative survey of 200 individuals with Severe Asthma accompanied the data from the interviews to validate and quantitate the in-person findings. Further details of the study population, investigators, and process are available on pages 28 to 31 of the full report.

In addition to the information gathered from the Severe Asthma report from 2014, Asthma Canada also conducted a survey to hear directly from patients about the impact that the triple-therapy drug, Indacaterol acetate/glycopyrronium bromide/mometasone furoate, would have on them. We also asked questions about a new Dry Powdered Inhaler device, the Breezehaler®. Asthma Canada conducted an online survey via our Asthma Canada Member Alliance from Monday, April 27, 2020, to Friday, May 8, 2020. Data gathered from Canada.

The survey received 192 responses. The demographics of the respondents were as follows:

- 171 respondents were people living with asthma, 21 were caregivers;
- 165 respondents were female, 26 male, 1 transgender person;
- 96 of the respondents were from Ontario, 28 from British Columbia, 25 from Alberta, 13 from Quebec, 7 from Nova Scotia, 6 from Manitoba, 6 from Saskatchewan, 5 from New Brunswick, 3 from Newfoundland and Labrador, and 1 from Yukon. Two of the respondents were from outside of Canada. North West Territories, Nunavut, and Prince Edward Island had no respondents.

Disease Experience

Asthma is a chronic disease characterized by inflammation in the airways. Symptoms of asthma include wheezing, coughing, shortness of breath, and a sensation of tightness in the chest. Asthma symptoms can occur in both a chronic manner and also as a more sudden, severe attack, known as an exacerbation. A variety of allergic and non-allergic causes can cause these exacerbations. Data from The Government of Canada show that more than 3.8 million Canadians live with some degree of asthma, with upwards of 250,000 of these people living with Severe Asthma (PHAC, 2018).

The most recent international guidelines recommend classifying patients' asthma as severe if still uncontrolled despite optimal use of long-term controller and short-acting reliever medications (Holguin, 2020). According to the Global Initiative for Asthma (GINA), asthma is considered "uncontrolled" if, during the past four weeks, the patient has experienced **at least three** of the following (GINA, 2019):

- Daytime asthma symptoms more than twice per week
- Any nighttime waking due to asthma
- Reliever medication needed more than twice per week
- Any activity limitation due to asthma

Impact of Severe Asthma on People

Severe Asthma has many different effects and consequences that can impair patients' quality of life. In Asthma Canada's most recent patient journey study, respondents identified several crucial areas where asthma had a significant impact (Severe Asthma, 2014):

- **Physical activity**: Over 70% of survey respondents reported limitations to daily activities and exercise due to their asthma, even though 89% agreed that, ideally, asthma should not be a reason for avoiding physical exertion;
- **Social interactions**: Almost 2/3 of respondents said that they have felt stigmatized because of their asthma at some point, and that asthma interferes with their social activities and interactions with others;
- **Work/school productivity**: More than half of respondents mentioned that asthma had affected their attendance or performance at work or school, with about 40% of people saying it affected them "a great deal."
    - About 30% of respondents mentioned that asthma had caused them to miss days of work or school in the previous year; of these, about 2/3 missed 5 days or more, and about 1/3 reported missing more than 10 days
- **Emergency room visits and hospitalization**: About half of the respondents had needed to visit an emergency room in the previous year because of asthma symptoms. One-third went more than once during this period, and one in five needed hospitalization.

Patient quotes:

"I'm just so tired that I can't do anything anymore. Severe Asthma has changed everything."

"I can't even take my son hiking because of my health. My limitations affect other people, and it makes me angry that I can't do the things others can and that I used to be able to do."

Experiences With Currently Available Treatments

In current Canadian practice, the cornerstones of asthma management are:

- Identification and avoidance of triggers that worsen symptoms or cause exacerbations;
- Long-term controller medication(s) taken on an ongoing basis to reduce inflammation and reactivity in the airways. The most common controllers are inhaled corticosteroids (ICS) delivered through a puffer. Potential additional medications include leukotriene receptor antagonists and long-acting bronchodilators. For patients requiring a higher corticosteroid dose than an inhaler can provide, oral corticosteroids (OCS) are availed of by patients in healthcare settings; this is particularly common in patients with severe asthma;

- A short-acting reliever (bronchodilator) taken through a puffer to provide rapid relief of exacerbations or severe symptoms.

While these measures are adequate to control asthma symptoms and exacerbations in people with mild asthma, a person whose asthma is severe may still experience symptoms that can drastically reduce their quality of life and lead to systemic dependence of oral corticosteroids (OCS). The definition of Severe Asthma, therefore, carries within it an unmet need for treatment options that go beyond the existing standard of care.

Patient Use Of Current Therapies

Asthma Canada's most recent patient research reveals that many patients do not use their medications appropriately and are not well-equipped to manage their Severe Asthma. Many respondents do not carry their short-acting reliever medication with them, and more than half admit to not regularly taking their long-term controller medication. Most often, this was due to patients' perception that they were asymptomatic and did not need to continue taking their controller medication. These findings indicate both a lack of patient understanding regarding the purpose of controller treatment and the assumption that their asthma is well controlled. Other reasons cited for not using medications as directed included lack of efficacy (repeated exacerbations despite past use) and unpleasant side effects (Severe Asthma, 2014).

Financial Barriers To Optimal Asthma Control

Financial considerations are another critical barrier to optimal asthma medication use. In Asthma Canada's survey, about one-third of patients reported that they had skipped filling a prescription for an asthma medication because they were unable to afford it. Many private insurers do not provide complete coverage for asthma medications, placing a significant portion of the burden on patients. Since many patients with Severe Asthma have lower incomes (more than one-third of survey respondents had household incomes under $50,000) or are unable to work because of their asthma, even having to pay a small percentage of the drug cost can be a significant financial concern (Severe Asthma, 2014).

Patient quotes:

"I have prescription coverage that [covers] birth control, but it won't cover my inhaler. Sometimes I just want to give up."

"My doctors help me with the cost by giving me samples of most of my inhalers, but when I have to pay for them…I have to take on extra work to help pay for my medication."

"…many of my patients cannot afford the medication they need to control their [symptoms]."

Specific Concerns Regarding Oral Corticosteroids (OCS)

The use of oral corticosteroids in patients who fail to achieve adequate asthma control with inhaled corticosteroids (ICS) deserves special mention due to the short- and long-term side effects of the systemic use of oral corticosteroids. This issue is of particular concern to the population of patients with Severe Asthma, where many patients depend on long-term oral corticosteroids to provide some degree of inflammation control after other options prove to be inadequate (de Groot, 2015).

Since the activity of inhaled corticosteroids is mainly limited to the lungs and airways, the risks of systemic side-effects are low, and they can be used long-term with few safety concerns. Alternatively, oral corticosteroids can have significant systemic adverse effects, both in terms of physical changes (e.g., cataracts, bone density variations, adrenal suppression) and patients' psychological and emotional well-being (e.g., irritability, agitation, insomnia). Both categories of effects can have a significant impact on patient health and quality of life; as such, the recommended practice is to use systemic steroids for as short a duration as possible and to approach long-term use with caution and regular monitoring. Although this principle and the adverse effects of long-term reliance on oral corticosteroids are well-known, the burden of oral corticosteroid use evaluation is not robust in clinical asthma studies. The lack of cross-examination of this burden by the existing asthma-related and Health-Related Quality of Life (HRQoL) scales is detrimental. Therefore, the real impact of oral corticosteroid use on patient experience and the improvements associated with discontinuation of oral corticosteroids may be even more significant than is currently known (Hyland, 2015).

Even so, clinical studies in patients with Severe Asthma have demonstrated that patient quality of life, as validated by Health-Related Quality of Life scales, improves significantly with the introduction of a non-oral corticosteroid supplementary medication (Nelson 1999, Schmier 2003). While research specific to Indacaterol acetate/glycopyrronium bromide/mometasone furoate, they have not yet been performed in the Severe Asthma population or for mepolizumab specifically. Since many of the HRQOL improvements link with the elimination of OCS-related side effects, it should be possible to extrapolate these findings to patients who can reduce or discontinue OCS after receiving mepolizumab (see section 3.2).

Patient quote:

"[I] hate the side-effects of prednisone. [I] wish asthma could be controlled without needing it."

Improved Outcomes

Three major themes emerged from the data collected from our patient evidence submission survey. First, the primary concern for people living with asthma and their caregivers was the ability to control their day-to-day symptoms. As mentioned previously, more than half of people with Severe Asthma do not regularly take their controller medication, leading to the possibility of an unnecessary increase in healthcare system usage. Patients must be able to more easily control their Severe Asthma to live healthy and active lives.

The second most crucial factor for patients with Severe Asthma was the ability to control exacerbations. Asthma exacerbations put patients at risk of airway distress and hospitalization; therefore, the proper combination of controller and reliever medications is critical to managing Severe Asthma correctly.

Third, people living with asthma cited the cost of medications as a vital factor in receiving proper asthma treatment. Without coverage for current and upcoming treatments, people living with asthma and their caregivers may have to reduce their medication usage or stop taking them altogether. This lack of coverage may add to the staggering statistics of more than 1.6 million Canadians unable to fill a prescription due to cost (Law at al., 2018). In addition to the cost of more widely-available medications, specialized and novel medication therapies (such as the ones under review for this patient evidence submission) play a critical role in reducing the cost of healthcare utilization and help improve the lives of over 250,00 Canadians living with Severe Asthma.

People living with asthma and their caregivers surveyed cited that new treatments for asthma needed to accomplish a host of things to make their lives better. These improvements included: a more substantial increase in lung function (101 respondents), a more significant reduction in asthma exacerbation (97 respondents), easier management of Severe Asthma through novel medications (86 respondents), and a reduction of fear and anxiety when it comes to managing their asthma (55 respondents).

It is worth highlighting the need for the majority of people living with asthma who want to be able to control their day-to-day symptoms and reduce exacerbations. Although medications are one part of this equation, people with asthma understand that the delivery device plays an integral role as well. The new drug under review uses a new Dry Powder Inhaler to deliver all three medications at once, reducing the time it takes to administer the medication. Also, the device design is such that patients can see that they have taken all of their medication correctly. When asked how important it is to know if you have taken your medication correctly, people living with asthma said that it was essential, rating this importance as nine (9) out of ten (10). Eighty-four percent of respondents agreed that being able to combine medications into one device safely would be very beneficial to them. A person's experience taking their medication is vital to improving and maintaining proper adherence, thus improving day-to-day symptom control, reducing exacerbations, and improving quality of life.

Concerning trade-offs patients currently face trying to manage their asthma, side-effects are the most prevalent compromises that patients make. These current side-effects include difficulty sleeping, dry mouth/thrush, hoarseness, and increased heart rate, among others. For people living with Severe Asthma, these side-effects regularly disrupt activity levels, including social and work interactions, and can lead to a much lower quality of life.

Patient quote:

"I worry about all side-effects to any and all medications that I'm taking on a daily basis. Asthma inhalers, high blood pressure, high cholesterol, and hypothyroidism [medications]. I'm hoping that one day I might be able to stop one or more in the near future."

Experience With Drug Under Review

Our Asthma Canada Member Alliance has no experience with the drug under review at this time.

Companion Diagnostic Test

Asthma Canada is not aware of any current companion diagnostic test for the drug under review beyond standard asthma diagnostics. The diagnosis of asthma happens through spirometry or the methacholine test.

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Appendix A: Patient Group Conflict of Interest Declaration

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

No

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

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have a 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
Teva, Merck		X		
Sanofi Genzyme, Novartis, Sanofi Pasture, Pfizer			X	
Astra Zeneca, GSK				X

I hereby certify that I have the authority to disclose all relevant information concerning 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: Jonathan Kirby
Position: Manager, Programs and Services
Patient Group: Asthma Canada
Date: May 20, 2020

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Indacaterol glycopyrronium / mometasone furoate** **Asthma maintenance**
Name of the Patient Group	**Lung Health Foundation (formerly 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 is a registered charity operating as the Lung Health Foundation.

The Lung Health Foundation is dedicated to ending gaps in the prevention, diagnosis, and care of lung disease in Canada. We invest in the future by driving groundbreaking research, and we give patients and their families the programs and support they need today.

www.lunghealth.ca

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 in this submission was obtained from three phone interviews with patients living with asthma (completed in May 2020). All respondents were female, over the age of 30 years and living in Ontario. 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?

The symptoms and challenges that people experience as a result of Asthma are shortness of breath, chest tightness, fatigue, wheezing, coughing and difficulty fighting colds and infections. When asked whether this condition affected their day-to-day life, respondents indicated that it did indeed impact greatly their physical and leisure activities, and to a lesser extent, their work, ability to travel and socialize. A few direct quotes are:

- "Asthma affects most aspects of my day-to-day life. There are days that I struggle to keep my symptoms controlled."
- "I must monitor my triggers and adjust my daily routine accordingly"
- "Exercise can be difficult for me and I am unable to lead a really active life."
- "When I get a cold, it seems to last for a long time and I experience congestion and coughing - which cause me to feel short of breath."
- "My cough can be frustrating, especially at night."
- "I become short of breath with most kinds of exertion and exercises." "When my allergies are triggered, they cause wheezing and shortness of breath."

The aspects of the condition that are most important to control for people living with it are first - **shortness of breath** and second – **coughing and fatigue.** Two people indicated they would like to use their inhaler less often and would like better control with wheezing / shortness of breath when exercising.

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 on the phone include: Symbicort, Ventolin, Advair, Spiriva, Prednisone, and Singular. Nasonex, Reactine and other antihistamines are used for allergies as needed.

Current treatments do provide some relief for: fatigue, shortness of breath, wheezing, cough and reduced energy.

The side effects indicated from using the above-mentioned dugs include: dry mouth, appetite loss, impact on mood and “feeling jittery / shaky”.

When asked about whether the treatments affected their life in any other way, one respondent indicated that the cost burden was an issue, and a second respondent indicated that the lack of sleep from her uncontrolled asthma (which was not being addressed with her current treatments) was affecting her ability to perform well at work.

They all expressed dissatisfaction with their treatments in terms of improving their ability to exercise.

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?

The key outcomes of their asthma treatments that these patients would most like addressed are: reduced shortness of breath, reduced coughing, reduced fatigue and an improved ability to exercise (higher energy level).

They would also like an increased ability to fight colds / infections without each one becoming a long drawn out process.
Ideally and simply stated, these patients would experience an improved quality of life and improved lung function.

Administration of medication, side effects and cost burden were the three most commonly mentioned things that are evaluated when considering new therapies. Having insurance that covers the cost of medications was noted by two people as
a key reason there were able to access the medications they were taking.

The main trade-offs for people when discussing options with their doctor are cost and likelihood of effectiveness. “My doctor once said that I could try adding another medication into the mix to help with management, but noted that it was more expensive and only worked in a relatively small percentage of patients. That didn’t seem worth it.”

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 have used the drug Indacaterol glycopyrronium / mometasone furoate

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
Norvartis Pharma Inc.			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
Date: May 21, 2020