CADTH

CADTH REIMBURSEMENT REVIEW

Patient Input

dupilumab (Dupixent)

(Sanofi Genzyme, a division of sanofi-aventis Canada Inc.)

Indication: Asthma

CADTH received patient input from:

British Columbia Lung Association & Lung Groups
Lung Health Foundation / Ontario Lung Association

December 17, 2020

Template for Submitting Patient Group Input to the Common Drug Review at CADTH

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Dupixent(Dupilumab)
Name of the patient group		British Columbia Lung Association & Lung Groups
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		
Patient group contact information:	Email	ablog@bc.lung.ca
	Telephone	604.731.5864
	Address	2675 Oak Street, Vancouver , BC
	Website	www.bc.lung.ca
Permission is granted to post this submission		X☐ Yes ☐ No

CADTH will post this patient input submission on its website if permission is granted. See CDR Update — Issue 99 for details.

- This template form is to be used by patient groups to submit patient group input.
- Individual patients should contact a patient group that is representative of their condition to have their input added to that of the patient group.
- Please ensure that the input is in English, and that it is succinct and clear and in a ready-to-publish format.
- Please use a minimum 11-point font and do not exceed six-typed pages (approximately 3,500 words). You may delete the instructions and examples under each heading for more space.
- Patient input submissions must be provided as a Word document.
- Use the "Submit" link in the table on the Patient Input page to file the submission.
- The patient group input for this drug must be submitted by the deadline date posted on the Patient Input page of the CADTH website to be used in the CDR process.
- Privacy: The information provided in submissions to CADTH will be shared with reviewers, the Canadian Drug Expert Committee (CDEC), publicly funded drug plans that participate in the CDR, and may be included in publicly available documents. All patient input submissions for a drug under review will be collated and summarized in one document that will be posted as part of the CDR Clinical Review Report. All patient input submissions for which permission to post has been granted will be posted in their entirety on the CADTH website. Personal information will not be publicly available.

Should you have any questions about completing this form, please contact CADTH by telephone at 613-226-2553 or email requests@cadth.ca.

For information about the CDR process and CDEC see the CDR section on the CADTH website; for information regarding patient input to CDR and CDEC, see the Patient Input section.

1.1 Submitting Organization
Wednesday, December 16, 2020

Please provide an overview of the organization that is making the submission, including the purpose or aim(s) of the organization and an outline of the type of membership.

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 our areas of interest and expertise include the entire scope of respiratory diseases including Asthma, Occupational Asthma, Idiopathic Pulmonary Fibrosis, ILD Interstitial Lung Disease, COPD (chronic bronchitis and emphysema), Lung Cancer, Sleep Apnea, Influenza, Pneumonia, and Tuberculosis. We work together with the Canadian Lung Association and other partners to help the one in five Canadian who have breathing problems.

Our staff and volunteers include health professionals and interested individuals and patients with a broad range of training and 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 British Columbia Lung Association 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 rigorous national peer review system so that the most promising research can be explored. This world class research is discovering the causes of lung disease, finding new treatments, and giving hope for a future free of lung disease.

1.2 Conflict of Interest Declarations

CADTH requires that all participants in the CDR process disclose any conflicts of interest to ensure that the objectivity and credibility of the CDR process is maintained. Patient groups must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. This information is requested for transparency — a declaration of conflict of interest does not negate or preclude the use of the patient input.

(Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry [e.g., educational or research grants, honorariums, gifts, and salary], as well as affiliations or personal or commercial relationships with drug manufacturers or other interest groups.) The names of all manufacturers providing funding should be listed, not just the manufacturer of the drug under review.

The British Columbia Lung Association has several sources of funding for programs and operations and is supported by individual and corporate donations, and through service contracts with government organizations. Funding sources include direct mail campaigns such as the Christmas Seals campaign, memorial giving, bequests, Special events such as Climb the Wall: Stair Climb for the fight against lung disease!, Bicycle Trek for life and breath now virtual because of COVID-19. The Lung Association, does, from time to time receive program grants from health industry/pharmaceutical companies. Our relations and interactions with pharmaceutical companies remain transparent and positions of the Lung Association are developed without industry influence.

The BCLA has received health educator's & patient program grants from the following pharmaceutical companies: GlaxoSmithKline, $50,000(2020), Astra Zeneca, $10,00(2019), professional education, Boehringer -Ingelheim, $20,000(2019) patient education program, Sanofi, $8,000(2019), Influenza Awareness, Novartis $15,000(2019) Asthma patient education

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

Neither the principal author, nor the BCLA, has conflicts to declare in respect to the compiling of this submission

Section 2 — Condition and Current Therapy Information

In each of the following sections, guidance or examples are provided to help identify the type of information that CADTH, CDEC, and participating drug plans will find most helpful in understanding the needs and preferences of the majority of patients. Objective, experiential information that is representative of the majority of the patient group is preferred. There is no need for patient groups to submit published information, as CADTH's CDR review team and CDEC have access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search. However, relevant unpublished studies may be submitted in addition to the completed template.

2.1 Information Gathering

Please briefly identify how the information to complete Section 2 was obtained. Was it obtained, for example, through personal experience, focus groups, one-to-one conversations with a number of patients using the current therapy, printed sources, etc.?

The BCLA is significantly invested and involved in Asthma and other respiratory disease research and provision of patient services and programs. We have Certified Respiratory Educators on staff providing expert educational consultations to respiratory patients, their family members and caregivers dealing with Asthma and other lung diseases. The vast knowledge and experience garnered through research, best practice guidelines and direct involvement with patients is the basis of the information provided.

2.2 Impact of Condition on Patients

What are the condition-related symptoms and problems that impact the patients' day-to-day life and quality of life? Examples of the type of information that could be included are:

- What aspects of this condition are more important to control than others?
- How does this condition affect day-to-day life?
- Are there activities that the patients are unable to do as a result of the condition?

Severe Asthma constitutes illness is a relatively small proportion of all patients with asthma but it is a major public health problem with considerable effect on morbidity, mortality, as well as a high burden on health care resources. Regardless of effective treatments being widely available and the existence of treatment guidelines, a large population of severe asthma cases remain uncontrolled. Achieving and maintaining asthma control in this group of patients is, therefore, of utmost importance.
Asthma is a complex heterogeneous disease, with different pathogenic mechanisms, clinical presentations, and responses to treatments, usually characterized by chronic airway inflammation. Wheeze, shortness of breath, chest tightness and cough that vary over time and intensity, together with variable expiratory airflow limitation, are the main asthma features. Asthma affects an estimated 241 million children and adults in the world. Approximately 5-10 percent of the asthmatic population is affected with severe asthma, requiring high-dose inhaled & oral corticosteroids (ICS & OCS) in addition to a second controller (and/or systemic corticosteroids) to prevent it from the disease becoming uncontrolled or for asthma that remains uncontrolled despite combination therapy. There are 3.8 million patients with asthma in Canada and in BC we have 323,500 prevalent cases (2012/2013)
That amounts to 16,000 new cases in BC. The prevalence of asthma in BC has steadily increased since 2000/01. There are 5% of the asthma population in BC who are diagnosed with severe asthma.
Breathlessness & shortness of breath are some of the key symptom and complaints of patients with asthma with rapid decline in lung function intolerance. Breathlessness can affect day-to day activities such as showering, climbing stairs, getting dressed and eating. As inflammation in the lungs gets worse, breathlessness may prevent all activities. The physical deterioration of the individual with severe asthma is profound and commonly emotionally demanding. The goal of therapy is to relieve symptoms, prolong life, reduce disability and stabilize lung function and slow disease progression to allow physical and social functioning to the highest - level possible. Medication side - effects are particularly common & problematic with OCS (oral corticosteroid) which in the past were a mainstay of treatment for severe asthma. Adverse effects of long-term OCS include obesity, diabetes, osteoporosis, cataracts, hypertension and adrenal suppression, psychological side-effects such as depression and anxiety are particularly concerning for patients. Even short-term use of OCS is associated with sleep disturbance, and increased risk of infection and thromboembolism. Strategies to minimize need of OCS are therefore a high priority.
Severe asthma sufferers will often require assistance and become increasingly dependent on others to the most basic human task of daily living activities. Depression and feelings of hopelessness are common among patients with severe asthma especially with difficulty breathing.
Lung attacks or flare-ups drive disease progression. As the disease progresses frequency of flare-ups increase, overall lung function and lung health typically decline and risk of hospital admission increases as well as rate of mortality.

2.3 Patients' Experiences With Current Therapy

How well are patients managing their condition with currently available treatments?
Examples of the types of information that might be included are:

- What therapy are patients using for this condition?

- How effective is the current therapy in controlling the common aspects of this condition?
- Are there adverse effects that are more difficult to tolerate than others?
- Are there hardships in accessing current therapy?
- Are there needs, experienced by some or many patients, which are not being met by current therapy? What are these needs?

The therapies used for severe asthma are recommended and written in the guidelines by the Canadian Thoracic Society. Therapies currently approved for Asthma in Canada, Omalizumab, Mepolizumab, Reslizumab, Benralizumab
Other medications, Corticosteroid pills (OCS) systemic corticosteroids to reduce swelling in the lungs by suppressing the immune system, Inhaled Corticosteroids & Long acting beta-agonist bronchodilator combinations (ICS-LABA), Leukotriene modifiers especially for children, Add-on Controller medications, Long acting anticholinergic, Anti-IgE, Anti-IL5R/Anti-IL5R, Anti-IL4R, Reliever medications such as SABA, short acting beta-agonist, Low dose ICS–formoterol, & short-acting anticholinergics.

In two BC Severe Asthma Clinic both Respirologist have a lot of patients with severe asthma who have participated in the Clinical Trials of Dupilumab(Dupixent) I have spoken to some patients(8 patients in total) who are members of our BC Lung Support Group that are taking Dupilumab(Dupixent)they are very happy & excited about the maintained effects of the new biologic medication as a maintenance therapy. Today with most patients with severe asthma Dupilumab(Dupixent) remains out of reach for many patients especially seniors who no longer have private coverage and rely strictly on government funding for access. Dupilumab(Dupixent) with moderate to severe asthma who were uncontrolled on standard care(medium to high dose ICS and one or more controller therapies) or who were OCS dependent, dupilumab(dupixent) demonstrated statistically and clinically relevant benefits, reducing severe asthma exacerbations(asthma attacks), improving lung function & sustaining, asthma control. Dupilumab(Dupixent) was very well tolerated.

Unmet Needs: Of critical importance to the treatment of patients with severe asthma are medicines that will help reduce or stop the progression of the disease and subsequent hospitalizations. Additional therapies are needed that go beyond symptomatic relief. New treatments are urgently needed that will work to improve overall lung function. New treatment options are required as the disease progresses. The BCLA believes that access to medications such as Dupilumab(Dupixent)as an add-on maintenance treatment for moderate to severe asthma characterized by type 2 inflammation and as a maintenance therapy for oral-corticosteroid-dependent asthma to improve lung function will serve to reduce cost on admissions to hospital and improve the overall lung health of patients with Severe Asthma. The BCLA support the quick access to evidenced- based respiratory medications such as that for Severe Asthma patients and recommended by the Canadian Thoracic Society
We recognize that not all patients or individuals respond the same to various types of formulations of medications and BCLA support having access to the medications to which a particular patient responds better. The new medication is given subcutaneously.
Unmet Needs: Medications are of critical importance in the treatment and management of Severe Asthma. It improves lung function and breathing, reduce lung attacks and prevent patients with repeat admission to hospital there by improving the lives of patients

2.4 Impact on Caregivers

What challenges do caregivers face in caring for patients with this condition? What impact do treatments have on the caregivers' daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

Our health care system places a lot of demands on both the patient and caregivers. Caregivers are often the spouse, the children and other relations. Financial challenges are the obvious ones, depending on the level of reimbursement for medicine.
Another major impact identified by patients and care givers is physical activity. The impact is most noticeable on patients' progressive inability to perform daily tasks as they begin to notice that they had previously taken for granted (e.g. negotiating a staircase that they climb every day because of breathlessness)
As the patient's condition deteriorates, they tend to stay at home more which means that their fitness levels further deteriorate and their body's ability to use oxygen efficiently is further compromised. As the condition progresses, further compromises are made in patient's independence with huge implications for caregivers. Patients with Severe Asthma and their caregivers experience anxiety and depression. This disease has a progressive debilitating course and sadly it increases mortality.
Caring for someone with Severe Asthma can be both physically and emotionally demanding. Caregivers may experience a great deal of stress and anxiety, resulting from their loved one's deterioration. Frequently these feelings have a negative impact on the caregiver's health and well- being. Frequent visits to medical professionals, increasing medical needs, restrictions in activities leading to the caregiver taking a larger role may impact the caregiver significantly. The BCLA sponsor and help a number of support groups in BC called
"Better Breather's Group" they are for individuals with Lung Conditions and their caregivers and help the caregiver cope more effectively.

Section 3 — Information about the Drug Being Reviewed

In this section, guidance or examples are provided to help identify the type of information that CDR, CDEC, and participating drug plans will find most helpful in understanding the needs and preferences of the majority of patients. Objective, experiential information that is representative of most in the patient group is preferred. There is no need for patient groups to submit published information, as CDR and CDEC have access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search. However, relevant unpublished studies may be submitted in addition to the completed template.

3.1 Information Gathering

Please briefly identify how the information to complete Section 3 was obtained. Was it obtained, for example, through personal experience, focus groups, one-to-one conversations with a number of patients using current therapy, printed sources, etc.?

The BCLA is significantly invested and involved in Severe Asthma and other respiratory research and provision of patient's services and programs. On staff we have Canadian Certified Respiratory Educator's that provide educational expert consultations to respiratory patients with Severe Asthma, their family members and caregivers. The vast knowledge and experience garnered through research, best practice guidelines and direct involvement with patients is the basis of the information.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

- Is it expected that the lives of patients will be improved by this new drug, and how?
- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?
- Would patients be willing to experience serious adverse effects with the new therapy if they experienced other benefits from the drug?
- How much improvement in the condition would be considered adequate? What other benefits might this drug have — for example, fewer hospital visits or less time off work?
- Dupilumab(Dupixent) is indicated in adults and adolescents 12 years and older as an add-on maintenance treatment for moderate to severe asthma characterized by type 2 inflammation. It is also indicated as a maintenance therapy for oral corticosteroid-dependent asthma irrespective of type 2 markers. British Columbia Lung Association on behalf of our lung patients with Severe Asthma who does not respond to other medications such as corticosteroids/or other therapies, we urge CDR at CADTH for the easy access and approval of Dupilumab(Dupixent) the medication for Severe asthma. It is also imperative to make easy access to our patients in the Provincial/Territorial drug formularies.
  We support access to those medications recommended by the CTS. Please provide access to the new medication Dupilumab(Dupixent) for our Severe Asthma Patient
  Dupilumab(Dupixent) is also approved for the treatment of moderate-severe atopic dermatitis

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

- What positive and negative effects does the new drug have on the condition?
- Which symptoms does the new drug manage better than the existing therapy and which ones does it manage less effectively?
- Does the new drug cause adverse effects?
- Which adverse effects are acceptable and which ones are not?
- Is the new drug easier to use?
- How is the new drug expected to change a patient's long-term health and well-being?

Many patients with Severe Asthma have suboptimal control despite available therapies, including current biologics, Dupilumab(Dupixent) has the potential to address the significant unmet needs of patients with Severe Asthma, and OCS(Oral corticosteroid) dependent Asthma as it is the first targeted biologic therapy with a broad spectrum of activity against type 2 inflammation that is applicable to all asthma phenotypes-allergic, eosinophilic , and OCS (Oral corticosteroid) dependent asthma.

Some side effects: reactions at injection site are common but minor, Blood eosinophilia occurs in some patients.

Please refer to 3.2

Section 4 — Additional Information

Please provide any additional information that would be helpful to CADTH, CDEC, and participating drug plans. This could include suggestions for improving the patient input process, indicating whether the questions are clear, etc.

On behalf of our Severe Asthma patients, please make easy access of Dupilumab(Dupixent)
Many …many …thanks
I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with our organization or entity that may place this patient group in a real, potential, or perceived conflict of interest situation: Kelly Ablog Morrant, Vice President, Advocacy & Partnerships, Pulmonary Division, BCLA
BCLA, Patient Lung Groups

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Dupilumab (Dupixent)** **Asthma**
Name of the Patient Group	**Lung Health Foundation / 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 Ontario Lung Association,newly named Lung Health Foundation is registered with the CADTH and pCODR (www.lunghealth.ca).

The Lung Health Foundation is the leading health charity dedicated to improving lung health through a uniquely integrated approach that:

- Identifies gaps, and fills them by developing the agenda and strategically investing in ground-breaking research;
- Drives policy/system and practice change;
- Invests in urgently needed programs and supports; and
- Promotes awareness about lung health issues affecting everyone.

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 sixteen on-line surveys completed by people living with Asthma and two caregivers to people living with Asthma (input received December 2020). All respondents live in Ontario. Information on age and gender was not collected within this survey. 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 18 people replied to our questions focused on disease experience, and in order of significance, the symptoms and challenges that people experience as a result of their Asthma are shortness of breath (88%), fatigue (69%), chest tightness (56%), wheezing (44%), and coughing (44%). When asked whether this condition affected their day-to-day life, respondents indicated that it did indeed impact greatly their ability to play sports / exercise (56%), work (50%), travel (38%), and participate in hobbies and leisure activities (31%). A few direct quotes are:

- "Not being able to do activities I want to do because of daily breathing issues."
- "Exercise can be difficult for me and I am unable to lead a really active life."
- "This condition negatively effects my emotional and social life."
- "I have an anxiety about nights, because quite often at nights, I cannot breathe properly."
- "I cannot walk quickly. My condition deteriorates during cold season, because of the low temperature. I have difficulty breathing when I am changing warm environment to cold."
- "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 – **fatigue and coughing.** Two people indicated they would like to use their inhaler less often. One respondent indicated that when it's humid outside, they must stay inside to safely manage their breathing.

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 include: Symbicort, Ventolin, Advair, Spiriva, Prednisone, Trelegy, Onbrez, Alvesco, Salbutomal, Breo and “puffers”. 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. But there was dissatisfaction expressed with their treatments in terms of improving their ability to exercise.

The side effects indicated from using the above-mentioned dugs include voice hoarseness, dry mouth, appetite loss, impact on mood and difficulty sleeping.

One patient mentioned the need for more “fragrance free zones.” Another patient indicated there is a need for greater public education about Asthma.

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?

When asked about the most important benefit or outcome they would like to experience from a new medication or treatment for their Asthma, respondents indicated: reduction in symptoms (85%), improved quality of life (77%) and improved symptom management (46%).

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, these patients would like to experience overall 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 also noted.

The main trade-offs for people when discussing options with their doctor are cost and likelihood of effectiveness.

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 Dupilumab / Dupixent

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
Regeneron	X			
Sanofi				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: December 17, 2020