CADTH

CADTH COMMON DRUG REVIEW

Patient Input

OFEV (nintedanib)

(Boehringer Ingelheim (Canada) Ltd)

Indication: Chronic fibrosing interstitial lung diseases

CADTH received patient input from:

British Columbia Lung Association & Lung Groups

Canadian Pulmonary Fibrosis Foundation

Scleroderma Canada

The Ontario Lung Association / Lung Health Foundation

August 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		Ofev (nintedanib)chronic fibrosing interstitial lung disease
Name of the patient group		British Columbia Lung Association & Lung Groups
Name of the primary contact for this submission:		Kelly Ablog Morrant
Position or title with patient group		Vice President, Advocacy & Partnerships, Pulmonary Division, BCLA
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Name of author (if different)		
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	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

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 Idiopathic Pulmonary Fibrosis, ILD Interstitial Lung Disease, COPD (chronic bronchitis and emphysema), asthma, lung cancer, sleep apnea 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 IPF and other respiratory disease research and provision of patient services and programs. We have Certified Respiratory Educators on staff who provide expert educational consultations to respiratory patients, their family members and caregivers dealing with IPF 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?

Pulmonary Fibrosis-ILD is an interstitial lung disease that has a devastating impact on the patient. It is a debilitating and fatal disease. After diagnosis many patients with Interstitial Pulmonary Fibrosis (IPF-ILD) are in steady decline experiencing breathing difficulties (shortness of breath or dyspnea), chronic cough and tremendous fatigue. About 85% of people with PF-ILD have a chronic cough that last longer than 8 weeks; some people may cough up sputum and phlegm. Sadly PF-ILD has a very high mortality rate: Approximately 5,000 individuals will die from IPF each year.

Pulmonary Fibrosis-ILD affects each person differently and progresses at varying rates. Generally, the individual's respiratory symptoms become worse over time. Breathlessness is a key symptom and complaints of PF-ILD patients with rapid decline in lung function leading to fatigue and exercise intolerance. Breathlessness can affect day-to day activities such as showering, climbing stairs, getting dressed and eating. As scarring in the lungs gets worse, breathlessness may prevent all activities. The physical deterioration of the individual with IPF-ILD is profound and commonly emotionally demanding. The goal of available therapy to date has been to prolong life, reduce disability and stabilize lung function and slow disease progression to allow physical and social functioning to the highest level possible.

PF-ILD 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 PF-ILD

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 and recommended by the Canadian Thoracic Society
  There is no known cure for PF-ILD, The other therapies used in PF-ILD include pulmonary rehabilitation programs that may ease some of the symptoms include Oxygen therapy which helps to reduce breathlessness, Corticosteroid pills to reduce swelling in the lungs by suppressing the immune system, pulmonary rehabilitation program to teach breathing techniques and exercises for people with PF-ILD and Lung transplantation for patients below age 65.

What is current standard of care for PF-ILD patient?

In one BC IPF clinic a Rheumatologist usually prescribes Methotrexate indicated for use in Canada for the treatment of adults with mild to moderate pulmonary fibrosis –Interstitial Lung Disease (PF-ILD), such as Sarcoidosis, Scleroderma to name a few indication. When patients begin to show pulmonary symptoms or CT evidenced fibrosis they are prescribed by the Lung Specialist Mycophenolate or Azathioprine, systematic anti-fibrotic and anti-inflammatory properties has been shown to slow the progression of scarring (fibrosis) and has been shown to be effective in decreasing decline in lung function in some patients. It is not yet funded by provincial/territorial drug program. PF-ILD patients can only access the treatment through private insurance or personal financial means. Today, OFEV for PF-ILD, patients remains out of reach for many patients especially seniors who no longer have private coverage and rely strictly on government funding for access.

Unmet Needs: Of critical importance to the treatment of PF-ILD 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 PF-ILD medications such as Ofev will serve to reduce cost on admissions to hospital and improve the overall lung health of patients with PF-ILD. The BCLA support the quick access to respiratory medications such as that for PF-ILD 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.
We also recognize that not all patients are able to use inhalation devices effectively and we also support having access to the inhalation devices which the patient are able to use correctly. Delivery of the medication effectively is important in the treatment of PF-ILD. The new medication is available in oral preparation.
Unmet Needs: Medications are of critical importance in the treatment and management of PF-ILD It improves lung function and breathing, reduce lung attacks and prevent patients with repeat admission to hospital there by improving the lives of PF-ILD 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 day to day tasks as they begin to notice that they had previously taken for granted (e.g. negotiating a staircase that they climb every day)
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 PF-ILD and their caregivers experience anxiety and depression. This disease has a progressive debilitating course and sadly it increases mortality.
Caring for someone with PF-ILD 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 called
"Better Breather's Group" and the "Pulmonary Fibrosis Patient Group" at St. Paul's Hospital 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 PF-ILD 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 PF-ILD, 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.
(Add patient survey results here)

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?
-

Nintedanib (OFEV) is an anti-scarring (anti-fibrotic) medication that slows progression of IPF and PF-ILD. This new medication indication for PF-ILD is not yet available in British Columbia. British Columbia Lung Association on behalf of our lung patients with the deadly disease PF-ILD who does not respond to other medications such as corticosteroids/or other immunosuppressive therapies, we urge CDR at CADTH for the easy access and approval of Nintedanib (OFEV) the medication for PF-ILD. It is also imperative to make easy access to our PF-ILD patients in the Provincial/Territorial drug formularies. There are approximately less than 150 patients who would benefit with Ofev(nintedanib) as of today in BC.
We support access to those medications recommended by the CTS.
There have been 15 Countries, 153 clinical trials sites who participated in on (Nintedanib) OFEV for PF-ILD in several pulmonary research clinics in Canada (4 in total).
Nintedanib slowed the progression of ILD, as demonstrated by a lower rate of decline in FVC, with a consistent effect between patients with a UIP-like fibrotic pattern and other fibrotic patterns on HRCT. Using data up to first database lock, nintedanib was associated with a numerically reduced risk of acute exacerbation of ILD or death, and of death.

OFEV (nintedanib) is an important new advance in the treatment of PF-ILD
It is an important new choice for the PF –ILD patients
OFEV has a convenient dosing schedule of 150 mg twice a day, and it has manageable side-effect profile.
The patient's choice of delivery device must be individualized to what is best suited for the individual patient. We support having access to oral medications and inhalation devices which the patient is able to correctly use with ease and which improve the effective delivery of the medication to the lungs.
Please provide access to the new medication for this rare and fatal lung disease!

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?

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.
I am including the result of the Canadian Pulmonary Fibrosis Foundation PF-ILD Patient & Caregiver Survey Report, which was kindly shared with the British Columbia Lung Association, June 26,2020

There were 111 patients living with PF-ILD, 23 Main caregiver of someone with PF-ILD, 2 answering on behalf of patient who passed away from PF-ILD
Three not the primary caregiver but answering on behalf of loved one with Pulmonary Fibrosis
Majority of patients that responded were over the age of 60, from Ontario and West and live near a major city. Caregivers were aged 61-80 who was likely their spouse, majority were from West & Ontario.
Impact on Life: Their ability to work and do leisure activities have been majorly impacted, physical symptoms like shortness of breath and general weakness/tiredness have had a large impact on their life, their mental health has been impacted by feeling limited in what they are able to do, does not feel they are able to work and do all their activities despite their lung disease and things they need to do to treat their condition, & have to spend less than 1-2 hours per day extra to take care of different aspects of their PF.
Some of the patients are currently receiving oxygen, other anti-inflammatory drugs, and mycophenolate that are covered by their benefits/insurance, but 1 in 7 patients receiving anti-fibrotic drugs are paying out of pocket and do not have it covered by benefits/insurance, & 1 in 25 patients are in need of anti-fibrotic drugs but have difficulty accessing due to lack of benefits/insurance coverage.
The British Columbia Lung Association and the Canadian Pulmonary Fibrosis Foundation helps ensure that new medication treatments are available and affordable to our lung patients especially our PF-ILD patients, we are raising awareness of Pulmonary Fibrosis/interstitial lung disease among the public across Canada & help raise awareness of ongoing and upcoming clinical trials in pulmonary fibrosis/interstitial lung disease, and help raise awareness of treatment options of PF-ILD

On behalf of our PF-ILD patients, please make easy access of Ofev (nintedanib) to our PF-ILD patients
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	**Ofev (nintedanib) for progressive fibrosing interstitial lung diseases (PF-ILD)**
Name of the Patient Group	**Canadian Pulmonary Fibrosis Foundation**
Author of the Submission	**Sharon Lee and Adam Waiser**
Name of the Primary Contact for This Submission	**Sharon Lee**
Email	**sharon@cpff.ca**
Telephone Number	**(416) 903-6925**

Section 1 – Patient Group Overview

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

The Canadian Pulmonary Fibrosis Foundation (CPFF) was established to provide hope and support for people affected by pulmonary fibrosis. Robert Davidson, president of the CPFF, created the organization in 2009 to raise money to find causes and treatments for pulmonary fibrosis, provide education and support for people affected by pulmonary fibrosis, and to help answer those non-medical questions frequently asked by those suffering with the disease. The CPFF is a registered Canadian Charitable Foundation. Our vision is to make lung transplants the LAST resort not the ONLY resort for people with pulmonary fibrosis. Our mission is to raise funds to finance research to better understand, develop treatment and find a cure for pulmonary fibrosis. The CPFF has provided $1,000,000 in research grants over the last 10 years to leading institutions and researchers in Canada including the University Health Network, the University of Alberta's Lung Health Centre, St Joseph's Hospital Foundation and the Toronto General Hospital Foundation. www.cpff.ca

Our key objectives in the battle against pulmonary fibrosis are to:

- Support those affected by pulmonary fibrosis
- Raise public awareness about this debilitating and fatal disease
- Fund research focused on better understanding pulmonary fibrosis and finding a cure
- Advocate for Canadians affected by pulmonary fibrosis to government, healthcare professionals, the media and the public

The CPFF works closely with the medical community and receives support from Canadians from coast to coast. Our staff and volunteers include patients, caregivers, healthcare professionals and individuals with an interest in improving the lives of people affected by pulmonary fibrosis.

Section 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.

Led by the CPFF Executive Director and volunteer board members, we collaborated with G4Change and Pearl (consultants) to develop survey questions to gather the personal experiences of Canadians affected by pulmonary fibrosis (PF). We distributed online surveys to the Canadian PF community through the CPFF mailing list and via our Facebook page. The survey was active for patients and caregivers between April 8 and April 24, 2020. The survey included a total of 139 respondents affected by PF-ILD broken down as follows:

- Patients living with PF-ILD (N=111)
- Main caregiver of someone with PF-ILD (N=23)
- Answering on behalf of a patient who passed away from PF-ILD (N=2)
- Not the primary caregiver but answering on behalf of loved one with pulmonary fibrosis (N=3)

All respondents were Canadian, representing British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, Nova Scotia, New Brunswick, and Newfoundland & Labrador. The data includes the experiences of CPFF board members who are PF patients and caregivers as well as conversations between CPFF's Executive Director and patients and caregivers across the country. The results of this survey are used in sections 3 and 4.

CPFF had tremendous difficulty finding patients with Ofev treatment experience despite efforts by staff and an independent contractor. Telephone interviews were conducted between July 27 and July 29, 2020, with four patients who had Ofev treatment experience for PF-ILD. All respondents were Canadian, representing Nova Scotia, Ontario and Saskatchewan. These patients' experiences are profiled in section 6 and their feedback is used in sections 5 and 6.

Section 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?

Of the 139 patients identified in the survey, 41% had PF-ILD due to a connective tissue or autoimmune disease, 21% had hypersensitivity pneumonitis, 16% had a different form of PF-ILD and 22% said that they didn't know what type of PF-ILD they had.

3.1 Impact of Condition on Patients

National Survey Results: Symptoms And Impact On Quality of Life

Q: For each of the following symptoms, please rate how much each of them impacts your quality of life. (Top 2 Box – Somewhat/Very Large Impact) (Listed here in descending order)

Ability to work like I did before (64%)

Ability to do leisure activities that I enjoy – e.g. sports, hobbies (59%)

Shortness of breath/difficulty catching my breath (54%)

General weakness or feeling tired all the time (46%)

Ability to do activities I need to do to take care of my family or myself – e.g. housework, personal hygiene, preparing meals (36%)

Fear of not being able to catch my breath or recover (27%)

Ability to keep mental focus on things that require my attention – e.g. reading books or articles, paying bills, driving (14%)

General fear, anger, embarrassment, or depression about my health (25%)

Nausea, constipation, diarrhea or other digestion problems (21%)

Ability to keep mental focus on things that require my attention – e.g. reading books or articles, paying bills, driving (14%)

Fear of losing my balance or falling down (13%)

Loss of appetite or interest in food or ability to taste or enjoy food (9%)

National Survey Results: Impact on Life – Work & Activities

72% of patients said they are not able to perform their work and activities as a result of their PF-ILD

44% require 2+ hours a day to care for their PF-ILD

Direct Quotes from PF-ILD Patients about Disease Experience:

"Difficulties in breathing as I try to exercise. Everyday chores seem to take enormous amounts of time and energy."

"I am becoming more housebound because I have a difficult time breathing. My condition is getting worse and I fear this disease is going to take my life before I get a transplant (or if)"

"I have retired since my disease progressed but what I miss the most is not being able to participate in family get-togethers and because of being immunosuppressed. I miss the campfires and theatres and all the things I looked forward to in retirement!"

"By the time my "must do's" are done in a day, I am exhausted so too tired for much else."

"I worry about the impact on my heart, and being found dead in my home."

"Living with this disease has made it impossible to walk more than a few feet...so no bike riding or exertion.....no visiting grandkids...no water skiing, I have no energy to volunteer any more...I love gardening but am unable to do it"

"Feel old and helpless"

3.2 Impact of Condition on Caregivers

National Survey Results: Caregiver Challenges – Impact On Life

Q: Caregiving for a loved one living with lung disease can be challenging. For each of the following items, please rate how much each of these items impacts your quality of life (Top 2 Box – Somewhat/Very Large Impact)

Ability to do leisure activities that I enjoy – e.g. sports, hobbies (50%)

Impact on my physical well being (35%)

Feelings of hopelessness and/or depression (35%)

Navigating social systems (31%)

Ability to do basic activities I need to do for myself or my family beyond my care recipient (30%)

Taking care of my loved one's day-to-day needs (27%)

Travelling to/from medical appointments and my loved one's home (26%)

Advocating for my care receiver (26%)

Ability to enjoy time with loved ones (26%)

Handling crises and arranging for assistance (17%)

Ability to work (17%)

Calling doctors while I'm at work (17%)

Ability to focus on things that require my attention – e.g. reading, paying bills (9%)

Conflict and/or tension with siblings and extended family (9%)

National Survey Results: Impact on Life – Work & Activities

48% require 2+ hours a day to care for their loved one with PF-ILD

26% of caregivers said they are not able to perform their work and activities as a result of their loved one's PF-ILD

Direct Quotes from PF-ILD Caregivers about Disease Experience:

"It sucks watching him struggle to retain some sense of normalcy"

"What consumes my husband controls my life as well"

"Home life has changed over the years. Physically active lifestyle is gone. Emotional changes have strained partnership."

"It's a huge emotional and time commitment"

Section 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).

Progressive fibrosis of the lungs can have a devastating impact on patients. However, except for idiopathic pulmonary fibrosis and a new therapy for use with scleroderma-associated interstitial lung disease in the USA, **there are no approved medications for treatment of PF-ILDs.**

Current therapies for PF-ILD include pulmonary rehabilitation programs that may ease some of the symptoms - oxygen therapy which helps to reduce breathlessness, off-label use of mycophenolate and other anti-inflammatory drugs to reduce swelling in the lungs, pulmonary rehabilitation programs to teach breathing techniques and exercises for people with PF-ILD, and lung transplantation for patients below age 65. However, **almost half of patients surveyed feel their treatments/routines are not effective for helping them manage their PF-ILD.** Lung transplantation is a last resort but comes with its own consequences.

Our patients need new effective treatments they can count on.

National Survey Results: Treatments Currently Being Received (n=139)

Mycophenolate (56%)

Other Anti-inflammatory drug(s) (49%)

Oxygen (47%)

Other equipment (34%)

Physiotherapy (30%)

Azathioprine (25%)

Individual counselling or emotional support (29%)

Anti-fibrotic drug (28%)

Rituximab (22%)

Palliative Care or End of Life Planning Advice (6%)

Direct quotes from patients about current treatments:

"Oxygen is a necessary evil!"

"Carrying oxygen makes each trip tiring and each time I go, I feel like I am packing for a month when it is only a day trip!"

"Being on Prednisone for over four years was a challenge, with many unpleasant side effects, particularly being manic. Put a strain on some relationships but lost only one friend. Felt horrible most of the time, but it did its job."

"I still don't have any drug therapy intervention that worked."

Section 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 patients were asked to evaluate the importance of different outcomes for their PD-ILD treatment on a scale of 1 (not important) to 5 (very important), all of the potential outcomes were considered important with each receiving an average rating of 4 or higher. However, **controlling disease progression was identified as the most important treatment outcome by PF-ILD patients.**

Outcome	Rating Average
Controlling disease progression	4.75
Reducing symptoms	4.5
Maintaining quality of life	4.5
Managing side effects	4

Section 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.

Patients with Ofev Experience for the Treatment of PF-ILD

1. A female patient from Ontario, 63 years of age, Patient A was diagnosed in January 2014 with unspecified PF-ILD. She has been treated with Ofev since January 2018. Her dosage was reduced from 150mg to 100mg due to adverse side effects. She has also been treated with steroids.
2. A female patient from Ontario, 39 years of age, Patient B was diagnosed just over 10 years ago with chronic hypersensitivity pneumonitis. She has been treated with Ofev on and off for 2 ½ years. Her dosage was reduced from 150mg to 100mg due to nausea and liver enzyme levels. She has also been treated with other medications.

3. A male patient from Saskatchewan, 58 years of age, Patient C was diagnosed four years ago with dyskeratosis congenita. He has been treated with Ofev for 1 ½ years. His dosage was lowered from 150mg to 100mg. He did not report any other form of treatment.
4. A female patient from Nova Scotia, 54 years of age, Patient D was diagnosed in October 2017 with nonspecific interstitial pneumonia. She has been treated with Ofev since April of this year. She has also been treated with other medications.

While we were only able to connect with 4 individuals who trailed on Ofev, they all believe that it has stabilized their conditions. All 4 patients continue to receive successful treatment on Ofev for PF-ILD.

Recommend Ofev: When respondents were asked if they would recommend Ofev to other patients with PF-ILD based on their personal experience, the responses were "Yes", "Yes", "Definitely", and "Absolutely". **All four respondents would recommend Ofev for patients with PF-ILD.** Some of the comments included:

- "I feel strongly that this medication should be available so that other people can have the chance to control their disease." (Patient B)
- "I'm taking my chance to take it because I want to get better. I don't want to get worse." (Patient D)
- "I'm just happy that there is something that can help." (Patient A)
- "I feel like it gives me some hope for future." (Patient B)
- **"I firmly believe that it has helped me." (Patient C)**

PF-ILD Management: When asked if they agreed or disagreed with the statement - *"Ofev is able to manage my pulmonary fibrosis"*, Patients A and D answered Completely Agree, while Patient B said Somewhat Agree. Patient C declined to answer. **All respondents to this question agreed that Ofev helped to manage their pulmonary fibrosis.**

When asked about symptoms that Ofev has helped to control, Patients A, B & D all mentioned reduced coughing. Tissue scaring and volume capacity were also cited as symptoms which Ofev had helped to control and Patient C described a psychological benefit to use of the drug.

Side Effects: While the persons taking Ofev reported gastrointestinal side effects, primarily diarrhea, they also indicated that these were tolerable in the context of the benefit the drug provided to their primary disease.

Overall Assessment: When asked to describe the positive and the negative aspects of their experience with Ofev, these were some of the patient responses:

- "The positive is it's made my life better. I don't know what it would have been like without it. It gave me a few more months with comfortability." (Patient C)
- "I feel hopeful that I can stay steady. My lungs are terrible, right, but if I can stay at this level of terrible, and avoid needing to have a lung transplant, then I am willing to put up with a lot." (Patient B)
- "The negative would be the side effects even though I believe those are minimal. Positive is just knowing that this medication may slow down the progression of my disease." (Patient A)

Section 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.

Section 8: Anything Else?

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

Key Points:

1. Except for IPF, there are no approved medications for treatment of PF-ILD in Canada.
2. Almost half of patients feel that current treatments are not effective for helping them manage their PF-ILD.
3. Ofev reduced disease progression and helped to manage symptoms among PF-ILD patients.
4. Side effects associated with Ofev were considered tolerable by respondents.
5. Respondents with Ofev treatment experience unanimously recommended Ofev to other patients with PF-ILD.

We hope that when this medication is added to provincial drug plans, we will see more PF-ILD patients living with an improved quality of life. We also believe that we will see fewer lung transplants in this population with a corresponding decrease in all of the consequences and healthcare costs associated with these procedures.

This drug has given all four patients hope for a future that they thought they might not have. They now have the opportunity to see their children mature into adults and complete their bucket lists.

We would also like to note that the Lung Association of Nova Scotia has formally endorsed this submission. A letter of support from Robert MacDonald, President and CEO, will be submitted concurrently.

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.

CPFF Executive Director completed questions #1 to #4, and edited the submission while independent consultant, Adam Waiser, interviewed patients with Ofev treatment experience for us and helped add this information to the CPFF submissions for CADTH and INESSS.

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.

Led by the CPFF Executive Director, volunteer Board members, we collaborated with G4Change and Pearl (consultants) to develop survey questions to gather the personal experiences of Canadians affected by pulmonary fibrosis (PF). Online surveys were distributed to the Canadian PF community through the CPFF mailing list and via our Facebook page.

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
Boehringer Ingelheim Canada				x
Hoffman-La Roche 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: Sharon Lee
Position: Executive Director
Patient Group: Canadian Pulmonary Fibrosis Foundation
Date: August 10, 2020

BREATHE
the lung association

The Lung Association – Nova Scotia
6331 Lady Hammond Road, Halifax, NS B3K 2S2
T 1-902-443-8141 | F 1-902-445-2573 | info@ns.lung.ca | **ns.lung.ca**
Lung Health Information Line 1-888-566-LUNG (5864)

August 24, 2020

Dear Canadian Agency for Drugs and Technologies in Health,

This letter is in support of the Canadian Pulmonary Fibrosis Foundation's submission for the drug nintedanib. As an association that deals with various lung health issues, we are well aware of the lack of medications that can improve the lives of Canadians living with progressive fibrosing interstitial lung disease (PF-ILD). The Lung Association of Nova Scotia aided in the dissemination of their impact survey, which shed light on patients' and caregivers' experiences with PF-ILD, and the benefits that Ofev (nintedanib) could provide patients.

There are few effective options for Canadians living with PF-ILD, but Ofev could help manage this devastating disease and reduce the significant economic and health burdens of lung transplant. We thank you for the consideration of this submission and please contact us should your require any further information.

Yours in Lung Health,

Robert MacDonald
President & CEO, Lung Association of Nova Scotia

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**OFEV® (nintedanib) capsules is an FDA-approved prescription medicine used: to treat people with a lung disease called idiopathic pulmonary fibrosis (IPF), to treat people with a chronic (long lasting) interstitial lung disease in which lung fibrosis continues to worsen (progress), or to slow the rate of decline in lung function in people with systemic sclerosis-associated interstitial lung disease (also known as scleroderma-associated ILD).**
Name of the Patient Group	**Scleroderma Canada (SC)**
Author of the Submission	**Maureen Worron-Sauvé, Vice President, Advocacy and Public Relations, Scleroderma Society of Canada**
Name of the Primary Contact for This Submission	**Maureen Worron-Sauvé, Vice President, Advocacy and Public Relations, Scleroderma Society of Canada**
Email	**maureen@Scleroderma.ca**
Telephone Number	**905-973-9904**

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.

1.1 Submitting Organization

Scleroderma (also known as systemic sclerosis—SSc) is a complex, chronic, systemic disease that is characterized by fibrosis of the skin and internal organs, vasculopathy, and auto-immune activation. The leading cause of death for people with scleroderma is lung failure due to interstitial lung fibrosis (scarring of the lungs), otherwise known as interstitial lung disease (ILD), and pulmonary hypertension.

Scleroderma Canada (SC) is a registered Canadian Charitable Foundation established to advance the quality of life for those living with scleroderma. SC is dedicated to furthering its' mandate in creating a "world free from scleroderma." Under a national umbrella, our key objectives in the battle against scleroderma are to:

- Raise public awareness about this debilitating and fatal disease;
- Support those affected by scleroderma;
- Fund research focused on better understanding scleroderma and finding a cure;
- Advocate for Canadians affected by scleroderma to government, healthcare professionals, the media, and the public.

SC works towards accomplishing these goals by: facilitating peer-to-peer support groups, hosting social engagement activities and patient education forums, and coordinating fundraising events. As a result, our work helps people living with scleroderma learn more about medical treatments and lifestyle choices that will help them manage the symptoms of their disease. Money raised from fundraising events goes towards further advocacy, patient support, health education, and scleroderma research. The SC works closely with the medical community and its members, from coast to coast, towards achieving our vision and mission. Our staff and volunteers include patients, caregivers, health professionals, and individuals with an interest in improving the lives of people affected by scleroderma. More information about the work we do can be found at the Scleroderma Canada website: https://www.scleroderma.ca/

1.2 Conflict of Interest Declarations

Scleroderma Canada's submission is supported and endorsed by our Canadian Patient Organizations including:

- The Scleroderma Association of British Columbia;
- Scleroderma Association of Alberta;
- Scleroderma Association of Manitoba;
- Scleroderma Ontario;
- Sclerodermie Quebec;
- Scleroderma Nova Scotia;

Scleroderma Canada has several patient organizations partnerships which are listed on the SC website (see link: https://www.scleroderma.ca/about-us). These include:

- The Canadian Organization for Rare Disorders (CORD);
- The Scleroderma Patient Intervention Network (SPIN);
- The Canadian Skin Patient Alliance (CSPA);
- The Canadian Scleroderma Resource Group (CSRG);
- The Scleroderma Resource Foundation;
- The Arthritis Alliance of Canada (AAC);
- The Pulmonary Hypertension Association of Canada.
- The Canadian Pulmonary Fibrosis Foundation.

The primary source of funding for SC comes from private donations and sponsorships from health industry/pharmaceutical companies, and support from our regional and provincial Canadian Patient Organizations. Our relations and interactions with pharmaceutical companies remain transparent, and positions of the SC are developed without industry influence. Over the past two years, the SC has received sponsorship for unrestricted educational funds from Boehringer Ingelheim, the manufacturer of nintedanib (Ofev), Mallinckrodt, Corbus Pharmaceuticals, Actelion/Janssen, MedReleaf Corp., and Bayer.

Neither the principal author nor the Scleroderma Society of Canada has conflicts to declare in respect to the compiling of this submission.

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.

2.1 Information Gathering

Data used to inform this patient input submission has been acquired from a number of different sources (patient interviews, focus groups, surveys, and personal experiences). Key sources of evidence include:

1) A National Scleroderma Patient Health Concerns and Priorities Survey (patient self-report measures) which was launched across Canada in 2018. Data from the survey was analyzed in 2019, and a 32-page report was created. Over 200 persons living with scleroderma responded to the survey, with most being female (85.1%), and persons residing in Ontario (44%). From the Scleroderma Patient Healh Concerns and Priorities Survey, it was determined that 7 out of every 10 persons living with scleroderma experience lung disease symptoms, of which almost half (42.5%) is attributed to interstitial lung disease (ILD). Most of these patients have been prescribed Ofev (the drug under review) or have received Ofev through clinical trial participation;

2) Patient self-report quality of life and disease activity data from a National Scleroderma Clinical Research Database (compiled by the Canadian Scleroderma Research Group). This database houses data from over 1,500 patients in 11 geographic locations across Canada (i.e., Halifax, Montreal, Sherbrooke, Quebec City, Hamilton, London, Ottawa, Newmarket, Winnipeg, Edmonton, and Vancouver). Data collection for this database is ongoing. Scleroderma Canada requested a data summary of patient self-report quality of life and disease activity in September 2019. Extrapolating what we know about the prevalence and treatment of ILD within the scleroderma patient community, approximately 630 patients have experience with Ofev (the drug under review);

3) Patient and family caregiver interviews/personal stories. These are gathered on an ongoing basis and are featured on the SC website, the SPIN website, the CSRG website, and in our patient newsletters (see links: https://www.scleroderma.ca/patient-stories https://www.spinsclero.com/news-media/2016/04/15/share-your-scleroderma-story https://sclerodermabc.ca/testimonials-faces-of-hope/). Patients with ILD describe their experiences with breathing difficulties before and after having taken Ofev;

4) Patient/family caregiver focus groups. These were conducted during our scleroderma advocacy days in November 2019. Twenty-three scleroderma patients and sixteen family caregivers shared their stories about what it is like living with scleroderma and ILD and caring for family members with scleroderma and ILD with members of the Ontario, Alberta, and Quebec Legislatures.

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?

3.1 Impact of Condition on Patients

Systemic sclerosis (SSc) is an autoimmune disorder that affects various organs via inflammation, vascular damage, and fibrosis. It can affect the heart, lungs, kidneys, gastrointestinal tract, and blood vessels. Systemic sclerosis has the highest case-specific mortality among the systemic autoimmune diseases. It is estimated that SSc affects approximately 16,000 Canadians. There is no medication that can cure or stop the overproduction of collagen that is characteristic of scleroderma, but there are medications that can help control scleroderma symptoms and prevent complications. It is important to understand that the limitations and challenges and health related quality of life living with scleroderma are significant, before the added burden of Progressive Fibrosing-ILD.

On the top of severe organ involvement such as ILD, myocardial fibrosis, pulmonary hypertension and renal crisis, individuals diagnosed with SSc may suffer from a number of comorbidities. The interplay between the disease activity and associated conditions are clinically complex and may lead to increased morbidity and mortality. Comorbidity in patients with SSc-ILD is associated with worse health outcomes, more complex clinical management, and increased health care utilization.

People living with SSc-ILD have significantly low quality of life measures. ***For many, the development of ILD has been feared as an endpoint since receiving their initial scleroderma diagnosis. These patients are generally aware that this condition is typically fatal, and as a last resort, these patients are put on a waiting list for a lung transplant. At the point when ILD is diagnosed, these patients are emotionally and psychologically fragile.***

The most common symptoms of SSc-ILD include shortness of breath (especially with exertion), tremendous fatigue and weakness, loss of appetite, loss of weight, chronic dry cough, discomfort in the chest and laboured breathing. ***For those of our patients who have ILD & PAH, these symptoms and the impact on their quality of life are exacerbated.***

From the Scleroderma Patient Report, it was determined that;

- 7 out of every 10 persons living iwith scleroderma experience lung disease symptoms, of which almost half (42.5%) is attributed to interstitial lung disease (ILD). Extrapolating this data to a larger Canadian population, this equates to approximately 4,473* Canadians diagnosed with scleroderma induced ILD. Due to the diagnostic and reporting challenges associated with scleroderma, (as it is a complex multi-symptom disease that many physicians are unfamiliar with), researchers predict that these numbers may be even higher;
- Since the most common symptom associated with scleroderma induced ILD is shortness of breath (65% of scleroderma patients experience shortness of breath), using data from the report, we can hypothesize that a there may be as many as 9,773** persons who may be impacted by SSc-ILD (both diagnosed and undiagnosed);
- Likewise, in certain Canadian communities, especially Indigenous communities of women ages 45 years and older, where scleroderma prevalence rates have been determined to be twice that of the national population average, SSc-ILD may even be higher.

Shortness of breath, fatigue, dizziness, fainting, and swelling of the arms and legs are symptoms consistently reported in the survey as most affecting the patient's ability to be reasonably functional on a day to day basis. Theese are also the symptoms most important to control.

Patients report that they need to ration their energy and take frequent rests to try to control the fatigue and shortness of breath. Patients end up Takitg a shower then having to rest, getting dressed then having to rest, brushing their teeth then having to rest, etc. This type of task management as a coping skill is commonly reported in everything a person dones -- from basic hygiene to household chores and is varied only in the degree to which the tasks are broken down. While this balancing of energy and effort is helpful, it is not always adequate. Patients report that they attempt to balance their week by ensuring a free day before and after medical appointments or social engagements that they know are likely to tax their energy reserves.

Shortness of breath limits everything a patient does. At its most extreme, people living with scleroderma experience shortness of breath from walking just a few feet, stairs are an impossible obstacle, and day to day functioning is severely limited. Even when the shortness of breath is more controlled, they report fear of being out of breath and becoming dizzy or fainting as limiting their independence and ability to enjoy some of the simplest things in day to day life. From housework to the ability to walk a dog, play with children, and enjoy sexual relations, their quality of life is severely diminished.

Difficulty lifting without causing shortening of breath is also cited as a common and significant problem. Bending over or standing up suddenly are the type of activities where patients report dizziness and feelings of tightness in their chests. Patients report that it is a challenge to start the day as they take time to ensure that they slowly get out of bed and begin to dress. Everything they wear from the waist down; underwear, pants, socks and shoes, requires that they bend over to put on. Throughout the day, as patients reach into cupboards, as they cook and do laundry, they struggle to find ways to maintain independence without bending, lifting, or climbing stairs.

Fainting spells cause tremendous anxiety and limit many patients' day to day activities. Something as simple as a walk with the family has reportedly brought on fainting episodes. These episodes cause many patients to fear being alone, or going out alone in public. Dizziness and fainting have a significant impact on a patient's degree of independence and ability to function in a day to day fashion.

The degree to which this problem affects patients lives varies based on disease progression and the extent to which their symptoms are controlled by existing treatments, but also varies based on the family dynamics. In households with older children or no children, household chores can often be delegated so that the laundry, cleaning, and grocery shopping are done by other family members. But in a household with young children, the dynamics and psychological impact of this limitation are significantly different, as our patients attest.

From the 2018 National Scleroderma Patient Health Concerns and Priorities Survey (patient self-report measures), the following was reported:

- 56% reported difficult washing him/herself;
- 78% reported difficulty putting on socks;
- 78% reported difficulty walking;
- 87% reported difficulty climbing stairs;
- 77% reported difficulty getting in/out of a car;
- 88% reported difficulty exercising;
- 88% reported persistent coughing.

Notes:

- *(37.59 million Canadians x 1/2500 persons with scleroderma x 7/10 with lung disease symptoms x 42.5% diagnosed with ILD) = 4,473 Canadians diagnosed with scleroderma induced ILD;
- **(37.59 million Canadians x 1/2500 persons with scleroderma x 65% with shortness of breath) = 9,777 Canadians potentially living with scleroderma induced ILD.

Direct Quotes from Scleroderma Patients Living with Interstitial Lung Disease (ILD):

- *The coughing associated with ILD is very annoying for me and everyone else, particularly at this time of COVID 19. Coughing is frequent and at times uncontrollable. I wear a mask when shopping but have to limit the time to 5 or 10 minutes because **I cannot tolerate the mask for longer—it makes it very difficult to breath**. At times I have to leave and return later when the coughing has settled." Elizabeth*
- *"Everyday **I have to push myself just in order to breath**." Tamanya*
- *"**I have no energy and am out of breath all the time. I feel lost, hopeless, and like a failure in my life, to my family and as a mom**." Joe*
- *"I find myself in limbo. **I have been just over three years on the transplant list and still waiting. My breathing is so bad that I need to use my oxygen machine full-time.** After being diagnosed with interstitial lung disease and not being able to breathe without my oxygen machine, I decided not to return to work as a teacher, because constant exposure to infections from a classroom setting is a serious danger to my health. I am lucky because I have great benefits from my union, but not everyone has the luxury to make such a decision without serious financial difficulties." Beth*
- *"Most times I feel invisible since **many people don't realize how sick I am**." Liz*
- *"I remember very well the day I had met with my local rheumatologist at the hospital for a follow-up exam after several months of tests. He said, 'Jenn I believe you have an autoimmune disease called scleroderma. 'Ok.' I said. 'What does the treatment plan look like?' I was familiar with autoimmune diseases as they ran in my family. I figured like other conditions, there must be a reasonable treatment option. No problem. I've got this. **Little did I know the storm had just began and I was about to enter the fight of my life**." Jenn*
- *"I was 19 when **scleroderma entered my life and hijacked my future goals**." Tiasha*
- ***"Living with scleroderma and ILD is like living with a noose around my neck that is tightening everyday. Breathing with the assistance of oxygen and knowing that each time I increase my***

oxygen settings that I am one day closer to death. I try to be strong for my family, and I see how much it affects them, how much it hurts them to watch me struggle. but I am losing hope. The time I have with them is invaluable and yet I am losing hope." *Bernadette*

3.2 Impact of Condition on Caregivers

Scleroderma can strike anyone, but its most common victims are women. These women are in the prime of life, raising children, caring for elderly parents, leading their communities. These are primary family caregivers, which means that one diagnosis creates many victims. As such, the progression of ILD in scleroderma patients has a tremendous impact not only on their ability to provide care for their family but also on their families' ability to provide care for them.

Although many Canadians with SSc-ILD live at home with supported care from family, these caregivers often experience emotional distress in their caregiving role, as they see their loved ones struggle with symptom disfigurement, reduced participation in activities of daily living, and disability caused by the disease. Caring for people living with SSc-ILD is both physically and emotionally demanding. Many caregivers have reported emotional stress and feelings of hopelessness, and depression, as a result of their loved one's health deterioration. Frequently, these feelings have a negative impact on caregivers' health and well-being. Overall the impact on caregivers can be summed up as severe. Spouses struggle with increased responsibilities and additional stress in the household. Most household duties from cleaning to shopping and to taxiing children fall to the caregiver. Working and organizing from the moment they wake up until the moment they fall into bed is how many partners have characterized their daily routine. These daily time pressures have led some to describe themselves as single parents. While they are needed to accompany their spouse on regular errands such as medical appointments, it creates added stress at work. Both the problems with getting the required time off of work and the financial strain that results from taking time off work exacerbates this issue.

There are unique challenges for persons living with SSc-ILD when there are children in the home. The parent of a young child spends a lot of time bent over whether to talk to the child, wipe the child's hands and faces, or pick up toys, etc. Simple things such as playing with a ball, going for a walk to the park, and swimming are compromised due to shortness of breath. The inability to pick children up and carry or hold them without worrying about being short of breath, getting dizzy, or fainting has been reported. Patients with SSc-ILD have expressed worry that they are worsening their health through the simple act of caring for their families. The limitations on their ability to care for their families, the fear of dying, and of knowing that there is limited time to enjoy their children and mentor them has a profound effect on the psychological well-being of people living with SSc-ILD. The effects on the children of these patients are significant. Their parent's limited ability to interact in family activities, playing in the yard, swimming, or biking is often resented. In many cases, children of parents with SSc-ILD performance and behaviours in the academic setting have led to the involvement of social workers and grief counsellors. Some of these children have been traumatized when their parent's need for emergency medical services due to a fainting spell has resulted in 911 calls and resulting ambulance delivery to the hospital. These children's fears and concerns over their parent's situation and prognosis add tremendous emotional strain to both the patient and the caregiver.

It would be significantly easier to list the athletic and recreational activities available to people living with SSc-ILD (i.e., anything sedentary or extremely low energy; reading, watching movies, playing cards or board games), than it is to list the types of activities and sports that they can no longer participate in. Their dependence upon other members of the household due to this and the potential for dizziness and fainting results in a significant loss of independence with the resulting burden impacting the rest of the household. When we factor in pain, fatigue, loss of or limited intimacy with their partners, and other emotional aspects of living with a terminal illness, it is difficult to define what part of their day to day lives are not significantly affected. The impact on these people living with SSc-ILD and their families is profound. It is a daily battle for the caregiver to juggle the many serious needs and demands of all of the family members. Maintaining a stress-free environment for their spouses is next to impossible under all of these strains.

In summary, the emotional, psychological, physical, and financial impact of ILD on caregivers is profound.

Direct Quotes from <u>Caregivers</u> of People Living with Scleroderma Induced ILD:

- ***"My wife worked as an RN for many years, but a year after her diagnosis of SSc-ILD, the fatigue and decreased stamina forced her to stop working and go on long term disability. This has meant a big reduction in income of course and it is heartbreaking to watch this hard working independent woman reduced tp struggling to walk up a flight of stairs or slight incline without becoming short of breath. I feel so helpless watching her get worse."*** *Bob*

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).

Progressive fibrosis of the lungs can have a devastating impact on people living with scleroderma induced ILD as there are no approved treatment options for use in SSc-ILD in Canada and there are no medications approved for the treatment of progressive fibrosing ILDs.

Therapy of SSc-ILDs is a challenge that requires interdisciplinary care, especially by respirologists and rheumatologists. Therapies used include pulmonary rehabilitation programs that include oxygen therapy to help reduce breathlessness, mycophenolate and other anti-inflammatory drugs to reduce swelling in the lungs, pulmonary rehabilitation programs to teach breathing techniques and exercises for people with SSc-ILD, and lung transplantation for patients below age 65. Patients surveyed were unhappy with the effectiveness of these treatments, particularly in light of the fact that none of these treatments offer a longer term solution, such as the halt in progression or delay in progression.

The presence of Pulmonary Arterial Hypertension (PAH) has a significant adverse impact on survival in SSc-ILD. Treatment effectiveness for SSc-ILD and long term survival continue to be worse than in other subsets of ILD patients. Current therapies do not go far enough in extending life expectancy.

Unmet needs: Of critical importance to the treatment of SSc-ILD are medicines that will help reduce or stop the progression of the disease and subsequent hospitalizations. Additional therapies are needed that go beyond symptom management. Access to new treatments that are covered by benefits and/or insurance are urgently needed that go beyond symptomatic relief to slow the disease progression.

Access to ILD therapies is challenging at best. The high costs associated with such treatments means that private insurance rarely covers all of the cost, and the process of special approvals from the various provincial plans is stressful. Access to treatments is not universal throughout Canada, leaving some patients with few options but to try to enroll in clinical trials. This could be a short term solution to their dilemma if the trials are not blinded. However, the fact remains that when the only treatments available to them are not controlling their disease, their prognosis for survival and quality of life are grim.

According to the 2018 National Scleroderma Patient Health Concerns and Priorities Survey (patient self-report measures):

- 79.9% reported not having a government medical/health insurance plan;
- 29.6% reported having partial coverage of prescription medication;
- 25.4% reported having no coverage of prescription medication;
- Over 55% of patients indicate (based on their experience) that insurers DO NOT cover new treatments for scleroderma, as they become available;
- Over 30% of patients indicate that their doctors won't prescribe medications if patients can't get coverage/afford to pay for it;
- Over 23% of patients have stopped taking prescribed medication due to cost.

Direct Quotes from People Living with Scleroderma Induced ILD receiving ILD treatment:

- *"**I hate being tied to the oxygen machine**. I guess I am lucky because I don't need it 24/7 but my cough is getting worse."* *Irene*
- ***"I am so tired all the time. I know that soon I will need oxygen, but what I need more is the medicine that will slow down this horrible disease. I don't want to lose hope, but I am going to have to give up working if something doesn't slow this down**."* *Cynthia*
- *"**I am on long-term disability from my job as an RN due to the fatigue and decreased stamina.** This has meant a big reduction in income but I was able to continue with my group benefits until retirement which will be this month. I will be 65 at the end of this month and will then be on Ontario Drug Benefits through the provincial plan. I'm not yet sure what other drug benefit I can then obtain or afford. **The new drug nintedanib sounds promising but at this point I cannot afford it.**"* *Elizabeth*

Direct Quotes from Caregivers of People Living with Scleroderma Induced ILD receiving ILD treatment:

- *"**How can you watch your loved one struggle to breath and not do something to help?** I do as many of the household chores without upsetting my wife. She is a proud woman and so determined. I will do anything I can to help her, but it is never enough. I can't complain about how tired I am trying to work and care for her and the house, as I know that she is just so exhausted all of the time. **I miss the woman she was, but feel guilty saying that.**"* *Tom*
- *"**I listen to her cough and struggle to catch her breath. She tries hard not to worry me and is always positive. I wish I could be. This disease is stealing the amazing life that we have built and the future we had planned**."* *Matt*

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 SSc-ILD that patients and their caregivers would most like addressed are:

- to stop or slow the progression of the disease;
- to reduce fatigue, cough, and shortness of breath;
- to have increased energy levels;
- reduce reliance on oxygen.

Shortness of breath is the number one symptom impacting their lives, so an improvement in this symptom would make a difference for both patients and caregivers.

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.

The use of Nintedanib within the SSc-ILD community has been limited to date largely due to the fact that few have the benefits to pay for the drug. We have had feedback from a small sample of only 3 patients. One who was involved with the clinical trial, two had private insurance. Side effects reported included:

- Diarreah was reported by 1 patient. Medication was temporarily reduced and the diarreah resolved mostly;
- Nausea was reported by all 3 patients. Two have controlled the nausea with dietary changes (food with medication) while the 3rd patient reported the nausea resolved itself;
- Only one patient has been taking the medication long enough to confirm that the rate of decline in lung function has improved by almost 50% of expected decline;
- All patients reported feeling less out of breath, less anxious and more hopeful;
- Family members reported concerns about the initial side effects and relief that they had been minimized or resolved.

Nintedanib has been proven to reduce the rate of decline in lung function. For those with this progressive and deadly disease that reduction means both a delay in the reduction of their quality of life and an increase in quantity of life. This medication brings hope to our patient communityand their caregivers.

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 – the drug under review has no companion diagnostic.

8. Anything Else?

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

We have attempted to present the challenges of Chronic Fibrosing ILD within the context of the Scleroderma Patient experience. The development of ILD adds an additional layer of disease burden on top of a significant pre existing burden. This is our sickest subpopulation of patients and they are anxious

for this drug to be approved before their lung function declines further. This has been stated clearly and often to us. There is a huge unmet need for a disease that is 100% fatal.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.
   - No
2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.
   - No
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Mallinckrodt ($10,000 - $50,000)				X
Corbus ($5,000 - $10,000)		X		
Actelion/Janssen ($10,000 - $50,000)				X
BI ($50,000+)		X		
MedReleaf Corp. ($5,000 - $10,000)				
Bayer ($0 - $5,000)	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: Maureen Worron-Sauvé
Position: Vice President, Advocacy and Public Relations
Patient Group: Scleroderma Society of Canada
Date: August 10th, 2020

CADTH

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Ofev / Nintedanib** **Indicated for - Chronic Fibrosing Interstitial Lung Diseases**
Name of the Patient Group	**The Ontario Lung Association / Lung Health Foundation**
Author of the Submission	**Peter Glazier, Executive Vice President**
Name of the Primary Contact for This Submission	**Peter Glazier**
Email	**pglazier@lunghealth.ca**
Telephone Number	**(416) 864-9911, ext. #251 or (416) 879-1953**

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 nine phone interviews completed in August 2020. Three respondents were female and six were male, and all were between the ages of 57 – 84 years. Diagnoses included: Idiopathic Pulmonary Fibrosis (IPF) (4 respondents), Interstitial Lung Disease (2 respondents), Hypersensitivity Pneumonitis (1 respondent), Pulmonary Fibrosis (PF) (1 respondent) and the last respondent was the recipient of a double lung transplant resulting from his IPF. Six of the respondents live in Ontario and three of the respondents live in the United States (California, Idaho and Wisconsin). Five of the nine respondents had experience using Ofev. 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?

Each respondent that provided input indicated that shortness of breath had the greatest negative impact on their daily life and quality of life. Fatigue, low energy, muscle weakness, cough and difficulty sleeping were also mentioned as negatively impacting their quality of life. A few direct quotes include:

"I can't do everything I want to do. Going from point A to point B takes so much effort, and each month it seems I can do less and less."

"I am very weak, I can hardly walk at times. It is a very debilitating condition."

"I have to wear oxygen, just to get my mail."

"I have had to sacrifice so much because of this illness – I moved to be closer to the treatment program, I now have groceries delivered because it's too hard to do myself, and I can no longer go to church. "

"It is very limiting to live with IPF, if I do an activity or outing on one day, I have to take a "day off" the next one to recover from it."

"I am going to have to sell my cottage, which is something I worked my whole life to build, because I simply cannot maintain it anymore."

All patients indicated that their level of activity was dramatically reduced as a result of their lung disease. Patients described being active with housework, golf, walking, various clubs and caring for grandchildren before their diagnosis, all of which have ended for them.

Other issues these patients experience from their chronic lung diseases are feelings of isolation, sadness and in some cases depression. All patients indicated that the psychosocial support received from spouses, children, friends and (in some cases) support groups were instrumental in making daily life manageable and keeping their spirits lifted. “Being able to speak with others living with the same lung condition as myself has made me feel less alone in this awful journey.” (female patient)

“Simply stated, my ILD has impacted all aspects of my day-to-day life.” The ability to socialize with family and friends, participate in leisure and physical activities, and enjoy hobbies has been lost due to the fatigue and shortness of breath experienced by the patients interviewed.

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 this group of respondents interviewed included: Ofev, Esbriet, Mycophenolate mofetil/mycophenolic acid (CellCept), Prednisone, and Ventolin (as needed). Almost also patients were also using oxygen in varying levels of strength. All those taking Ofev had a treatment regimen of taking it twice daily, approximately 12 hours apart.

Ofev has a few side effects for patients, but the most common one mentioned was gastrointestinal discomfort and diarrhea. For some the diarrhea was described as “a significant negative side effect” that impacted their ability to leave the house for parts of each day. One patient has chosen to wear an adult diaper to help deal with this issue. Another patient is taking over-the-counter medications to try and manage the diarrhea. All patients would like relief from this particular side effect of Ofev.

The other side effects mentioned were: loss of appetite, weight loss, difficulty with “fog brain” and recall of information, and for one male patient smell and taste were negatively impacted. Although difficulty sleeping was mentioned by all but one patient, it was unclear if this was caused by their chronic lung condition, by their treatment or perhaps by both.

The desire for fewer medical appointments was mentioned by 50% of the patients. Seven of the nine patients were dependent on others to get them to and from their appointments.

Quality of life was mentioned as being very important to all patients. They would like to feel well enough to enjoy time with family and friends. Short of a cure, they would like more energy and less shortness of breath so that day-to-day life was manageable and their dependence on others for help was less.

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 that patients would most like addressed are: to stop or slow the progression of the disease, to reduce fatigue, cough and shortness of breath, and to improve energy. "I would like to see a real change to the quality of my life."

Shortness of breath is the number one improvement patients would like to experience from any new drug or treatment, followed by a reduced need for oxygen.

The patients indicated that they would be able to live with some side-effects, but nothing worse than they are already experiencing and nothing that was irreversible.

They would also like there to be less or no cost burden associated with new treatments. They would like to be less dependent on others for transportation and help with daily activities.

On a practical level, patients would like the ability to take treatments at home, so it would remove the need for the patient or the caregiver to take time off of work. This would also disrupt the daily routine less.

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.

Five of the nine respondents had experience with Ofev. Compared to previous treatments, Ofev was described as better with helping to improve / provide some relief for shortness of breath and fatigue. However, the gastrointestinal side effects (specifically the intense and hard to manage diarrhea) is a definite negative draw back for patients. Ease of taking this medication (twice daily) is considered a benefit.

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No information obtained for this question

8. Anything Else?

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

All patients interviewed indicated that greater access to psychosocial support, whether that be in the form of individual counselling or support groups, is needed. “This disease is very isolating and we need to be connected to others.”

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No – not applicable

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Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Boehringer Ingelheim (Canada) Ltd.				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: August 17, 2020