



Common Drug Review *Patient Group Input Submissions*

fluticasone furoate and vilanterol (Breo Ellipta) for asthma

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

British Columbia Lung Groups — permission granted to post.

Ontario Lung Association — permission granted to post.

CADTH received patient group input for this review on or before August 20, 2015.

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

British Columbia Lung Groups

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	BREO ELLIPTA
Name of patient group	British Columbia Lung Groups
Name of primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
Telephone number(s)	[REDACTED]
Name of author (if different)	
Patient group's contact information:	
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1.1 Submitting Organization

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

The BCLA is a major Canadian charitable organization with more than a century of experience and leadership in lung disease prevention, treatment and management. Today its areas of interest and expertise include the entire scope of respiratory diseases including COPD, asthma, lung cancer, sleep apnea, idiopathic pulmonary fibrosis, alpha 1 antytrysin and tuberculosis. We work together with the Canadian Lung Association and other partners to help the one in five Canadians 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. This enables our organization to develop and lead programs of education and health promotion at the highest standard. The BC 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 a 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

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

The BC Lung Association has multiple 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 our Christmas Seals campaign, memorial giving, bequests, special events and service contracts with government organizations. From time to time we have received unrestricted educational grants from the following pharmaceutical companies: Astrazeneca, Boehringer Ingelheim, GlaxoSmithKline, Merck Frosst, Novartis, Pfizer, and Grifols. Our relations and interactions with pharmaceutical companies remain transparent, and policy positions of the BC Lung Association are developed without industry influence.

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, Kelly Ablog Marrant, nor the BC Lung Association, has any conflicts to declare in respect to the compiling of this submission.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The British Columbia Lung Association is significantly invested and involved in both Asthma research and provision of patient services and programs. We have Certified Educators on staff that can provide expert consultations/advise to respiratory patients, their family members and caregivers dealing with Asthma and Allergies and other with lung disease.

2.2 Impact of Condition on Patients

The symptoms experienced by all were shortness of breath, chronic cough (a dry cough) sometimes wheezing and fatigue as a result of Asthma. Other symptoms include depression and frustration because they are no longer able to be active and do the things they were once able to do. Depression plays a factor when you are restricted from doing things. It adds to the negativity.

Patients who report negative experiences with the diagnostic process are much more likely to experience a negative mindset with respect to Asthma.

Four primary emotional responses were evident in patients as, Asthma progresses: combative-determined to prolong normality; serene-focus on living normally with family; dejected-mentally and physically exhausted; stoical- suffer in silence and increase in frustration that there is no cure for the condition and only relying on several medications. They become hopeful when a new choice of medication is discovered so that they can access the new medication if the other or current medication they are on is/ are not working for them.

2.3 Patients' Experiences With Current Therapy

Some of their medication works for them but there are some that does not work so they are very grateful when a new medication is available for them to try to relieve their symptoms.

UNMET NEEDS:

Asthma is an inflammatory disorder of the airways characterized by persistent symptoms such as dyspnea, chest tightness, wheezing, sputum production and cough. Symptoms worst at night and early morning.

Of critical importance to the treatment of Asthma are medicines that will help reduce or stop the progression of the disease and subsequent hospitalizations. Additional therapies are needed that go beyond symptomatic relief. New treatments are urgently needed that will work to improve overall lung function. New treatment options are required as the disease progresses.

2.4 Impact on Caregivers

Patients identify a need for balanced information starting at the point of diagnosis, which also impacts caregivers.

A major area of impact identified by patients with Asthma with obvious effects on caregivers, 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 struggle to cope with tasks that they had previously taken for granted (e.g. negotiating a staircase that they climb daily or plain walking on the street or walking around the house)

The first aspect of life where patients start to make adjustments/compromises are in leisure activities and travel. Typically there is an emotional cost to both patients and caregivers, as even the most optimistic people begin to come to terms with the progressive nature of the condition. At worst the impact on mobility can lead to isolation and depression, which is self-reinforcing. As the patient's condition deteriorates, they tend to stay at home or children miss school 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 the patient's independence, with huge implications for parents and caregivers. If the patient is working or has an active social life, this will start to be affected along with an impact on their family life.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The British Columbia Lung Association is significantly invested and involved in both Asthma research and provision of patient services and programs. We have Certified Educators on staff who provide expert consultations to respiratory patients, their family members and caregivers dealing with Asthma and other with lung disease. The vast knowledge and experience garnered through research, best practice guidelines and direct involvement with patients is the basis of the information provided in Section 3. Additional information is taken from several support group meetings we currently have with our lung patients with Asthma in the Province of BC

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

a) *Based on no experience using the drug:*

UNMET NEEDS:

This would be a new medication to try as often times the other medication they are on does not work for them. When it is effective it improves their quality of life.

The individuals interviewed with Asthma and Allergies understand that there is no cure for Asthma but they do understand that the drug slows the progression and relieves the symptom of Asthma. One statement from a patient said "it buys time". Another individual expressed the need for anything that would lessen the need at different times for oxygen, to help the panic breathing mode when you exert yourself. "It is frightening when you can't get enough oxygen to be able to stand up- you have to wait until you can get back to a reasonable state" or it is difficult not to be able to breath. "When you cannot breathe, nothing else matters".

Ontario Lung Association

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Name = Breo Ellipta / Fluticasone Furoate and Vilanterol (as trifenate) Indication = Asthma
Name of the patient group	Ontario Lung Association
Name of the primary contact for this submission:	██████████
Position or title with patient group	██████████
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Telephone number(s)	██████████
Name of author (if different)	
Patient group's contact information: Email	info@on.lung.ca
Telephone	416-864-9911 or 1-800-344-5864
Address	18 Wynford Drive, Suite #401, Toronto, ON M3C 0K8
Website	www.on.lung.ca

1.1 Submitting Organization

The Ontario Lung Association is a registered charity that assists and empowers people living with or caring for others with lung disease. It is a recognized leader, voice and primary resource in the prevention and control of respiratory illness, tobacco cessation and prevention, and air quality and its effects on lung health. The Association provides programs and services to patients and health-care providers, invests in lung research and advocates for improved policies on lung health. It is run by a board of directors and has approximately 70 employees, supported by thousands of dedicated volunteers and works out of a provincial office in Toronto and nine community offices throughout Ontario. The Ontario Lung Association is part of a federated model and works closely with 9 other provincial lung associations and the Canadian Lung Association.

1.2 Conflict of Interest Declarations

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

The Ontario Lung Association receives sponsorship and grants from a number of pharmaceutical companies which support educational and research initiatives. Companies who provide funding to the Ontario Lung Association include: Pfizer, GlaxoSmithKline, Boehringer Ingelheim, AstraZeneca, Merck, Novartis, J&J, Roche, RX&D, Eli Lilly and the Ontario Home Respiratory Services Association (OHRSA). None of these organizations participated in any way in this submission.

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

(Nothing to declare)

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information provided in section two was obtained from 5 recently completed on-line surveys by people living with asthma, as well as input from a certified respiratory educator.

2.2 Impact of Condition on Patients

The symptoms and challenges that people experience as a result of Asthma are coughing (with or without mucus), wheezing, shortness of breath, difficulty fighting infections and weight loss. When asked whether this condition affected their day-to-day life, respondents indicated that it did indeed impact both their physical and leisure activities, as well as their work, ability to travel and socialize. One respondent also indicated that it impacted their independence, financial situation, and relationships with family and friends. A few direct quotes are:

- “I cannot play more intensive sports such as soccer and hockey”
- “My asthma is mostly exercise induced, with allergens being a trigger – so it is worse in the early spring and late summer.”

The aspects of the condition that are most important to control for people living with it are shortness of breath, coughing, wheezing and fatigue – they would also like to manage their weight loss better and have an increased ability to fight infections.

2.3 Patients’ Experiences With Current Therapy

Treatments tried by those who completed the survey included: Symbicort, Ventolin, Alvesco with salbutamol and one person had tried Breo Ellipta.

Current treatments do provide some relief for: fatigue, shortness of breath, cough, low energy, poor appetite and the inability to fight infection, but patients also indicated they want to experience greater assistance with managing all of these symptoms. The side effects indicated from using the above-mentioned drugs include: hoarse voice, increased mucus, low energy/ fatigue, appetite loss and impact on mood.

When asked about whether the treatments affected their life in any other way, the respondents indicated that the cost burden was an issue, as was the time required to travel to health-care settings, the time required off work for these appointments and the changes to their daily routine to accommodate treatment.

2.4 Impact on Caregivers

No information was received for this question.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information provided in section two was obtained from 5 recently completed on-line surveys by people living with asthma, as well as input from a certified respiratory educator.

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:

Key treatment outcomes of asthma that patients would most like addressed are: reduced shortness of breath, reduced coughing, reduced fatigue and improved appetite. They would like an increased ability to fight infections and to have a higher energy level. Ideally, patients would experience an improved quality of life and improved lung function.

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

Only one patient within this evidence group submission has used the drug Breo Ellipta. He/she indicated that one benefit has been reduced coughing, but when comparing it to other drug treatments he/she rated it "worse than" in the areas of administration of drug, side effects and cost burden. The side effects noted were fatigue and impact on mood.