



Common Drug Review *Patient Group Input Submissions*

tiotropium olodaterol (Inspiroto Respimat) for Chronic Obstructive Pulmonary Disease (COPD)

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

Ontario Lung Association — permission granted to post.

CADTH received patient group input for this review on or before June 25, 2015

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.

Ontario Lung Association

Section 1 – General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Name = Inspiolto Respimat / Tiotropium olodaterol Indication = Chronic Obstructive Pulmonary Disease (COPD)
Name of the patient group	Ontario Lung Association
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
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Permission is granted to post this submission	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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. Provincial associations from British Columbia, Alberta, Saskatchewan, Manitoba, New Brunswick and Nova Scotia have also provided support for this submission.

1.2 Conflict of Interest Declarations

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

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information provided in section two was obtained from 11 recently completed on-line surveys sent to patients living with COPD and their caregivers and physicians (5 surveys were completed by patients, 3 by caregivers, 2 by physicians and 1 unidentified), as well as three phone interviews with patients, input from a certified respiratory educator, and previous patient surveys completed within the last year. It is also worth noting that the surveys were sent outside of Ontario, so the input included in this submission has been received from across Canada.

2.2 Impact of Condition on Patients

The symptoms and challenges that patients experience as a result of COPD are many, but at the top of the list were shortness of breath, cough (with or without mucus) and fatigue. These were followed closely by wheezing and exercise limitation. Patients also identified anxiety, depression and loss of self-worth. Patients with COPD may have more difficulty fighting infections. Exacerbations can lead to worsening of lung function. Tasks like opening doors, getting the mail or walking up stairs causes shortness of breath and fatigue. Carrying groceries into the house must be done in several trips with resting periods in between. All day to day tasks take much longer. Increased incidence of infections was noted as an ongoing issue, in fact one respondent stated: “when I travel, I often end up with an infection that requires antibiotics.” The need for medications are often prescribed and in some cases, supplemental oxygen may be required. The inability to do daily activities like housework, cooking or showering leave some people feeling frustrated and without hope. COPD impacts almost all aspects of day-to-day life for people living with it. It affects: the ability to participate in physical and leisure activities (as noted by every respondent in the survey responses), the ability to work, travel and be independent. A few direct patient quotes are:

- “I need to take frequent rests to regain my breath, many heavier jobs I can no longer do, such as vacuuming.”
- “It makes it very hard to do day to day activities such as house cleaning, cooking or exercising.”
- “I am unable to do things like I used to do, such as: showering, cooking or housework. Physical exertion causes my breathing to get worse.”
- “It is a constant fight to maintain independence and reduce depression. Each plateau you reach means adjustments, and the inability to earn an income means having to “make do” all the time.”

The aspects of the condition that are most important to control to patients are shortness of breath, coughing and fatigue – they all clearly indicate they would like these symptoms reduced. They would also like to experience an increase in energy and an increased ability to fight infections.

2.3 Patients’ Experiences With Current Therapy

Treatments tried by those interviewed included: Spiriva, Advair, Symbicort, Daxas, Prednisone, Ventolin, Atrovent, Serevent, Seebri, and Onbrez.

Current treatments do provide some relief for: fatigue, shortness of breath, cough, low energy, and the inability to fight infection, but clearly patients want to experience greater assistance with managing

these symptoms. The side effects indicated from using the above-mentioned drugs include: dry mouth, increased choking when eating, mouth sores, vision and urinary problems and impact on mood. One patient stated: “it is difficult to tell which medication is responsible for what when you take multiple ones.”

The desire for fewer medical appointments was mentioned several times as these require time to travel and changes to their daily routine. There is also a wish for less cost burden as many medications are not covered by the patients’ drug plan. Current therapies do not reduce mucus production enough or hold oxygen levels high enough. Overall, patients would like their treatments to provide enough help that they will experience improved independence and require less assistance from others. The desire for more / increased energy was noted many times throughout the survey. It was stated: “I am getting a bit better at managing this disease as I learn how to exercise. I joined a program at the YMCA and am slowly seeing improvements with my breathing and my ability to manage the disease.” It is worth noting that exercise was mentioned several times in this survey as a “therapy” being used by patients to help manage their COPD.

2.4 Impact on Caregivers

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

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information provided in section two was obtained from 11 recently completed on-line surveys sent to patients living with COPD and their caregivers and physicians (5 surveys were completed by patients, 3 by caregivers, 2 by physicians and 1 unidentified), as well as three phone interviews with patients, input from a certified respiratory educator, and previous patient surveys completed within the last year. It is also worth noting that the surveys were sent outside of Ontario, so the input included in this submission has been received from across Canada.

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

Key treatment outcomes of COPD that patients and their caregivers 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 have to a higher energy level. Ideally, patients would experience an improved quality of life, improved lung function and reduced hospital admissions.

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

Patients do not want to travel to a health-care setting to receive new treatments. They do not want to have to make additional changes to daily routines for themselves or their caregivers and do not want anyone to have to take time off work to accommodate treatments. Patients want to improve enough so that they would be less of a burden to their family.

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

Section 4 — Additional Information

All patients indicated that shortness of breath and fatigue were the symptoms they would most like to improve. Patients would like to be less dependent on oxygen. Patients also indicated that they would like to know more about new treatments for their condition – when they become available / how to be a part of trials or experimental groups. Many patients also expressed interest in accessing information on new therapies.