



CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

olopatadine hydrochloride and mometasone (Ryaltris)
(Bausch Health)

Indication: For the symptomatic treatment of moderate to severe seasonal allergic rhinitis (SAR) and associated ocular symptoms in adults, adolescents, and children aged 6 years and older.

July 8, 2024

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CADTH in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

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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 identifying personal information or personal health information is included in the submission. The name of the submitting group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

Patient Group Input

Name of Drug: <Ryaltris>

Indication: <Treat the symptoms of allergic rhinitis>

Name of Patient Group: <Allergies Québec>

Author of Submission: <Dominique Seigneur>

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

<Allergy Quebec's mission is to promote safety and improve quality of life for those living with food allergies, through information, support, education, training and awareness programs. As the main reference centre in Quebec for food allergies, our association brings together allergists, nutritionists, pharmacists, institutions (schools, daycares, hospitals) as well as companies in the food sector. www.allergies-alimentaires.org/en/>

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.

<N/A>

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?

<Allergic rhinitis can cause uncomfortable symptoms like nasal stuffiness (congestion), sneezing and runny nose. Red, itchy of watery eyes, headaches, sinus pressure and tiredness can happen. Wheezing, coughing and trouble breathing are also noticed. People with airborne allergies have a higher risk of ear infections and sinus infections.>

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).

< Treatment include corticosteroids, oral and intranasal antihistamines >

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?

<It's an all-in-one medication that treats many aspects of the allergic rhinitis>

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.

<It's an all-in-one medication>

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.

<N/A>

8. Anything Else?

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

<No>

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, 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.

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

<No>

1. 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>

2. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<Bausch Health 2023>			40 000\$	
<Bausch Health 2024>	5000\$			

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: <Dominique Seigneur>

Position: Director of communications

Patient Group: Allergies Québec

Date: June 20th 2024

Name of Drug: **Ryaltris** (olopatadine hydrochloride and mometasone furoate nasal spray)

Indication: symptomatic treatment of **moderate to severe seasonal allergic rhinitis** (SAR) and associated ocular symptoms in adults, adolescents, and children aged 6 years and older

Name of Patient Group: **Asthma Canada**

Author of Submission: **Zoe Ulyett**, Research and Communications Intern, Asthma Canada and **Jenna Reynolds**, Director, Programs and Services, Asthma Canada

1. About Your Patient Group

[Asthma Canada](#) (AC) is a national charitable patient-driven organization focusing on improving the quality of life and health for people living with asthma and respiratory allergies. AC has 50 years of experience in providing health education services to consumers and health care professionals. AC offers evidence-based and age-appropriate asthma and allergy education, and disease management programs. Our *vision* is a future without asthma while our *mission* is to help Canadians with asthma lead healthy lives through education, advocacy, and research.

We help patients take control of their disease by providing credible and leading-edge information, guidance, and education to live a symptom free life. We lead and advocate for the best interests of Canadians with asthma and allergies through effective collaboration with policymakers, researchers, and health care providers. The *goals* established by our Board of Directors provide guidance to Asthma Canada's strategic direction.

Asthma Canada is a registered charitable organization (BIN 89853-7048-RR0001). For more information about our organization, visit our website at: www.asthma.ca.

2. Information Gathering

Information for this submission was attained quantitatively and qualitatively. On June 6th, 2024, *the Annual Asthma Survey – A snapshot of Asthma in 2024* opened to Canadians living with or caring for someone with asthma. This survey received 1407 responses as of July 2nd, 2024. Out of the 817, respondents who completed the questions on demographics include: 92 AB, 142 BC, 36 MB, 47 NB, 38 NL, 2 NT, 60 NS, 0 NU, 327 ON, 12 PE, 31 QC, 30 SK, and 0 YT. From the total of 1407 responses, 1183 are patients (i.e. living with asthma), 93 are parents/caregivers to a child(ren) with asthma, and 54 are caregivers for an adult with asthma.

It was found that 37% of respondents experience allergic rhinitis as a comorbidity of their asthma.

Both open and closed ended questions were included in the survey. The questions regarding allergic rhinitis were included in a separate section in the survey which were optional for participants to answer. A total of 102 participants left their contact information on this section.

To further the research, two one-on-one interviews were conducted to gain more in-depth knowledge of the impacts of allergic rhinitis on quality of life. The participants were chosen at random from the list of participants who completed the allergic rhinitis portion of the survey and provided their contact information to Asthma Canada. Interview A took place on June 24th, 2024 while interview B took place on June 26th, 2024. The interviews both lasted approximately 30 minutes and were conducted over Zoom. The interviews were recorded and later transcribed. Interviewee A lives with asthma, between the age of 51-65, identifies as a female, lives in a suburban city in Ontario, Canada, with a college degree as their highest educational level, and never married. Interviewee B lives with asthma, above the age of 65, identifies as a female, living in a suburban city in British Columbia, Canada, with a post-graduate degree as their highest educational level, and is married.

3. Disease Experience

Allergic rhinitis (also known as hay fever) is when the body reacts to small particles in the air called allergens which enter the body through the nose or mouth. There are two classifications of allergic rhinitis: seasonal, which can affect people during specific seasons/time of year, and perennial which can impact people year-round.

In Canada approximately 4.6 million Canadians have asthma and approximately 8.4 million Canadians above the age of 12 have allergic rhinitis (see [Allergies in Canada: Stats, types, and resources | Healthing.ca](#)), while approximately 80% of patients with allergic asthma also have allergic rhinitis symptoms. Overall, it is estimated that 60% of people with asthma are allergic to aeroallergens (see [Aeroallergens in Canada: Distribution, Public Health Impacts, and Opportunities for Prevention. Int J Environ Res Public Health.](#)) Studies have shown that asthma and allergic rhinitis are interconnected with similarities in histology, type 2 inflammatory mediators, and methods of management (see [The Burden of Asthma and Allergic Rhinitis: Epidemiology and Health Care Costs. Otolaryngologic Clinics of North America](#)).

To the question asked “do you/they experience seasonal allergic rhinitis (hay fever), it was found that, 512 out of 807 (63%) answered yes, 181 out of 807 (22%) answered no, and 114 out of 807 (14%) answered unsure.

To explore how allergic rhinitis impacted patient’s and caregiver’s day-to-day life and quality of life, the question “what is the most frustrating/difficult thing about living with allergic rhinitis” was asked. Some answers mentioned:

- Runny/itchy nose
- Nasal congestion
- Sinus pain

- Swollen/itchy eyes
- Disturbed sleep
- Coughing
- Pressure headaches/migraines
- Negative impact on daily activities

"I feel miserable like I do when I'm sick – brain fog, bad congestion – plus itchy eyes."

"I feel sick, unwell, like I have a cold and it interferes with my day-to-day affairs."

"Stuffy nose and increased mucus production makes it harder to

82% of responses indicated that the most difficult/frustrating aspect of living with allergic rhinitis are the physical symptoms that they experience. As the survey was sent to people living with asthma or caring for someone with asthma, the responses further highlighted the fact that their allergic rhinitis worsened their asthma symptoms (tightness in chest, difficulty breathing). Other comments reflected how allergic rhinitis impacts their quality of life by causing stress, since they are unaware when they will experience symptoms (spontaneously triggered), having to use nasal spray daily, being consistently tired, having to avoid the outdoors, and missing activities/school/work. As for caregivers of children impacted by allergic rhinitis, they may not physically experience symptoms, but they endure watching their children suffer.

"Our child suffers from allergic rhinitis. They have difficulty breathing followed by a lack of understanding by others."

Overall allergic rhinitis limits what people can do on a day-to-day basis and negatively impacts their quality of life.

A further question asked, "what is one thing that would make living with allergic rhinitis easier", some answers mentioned:

- No rhinorrhea (runny nose)
- No symptoms/reduced symptoms
- Better relief/more effective medications
- Does not trigger asthma flare ups

"If there was a drug that could control the symptoms and stop the postnasal drip and inflammation."

"The constant need for my inhaler."

"Having to stay inside during the season."

As most participants mentioned that dealing with allergic rhinitis symptoms was the most difficult aspect, finding a solution and/or treatment to eliminate or significantly lessen their symptoms would make living with allergic rhinitis easier.

4. Experiences With Currently Available Treatments

A question in *the Annual Asthma Survey – A Snapshot of Asthma in 2024*, asked participants if they found that their current treatment controls the most common aspects/symptoms. Out of the 378

participants, 164 (43%) answered “yes” or “most of the time/mostly” to this question and 214 (57%) participants answered with “somewhat”, “sometimes” or “no”.

Some current treatments that patients mentioned they take are antihistamines such as Reactine, Blexten, and Desloratadine, while others use saline rinses and nasal sprays.

Nasal sprays can be found in two classes non-prescription and prescription. Some available non-prescription options are decongestants (oxymetazoline and xylometazoline) and corticosteroids (fluticasone propionate and triamcinolone acetonide). While some prescription options are anticholinergics (ipratropium), antihistamines (levocabastine), corticosteroids (beclomethasone, budesonide, ciclesonide, fluticasone furoate, and mometasone).

Additional over-the-counter (OTC) medication that can be used to combat allergic rhinitis are decongestants such as oxymetazoline and xylometazoline, corticosteroids such as fluticasone propionate and triamcinolone acetonide, while prescribed ones include anticholinergics (ipratropium), antihistamines (levocabastine), and corticosteroids (beclomethasone, budesonide, ciclesonide, fluticasone furoate, and mometasone). Another way to combat allergic rhinitis is through allergen specific immunotherapy (AIT), subcutaneous immunotherapy (SCIT) also known as “allergy shots”, and sublingual immunotherapy (SLIT).

Unfortunately, some patients experience side effects from these medications such as drowsiness and needing to use their inhaler as their asthma symptoms are further triggered.

“Better medication to control symptoms: most medications make me drowsy.”

A further concern reflects the fact that antihistamines are costly and are inaccessible because they may not be covered by insurance. Most patients tend to use OTC products since getting a prescription for alternative medication or allergy shots can be difficult for some depending on their location and the drug’s availability at their local pharmacy or clinic.

“Prescription antihistamines to be covered by government.”

Some additional comments that focused on management discussed the need to double-up on medication, taking medication before symptoms got out of control, medication not lasting long enough, and being unable to take allergy medication due to a heart condition.

“Allergy medication/treatment/management is expensive and not covered by insurance.”

Interviewee A mentioned that on their current medication of Nucala (for asthma and nasal polyps’ management) and a daily nasal rinse (NeilMed irrigation with Pulmicort) has improved their symptoms significantly. However, their previous medication of Xolair, occasionally was not able to mask some of their symptoms of sneezing, watery eyes, and nasal blockage which meant taking supplementary antihistamines, specifically Aerius and a nasal decongestant, Dristan. Prior to self-injections, there were some accessibility and communication problems that occurred which made receiving the previous treatments difficult.

Interviewee B voiced that they have had a long journey with finding medications that help treat their allergic rhinitis symptoms. They started with taking desensitizing shots but found that the results did not last. They then took antihistamines regularly, specifically Reactine, and found that they still endured symptoms and their “quality of life was still eroded”. They had also tried Aerius but found that it did not work. Their current treatment consists of taking quercetin in combination with bromelain and vitamin C about a month before grass pollen season starts. This treatment plan has been working since she started it; however it does result in nasal dryness. Lastly, when she is exposed to allergy triggers, she takes a homeopathic remedy called RhinAllergy.

“I was taking antihistamines as if they were candy.”

5. Improved Outcomes

Medications are an important component of the treatment plan for many affected by allergic rhinitis. However, many of the currently available medications cause unwanted side effects that can be as debilitating as the allergic rhinitis symptoms themselves or may result in the patient having to use additional medication to offset side effects caused by their prescribed medication. Patients also express a desire that their medications treat their symptoms better by providing them with sustained relief, not wearing off as fast, or not having to double their prescription in order to benefit.

“[I need] a drug that does the job, but also doesn’t have significant side effects.”

Interviewee B stated her quality of life would significantly improve if new medication was available that did not cause additional side effects. It is important for her to be able to participate in family activities without having to take multiple medications. She also indicated that her husband’s sleep quality is impacted because current medication does not relieve her congestion enough to alleviate her snoring.

Interviewee A mentioned that a difficulty she experiences with her treatment is that the containers that hold the medication can be tricky to operate and that it can be difficult to determine how much medication is left in the container. This led to them missing doses or not knowing it was time to refill the prescription prior to it running out.

When choosing what therapy to use to combat their symptoms, the survey respondents are willing to pay the cost. Some patients do not have private health insurance and even among those that do, certain medications may or may not be covered, or may only be partially covered. Nevertheless, if the interviewees had to pay out of pocket for the medication, they would still do so as, “I still have to live and have a life”. Having to pick between your health and the financial cost of medications is a problem that many Canadians encounter. Lastly, choosing which treatment to take means that some people must decide if the costs, either financial or health, outweighs the impacts that can be caused by the new treatment on their health and well-being.

“It’s hard because it is your health”

If the new medication meant that there were small drawbacks, such as drowsiness, stuffy or dry nose, patients would be willing to endure them if that meant that they were able to complete their daily activities and go back to living a good quality of life.

“If the treatment improves my symptoms sufficiently, does not need to completely erase the, I am willing to deal with some sneezing if it is not debilitating.”

6. Experience With Drug Under Review

We did not interview anyone with direct experience of using Ryaltris. However, both interviewees noted that they would be willing to try it if it improves their symptoms.

“Willing to try anything as long as I am not bedridden.”

7. Companion Diagnostic Test

Asthma Canada is not aware of any current companion diagnostic test for the drug under review.

8. Anything Else?

The ability for those living with allergic rhinitis to afford and access new, innovative drugs in Canada is essential to our community’s wellbeing. It can be the difference between living a healthy, active life and not being able to function and complete daily tasks. The addition of a new allergic rhinitis medication provides another treatment option to those living with ongoing symptoms which are not controlled by their current medications. Patients and caregivers value the positive impact that available treatments have created by curbing their debilitating symptoms, however the financial burden continues to affect many and reduces the likelihood that people will be able to access the appropriate medication.

For patients with asthma and allergic rhinitis, a new treatment option is necessary to better control symptoms that may lead to an asthma exacerbation and/or worsening of allergic symptoms, thereby further impacting quality of life and the ability to properly manage their asthma and SAR.

“My health comes first.”

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AstraZeneca				X
GSK				X
Sanofi				X
Pfizer			X	
Novartis		X		
Bausch			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: Jenna Reynolds

Position: Director, Programs and Services

Patient Group: Asthma Canada

Date: July 5th, 2024

Clinician Group Input

No clinician group input was received.