

# Patient and Clinician Group Input

dupilumab (Dupixent)
(Sanofi-Aventis Canada Inc.)

**Indications:** As add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyposis (CRSwNP) inadequately controlled by systemic corticosteroids and/or surgery.

January 06, 2025

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. If your group has submitted input that is not reflected within this document, please contact Formulary-Support@cda-amc.ca.

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### **Patient Input for CADTH Reimbursement Reviews**

Name of Drug: Dupixent® (dupilumab injection)

Indication: An add-on maintenance treatment for adults with severe **chronic rhinosinusitis with nasal polyps (CRSwNP)**, inadequately managed by systemic corticosteroids and/or surgery.

Name of Patient Group: Asthma Canada

Author of Submission: Maemuna Azka (Programs and Research 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 the public 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 people with asthma across Canada 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) incorporated in 1974.

#### 2. Information Gathering

Information for this submission was attained quantitatively and qualitatively. On October 30<sup>th</sup>, 2024, our Patient Submission on Dupilumab for CRSwNP Survey opened to Canadians living with or caring for someone with nasal polyps to understand their experiences with the condition. This survey received 8 responses and closed on November 28<sup>th</sup>, 2024. Out of the 7 people who filled out the demographics, 3 people live in BC, 1 person lives in MB, 3 live in ON. From the total of 7 people who filled out the survey, all of them classified themselves as adults living with nasal polyps.

To further the research, 1 one-on-one interview was conducted to gain a more in-depth knowledge of the impacts of nasal polyps on their quality of life. The participant was chosen at random from the list of emails left in the demographics section of the survey. The interview took place on November 19<sup>th</sup>, 2024. This interview lasted approximately 20 minutes and was conducted virtually over Zoom. The interview was recorded and later transcribed. The interviewee lives with nasal polyps, is 65+, white, lives in a suburban city in Ontario, Canada, worked as a dental assistant and is retired.

#### 3. Disease Experience

Nasal polyps are soft, painless, non-cancerous growths on the lining of nasal passages or sinuses. They hang down like teardrops or grapes in nasal passages. If the polyps are small, there may not be many symptoms. Larger growths or groups of nasal polyps can block nasal passages, causing a loss of sense of smell, trouble breathing or frequent infections. The blocked nasal passages and sinuses can also worsen asthma symptoms.

CRSwNP is present in 2%–4% of the adult population (see <u>Nasal polyps in patients with asthma: prevalence, impact, and management challenges - PMC)</u>. Asthma is present in 11.94% of the Canadian population, but this rate increases significantly in individuals with CRSwNP, ranging from 20% to 60% of these patients. CRSwNP is often linked to adult-onset asthma, particularly in those over 18,



and some cases involve late-onset asthma in patients over 40. Studies have shown that about 50% of CRSwNP patients eventually develop asthma. The presence of asthma in CRSwNP patients is associated with more severe disease, worse quality of life, and higher rates of hospitalizations and surgeries. Conversely, CRSwNP worsens asthma outcomes, leading to increased symptoms, emergency visits, and systemic corticosteroid use (see <u>Canadian multidisciplinary expert consensus on the use of biologics in upper airways: a Delphi study | Journal of Otolaryngology - Head & Neck Surgery | Full Text).</u>

Symptoms of nasal polyps can include:

- · stuffy or blocked nose and feeling congested
- trouble breathing
- frequent sneezing
- postnasal drip
- runny nose
- · impaired sense of smell
- loss of sense of taste

Among the respondents of the survey who have nasal polyps, they were asked about the most difficult aspects of living with nasal polyps. Answers included:

- "No sense of smell or taste"
- "Plugged nostril because of large polyps on one nostril"
- "The most difficult aspect of living with nasal polyps is when I experience problems breathing through my nose and nasal congestion"
- "Breathing is impossible through that nostril when I have a cold"
- "Being stuffed up makes me ill because it sometimes runs down back of throat. Causes nausea and usually severe asthma symptoms"
- "When they are bad the daily struggle with system. Also the looming surgeries. It is very painful and I've had them about every 10 to 15 years since childhood. I'm now in my 50's"

In relation to their asthma, 4 respondents said their nasal polyps make it harder to control their asthma symptoms, 5 respondents said their nasal polyps require additional medications for management and 2 respondents said that their nasal polyps lead to more frequent asthma flare-ups.

When asked about the challenges family and caregivers face in caring for individuals with nasal polyps, respondents said that there is an increased financial difficulty, impacted quality of life and an increase in missed work/school days. Furthermore, respondents also mentioned that when caring for individuals with nasal polyps, family and caregivers have to deal with frequent doctor's appointments, managing medications and having an impact on their sleep.

"He can't go out if I am sick"

The last question of the survey asked respondents to share one thing that would make living with nasal polyps easier, to which individuals shared:

- "Feeling like I can breathe more easily"
- "Less throwing up, less asthma attacks, better sleep be able to eat entire dinner without getting ill because too much phlegm"
- "Right now, with the medications I am taking, I am stable. Medications, however, are so costly"

In the interview that was done with a patient living with nasal polyps, they shared that nasal polyps and related issues, such as asthma, have caused significant disruption to daily life. Initially misdiagnosed multiple times, the patient experienced years of ineffective treatments, resulting in severe symptoms like nasal congestion, sleep deprivation, and difficulty breathing. Environmental triggers, such as seasonal changes and certain smells, exacerbated the condition. The most important aspect for the patient to control is nasal congestion, as it directly impacts sleep and overall well-being. Without effective medication, controlling the condition becomes extremely difficult, as the patient experienced years of unresolved symptoms before finding the right treatment.

"...I had a really tough time with specialists, Ear Nose Throat. I was misdiagnosed several times. And meanwhile, every time I was misdiagnosed, I was either on the wrong medication or I wasn't on any medication. And a nasal congestion problem developed into a very severe debilitating cough. And again, I went to specialists and a respirologist and they said it was in my



head when all along I had asthma and I could have, fortunately it didn't happen. But I could have died because now that I know, that I have the knowledge, I could have died because I had severe asthma attacks."

#### 4. Experiences With Currently Available Treatments

In the Patient Submission on Dupilumab for CRSwNP Survey, when asked about how effective current treatment is in controlling the symptoms of CRSwNP, 4 out of 7 respondents shared that their current treatment is ineffective. The current treatment options that patients mentioned they were taking included: intranasal corticosteroid sprays, over-the-counter nasal sprays, nasal irrigation/saline rinse and biologics. Nasal sprays can be found in two classes: non-prescription and prescription. Some available non-prescription options are corticosteroids (fluticasone propionate and triamcinolone acetonide) and prescription options also include corticosteroids (beclomethasone, budesonide, ciclesonide, fluticasone furoate, and mometasone).

Additional treatments include oral corticosteroids (prednisone, dexamethasone) and biologics (dupilumab, mepolizumab, omalizumab). If medications are not successful in treating nasal polyps, surgery is also an option to remove the polyps. While there are various treatment options, patients noted that their current treatments are largely ineffective, expensive and show poor symptom control.

"I find absolutely no relief"

Furthermore, patients also experience various side effects from these medications, including an increased risk of sinus infection, allergic reactions and headaches/dizziness. One major concern that patients highlighted was the adverse effects associated with oral corticosteroids. Six out of 7 respondents in the survey expressed their concern with the adverse effects of these medications and how it impacts their health.

"I don't like Prednisone and how it makes me feel. I only do short bursts when absolutely required"

Another concern that patients emphasized was the financial difficulties they face in attaining the medications for nasal polyps' treatment. Many patients noted that the drugs are costly, and while some do have insurance coverage, it does not cover the entire cost of medication.

• "There are financial difficulties. Fortunately, I have independent private insurance, but it doesn't cover my medications plus the biologic medication. I am getting funding, but it can be a hassle"

From the patient interview that was done, the patient is currently using Nucala (mepolizumab) and reported good results in managing both asthma and nasal polyps. However, they shared their prior struggle with finding effective treatment, including two surgeries and a short trial with Xolair (omalizumab) until it stopped working. While their medications are now covered by insurance, they fear losing this coverage and being unable to afford their biologic medication without it.

• "I get really nervous because I'm afraid of being cut off. I'm afraid, you know, I can sort of pay for my other medications for a little while, but the \$2,400 for the Nucala, there's no way I can do that. So I get very uptight about that being cut off"

#### 5. Improved Outcomes

Medications play a crucial role in managing nasal polyps for many patients. However, current treatments often come with significant challenges, including side effects that can be as disruptive as the symptoms caused by the polyps themselves. These side effects may require patients to take additional medications to counteract them, adding complexity to their treatment plan. Furthermore, in the survey, patients expressed a need for more effective symptom relief for day-to-day symptoms, emphasizing the desire for medications that provide longer-lasting benefits and reduce recurrence.

• "Something that actually works. I have tried everything. Every time my nose stuffs up usually asthma follows. Sometimes I throw up because of the amount my nose runs"

When asked about what aspects of a new treatment would be most important to survey respondents, 3 respondents chose easier management of symptoms and better long-term results. Furthermore, other important aspects of a new treatment that respondents chose were a reduced need for surgery, reduced reliance on oral corticosteroids and overall, less anxiety about their nasal polyps. These preferences underline the desire for treatments that not only alleviate immediate symptoms but also provide sustainable relief and minimize the physical and emotional burdens associated with managing the condition. A new treatment addressing these priorities



could significantly enhance patient satisfaction and quality of life. Notably, 4 respondents mentioned that these benefits would outweigh the potential side effects of such a treatment.

"I will sleep better, be able to eat with out what I call 'phleming' out"

Based on the interviewee's insights, they expressed a deep appreciation for treatments that effectively manage their symptoms, improve their quality of life, and eliminate the need for invasive procedures like surgery. Reflecting on past challenges, they emphasized the importance of a treatment that ensures consistent symptom control, reduces the impact of environmental triggers, and minimizes flare-ups. They also highlighted the value of affordability and ease of access, noting the financial and administrative hurdles they've faced with biologic medications. A new treatment would ideally offer sustained relief, prevent the reemergence of polyps, and address other complications, such as ear polyps, while maintaining a patient-friendly approach with minimal side effects. For the patient, a treatment that brings peace of mind and alleviates the anxieties tied to managing their condition would be invaluable.

• "I've had two surgeries and eventually I got onto the biologic medication Xolair, December 2015. And I got a good run out of it. And then I think it was in March 2023. All of a sudden I was having problems and all this junk was coming out of my nose. I could breathe, because the surgery that the ENT did opened up things so the stuff would come out. But the stuff was not nice to look at."

The patient emphasized their gratitude for the effectiveness of biologic medications, despite acknowledging the significant financial burden they entail. Reflecting on their journey, they expressed relief and gratitude for finally finding a treatment that successfully manages their symptoms and enhances their quality of life. This perspective highlights a willingness to bear the associated costs of the medication because the benefits—such as improved breathing, reduced congestion, and avoidance of surgery—far outweigh the challenges. For the interviewee, the ability to lead a more comfortable and functional life is paramount, making the financial strain a secondary consideration in light of the treatment's impact.

• "The only problem with biologic medication, it's very, very costly. It's very difficult with the funding and the paperwork and all the stuff in between. That's what I don't like."

#### 6. Experience With Drug Under Review

We did not interview anyone with direct experience of using Dupilumab. However, in the survey we conducted, 4 out of 7 respondents answered "yes" to the question asking, "Regarding the Dupixent (dupilumab) treatment, do you believe the advantages outweigh the potential side effects in improving the management of your nasal polyps?". Regarding the outcomes of the Dupilumab treatment, 3 out of 7 respondents answered that easier management of symptoms and better long-term results are most important to them.

#### 7. Companion Diagnostic Test

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

#### 8. Anything Else?

Living with nasal polyps can have a profound impact on a person's quality of life. The symptoms of nasal congestion, difficulty breathing, and the physical discomfort caused by nasal polyps can interfere with daily activities, sleep, and overall well-being. For those who have tried various treatments with limited success, the availability of a new treatment option is crucial. A more effective medication could help patients better manage their symptoms and avoid the need for frequent surgeries, reducing both the physical and emotional toll of living with this condition. However, the financial burden associated with some treatments, particularly biologic medications, remains a significant challenge for many. Access to innovative drugs that manage nasal polyps more effectively could provide patients with the opportunity to regain control of their lives, leading to improved health outcomes and reduced reliance on other medical interventions. The addition of a new treatment would be particularly beneficial for those who are struggling to manage the condition with current options, offering hope for a better quality of life.



• "In a perfect world, I wish I didn't have to take any medication. Reality is that I am dependent on medication in order to live a physically and emotionally stable life."

#### **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.

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 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
AstraZeneca				Х
Sanofi				Х
GSK				X
Novartis			Х	
Seqirus			X	
Pfizer			Х	
Bausch Health		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: December 23, 2024

## Clinician Group Input

No clinician group input was received for this review.