



Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

mirikizumab (Omvoh)

Eli Lilly Canada Inc.

Indication: the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, loss of response, or were intolerant to either conventional therapy or a biologic treatment.

March 18, 2025

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC 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.**

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CDA-AMC and do not necessarily represent or reflect the views of CDA-AMC. No endorsement by CDA-AMC is intended or should be inferred.

By filing with CDA-AMC, the submitting organization or individual agrees to the full disclosure of the information. CDA-AMC does not edit the content of the submissions received.

CDA-AMC 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



Patient Input Template

Name of the Drug and Indication	OmvoH (mirikizumab)
Name of the Patient Group	Canadian Digestive Health Foundation
Author of the Submission	Kelsey Cheyne (Peltzer)

1. About Your Patient Group

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

The Canadian Digestive Health Foundations (CDHF) is Canada's trusted resource on digestive health. Committed to providing useful, up-to-date information and research to help Canadians better manage digestive conditions and live healthier lives. Our mission is to reduce suffering and improve quality of life by empowering individuals to manage their digestive health with confidence and optimism.

<https://cdhf.ca/en/>

2. Information Gathering

Canada's Drug Agency (CDA-AMC) 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.

This information was gathered from CDHF's experience with IBD patients, through feedback on surveys, and social media campaigns. No focus groups were conducted or specific interviews.

3. Disease Experience

CDA-AMC 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?

Providing treatment options to improve and control burdening symptoms for patients with chronic digestive conditions, such as IBD, is very important.

IBD symptoms include increased stool frequency, diarrhea, abdominal discomfort, rectal bleeding, reduced appetite, fatigue, bowel urgency, and fecal incontinence. Among these, bowel urgency, the sudden and immediate need to have a bowel movement, is the most bothersome for patients often due to the fear of fecal incontinence. The burden of fecal urgency on patients' lives is underestimated, with ramifications ranging from disruption in daily activities, social interactions, and emotional distress with resultant impairment in quality of life (QoL).

60% to 74% of patients with CD experience bowel urgency, with 25% to 50% of patients experiencing bowel urgency at least once daily (More than 80% of patients with UC). Bowel urgency contributes to a considerable amount of disease-related stress resulting from various situations involving episodes of fecal incontinence, fear of using public toilets, and adaptive behaviors, such as bathroom mapping (knowing the location of the nearest bathroom), wearing an adult diaper, or carrying a cleanup kit. Such psychological stress associated with the experience or fear of bowel urgency-related accidents severely impacts patients' well-being, which in turn can aggravate IBD symptoms.

4. Experiences With Currently Available Treatments

CDA-AMC 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).

IBD requires ongoing management through a combination of medications, lifestyle adjustments, and, in some cases, surgical interventions.

Currently patients with IBD can be on:

- Aminosalicylates
- Corticosteroids
- Immunomodulators
- Biologic therapies
- Janus kinase (JAK) inhibitors
- Surgery – Required in severe cases where medication is insufficient, including colectomy for ulcerative colitis or bowel resection for Crohn's disease.

Benefits include symptom control, remission maintenance and the availability of different drug classes that allow for a more tailored treatment plan based on the patients needs.

Challenges include the side effects, access to treatment, and psychosocial and reduced quality of life.

The management of IBD treatments involves balancing efficacy with potential side effects, including osteoporosis and infections from corticosteroids, serious infections and infusion reactions from biologics, liver toxicity and cancer risk from immunomodulators, and blood clots from JAK inhibitors. Access to these treatments is often limited by high costs, insurance coverage gaps, and logistical barriers, especially for infusion therapies. While oral JAK inhibitors provide an alternative to injections, insurance restrictions remain a challenge. Beyond medical concerns, IBD significantly impacts mental health, causing stress and anxiety for patients, while caregivers face emotional and logistical burdens in providing support.

5. Improved Outcomes

CDA-AMC 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?

For patients with IBD and their caregivers, key outcomes when evaluating new therapies would be improving disease control with fewer side effects, reducing flare-ups, maintaining remission for longer periods, and addressing debilitating symptoms like bowel urgency. Currently available treatments may not always provide consistent symptom management or may come with significant side effects, like mood changes, infections, or the need for frequent clinic visits for infusions. Bowel urgency, in particular, remains a major concern for patients, affecting their ability to work, travel, and participate in daily activities without fear of sudden flare-ups. If new treatments could offer these improvements, patients might experience fewer disruptions to daily life, enabling them to engage more fully in work, social activities, and family life.

6. Experience With Drug Under Review

CDA-AMC 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.

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.

8. Anything Else?

Is there anything else specifically related to this drug review that CDA-AMC should know?

CDHF knows that every patient is different. What works for one may not work, or be tolerated, by another. Therefore, it is important to provide patients and their healthcare providers with as many treatments options as possible. Omvoh (mirikizumab) is one of these options and CDHF supports the approval of Omvoh (mirikizumab) for the treatment of adult patients with moderately to severely active Crohn's Disease.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the 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. CDA-AMC 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
Lilly		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: Kelsey Cheyne (Peltzer)

Position: Executive Director

Patient Group: Canadian Digestive Health Foundation

Date: March 20th, 2025

CDA/AMC – Canada's Drug Agency**March 9, 2025**

RE: Approval Support Submission - Omvoh (mirikizumab) for the treatment of adult patients with moderately to severely active Crohn's Disease.

To Whom It May Concern,

The Canadian Digestive Health Foundations (CDHF) is Canada's trusted resource on digestive health. Committed to providing useful, up-to-date information and research to help Canadians better manage digestive conditions and live healthier lives. Our mission is to reduce suffering and improve quality of life by empowering individuals to manage their digestive health with confidence and optimism.

Providing treatment options to improve and control burdening symptoms for patients with chronic digestive conditions, such as IBD, is very important. To this point, CDHF acknowledges the clinical evidence to support the approval of Omvoh (mirikizumab) for the treatment of adult patients with moderately to severely active Crohn's Disease.

IBD symptoms include increased stool frequency, diarrhea, abdominal discomfort, rectal bleeding, reduced appetite, fatigue, bowel urgency, and fecal incontinence. Among these, **bowel urgency**, the sudden and immediate need to have a bowel movement, is the most bothersome for patients often due to the fear of fecal incontinence. The burden of fecal urgency on patients' lives is underestimated, with ramifications ranging from disruption in daily activities, social interactions, and emotional distress with resultant impairment in quality of life (QoL).

60% to 74% of patients with CD experience bowel urgency, with 25% to 50% of patients experiencing bowel urgency at least once daily (More than 80% of patients with UC). Bowel urgency contributes to a considerable amount of **disease-related stress** resulting from various situations involving episodes of fecal incontinence, fear of using public toilets, and adaptive behaviors, such as bathroom mapping (knowing the location of the nearest bathroom), wearing an adult diaper, or carrying a cleanup kit. Such **psychological stress** associated with the experience or fear of bowel urgency-related accidents severely impacts patients' well-being, which in turn can aggravate IBD symptoms.

Getting inflammation under control and reducing the feeling of bowel urgency are key to improving patients experiences and outcomes. Controlling diarrhea with OTC medications, diet, and exercise is important. In some cases, the use of antidepressants will improve emotional wellbeing. However most importantly, medications that target and ease inflammation caused by IBD will improve bowel urgency. One of these medications is Omvoh (mirikizumab).

CDHF knows that every patient is different. What works for one may not work, or be tolerated, by another. Therefore, it is important to provide patients and their healthcare providers with as many treatments options as possible. Omvoh (mirikizumab) is one of these options and CDHF supports the approval of Omvoh (mirikizumab) for the treatment of adult patients with moderately to severely active Crohn's Disease.

Sincerely,



Kelsey Cheyne, Executive Director, CDHF

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: Omvoh (mirikizumab)

Indication: Crohn's disease

Name of Patient Group: Crohn's and Colitis Canada

Author of Submission: Patrick Tohill

1. About Your Patient Group

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

[Crohn's and Colitis Canada website \(https://crohnsandcolitis.ca/\)](https://crohnsandcolitis.ca/)

Crohn's and Colitis Canada is the only national, volunteer-based health charity focused on finding the cures for Crohn's disease and ulcerative colitis, the two main forms of inflammatory bowel disease (UC), and improving the lives of children and adults affected by these diseases.

Crohn's and Colitis Canada is one of the top health charity funders of Crohn's and colitis research in the world, investing over \$150 million in research since our founding in 1974. The organization also delivers on its promise through patient programs, advocacy and awareness. We help improve the quality of lives today by:

- Sharing accurate and reliable information on treatments, research and issues related to life with Crohn's and colitis through website, print materials, webinars and live events;
- Increasing public washroom access through the GoHere program;
- Raising awareness about these Canadian diseases with bilingual public communication;
- Offering kids with Crohn's or colitis camp experience;
- Providing a peer support program to newly diagnosed people; and
- Advocating on behalf of the patients and caregivers on priority concerns and needs.

Crohn's and Colitis Canada is comprised of approximately 65,000 supporters including volunteers, donors or individuals interested in engaging with the organization. There is no paid membership. Crohn's and Colitis Canada is governed by a national volunteer Board of Directors. The organization has a network of volunteer-led Chapters in 24 communities across the country, offering information, events, fundraising opportunities and encouragement. There are thousands of volunteers from coast-to-coast supporting Crohn's and Colitis Canada's mission.

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.

Information summarized in this section was compiled from a variety of sources. Information was drawn from Crohn's and Colitis Canada's report *2023 Impact of Inflammatory Bowel Disease (IBD) in Canada* Report as well as an online survey undertaken in 2022, that was deployed to our community to better understand unmet needs and priority concerns. The survey included responses from 1706 Canadian patients with Crohn's disease and ulcerative colitis and caregivers, including 687 patients who identified as having moderate to severe Crohn's disease.

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?

Crohn's disease (CD) is a life-long, episodic, autoimmune disease that primarily affects the large intestine. CD can be diagnosed in all age groups but most diagnoses are amongst youth, young adults (16 – 30 years) and seniors. The majority of Canadians living with CD are working-age Canadians. CD can affect anywhere in the gastrointestinal system, from mouth to bum. Symptoms include unpredictable urgent bowel movements, bloody diarrhea, bloating, unbearable pain and often debilitating fatigue.

CD affects every aspect of a person's life from family, friends and work activities. Due to unpredictable urgency of bowel movements, accidents are not uncommon, especially when a patient is experiencing a flare. Patients often hide their disease from work colleagues, friends and even relatives because of the perceived stigma of the condition being a "poop" disease.

Unable to predict when their next flare will occur and how to control their flare, isolation, stress and anxiety are companions to the patient's disease journey. In extreme cases, patients have thought of suicide because of their inability to control/ cope with the impacts of CD on their personal and social lives, as well as consequences in their career or school.

The results from the patient survey provide a window into how patients with moderate to severe Crohn's disease patients live and manage their symptoms.

Asked about their most common IBD-related symptoms, those they'd experienced within the past two weeks, the most common were *fatigue* (100%), *abdominal pain/ cramps* (99%), *pain* (98%), *constipation* (97%), *gas* (95%), *bloating* (79%), *urgency to use the bathroom* (78%), and *diarrhea* (73%). Less common were *nausea and vomiting* (39%), *diminished appetite and weight loss* (38%), *sores around the anus* (34%), *rectal bleeding* (34%), *sores in the mouth* (28%) and *fever* (15%).

Asked what IBD-related complications they were currently experiencing, the most frequently reported were *stress and mental health disorders* (42%), followed by *joint inflammation and arthritis* (38%), *anal fissures and hemorrhoids* (22%), *skin conditions* (22%), *anemia* (18%), *adhesions* (32%) and *malnutrition and weight loss* (8%). Far less common were eye inflammation, strictures, bowel obstruction, perianal fistulas and abscesses, internal (or intra-abdominal) fistulas or abscesses, stricture, ankylosing spondylitis (arthritis of the spine), liver conditions, and cancer.

Thinking back to when they were first diagnosed, 35% of IBD patients noted that they hid aspects of their diagnosis from friends, coworkers and classmates and 33% said they changed travel plans. While more than eight in ten (83%) agreed that a full and active life was still possible with proper treatment, slightly more than three in four (76%) said they thought it possible to feel better than they currently did. Nearly as many noted that they've had to change the expectations they have of themselves as a result of their IBD (72%) or that they always have to adapt their lifestyle to account for their IBD (72%). Slightly more than half (56%) said they had to give up activities because of their IBD and nearly as many said they'd had to change their career goals as a result of IBD (45%).

Most of the respondents said they believed that different treatment options could make them feel better (53% of those with moderate IBD and 60% of those with severe IBD). At least half of these patients felt they couldn't be as open about their IBD as they'd like (51% moderate and 61% severe). Many reported feeling isolated as a result (50% moderate and 75% severe) and quite a few believed that their IBD has had a negative impact on their romantic relationships with their spouse or partner (43% moderate and 73% severe).

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).

Disease management is incredibly important to ensuring patients can live a life of normalcy. In our 2022 survey, most patients with Crohn's disease reported having used a combination of medications, with the most common being biologics and biosimilars (83%), systemic steroids (79%), immunomodulators (65%) and antibiotics (61%) being the most common, followed by sulfasalazine & 5- Aminosalicylates (45%) and non-systemic steroids (43%). Importantly, severity of their IBD plays an important role in deciding which medications are being used. Those who described their condition as severe were more likely to have used these medications than those who described their condition as moderate or mild.

Steroid use is an important aspect in symptom management, though many patients aren't particularly supportive of this treatment option. Almost all patients surveyed agree that they only take systemic steroids if absolutely necessary (93%) with more than four in five (81%) reporting they've had side effects from systemic steroids and a similar number (82%) in agreement that they wish they could eliminate systemic steroids from the list of medications they use. More than half (52%) agreed that systemic steroid use is / was a burden in their management of their IBD. This is particularly true among those with severe IBD (64%) and among women (55%). Among those who are using steroids, 59% have been on systemic steroids for less than 12 months, 19% for 1-2 years, 11% for 3-5 years and 9% for more than six years.

Among patients who say managing medication use is important, having enough of their treatment options, understanding side effects, and minimizing steroid use were most important. Women are more likely than men to find it important to ensure they have enough treatment options, understand the side effects of long-term use, and minimize the use of steroids.

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?

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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.

We were unable to identify and interview patients involved in the clinical trials in time for this review so cannot provide commentary in this 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.

We were unable to identify and interview patients involved in the clinical trials in time for this review so cannot provide commentary in this section.

8. Anything Else?

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

Patients and clinicians need a range of options so that the right treatment can be prescribed to the right patient at the right time. Many patients will appreciate that Omvoh is delivered via self-injection after the initial induction which is by infusion. The ability to self-inject at home was chosen as a top three issue by 40% of the respondents in our unmet needs survey.

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.

The first survey was conducted in collaboration with Leger who performed the initial analysis of the data.

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.

Crohn's and Colitis Canada receives grants, sponsorships and scholarship funding from pharmaceutical companies involved in the treatment of Crohn's disease and ulcerative colitis. These funds are used to sponsor patient education events, community programs, research and medical conferences, educational brochures, kid's camps, post-secondary scholarships as well as outreach and advocacy activities on behalf of Canadians living with Crohn's and colitis. The vast majority of Crohn's and Colitis Canada's funding comes from individual donors contributing to fundraising events such as the Gutsy Walk. Crohn's and Colitis Canada is participating in this review as part of our advocacy for Canadians living with inflammatory bowel disease and does not endorse or recommend the use of specific products or treatment or attribute of any product. No sponsor was involved in developing the content of this submission.

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
Lilly 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: Patrick Tohill

Position: Director, Advocacy and Government Affairs

Patient Group: Crohn's and Colitis Canada

Date: 27 February 2025



Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: mirikizumab (Omvoh®)

Indication: Crohn's disease

Name of Patient Group: Gastrointestinal Society

Author of Submission: Jaymee Maaghop

1. About Your Patient Group

The GI (Gastrointestinal) Society is committed to improving the lives of people with GI and liver conditions, supporting research, advocating for appropriate patient access to healthcare, and promoting gastrointestinal and liver health.

We are a national charity formed in 2008 on the groundwork of its partner organization, the Canadian Society of Intestinal Research (CSIR), which was founded in Vancouver in 1976. We receive national and international attention, simply because we have earned the respect of both the gastrointestinal medical community and Canadians who battle GI and liver issues daily. Our [website](#), available in English and French, received 9,329,479 pageviews in 2023 and 8,890,977 in 2024.

All our programs and services focus on providing Canadians with trusted, commercial-free, medically-sound information on gut (including obesity) and liver diseases and disorders in both official languages. Our BadGut® lectures, quarterly *Inside Tract*® newsletter, pamphlets, support groups, and educational [videos](#) arm Canadians with the information they require to better understand and manage their specific needs. We also work closely with healthcare professionals and governments at all levels toward system-wide improvements in care and treatment.

2. Information Gathering

The information we used to complete this submission was obtained primarily through questionnaires and interviews:

1. 2025 roundtable with a dozen experts, including gastroenterologists and patients/patient groups across Canada, on revising the pan-Canadian IBD Criteria for Advanced Therapy. The report will be available soon.
2. 2024 survey about the unmet needs of individuals living with IBD, with 514 respondents from Canada, available at <https://badgut.org/2024-ibd-survey-results/>. We then conducted a follow-up survey focusing on opinions regarding biologics and biosimilars. This survey received 55 respondents.
3. 2023 interviews with seven individuals living with IBD, in both English and French, available on our website at <https://badgut.org/ibd-patient-interviews/>
4. 2022 survey about the IBD patient journey with 54 Canadian respondents with IBD
5. 2022 focus group with several persons living with IBD so we could map the patient journey and animate it (pictured here), which is available on our website at www.badgut.org/patient-journeys, and we encourage your reviewers to watch these short videos
6. 2020 survey on biosimilars with 145 respondents, most of whom had IBD (some had other inflammatory conditions)
7. 2020 survey completed by 579 respondents regarding the unmet needs of IBD
8. 2018 survey on the unmet need in IBD completed by 432 Canadians with IBD
9. 2015 survey on biologics and biosimilars (then called subsequent entry biologics) completed by 423 Canadians (English: 317 and French: 106) with inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis
10. We also had contact with patients affected by IBD through one-to-one conversations at our BadGut® Lectures, a patient roundtable, recent phone/email/social media interactions with individuals who have IBD, and stories submitted over time from patients.





3. Disease Experience

Crohn's disease is an inflammatory bowel disease (IBD) that can arise at any age, commonly occurring in young people. There is an increased risk for those who have a family member with the condition. Currently, Canada has among the highest prevalence and incidence of IBD yet reported in the world, with approximately 270,000 diagnosed individuals. A recent report from Crohn's and Colitis Canada predicts this to increase to 470,000 Canadians living with IBD by 2035.

Diarrhea, pain, rectal bleeding, and weight loss are common recurring symptoms of Crohn's disease. Inflammation decreases the intestine's absorptive surfaces, triggering watery stools that can lead to fecal urgency and poor control of bowel function. Low red blood cell count (anemia) can result from blood loss due to ulcerations in the intestine and from general malnutrition due to decreased nutrient absorption and the debilitating effects of the disease.

Some patients have extra-intestinal manifestations, including fever, inflammation of the eyes (uveitis) or joints (arthritis), ulcers of the mouth or skin, tender and inflamed nodules on the shins, and numerous other conditions. Anxiety, stress, and mental health are major factors.

Symptoms do not always reflect the level of inflammation, making regular testing essential. It's important for individuals with IBD to continue their medication, even if they feel well.

Crohn's disease often has a profound effect on an individual's life – physically, emotionally, and socially, both at home and at school or in the workplace. Symptoms can be relentless, embarrassing, and scary. The severity of the disease can fluctuate, making it necessary to go through routine testing, reassessments, and medication changes. It is particularly difficult for children and young adults, since it often affects a person's sense of self.

More than anything, patients have told us that sustained remission/treatment response is more important than relieving any one symptom. As a chronic disease, it is never just one flare that dominates the impact of the disease, but the constant concern that there will be future flares, possibly worse than the last, at unpredictable times, which can disastrously disrupt their lives.

The following quotes are from individuals describing what it feels like during an IBD flare, and what their biggest concern is, in their own words:

- "In my experience, some of the most difficult aspects of IBD, pain aside, are its **unpredictability** and the constant, often **overwhelming fatigue.**"
- "**Hopelessness**, for although I have done everything I can humanly do and researched my problem, I can't get any medical professional to listen to me or help or refer me. However, I was **approved for MAID** within 3 months time!!
- "It takes almost a year to determine a **drug isn't working** and then we do a scope, change drugs and the cycle starts all over again... **over and over with no improvements...** **depressing** and making me feel **suicidal.**"
- "Your gut aches and burns and there is often blood in the toilet. You lose your appetite and weight, unhealthily! **My biggest concern is I'm going to run out of meds to help!**"
- "It's like I can't control anything, I feel weak and can barely get up. My biggest concern is usually when I see blood and determining **at what point to go to the ER.**"
- "The **pain is worse than childbirth...** and I have 3 kids...1 labour without drugs."
- "Worst flu symptoms, fatigue, lethargy, like swallowing glass and chili and then having constipation and diarrhea at the same time. Gut cramps and hunger cramps at the same time. **Want to die. Biggest concern is needing a toilet at all times with zero minutes waiting time.**"
- "It feels like my guts are in a vise. **The nausea can be so bad I can't move or even vomit and the diarrhea is so painful I'll be literally screaming in the bathroom.**"
- "**It is so exhausting and feels like it will never end.** You start to question if you can still live the life you planned. And no-one gives you a break."
- "**A flare can come out of nowhere and completely disrupt your life.** Pain can sometimes be so bad that it keeps you in bed. **You mostly spend life either asleep or on the toilet.** My biggest concern during a flare is being able to keep up with my responsibilities (work, school, social, etc.)."
- "It feels like your body is betraying you. **You can't plan anything in advance because you don't know how your body will feel on a day-to-day basis.**"
- "There's a huge element of **fear and worry** and being faced with **mortality** at such a **young age.**"



It's one thing to read a list of common symptoms or data on how IBD affects patients, but it is the individual stories of these patients, as summarized above, which astound us and motivate us to support patients' need for more diversity in effective treatments. In addition, treatments should improve quality of life, not cause more symptoms, pain, frustration, or hardship.

4. Experiences With Currently Available Treatments

The treatment of Crohn's disease is multi-faceted; it includes managing the symptoms and consequences of the disease along with therapies targeted to reduce the underlying inflammation. Since IBD is a chronic disease and there is no cure, it is vital to have a variety of treatment options available. If untreated, it can lead to irreversible tissue damage, reduced quality of life, permanent disability, and even death.

Unfortunately, Canada has a jurisdictional patchwork of criteria to which gastroenterologists must follow when prescribing treatments for Crohn's disease. The specific government-established criteria involve a tiered approach, which differs from province to province. Typically, a patient starts on one type of treatment and, if there is inadequate response, then switches to another type. It starts with the use of 5-aminosalicylic acid (5-ASAs), followed by corticosteroids, immunomodulators, and advanced targeted therapies, such as originator biologics, biosimilars, Janus kinase (JAK) inhibitors, and sphingosine-1-phosphate (S1P) inhibitors. The exception to this approach is Quebec, which we describe below.

5-ASA helps to settle acute inflammation and, for some patients, keeps the inflammation inactive when taken on a long-term basis (maintenance). However, this type of medication can have side effects such as headaches, loss of appetite, and nausea. To reduce inflammation in moderate to severe cases, corticosteroids can help but they are not well-tolerated and can have potentially serious side effects, so they are best for short-term treatment only. For topical relief in the colon, corticosteroids are available in rectal formulations. These are inconvenient therapies that make it difficult for patients to keep a normal routine. Also, if a patient has significant diarrhea, then the rectal medications may be difficult to hold in place for sufficient time to be effective.

Immunosuppressive agents reduce dependence on steroids and can help patients who have steroid-resistant disease, but it could take up to six months or more of therapy to see results. Recent studies have shown that they are not as beneficial as biologics when used on their own, are less effective in healing the mucosa, and can increase the risk of some infections. Many individuals living with Crohn's disease have received, and continue to receive, off-label prescriptions for thiopurines, such as azathioprine (Imuran®) and mercaptopurine (Purinethol®). Health Canada has not approved these medications for IBD, and the Canadian Association of Gastroenterology has cautioned on their use.¹ Yet, many provincial governments require their use before patients can receive coverage for advanced, targeted therapies.

Biologics treat IBD when older medications fail to relieve symptoms. There are a variety of mechanisms through which they work. Patients also find the patient support programs associated with biologics to be significantly beneficial to their treatment plan and disease journey. As you may know, in 2024, CDA conducted a rapid review which found that early or top-down biologic treatments offer significant benefits for patients with Crohn's disease. This approach can improve clinical remission and promote mucosal healing, while also reducing the need for surgery, preventing relapse, and delaying disease progression when compared to conventional therapies.²

There are new classes of medications that target inflammation. These are Janus kinase (JAK) inhibitors and sphingosine-1-phosphate (S1P) inhibitors. JAK inhibitors typically work faster than biologics, pose no risk for immunogenicity, and are easy and convenient to take since they are in pill form. These include a pan-JAK-inhibitor tofacitinib (Xeljanz®) and a selective JAK-inhibitor upadacitinib (Rinvoq®). There are two S1P inhibitors available currently: etrasimod (Velsipity™) and ozanimod (Zeposia®).

To support patients in navigating the various kinds of medications available for inflammatory bowel disease, we created the IBD Medication Guide, available at <https://badgut.org/ibd-medication/search/>. It provides lay information on how the medications work, use in specific groups, such as children, pregnant/breastfeeding women, and older individuals, and links to the product monographs.

Patients with IBD still have a lot of difficulty obtaining remission or adequate symptom relief. In our 2020 survey, 33% of respondents did not believe that their IBD was well-controlled by their current medications. In our 2024 survey, this number was 29%, compared with 38% who find it well-controlled and 33% who were unsure. When asked how concerned they were about running out of treatment options, 82% were at least somewhat concerned. Patients are still suffering, and each person living with IBD has a different experience. This is why it is so important that those living with IBD have access to varied effective treatments.



Despite advancements in care and evidence, provincial government algorithms still follow a one-size fits all approach within each jurisdiction that is not recommended by gastroenterologists. These outdated protocols are not meeting the healthcare needs of those who are living with IBD. They also are not based on clinical practice guidelines, which have evolved. The STRIDE-II recommendations call for personalized treatment with mucosal endoscopic healing with clinical remission as the ultimate long-term treatment target.³

The exception is Quebec, where INESSS released recommendations that removed the requirement of trialing conventional therapy before patients living with IBD can receive coverage of biologic therapies (i.e., adalimumab, infliximab, and vedolizumab). These are evidence-based best practices recognized around the world, and we encourage CDA to follow this approach.

5. Improved Outcomes

Patients affected by Crohn's disease need access to medications that work. Inadequate access to medication results in preventable patient suffering (e.g., continual, debilitating disease symptoms; secondary illnesses such as depression and anxiety disorders; and loss of family/social interactions). It also leads to unnecessary usage of healthcare resources (e.g., hospital stays, surgeries, diagnostic procedures, other medications) and a ripple effect of financial burden on the government and taxpayers (e.g., through inability to work, long-term disability claims, biologic-related debt, and even bankruptcy).

When the Crohn's disease patient receives the right medication at the right time and for the right duration – as determined between physician and patient – these individuals can live full, rewarding lives as productive, valuable citizens who participate in the workforce and community. However, since patients are unique, they respond differently to various medications, and in some cases stop responding to medications after using them for some time, so it is important to have a variety of options available.

6. Experience With Drug Under Review

We know that biologics and biosimilars have revolutionized care for patients living with IBD. They are effective therapies for many, and they can heal the mucosa. While we have not spoken with individuals taking Omvoh® (mirikizumab) for Crohn's disease, we have conducted several patient surveys on biologics and biosimilars across several disease areas. Some of the patients we have interviewed have been taking biologics for several years to a decade or two. In one of our surveys, 63% of respondents reported symptom reduction on a biologic and 23% reported confirmed remission. Many of these individuals had been suffering for years trying to find a treatment that works.

We know that patients want more options, with a variety of administration methods and dosages to meet their unique needs. In our 2024 survey on IBD, 30% of respondents indicated that they have no preferred route of administration, 41% prefer a daily oral medication, and monthly injections were less preferred. When we followed up with respondents who have, or currently take, a biologic medication, 58% said they prefer to self-inject and 18% said that it doesn't matter. This data illustrates that patients have varied preferences for medication administration, influenced by a range of factors. What's crucial is that they have public coverage for a variety of treatment options that cater to their individual needs, without the requirement to trial conventional therapies before accessing targeted treatments.

7. Companion Diagnostic Test

n/a

8. Anything Else?

n/a

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
Eli Lilly				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: Jaymee Maaghop
Position: Health Policy & Outreach Manager
Patient Group: Gastrointestinal Society
Date: 2025-03-11

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- 2 Hsieh SC *et al.* Early Biologic Treatment for Inflammatory Bowel Disease. *Canadian Journal of Health Technologies.* 2024;4(10). <https://www.cda-amc.ca/early-biologic-treatment-inflammatory-bowel-disease>.
- 3 Turner D *et al.* STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target strategies in IBD. *Gastroenterology.* 2021 Apr;160(5):1570-1583. Epub 2021 Feb 19. <https://doi.org/10.1053/j.gastro.2020.12.031>