

CADTH COMMON DRUG REVIEW

Patient Input

VEDOLIZUMAB (Entyvio)

(Takeda Canada Inc.)

Indication: Crohn's disease

CADTH received patient input from:

Crohn's and Colitis Canada

Gastrointestinal Society

June 24, 2020

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

CADTH does not edit the content of the submissions.

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

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Entyvio (vedolizumab)
Name of the Patient Group	Crohn's and Colitis Canada
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	██
Telephone Number	

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

www.crohnsandcolitis.ca

Crohn's and Colitis Canada is the only national, volunteer-based charity focused on finding the cures for Crohn's disease and ulcerative colitis, the two main forms of inflammatory bowel disease (IBD), 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 \$130 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; and
- Providing a peer support program to newly diagnosed people.

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 46 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.

The information summarized in this section was compiled from a variety of sources. Information was drawn from Crohn’s and Colitis Canada (CCC) published reports, including the 2018 “Impact of Inflammatory Bowel Disease (IBD) Report”, the *Patient and Health Care Provider Input: Non-Medical Biosimilar Switch Policy for Patients with Inflammatory Bowel Disease* report and informational brochures found on the organization’s website. A series of surveys (June 2020) and interviews with 21 patients (cross-Canada) managing their Crohn’s disease with Entyvio also provided key patient perspective.

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 is a chronic disorder that causes inflammation of any area of the GI tract from mouth to anus; although, it most commonly affects the small intestine and/ or colon. The symptoms and complications of Crohn’s disease differ depending on what part of the intestinal tract is inflamed. Crohn’s disease is classified as mild, moderate, or severe based on the age at diagnosis, the location of the disease, and the disease behaviour (i.e., whether there is penetrating, stricturing, both, or neither).

Persistent diarrhea (loose, watery, or frequent bowel movements), cramping abdominal pain, fever and, at times, rectal bleeding are the hallmark symptoms of Crohn’s disease, but they vary from person to person and may change over time. Interviewees remarked that they experienced “a constant urgency to use the bathroom and the malabsorption [of nutrients] that comes from the frequent bowel movements”; “horrible cramping”, “the need to wear an adult diaper to bed at night” and “les douleurs abdominales, le nombre de selles liquide par jour avec parfois des périodes d’incontinence ainsi que les nausées et/ou vomissements.”

Loss of appetite and subsequent weight loss may also occur. However, the disease is not always limited to the GI tract. Individuals may experience symptoms outside of the intestine which may affect the joints, bones, eyes, skin and liver. One survey respondent said that “Crohn’s dramatically affected my liver which was very important for me to address with treatment”. Fatigue is another common complaint. Children who have Crohn’s disease may suffer osteoporosis and may fail to develop or grow properly. Some patients may develop tears

(fissures) in the lining of the anus, which may cause pain and bleeding, especially during bowel movements. Inflammation may also cause a fistula to develop. A fistula is a tunnel that leads from one loop of intestine to another, or that connects the intestine to the bladder, vagina, or skin. Fistulas occur most commonly around the anal area. If this complication arises, the patient may drain mucus, pus, or stool from this opening. Symptoms may range from mild to severe. Because Crohn’s disease is a chronic episodic disease, patients will go through periods in which the disease flares up, is active and causes symptoms. These episodes are followed by times of remission—periods in which symptoms disappear or decrease and acceptable health returns.

Most survey respondents sought remission in any treatment they were taking for Crohn’s disease. The description of “remission” varied widely from “ability to sleep at night without constant bowel movements” to “decreased number of bowel movements and lessened pain” to “absence of Crohn’s symptoms”.

Based on a December 2017 survey of Crohn’s and colitis patients (over 3,500 responses), pain and frequent unpredictable bowel movements were a couple of the top priority concerns amongst the respondents.

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).

Participants from surveys shared their treatment experience including the journey toward remission. Many have experienced multiple medications, some over many years. Side effects were varied and in some cases led to the discontinuation of particular treatment (e.g. kidney damage; skin reactions; liver damage). Some patients required invasive surgery due to ineffective treatments as the disease progressed; “I had my large intestine completely removed”, “I required surgery to drain my abscess”.

Patients describe their treatment journey as taking years “I have tried over 20 different treatments since 1998.” “Too many to list.”, with an underlying theme that no one treatment serves all patients – it is very much individualized.

The time commitment required for treatment that involves infusion clinics was shared by many. “I had to take time off work at least once a month depending on how often I needed an infusion. It was embarrassing to tell my supervisor why I constantly needed the time”, “I needed a full day away for infusions because it wasn’t close to my work at all and I was so tired afterward that I went home and slept.”

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?

Patients seek any treatments that can mitigate these symptoms to protect a patient's ability to work productively, attend school and social events, and even basic daily necessities like leaving the house to run errands or have the energy to maintain a household or raise children. Quality of life could be greatly improved in Crohn's patients if their flares are brought into remission, or indeed managed.

Patients, families and caregivers are always considering the challenges inherent in treatment regimens including infusion at clinics. A self-administered option is desirable to many patients considering treatment, though some may be intimidated at the outset. With the advent of COVID-19, gastroenterology and infectious disease specialists highlight the need for more self-administered options for patients with Crohn's. While the current scenario has infusion clinics designated as an essential service, pandemic preparedness should include options for at-risk patients to avoid clinic visits if necessary, or in the event that clinics must be closed for a time, a way for all patients to receive their treatment.

Patients interviewed described what they were looking for in a treatment prior to starting Entyvio. Some were hoping for an increase in wellness overall "I was looking for a medication that can keep the majority of days, between treatments, feeling well. I realize I have a disease and the likelihood of me to be completely symptom free is unrealistic. So as long as 80-90% of my days, that I feel fairly well then I'm happy."

Others sought remission that they had not achieved with previous treatments. "I was looking for something that would keep me in remission. Side effects are sometimes a trade-off but when they are too much to bear you have to look for another treatment."

Many spoke of general quality of life improvements including less sick days from work "Devoir souvent m'absenter du travail à cause des symptômes diarrhée, nausée, vomissements, ulcères buccales" and ability to more fully participate socially "my goal, and hope, was to be able to carry on with life in a more healthy, normal fashion."

One patient discussed living with cancer and requiring compatible treatment "My understanding is that Entyvio is currently the only treatment available that won't compromise my cancer status".

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.

Patients interviewed all indicated that if Entyvio managed the symptoms of their Crohn’s Disease, most side effects would be tolerated. The most commonly mentioned side-effect was fatigue:

“I feel exhausted the 24 first hours following my treatment; somewhat constantly tired”
 “Ainsi que la fatigue !”

Specific aspects of Entyvio treatment were appreciated:

“I like that Entyvio is gut specific”
 “Slowing down of the bowel movements no aches and pains, no rosacea”

General benefits of the treatment included:

“It kept me in remission”
 “Dans les jour qui suivent le soin je n’ai quasiment plus de symptoms”
 “My Crohn’s has been under control since I’ve been under Entyvio without too many side effects.”
 “I definitely feel that my symptoms are much better on Entyvio. With that being said I’m not symptom free but I am able to manage life very well. I still can work 40 hour work weeks, still maintain a regular social life (pre COVID) and have enough energy/ good health days to complete everything that comes up in my life.”
 “Kept me in remission which allowed me to enjoy more events socially.”
 “My life is very good, I’m happy to say. It appears that Entyvio has my Crohn’s symptoms in hand.”

Patients with Crohn’s disease who are at high risk for COVID-19 would absolutely benefit from the subcutaneous version of Entyvio (elderly, those with currently active disease). Further, some patients interviewed who have comorbid conditions have challenges with infusions due to difficulties finding an appropriate IV site.

Patients interviewed expressed significant challenges in receiving medication for Crohn’s via infusion due to the significant time commitment and time away from work and school.

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 CADTH reviewers or the expert committee should know?

Due to the challenges of the current pandemic conditions in Canada and the potential for further issues, it is important that patients with inflammatory bowel disease receive access to treatment that does not require an infusion centre visit. Since Entyvio (subcutaneous) for ulcerative colitis has already received a CADTH recommendation, anything that can be done to expedite this process for Crohn's Disease will be critical to ensure that the pan-Canadian Pharmaceutical Alliance may consider both UC and CD simultaneously. The faster that provinces and territories may have this option for patients the better during such a critical time. Information on at-risk IBD patients during COVID-19 may be found here:

<https://crohnsandcolitis.ca/About-Crohn-s-Colitis/COVID-19-and-IBD/Guidance>

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, 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 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
Pfizer Canada Inc.				X
Janssen				X
AbbVie				X
Merck				X
Takeda				X
Roche		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: Mina Mawani

Position: President and CEO

Patient Group: Crohn's and Colitis Canada

Date: June 23, 2020

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Entyvio® (vedolizumab) for Crohn's disease
Name of the Patient Group	Gastrointestinal Society
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	██████████
Telephone Number	██████████

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, 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 health care, and promoting gastrointestinal and liver health.

Canadian healthcare professionals request more than 600,000 of our BadGut® Basics patient information pamphlets each year, and tens of thousands of Canadians benefit from our important quarterly publication, the *Inside Tract® | Du cœur au ventre*^{MD} newsletter.

Our free BadGut® Lectures from coast to coast cover various digestive conditions for patients, caregivers, and other interested individuals. We also have dynamic websites in English (www.badgut.org) and French (www.mauxdeventre.org), which had more than 4,400,000 *unique visitors* in 2019. GI Society support group meetings offer a wealth of information for those newly diagnosed with a gastrointestinal disorder, as well as those who have lived with a condition for years.

Our highly trained staff and volunteers offer additional patient resources, including responding to information requests and participating in community initiatives. Staff and advisors work closely with healthcare professionals, other patient groups, and governments at all levels on behalf of GI patients. The GI Society, along with its sister charity, the Canadian Society of Intestinal Research (founded in 1976), has supported a number of significant clinical, basic, and epidemiological GI research.

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.*

The information we used to complete this questionnaire was obtained primarily through questionnaires: 1. 2015 survey on biologics and biosimilars completed by 423 Canadians (English: 317 and French: 106) with inflammatory bowel disease (IBD), including Crohn's disease. 2. 2018 survey on the unmet need in IBD

completed by 432 Canadians with IBD, 56% of whom had Crohn's disease. A current survey, which has not yet closed, has had approximately 500 respondents so far, and we have pulled some of their responses below.

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 Crohn's disease; and stories submitted over time by patients. One patient was part of a clinical trial with Entyvio®.

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 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 yet reported in the world, with approximately 135,000 diagnosed individuals.

Diarrhea, rectal bleeding, abdominal pain, 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 or joints (arthritis), ulcers of the mouth or skin, tender and inflamed nodules on the shins, and numerous other conditions. Anxiety and stress are major factors.

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. 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 of Crohn's disease. 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, and at unpredictable times, which can disastrously disrupt patients' lives.

The following quotes are from individuals describing what it feels like during a Crohn's disease flare, and what their biggest concern is, from our current survey, 2020, in their own words:

- "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 child birth...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."
- "The worst part is fear of irreversible permanent damage that will affect your day to day life forever."
- "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.”

It’s one thing to read a list of common symptoms or data on how Crohn’s disease 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

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).

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. Typically, a patient starts on one type of treatment and, if there is inadequate response, then switches to another type.

5-ASA helps to settle acute inflammation and, for some patients, keeps the inflammation inactive when taken on a long-term basis (maintenance). To reduce inflammation in moderate to severe cases of Crohn’s disease, corticosteroids can help. 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 help patients who have steroid-resistant disease, but it could take up to six months or more of therapy to see results.

Biologics treat Crohn’s disease when older medications fail to relieve symptoms. However, there are a variety of mechanisms through which they work.

While there are a few options available, patients still have a lot of difficulty obtaining remission or adequate symptom relief. In one of our surveys, we asked patients if the currently available medications are adequate to control their disease. Only 24% of those with IBD thought that the available medications are adequate. Conversely, 56% found them to be only somewhat adequate and 20% not adequate. Patients are still suffering, and they need new and effective options to achieve mucosal healing and reduce the debilitating symptoms of Crohn’s disease.

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?

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).

We know that biologics are effective at treating Crohn's disease; these medications have revolutionized treatment for inflammatory conditions. 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.

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 respond differently to various medications, and in some cases stop responding to medications after using them for some time, it is important to have a variety of options available.

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?

Patients have seen remarkable – sometimes miracle-like – results from biologics when other treatments failed. But not everyone responds to currently available treatments, including biologics. Even if they do, risk remains that one day the treatment will no longer work for them. More options are essential. Biologics come with a number of potential side effects and risk factors, and physicians only prescribe them when they believe these powerful medications are a patient's best hope of controlling Crohn's disease.

Entyvio® has already been approved for use in patients with ulcerative colitis, another type of inflammatory bowel disease, for whom this medication has been very effective.

With moderate to severe Crohn's disease, Entyvio® has the potential to improve the health and quality of life of many individuals currently suffering from ineffective treatments that put an unnecessary burden on them. When other medications don't work well or specific patients cannot tolerate them, Entyvio® could be an extremely valuable next step in getting a patient's symptoms under control and inducing and sustaining remission.

One thirty-year old man with Crohn's disease who we interviewed had previously been on Humira®. He was feeling well while taking Humira® but did not understand that he needed to take it consistently, even while feeling well, so he ended up losing efficacy with Humira®. He was selected to try Entyvio® as part of a clinical trial. His experience with Entyvio® was similar to the efficacy he experienced with Humira® before. Entyvio® was administered sub-cutaneously in the trial and he liked that delivery method. He said that going on Entyvio® made a "world of difference" in decreasing the number of bowel movements he had each day, and the associated pain. While his diarrhea is now manageable, he still experiences some urgency, but he says this has become his "new normal". While on biologics, he does experience some sacroiliitis, which he finds will go away as long as he keeps up his exercise regime. During our discussion, he volunteered an unsolicited assessment of his experience with Entyvio® as a 10 out of 10.

Each case of Crohn's disease is unique in that the physician is treating an individual patient, potentially with co-morbidities and other influences. What works for one person does not necessarily work for another. Choice among effective treatment options is essential for patients.

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:

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- *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 CADTH reviewers or the expert

Appendix: Patient Group Conflict of Interest Declaration

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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
Takeda Inc. 2019				✓
Takeda Inc. 2018			✓	

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: Gail Attara

Position: Chief Executive Officer

Patient Group: Gastrointestinal Society

Date: 2020-06-23