CADTH

Common Drug Review
Patient Group Input Submissions

adalimumab (Humira) for ulcerative colitis

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Crohn's and Colitis Canada — permission granted to post.
GI (Gastrointestinal) Society — permission granted to post.

CADTH received patient group input for this review on or before October 20, 2015
The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

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

Crohn's and Colitis Canada

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	adalimumab (Humira) for Ulcerative Colitis
Name of the patient group	Crohn's and Colitis Canada
Name of the primary contact for this submission:	[redacted]
Position or title with patient group	[redacted]
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Permission is granted to post this submission	Yes

1.1 Submitting Organization

Crohn's and Colitis Canada is a volunteer-based national charity dedicated to finding the cures for Crohn's disease and ulcerative colitis (two primary forms of Inflammatory Bowel Disease) and to improve the lives of children and adults affected by these chronic conditions. Crohn's and Colitis Canada delivers on its promise by investing in research, education and awareness. The organization is Canada's top funder of cure-directed research and is a world leader in non-governmental funding per capita of such research.

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. There are 45 large local community-based networks and 24 small community groups across Canada. The organization is governed by a Board of Directors. It is further supported by committees, groups and advisory councils.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

In the fiscal year 2013-2014 Crohn's and Colitis Canada received less than 10 % of total revenue from the following manufacturers: AbbVie, Aptalis, Celltrion, Ferring, Janssen, Shire, Takeda, Vertex and Werner

Chilcott. The funds are used to sponsor patient education events, research and medical conference, educational brochures, kid's camps and post-secondary scholarships for IBD patients. The vast majority of Crohn's and Colitis Canada's funding comes from individual donors contributing to fundraising events such as the Gutsy Walk.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

None of the pharmaceutical companies have played a role in contributing to this submission. This patient input submission was developed and prepared solely by the staff at Crohn's and Colitis Canada.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information summarized in this section was compiled from a variety of sources. Staff at Crohn's and Colitis Canada conducted telephone interviews with 10 Canadian patients, currently taking adalimumab (Humira), across the country who participated in the clinical trial of the current therapy.

Statistical evidence was taken from a 2011 national online survey that explored the physical, social and economic impacts of living with IBD. Over 430 people across the country participated in this survey.

Additional information was drawn from the Crohn's and Colitis Canada published reports, including the 2012 "Impact of Inflammatory Bowel Disease (IBD) Report" and informational brochures found on the organization's website.

2.2 Impact of Condition on Patients

Canadians have more reasons to be concerned about ulcerative colitis (UC) than anyone else in the world. Canada has one of the highest rates of those being diagnosed with UC. There are approximately 104,000 Canadians who live with UC. Sadly, there is also a sharp increase in the incidence of children under the age of 10. Families new to Canada are developing colitis for the first time – often within the first generation. UC is Canada's chronic condition. The burden that UC places on individuals, the healthcare system and society is significant and will continue to grow as the number of patients with this chronic condition increases.

A large majority of Canadians living with UC feel that the most important aspect of the condition to control and limit is the urgent and frequent need of bathroom visits when these diseases are in active stage. This corresponds with results based on a Crohn's and Colitis Canada 2011 survey where 73% of respondents, affected by inflammatory bowel disease (IBD). Respondents said they experienced between five to 20 bowel movements a day. In addition, 13% of respondents experienced more than 20 movements or urges a day. Other aspects of the condition they wished they could minimize included bloody diarrhea, fatigue and fluctuations in weight. Some were concerned about their increased risk of being diagnosed with colon cancer – a condition that is more likely to occur with longstanding UC.

Patient's lives are greatly affected by UC. The constant need to go to the bathroom makes it difficult to work, especially if you don't have a supportive work colleagues or an adaptable environment. People living with UC worry that their disease may affect their job and career because the disease results in an invisible disability; it is difficult for colleagues to understand a person's incapacity to work. According to a Crohn's and Colitis Canada's 2012 publication, The Impact of IBD Report, 43% of employed people with

UC and Crohn's disease took time off work per year, and each employed person with either ulcerative colitis or Crohn's disease took 7.2 days off per year due to their chronic condition. The report also highlights that people with ulcerative colitis or Crohn's disease are more likely to have lower labour participation rates than the general population, ranging from three to 13% less employment. Caregiver work absences in Canada are estimated to be $7 million per year for parents of paediatric IBD cases, plus $86 million per year for severely ill people with IBD.

When patients are not receiving effective treatments, they must limit their activities such as going out to dinners, movies and concerts, doing physical activities and using the public transportation system. Thirty-four per cent of survey respondents frequently missed out on playing sports, 22% missed school trips, 20% skipped family vacations, 40% avoided parties and 22% did not attend special events (graduations or family weddings). As one interviewee stated, "There is no quality of life. Virtually any activity that would take an individual away from the bathroom cannot be done."

2.3 Patients' Experiences With Current Therapy

Unfortunately, there are a limited number of treatment options available for people with ulcerative colitis (UC). As a first-line treatment, and depending on the severity of the disease, people with UC are prescribed aminosalicylates (i.e. mesalamine). If remission is not achieved or the severity of the condition is greater, then immunosuppressants (i.e. Azathioprine) and or steroids, either corticosteroids or prednisone, are prescribed. Steroid doses are increased when symptoms worsen.
These drugs often work well for those experiencing mild to moderate levels of UC, but often fail in maintaining remission for those experiencing severe forms of UC. For some interviewees, these treatments kept their condition in remission for long periods of time at different and early stages of their disease, and for others aminosalicylates or immunosuppressants the treatments did not change their symptoms and overall condition.

Most did not report experiencing side effects in taking the aminosalicylate or immunosuppressants, however interviewees did report side effects from steroid use. The negative impact of steroid use over the long term is well documented in scientific literature.

People living with ulcerative colitis require new therapies and treatments since some don't respond well to current options and others may eventually lose response due to antibody formation. Accordingly, medical experts and their patients demand more than one drug option within this therapeutic class, otherwise patients who lose response are left with the only remaining option of surgery.

Based on the Impact of IBD Report, 16% of people with ulcerative colitis have received surgery. The surgery for UC patients is a colectomy, a surgical procedure that removes all or part of a colon. Some patients require additional surgeries to construct an internal ileo anal pouch; however, surgery does not improve the quality of life. Post-surgery complications include soiling, poor pouch function, pouchitis and sexual dysfunction. Sadly, many females who undergo surgery for UC are at an increased risk of losing fertility. Surgery is unpleasant and is often the last resort, because of limited drug treatments available and sponsored by public programs. One male interviewee stated that "proposing surgery as a viable treatment option is inhumane and not fair. Surgery should be considered an option of last resort. It is a shame that there is nothing else to take."

Drug coverage continues to be a concern for people living with chronic conditions given the number of inequalities of accessing IBD treatments across the country. Provinces cover different medications at different costs, many Canadians living with ulcerative colitis do not have access to private health insurance and the costs of prescribed biologics are prohibitive for many. In a 2011 national online survey that explored the physical, social and economic impact of living with Crohn's and colitis, drug coverage was a concern for the majority of the 430 survey respondents. Though 66% of survey respondents said they have drug coverage through an employer or school, 24% of that group said they were denied insurance coverage for medications needed to manage their IBD. Approximately 19% of survey respondents relied on provincial and territorial drug programs and nearly 8% had no drug coverage at all. A quarter of the total number of survey respondents have admitted to borrowing money to pay for their vital IBD medications.

2.4 Impact on Caregivers

For many affected by ulcerative colitis, caring comes with challenges. Absences from work, high costs of care, fatigue and stress can generate negative emotional and mental health.

With increasing numbers of children being diagnosed with ulcerative colitis, parents play an important caregiver role. Based on the Impact of IBD Report, the caregiver costs for parents of children living with Crohn's and colitis totalled $7 million for the estimated 5,900 children with IBD in Canada in 2012. Potentially, the overall cost of caregiving for people living with severe forms of Crohn's disease and UC is estimated to be at $86 million annually.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information summarized in this section was compiled from several sources including Crohn's and Colitis publications, posted on the organizational website, a 2011 national survey and telephone interviews.

Interviews were conducted by Crohn's and Colitis staff with several people living with ulcerative who have or continue to participate in the clinical trials and are using the current therapy of adalimumab (Humira).

Data from a 2011 national survey on the impact of IBD has been incorporated into the responses. Over 430 people affected by IBD across the country participated in the survey.

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

The introduction of new biologic treatments will significantly improve the quality of life for people living with severe forms of ulcerative colitis. Many of the current first line treatments involve the potential use of prolonged steroid use or cause side effects that do not ease the number of bowel movements, bloody stools, bloating and gut pain experienced by the nearly 104,000 Canadians affected by ulcerative colitis. To date, infliximab (trade name: Remicade), adalimumab (trade name: Humira) and golimumab (trade name: Simponi) have been approved by Health Canada for ulcerative colitis (UC). The reality is that there are greater drug options available for individuals living with Crohn's disease than for those with UC and greater options for mode of administration.

It is expected that with new and proven biologics, many patients will be able to have a ‘normalized’ life and UC will become a minor inconvenience. Individuals will no longer need to plan their activities around sudden washroom visits. And for many women living with IBD, the introduction of new biologic treatments there is hope that women living with IBD can have the same fertility rates as women in the general population when their disease is in remission. Research has shown that flare-ups cause a decreased rate of fertility.

With the advancements of new medications, there is a reduced need for surgery. In the case of Crohn’s disease surgical rates have been falling as well as the rate of hospitalization. The Impact of IBD Report attributes the drop in surgeries to people diagnosed with Crohn’s disease receiving biologics, surgeries and immunosuppressants more immediately. The increased availability of new drugs would lead to fewer hospital visits and greater independence and quality of life.

Patients worry about the potential cost of the drug and the possibility that they may no longer be able to afford the treatment without adequate private or public insurance coverage.

Most people interviewed for this submission remarked on the method of use for adalimumab (Humira), stating that its ease of use gives it an advantage over other biologics. It is a self-injection that can be done at home and does not require travel to a hospital or a medical clinic. Where other first line treatments have failed, adalimumab has been able to keep patients on remission for lengthy periods of time. All interviewees were part of the clinical trials ranging from 7 months up to 5-6 years. Patients who have taken adalimumab for five years reported no side effects. Its positive effects were reported as ranging from immediately to one week.

Patients either self-inject or, for those who prefer, can have a caregiver administer the injection for them. For adalimumab, patients must remember to take the drug once every two weeks as directed by their medical practitioner or clinical trial. Adherence is critical and dependent on the patient. One female interviewee failed on both infliximab and adalimumab. She experienced an allergic reaction to infliximab and did not have any side effects on adalimumab. However, her sister who also lives with UC has been in remission since taking adalimumab. She says that “although Humira did not work for me, I appreciate the availability of drug options so I could try to see what worked best for me.” People with UC want the freedom of choice and availability to take the drug that is most effective for them.

Interviewees are concerned about the potential cost of the drug and fear they may not have proper coverage to access the drug once they have completed clinical trials.

An overall positive effect of adalimumab is that it has given patients hope that there can be a drug that works for their severe form of UC. It helps with reducing the number of bowel movements, reducing fatigue and keeping patients in remission. It also alleviates the psychological stresses and fears that come from living with inflammatory bowel disease – alleviating the stress and anxiety about where the next bathroom will be located.

GI (Gastrointestinal) Society

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Humira® (adalimumab) for ulcerative colitis
Name of patient group	GI (Gastrointestinal) Society
Name of primary contact for this submission:	[redacted]
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Website	www.badgut.org
Permission is granted to post this submission	Yes

1.1 Submitting Organization

Our mission: 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 health care professionals request more than 550,000 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 coeur au ventre*MC 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). Organized on a number of topics, 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 health care professionals, other patient groups, and governments at all levels on behalf of GI patients. In addition, we occasionally hold continuing education events for pharmacists, nurses, dietitians, and physicians. The GI Society, along with its sister charity, the Canadian Society of Intestinal Research (CSIR – founded in 1976), has supported a number of significant clinical, basic, and epidemiological research projects in the field of gastroenterology.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

The GI Society receives financial contributions from AbbVie Corporation and other pharmaceutical companies in support of our independent charitable work for Canadians affected by GI/liver conditions. Supporters have no input into the editorial content of our resource material, which is approved by the GI Society's Medical Advisory Council (made up of GI/liver health experts only). Other pharmaceutical companies from whom we have received support of any kind, such as charitable donations or grants, sponsorships, subscriptions to *The Inside Tract®* newsletter, etc. in the last two years include:

AbbVie Corporation, Actavis/Allergan, AstraZeneca Canada Inc., Canada's Research-Based Pharmaceutical Companies (Rx&D), Ferring Inc., Gilead Sciences Canada Inc., GlaxoSmithKline Inc., Janssen Canada, Merck Canada Inc., Pfizer Canada Inc., and Takeda Canada Inc.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

None. The GI Society has solely prepared this submission entirely independently of any outside groups or individuals.

Section 2 — Condition and Current Therapy Information

2.5 Information Gathering

This information was obtained primarily through a recent questionnaire completed by 133 Canadians (English: 105 and French: 28) with ulcerative colitis (or their caregivers or family members), contact with patients affected by ulcerative colitis, one-to-one conversations within the community during our BadGut® Lectures, which 729 individuals attended, at a recent patient roundtable, from patients who submitted their stories, and the expertise of our health care professional council and advisors (gastroenterologists, pharmacists).

2.6 Impact of Condition on Patients

Ulcerative colitis is a serious inflammatory bowel disease (IBD) consisting of fine ulcerations in the inner mucosal lining of the large intestine. Inflammation starts just above the anus and extends upward in a continuous manner, to variable distances. There is no cure.

A diagnosis of ulcerative colitis can occur at any point throughout life, with a high occurrence in young children and then again around 40-50 years of age. There is an increased risk for those who have a family member with the condition. Currently, Canada has the highest prevalence and incidence yet reported in the world, with approximately 104,000 diagnosed individuals. Patients are at a slightly increased risk for colorectal cancer after having ulcerative colitis for about 10-15 years.
Rectal bleeding, in varying amounts, occurs in most patients, where blood is obvious within and covering the stool. Low red blood cell count (anemia) can result if diarrhea and blood loss are severe. The second

most frequent symptom is diarrhea, accompanied by cramping abdominal pain. Constipation can also develop, as the body struggles to maintain normal bowel function.

Some patients have extra-intestinal manifestations of ulcerative colitis, 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.

Ulcerative colitis 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 ulcerative colitis. 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.

In our recent questionnaire, ulcerative colitis patients shared the following regarding the impact that their disease has on their day-to-day lives:

Normal Social Activities Severely Limited

- “I can't go out for a long period without having to find a toilet. Abdominal pain and noise of going to the toilet are annoying in public.”
- “It is frustrating having to use the bathroom so often, and when in public if bathrooms are not available. Having to wait to use the washroom causes more pain. I try to continue my life as usual but I do get tired of having to use suppositories & enemas. I love the outdoors & camping & this can be challenging to administer in these settings.”
- “Ulcerative colitis sometimes makes me change or alter my plans because of the symptoms or side effects. I also tend to limit the length of my outings and the locations.”
- “I am not as active as I was before my ulcerative colitis diagnosis.”
- “I limit which activities I do, especially if I have little energy or a flare-up. I tend to be more comfortable doing activities that I know will keep me in close vicinity to a washroom. Despite being in remission for quite some time, these issues are still on my mind.”
- “I have to limit distance driving.”
- “Doing outdoor activities where a bathroom would be difficult to find are now almost off limits if I am not in a remission stage.”
- “I'm also no longer able to run recreationally, as I'm always tired.”

Work Life

- “I miss work on a regular basis and it is affecting my chances of obtaining permanent employment as a teacher”
- “I have low energy, I'm tired often. My employer does not understand and it affects my attendance.”
- “After my ulcerative colitis diagnosis, I had to change to a less physically demanding job with less pay.”

Family Life

- “I was diagnosed young – age 9. More often now I am having to change things. Looking back, I was a very tired teenager but no one understood and thought I was lazy”
- (From caregiver/family member): “She spends less time doing the things she wants to do – sports, time with friends, etc.”

Living with Debilitating Pain and Discomfort

- “When I have flare-ups it causes me to interrupt my day to day functions as I have to frequently run to the bathroom.”
- “I’m in pain all the time.”

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

2.7 Patients’ Experiences With Current Therapy

The treatment of ulcerative colitis 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 ulcerative colitis, 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.

Monoclonal antibodies (biologics) treat ulcerative colitis when older medications fail to relieve symptoms. A patient can self-inject Humira®.

40 out of the 50 patients who responded to this part of a very recent questionnaire believe there is a gap in currently available treatments for ulcerative colitis. Of these patients, more than 80% felt that safer and more effective medication options are especially lacking.

Some problems they described with current treatments include the following:

- “On the prednisone I have developed the "moon" face, I face challenges with emotions. I experience depression off and on. I am really, really, really tired of using enemas & suppositories!”
- “I get many side effects when taking prednisone.”
- “With my current treatment, I often fail to get to the bathroom on time.” [Stop and imagine for one minute how much anxiety and mess this would cause!]

Patients know that biologics are expensive medications, and they believe that government decision-makers should consider the tremendous costs associated with the disease when they do not have appropriate treatment, as these costs are much more burdensome to Canadian taxpayers.

“While it is true that these drugs are exorbitantly expensive,” said one participant in a recent roundtable discussion, “in the long run they are less costly for society than the alternative, which is other numerous health care expenses, surgeries, and hospital stays, as well as lost work productivity and long-term disability funding.” Additional ripple-effect costs relate to depression and other mental health problems ulcerative colitis patients suffer when their disease is not under control for long periods.

Patients affected by ulcerative colitis need access to medications that work. Inadequate access to biologic 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 health care 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 IBD 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.

Surgery is also a treatment option and we discuss this more fully below.

2.8 Impact on Caregivers

When treatment does not provide effective relief, patients require more frequent use of hospital resources, increasing the public health care burden and disempowering individuals. In addition, caregivers may need to devote more resources to a family member suffering from ulcerative colitis flares who is unable to complete day-to-day tasks such as errands, cooking, hygiene, etc., because of unresolved disease problems.

Section 3 — Information about the Drug Being Reviewed

3.2 Information Gathering

This information was obtained primarily through a recent questionnaire completed by 133 Canadians (English: 105 and French: 28) with ulcerative colitis (or their caregivers or family members), contact with patients affected by ulcerative colitis, one-to-one conversations within the community during our BadGut® Lectures, which 729 individuals attended, at a recent patient roundtable, from patients who submitted their stories, and the expertise of our health care professional council and advisors (gastroenterologists, pharmacists).

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

Patients have seen remarkable – sometimes miracle-like – results from biologics when other treatments failed. Not everyone has responded to the current available treatments, so 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 inflammatory bowel disease's (IBD) difficult, sometimes incapacitating symptoms. Ulcerative colitis patients, even more so than Crohn's disease (another serious IBD) patients, have been suffering too long from an inadequate variety of treatment options.

As an injectable biologic medication for moderate to severe ulcerative colitis, Humira® 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, Humira could be an extremely valuable next step in getting a patient's ulcerative colitis symptoms under control and, for some, inducing and sustaining remission. Among many similar comments, one survey respondent said, "Since Humira has helped me completely cure UC symptoms for the time being it has helped me to become healthy as I was before UC."

Our experience is that each case of disease is unique in that the physician is treating a unique patient, potentially with co-morbidities and influences. One of the twelve ulcerative colitis survey respondents who used Humira said, "I was on Remicade but it stopped being effective for me. I am now on Humira and I inject myself once every 2 weeks." What works for one person does not necessarily work for another. **Choice among effective treatment options is essential for patients.**

Surgery versus Biologics

When the digestive system ceases to function properly due to ulcerative colitis, a physician may recommend removing the colon (colectomy). Typically, it may no longer be possible to eliminate waste (have a bowel movement) from the usual anatomic route. The surgeon will remove diseased tissue and then re-direct the end of the remaining intestinal tract to the surface of the skin, and the surface opening is called a "stoma" or ostomy. An appliance is attached to collect waste.

Since ulcerative colitis only involves the large bowel, removing this organ will remove the diseased tissue, but **this is not a cure**; removing the colon can lead to other symptoms and complications, and **the systemic disease remains**. The colon's primary function is to extract water from bowel contents, so with the loss of colon function, elimination remains frequent and is mostly liquid. This means that even after surgery, patients could face troublesome gastrointestinal symptoms – up to 20 bowel movements a day. If a patient has a surgically-created pouch to hold stool before elimination, it can become inflamed, a condition called pouchitis, which requires further medical attention.

Many patients will also continue to experience serious extraintestinal manifestations of ulcerative colitis, such as arthritis of the spine (ankylosing spondylitis), ongoing inflammation or ulcerations of the skin, and many other serious conditions.

While being successfully treated on biologic medications, such as Humira, patients are less likely to suffer from the extraintestinal manifestations of ulcerative colitis.

All except 1, out of 46 patients who responded, said they would rather receive a biologic medication, despite the potential risks and side effects, than get a colectomy. Even if their disease became very severe, they still said they would prefer a biologic medication over colectomy. One patient explained, "I have a strong desire to keep my body intact. The colon serves a myriad of beneficial functions and is self-cleaning.” Another told us, “I'm in remission and have been since beginning Humira. As such, I do not feel the need for surgery.”

Biologics Mean Hope for a Brighter Future for Many Patients

During a roundtable discussion the GI Society held recently with IBD patients who had taken biologic medications, all participants agreed or strongly agreed that biologic treatment has greatly increased their overall health and wellbeing, as well as work/school life. All except one person also reported that biologics also improved their home/social lives. In addition, 75% of respondents felt that taking biologic medications greatly improved their emotional wellbeing. However, of note is that most participants also spoke of how anxiety over financing their biologic has a negative effect on their emotional wellbeing.

One participant from that roundtable discussion, who had suffered through older, ineffective medications for about eight years, found that biologic medications improved every area of his life. Before biologics, going to work meant regular, humiliating accidents during which he experienced fecal incontinence in the office and on public transportation. Now, after successful treatment with biologics, he’s enjoying a rewarding career and participating in sports and other social activities. Where before he found there was nothing he could eat without pain and would avoid food, he is now at a healthy weight and is finally moving on with life. “Wish I had had this option 8 years earlier,” he said. “I have been able to have a life.”

A parent from that roundtable told us, “The use of biologics has restored our child’s quality of life. He is now able to attend school on a regular basis. He has recently started extracurricular activities such as skating. He still has to manage [some] symptoms… but biologics have made it possible for our child to regain some sense of normalcy.”

Another ulcerative colitis patient, who lives on an island, spoke to us of her frustration with obtaining biologic treatment. UC can be severe for some patients, as it is for this patient, who requires regular infusions to control disease activity. In addition to fears about her future and the long-term effects of treatment, she is very concerned about access to medications. She travels over 120 km every few weeks to receive an infusion. “Not only is access to the drug for rural residents challenging,” she explained, “but access to specialists is as well.” If a medication like Humira, which is administered by injection, were available and affordable, physicians would have other options to consider for their patients, which might help someone like this patient receive effective biologic treatment without the further expense and physical burden of constant travelling for infusions or other therapy.

Biologics are life-changing medications for some patients with inflammatory bowel disease, a chronic ailment with ongoing, frequently debilitating symptoms if not properly treated. Intensity of this condition varies greatly from one person to another and fluctuates greatly during a lifetime. Some patients may have an initial episode and then go into remission for a long period, some may have occasional flare-ups, and some others may have unrelenting disease. Because there is no cure, ulcerative colitis patients require ongoing medical care, and must adhere to a proper nutrition and medication regimen, even when things appear to be going well.

The GI Society believes strongly that the right medication should be affordably accessible to the right patient at the right time. There is no ‘one size fits all’ treatment for ulcerative colitis. What works for one patient may be ineffective or intolerable for another. Humira gives physicians another option for patients, which, for some, could mean the difference between experiencing sustained remission and returned quality of life or continued suffering with painful, debilitating symptoms that make it impossible to carry on work, family, or social lives. On behalf of these patients, we ask for a recommendation to include coverage of Humira for the treatment of moderate to severe ulcerative colitis.