Common Drug Review
Patient Group Input Submissions

Budesonide (Cortiment) 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 June 15, 2016
CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

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

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		CORTIMENT®[MMX] (Budesonide) for the induction of remission for patients with mild to moderate ulcerative colitis
Name of the patient group		Crohn's and Colitis Canada
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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 main forms of Inflammatory Bowel Disease (IBD), and improving 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 IBD-related research and is a world leader in non-governmental funding per capita of such research.

Crohn's and Colitis Canada is comprised of approximately 90,000 supporters including volunteers, donors and individuals interested in engaging with the organization. There is no paid membership. There are over 50 chapters and community groups across Canada. The organization is governed by a volunteer national Board of Directors. It is further supported by committees, groups and advisory councils

1.2 Conflict of Interest Declarations

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 2014-2015 Crohn's and Colitis Canada received less than 10% of its total revenue from the following manufacturers: AbbVie, Actavis Allergan, Ferring, Janssen, Shire, Takeda, P&G Canada, and Vertex. The industry-derived funds are used to sponsor patient education events, research and medical conferences, educational brochures, kids' camps and post-secondary scholarships for IBD patients. The vast majority (90%) of Crohn's and Colitis Canada's revenue comes from individual donations collected from community-based fundraising events such as Gutsy Walk.

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. Information was drawn from the Crohn's and Colitis Canada (CCC) published reports, including the 2012 "Impact of Inflammatory Bowel Disease (IBD) Report" and informational brochures found on the organization's website. Statistical evidence was taken from a CCC 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. Additionally, one-on-one telephone interviews were conducted with three Canadian patients (either currently taking or have taken Budesonide MMX).

2.2 Impact of Condition on Patients

Crohn's disease and ulcerative colitis (UC) are disabling, life-long gastrointestinal conditions that primarily affect working-age Canadians. These diseases are twice as common as multiple sclerosis or Parkinson's disease and are about as common as Type 1 diabetes or epilepsy. Sadly, Canada has a rate that ranks highest in the world. New evidence suggests that these diseases are now escalating in children at an alarming rate, especially those under 10 years old. Over the past 15 years, the number of children with Crohn's and colitis has increased by more than 40%. With an expected 10,200 new diagnoses every year, in addition to the nearly quarter of a million Canadian currently living with Crohn's and colitis, these diseases are becoming increasingly prevalent in Canada.

Overall, Canadians have more reasons to be concerned about Crohn's and colitis than anyone else in the world. With one in every 150 Canadians being diagnosed with Crohn's disease and ulcerative colitis - the two most common forms of Inflammatory Bowel Disease (IBD) - these conditions are becoming "Canada's diseases". Families new to Canada, predominantly those of South Eastern Asian descent, are developing Crohn's and colitis for the first time – often within the first generation. The burden that Crohn's disease and ulcerative colitis place on individuals and the healthcare system is significant and will continue to grow as the number of people diagnosed increases.

Ulcerative colitis is a chronic (ongoing) disease of the colon. The disease is marked by inflammation and ulceration of the colon mucosa, or innermost lining. Tiny open sores, or ulcers, form on the surface of the lining, where they bleed and produce pus and mucus. Because the inflammation makes the colon empty frequently, symptoms typically include bloody diarrhea and often "crampy" abdominal pain. There is also a sense of "dry heaves of the rectum" after bowel movements along with urgency. Some patients will have false urges and pass only tiny amounts of blood and mucus. The symptoms of ulcerative colitis, as well as possible complications vary depending on the extent of inflammation in the rectum and the colon. The rectum is mostly involved, but can extend up to and including the entire colon. Loss of appetite and subsequent weight loss and fatigue are common. In cases of severe bleeding, anemia may also occur. In addition, there may be skin lesions, joint pain, eye inflammation, and liver disorders. Children with ulcerative colitis may fail to develop or grow properly.

Complications of ulcerative colitis include profuse bleeding from deep ulcerations, perforation (rupture) of the bowel, or simply failure to respond appropriately to the usual medical treatments. Another complication is severe abdominal distension. However, if the distention is severe or of sudden onset, and if it is associated with active UC, fever, and constipation, a physician may suspect toxic megacolon. This is a rare development that is produced by severe inflammation of the entire thickness of the colon, with weakening and ballooning of its wall. The dilated colon is then at risk of rupturing. Treatment is aimed at controlling the inflammatory reaction and restoring losses of fluid, salts, and blood. If there is no rapid improvement, surgery may become necessary to avoid rupture of the bowel. The risk of colorectal cancer is a potential complication of longstanding ulcerative colitis.
The aspect that the majority of interviewees pointed out as the most unbearable is the lack of control over their bowel movements, including the urgent and frequent need of the bathroom. Based on a Crohn's and Colitis Canada 2011 survey, 73% of respondents affected said they experienced between five to 20 or more bowel movements a day during a flare. During times of active disease (flare ups), patients spend a lot of time in the bathroom, feeling like they live in the bathroom. Even during times of remission, people with ulcerative colitis feel that they can't be too far away from the bathroom. As one interviewee stated, "when you have to go to the washroom 20 times a day, it impacts everything you do."

IBD can significantly impact the quality of life of the patient, their caregiver/s and family, workplace, and community. It can impact career choices, lead to reduced work hours, impact family planning decisions, and lead to income disparity and depression. There are also concerns involving ongoing drug treatment, recurrent hospitalizations and surgeries. IBD can also complicate travel, life and working arrangements due to the need for bathroom access.

People living with ulcerative colitis must limit their activities. These diseases make it more challenging to work. "You simply can't lead a normal life of working and going to the office." Some of those interviewed had compassionate employers that allowed them to work from home, and others faced scrutiny from their bosses and colleagues for taking frequent 'bathroom breaks' or taking too many sick days of absence. These diseases result in episodic and invisible disabilities. Ignorance can easily set in at the workplace. Because of the stigma associated with these diseases, it is difficult for an individual to disclose their condition.

According to a Crohn's and Colitis Canada's 2012 publication, The Impact of IBD Report, 43% of employed people with Crohn's and colitis took time off work per year, and each employed person with either colitis or Crohn's disease took 7.2 days off per year due to their chronic condition. The report also highlights that people with 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 cost $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, which includes, graduations or family weddings. One interviewee missed the first few months of her newborn son's life because she was hospitalized for colitis. This is time lost that she will never gain back.

2.3 Patients' Experiences With Current Therapy

Canadians have one of the highest rates of prevalence of IBD, however, when compared with other Western countries, there are limited medical treatment options. The treatment of ulcerative colitis involves medications that decrease the abnormal inflammation in the colon lining and thereby control the symptoms, with the goal of maintaining this induced remission.

Current, medical options are centered around 5-ASAs and topical (rectal) therapy for people with mild to moderate symptoms. Corticosteroids are also used in several different ways and as part of several different steps along the stepped up approach to managing UC. Corticosteroids are not intended for long-term use but can be very beneficial at certain times. In the recently published Clinical Practice Guidelines for Ulcerative Colitis that was developed by consensus from leading Canadian IBD experts, oral budesonide MMX is suggested (despite its current unavailability in Canada) as an alternative therapy to 5-ASA as an initial treatment to bring about complete remission and for patients who did not respond to 5-ASA therapy in mild to moderate ulcerative colitis.

For those who are unresponsive to first line treatment or develop a moderate to severe form of IBD, second line treatments usually consist of immune-modulators/immunosuppressants (azathiopurine), sometimes together with corticosteroids and biologics. These classes of medication work to reduce inflammation by suppressing the immune system.

People living with Crohn's and ulcerative colitis require access to a wide variety of therapies and treatments since not all respond well to current options while others may eventually lose response. Patients should work with their doctor to get personalized treatment and get access to the right treatment at the right time.

In one-quarter to one-third of patients with UC, medical therapy is not completely successful or complications arise. Under these circumstances, surgery may be considered. This operation involves the removal of the colon (colectomy). Depending on a number of factors, including the extent of the disease and the patient's age and overall health, one of two surgical approaches may be recommended. The first involves the removal of the entire colon and rectum, with the creation of an ileostomy or external stoma (an opening on the abdomen through which wastes are emptied into a pouch, which is attached to the skin with adhesive). A more recently developed procedure also calls for removal of the colon, but it avoids an ileostomy. By creating an internal pouch from the small bowel and attaching it to the anal sphincter muscle, the surgeon can preserve bowel integrity and eliminate the need for the patient to wear an external ostomy appliance.

Surgery for ulcerative colitis patients may not improve the quality of life. Post-surgery complications include soiling, poor pouch function, pouchitis and sexual dysfunction. Unfortunately, many females who undergo surgery for ulcerative colitis 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."

2.4 Impact on Caregivers

For caregivers affected by Crohn's disease and ulcerative colitis, caring comes with significant challenges. Absences from work, high costs of care, fatigue and stress can take a toll on the caregiver's mental health and physical well-being. Caregivers often act as advocates for their loved ones and take on the burden of care, including financial out-of-pocket costs associated with managing these diseases.

The overall cost of caregiving for people living with severe forms of Crohn's and colitis is estimated to be at $86 million annually.

With increasing numbers of children being diagnosed with IBD, 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.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information was drawn from the Crohn's and Colitis Canada (CCC) published reports, including the 2012 "Impact of Inflammatory Bowel Disease (IBD) Report" and informational brochures found on the organization's website. Interviews were also conducted by Crohn's and Colitis Canada staff with people living with ulcerative colitis who have or continue to take budesonide MMX therapy

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

a) Based on no experience using the drug:

Oral corticosteroids are effective in treating active ulcerative colitis, but due to their adverse effects and poor health outcomes related to long term use they are usually reserved for select circumstances. Budesonide, coupled with a colonic release system (MMX Multi-Matrix System), is a novel formulation that is promising because it is effective in bringing about clinical and endoscopic remission yet minimizes the systemic side effects often associated with steroid use. Furthermore, its once-daily tablet dosage is convenient for patients and simple to adhere to.

It is expected that with new and proven treatments, many people with Crohn's disease and ulcerative colitis will be able to have a 'normalized' life and these diseases will become a minor inconvenience. Remission is the primary goal of treatment since individuals will no longer need to plan their activities and lives around sudden bathroom visits. People can focus on work and build their career paths. Young students will be able to focus on school and socialize with other children. And for many women living with IBD and wishing to have children, the introduction of new targeted treatments will avoid surgery – a treatment option that decreases fertility rates. Research has demonstrated that flare-ups can also lead to a decreased rate of fertility.

With the advancements of new medications, there is reduced need for surgery and fewer hospitalizations and emergency visits.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

Those patients that were interviewed, which are currently taking or have taken budesonide MMX, did not report any significant side effects. One interviewee, who currently accesses the medication through a contact in Europe, mentioned that she had been on prednisone in the past and experienced a serious bout of depression however, while on budesonide MMX she has not experienced any negative side effects which she describes as being "life-saving for me not to have the mental health issues anymore". Another interviewee, who had also been on prednisone previously, said she did not experience the "moon face" while on budesonide MMX.

According to those patients interviewed, budesonide MMX was easy to use and its oral administration simple to adhere to. Interviewees felt better while on treatment and did not need to visit the bathroom as frequently as before they were taking budesonide MMX. They felt it was successful in improving their symptoms, reducing the number of their flares (one patient reported they did not achieve full remission but noticed a remarkable improvement over previous treatment) and lowering CRP levels (indicator of inflammation), which resulted in less time off work and fewer hospital visits. One interviewee reported that "it worked well for a while, reduced my pain and bathroom visits, but I did have to eventually progress to a biologic treatment to control my disease". Overall, all interviews claimed that the drug had positive impact to their health and tremendous improvement to their quality of life.

GI (Gastrointestinal) Society

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		CORTIMENT®[MMX] (budesonide) for ulcerative colitis
Name of the patient group		GI (Gastrointestinal) Society
Name of the primary contact for this submission:		[redacted]
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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 ventreMC 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 or liver condition, as well as those who have lived with an illness 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/hepatology.

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 several pharmaceutical companies in addition to other corporations, governments, foundations, service clubs, and individuals 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., Boehringer Ingleheim, Innovative Medicines Canada, Ferring Inc., Gilead Sciences Canada Inc., GlaxoSmithKline Inc., Hoffman-La Roche Limited, Janssen Canada, Johnson & Johnson, LifeScan, Merck Canada Inc., Pfizer Canada Inc./Hospira, Shire 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

2.1 Information Gathering

This information was obtained primarily through a questionnaire completed by 133 Canadians (English: 105 and French: 28) who were patients with inflammatory bowel disease (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 1,245 individuals with Crohn's disease and ulcerative colitis attended, at a patient roundtable, from patients who submitted their stories over time, from patient volunteers, and is guided by the expertise of our Medical Advisory Council and health care advisors (gastroenterologists, pharmacists).

2.2 Impact of Condition on Patients

Inflammatory bowel disease (IBD) is a term that primarily refers to two diseases of the intestines: Crohn's disease and ulcerative colitis. These both involve inflammation of the digestive tract, which is limited to the inner mucosa of the colon in ulcerative colitis, but can include any area of the GI tract and can extend through the entire thickness of the bowel wall in Crohn's disease.

A diagnosis of ulcerative colitis can occur at any point in 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 with inflammation in the colon, 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.

Even though ulcerative colitis is limited to the colon portion of the digestive tract, it has associated 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 as patients manage an unpredictable disease.

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 survey, ulcerative colitis patients shared the following regarding the impact that this disease has on all aspects of their day-to-day lives, including work life, family life, social life, and normal activities:

- "I am constantly aware of where a bathroom is and always prepared for the urge to go. My activities are limited for the fear of not being able to find a washroom."
- "I don't want to do anything since this has total control over my life."
- "The biggest change is lifestyle. I need more sleep and rest. My diet is better but there are activities which I avoid or try to limit, such as camping."
- "My most important concern is the overall fatigue I feel. I am also always very worried when I see blood in the stool. Having to watch my diet is something I never had to do before - seems like I cannot eat much anymore."
- "It makes it difficult to leave my house, play with my son, work, etc when I am in a flare. When I'm not in an active flare I live in constant fear of when the next flare will occur"
- "It limits my social life; I stay in the house more than I did before. Very tired and weak. Lost 30 lbs, not as strong. Affects overall quality of life. Fatigue limits what I can do in a day."
- "My diet has changed completely, I used to enjoy eating. Going to work is sometimes so difficult, I wish I could just go back to bed."
- "My energy levels have decreased and I get fatigued much more easily, the fear of pain, bleeding, incontinence is horrible. The worst part is fearing the next big flare that will prevent me from being a mom to my 18 month old."

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 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.

2.3 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.

80% of the patients who responded to this part of our survey believe there is a gap in currently available treatments. 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." [Please stop and imagine for one minute how much anxiety and mess this would cause!]

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). Additionally, even though biologics are less costly for society than caring for a patient whose disease is out of control, they do not always work and patients can eventually lose response.

Surgery is also a treatment option, but not one patients want, and we discuss this more fully below.

2.4 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

3.1 Information Gathering

This information was obtained primarily through a recent questionnaire completed by 178 Canadians (English: 171 and French: 7) with ulcerative colitis (or their caregivers or family members), the product monograph, and the expertise of our Medical Advisory Council and health care advisors (gastroenterologists, pharmacists).

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had to Date with the New Drug?

a) Based on no experience using the drug:

Not every patient with ulcerative colitis will respond to the current available treatments, so more options are essential. Patients prefer to take medications with the fewest number of side effects and those that are less costly, if possible. Corticosteroids, immunosuppressive agents, and biologics come with a number of potential side effects and risk factors. Physicians only prescribe them when they believe these powerful medications are a patient's best hope of controlling the difficult, sometimes incapacitating symptoms of ulcerative colitis. Ulcerative colitis patients, even more so than those who have Crohn's disease, have been suffering too long from an inadequate variety of treatment options.

As a once-daily, oral formulation of the corticosteroid budesonide for mild to moderate ulcerative colitis, CORTIMENT®^{MMX} (budesonide) has the potential to improve the health and quality of life of many individuals currently suffering from failure of other treatments. For example, if 5-ASA treatment fails, CORTIMENT®^{MMX} (budesonide) could be a safer and more effective alternative to induce remission in some patients than currently available corticosteroids.

What works for one person does not necessarily work for another. **Choice among effective treatment options is essential for patients.**

CORTIMENT®^{MMX} (budesonide) oral, extended release tablets present a safer option than regular budesonide because they provide steroids targeted to the bowel, but with very little systemic exposure. Using multi-matrix system (MMX) technology, CORTIMENT®^{MMX} extends release of budesonide throughout the entire colon, whereas conventional budesonide formulations only release the active ingredient at the proximal colon and distal ileum, which might mean that patches of the left colon might not receive sufficient quantity of the drug. Sustained release means sustained disease remission and could mean that a patient does not need to progress to a biologic medication.

Studies mentioned in the product monograph did involve some adverse events, but most were mild or moderate in severity and occurred in similar percentages across all the treatment groups. These are still less than those associated with a biologic.

CORTIMENT®^{MMX} (budesonide) has the potential to be a life-changing medication for Canadians with ulcerative colitis, a chronic ailment with ongoing, frequently debilitating symptoms if not properly treated. The intensity of this condition varies greatly among those diagnosed and the experience 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. CORTIMENT®^{MMX} (budesonide) gives physicians another option to prescribe for patients, which, for some, could mean the difference between experiencing remission and returned quality of life versus 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 CORTIMENT®^{MMX} (budesonide) for the treatment of moderate to severe ulcerative colitis.

Section 4 — Additional Information

None.