

Report Card

BIOLOGIC COVERAGE

for Inflammatory Bowel Disease
in Canada



Who prepared this Report Card?

Two organizations that represent inflammatory bowel disease (IBD) patients in Canada collaborated on this Report Card. Extensive information on IBD is available on their websites. Their associated gastroenterologists and other IBD medical experts living throughout the

country contributed to this Report Card. They formed their recommendations using the most current evidence-based research on the appropriate management of IBD and on their clinical practices.

GI (Gastrointestinal) Society | www.badgut.org

As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the GI 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. The GI Society is a registered Canadian charity that, along with its sister registered charity, The Canadian Society of Intestinal Research, has been actively involved in Canadian health care since 1976. Collectively they own the BadGut® brand.

**Gail Attara, Chief Executive Officer
Gastrointestinal Society
gail@badgut.org 1-866-600-4875**



Crohn's and Colitis Canada | www.crohnsandcolitis.ca

Crohn's and Colitis Canada is a registered Canadian charity dedicated to finding cures for Crohn's disease and ulcerative colitis, and to improving the lives of children and adults affected by these diseases. To achieve these goals, Crohn's and Colitis Canada is committed to investing in inflammatory bowel disease (IBD) research

to foster advances in prevention, treatments, cures and health policy; educating patients, families, industry and government about IBD; increasing public awareness of IBD and Crohn's and Colitis Canada; and advocating to governments and stakeholders on behalf of those affected by IBD.

**Aida Fernandes, Chief Science & Education Officer
Crohn's and Colitis Canada
afernandes@crohnsandcolitis.ca 1-800-387-1479**



Why an IBD Report Card?

About 1 in every 150 Canadians has inflammatory bowel disease (IBD),ⁱ which is among the highest prevalence in the world. Of all digestive diseases, IBD is the most devastating. It is chronic, often challenging to manage, decreases quality of life, affects the ability to attend school or go to work, and can lead to death. The exact cause of IBD is unknown and there is currently no cure.ⁱ

Patients affected by IBD need medications that work. Biologic medications are extremely beneficial for many patients with moderate to severe IBD.ⁱⁱ However, biologics used in IBD offer varied responses, depending

on the patient; therefore facilitating biologic access is important to IBD patients.ⁱⁱ There is wide variation in provincial/territorial/federal drug plan coverage across Canada for IBD patients, preventing many from securing affordable access to the medications they need.

When an 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.

i Crohn's and Colitis Foundation of Canada. *The Impact of Inflammatory Bowel Disease in Canada: 2012 Final Report and Recommendations*. 2012. Available at <http://www.isupportibd.ca/pdf/ccfc-ibd-impact-report-2012.pdf>. Accessed 2014-02-18.

ii Sadowski DC *et al.* Canadian Association of Gastroenterology Clinical Practice Guidelines: The use of tumour necrosis factor-alpha antagonist therapy in Crohn's disease. *Canadian Journal of Gastroenterology*. 2009;23(3):185-202.

Summary of Results

As demonstrated in **Tables 1 and 2** of this Report Card, in most jurisdictions it is easier to obtain coverage for Crohn's disease than it is for ulcerative colitis. Specifically, coverage for Crohn's disease is more comprehensive in British Columbia, Manitoba, and Quebec while the guidelines for coverage for ulcerative colitis are more generous in Ontario, Saskatchewan, and Manitoba. However, this report also shows that long delays in making decisions to cover medications are problematic, especially in Ontario, which undermines its more favourable guidelines.

Canadian IBD experts recommend these pressing coverage improvements, applicable to most regions:

- Eliminate the 5-ASA trial as a mandatory criterion; the decision as to which medication to use for each patient should remain with the gastroenterologist. Time lost with ineffective therapies can allow the disease to progress needlessly.
- Allow for dose optimization; the gastroenterologist should make this determination, based on individual patient need.
- Provide coverage for biologic indications Health Canada approves, based on evidence for that medication, for use in Crohn's disease and ulcerative colitis. Although Remicade® (infliximab) has had Health Canada approval for the treatment of UC for many years, Simponi® and Humira® recently received approval in the fall of 2013. Other new products are, or will be, in the pipeline (i.e., vedolizumab) for both Crohn's disease and ulcerative colitis.

Public and private drug plans should provide coverage for all of these medications once approved by Health Canada. This way, physicians will have the right tools to manage the care of their many, varied inflammatory bowel disease patients. No patient will be on more than one product and it makes absolute sense to have options, so that physicians can choose the right medicine for each patient, in the correct dose.

This Report Card represents a united, urgent appeal for systemic improvements so that inflammatory bowel disease patients have fair and appropriate access to biologic medication coverage in all parts of Canada.

This document evaluates publicly funded medication formularies based on the coverage of medically necessary biologic medications for IBD in two separate charts, for Crohn's disease and ulcerative colitis. Because these formularies change frequently, we encourage you to contact the Ministry of Health in your province or territory with questions you may have about medication listings of concern to you.

What the grades mean

We have assessed all aspects of coverage (when applicable) and assigned a letter grade that represents overall access to coverage for each biologic medication approved by Health Canada.

A	OPTIMAL
B	ACCEPTABLE
C	NEEDS IMPROVEMENT
D	NOT ACCEPTABLE
F	NO COVERAGE

There is wide variation in provincial/territorial/federal drug plan coverage across Canada for IBD patients, preventing many from securing affordable access to the medications they need.

The Basics

Inflammatory bowel disease, which primarily attacks the digestive system, refers mainly to two related but distinct diseases – Crohn’s disease and ulcerative colitis. The key differences are the location of the inflammation,

the extent of inflammation, and the presenting symptoms. This chart helps demonstrate the similarities and differences:

INFLAMMATORY BOWEL DISEASE OVERVIEW	
CROHN’S DISEASE (CD)	ULCERATIVE COLITIS (UC)
<ul style="list-style-type: none"> the inflammation can be in multiple patches or one large patch, and may involve any area throughout the entire digestive tract, from the mouth to the anus (gum to bum), often affecting the last part of the small intestine (terminal ileum) inflammation can extend right through the entire thickness of the bowel wall, from the mucosa, through the muscle, and can even include the thin outermost layer of digestive tract cells (serosa) 	<ul style="list-style-type: none"> only affects part or all of the large intestine (colon) and always begins at the anus, with the disease continuously progressing upward in some cases, it can involve the entire large intestine (pancolitis) inflammation only involves the inner mucosa, which is the inner colon lining
<p>SHARED SYMPTOMS MIGHT INCLUDE:</p> <ul style="list-style-type: none"> stomach/abdominal pain diarrhea rectal bleeding decreased appetite anemia eye inflammation kidney stones gallstones fever, night sweats liver & bile duct inflammation primary sclerosing cholangitis arthritis & joint pains skin lesions 	<p>SHARED SYMPTOMS MIGHT INCLUDE:</p> <ul style="list-style-type: none"> stomach/abdominal pain diarrhea rectal bleeding decreased appetite anemia eye inflammation kidney stones gallstones fever, night sweats liver & bile duct inflammation primary sclerosing cholangitis arthritis & joint pains skin lesions
<p>CD-SPECIFIC SYMPTOMS</p> <ul style="list-style-type: none"> nutritional deficiency delayed growth in children weight loss nausea & vomiting weakness, fatigue perianal infection or abscess anal & perianal ulceration fistulising disease 	<p>UC-SPECIFIC SYMPTOMS</p> <ul style="list-style-type: none"> tenesmus more mucus and blood in stool

These are the typical symptoms, but it is very important to recognize that IBD can play out quite differently in different persons. The symptoms of IBD can come and go over long periods. Patients may experience periods of severe symptoms (or flare-ups), and go through periods when they have few or no symptoms at all (remission). Sometimes there can be no obvious symptoms and yet on examination of the GI tract via a scope, disease is present.

Medical professionals are not exactly sure why Crohn’s disease and ulcerative colitis happen, but it appears that some sort of environmental factor in

genetically susceptible individuals causes the immune system to malfunction.

IBD can first appear at any time during life, from infancy into adulthood, with the bulk of diagnoses occurring in young people ages 15-25.¹ There is a slightly increased risk for those who have a family member with the condition.¹

For an interesting, visual explanation of IBD we encourage you to view our collaborative IBD video on either the GI Society (www.badgut.org) or Crohn’s and Colitis Canada (www.crohnsandcolitis.ca) websites.

Treatment

Currently, there is no cure for IBD.ⁱ Many of the treatments that effectively manage IBD target the immune system, so medications such as 5-ASA and corticosteroids, which help reduce inflammation, or immunosuppressants, are often used. However, not all of these medications are appropriate for every patient to try; physicians must be able to prescribe the right medication for each patient based on the individual's specific disease circumstances and current, evidence-based research.

Medicines called “biologics” have become an important treatment option for those who have moderate to severe IBD. They work by using specially developed antibodies to selectively block the effects of molecules that are involved in the inflammation of the gut wall.

Some of these medications move beyond symptom management and heal the mucosal lining, which can lead to remission and prevent future hospitalizations and surgery. Patients for whom biologics are the most appropriate option should have equal and adequate coverage for them, no matter where in the country they reside.

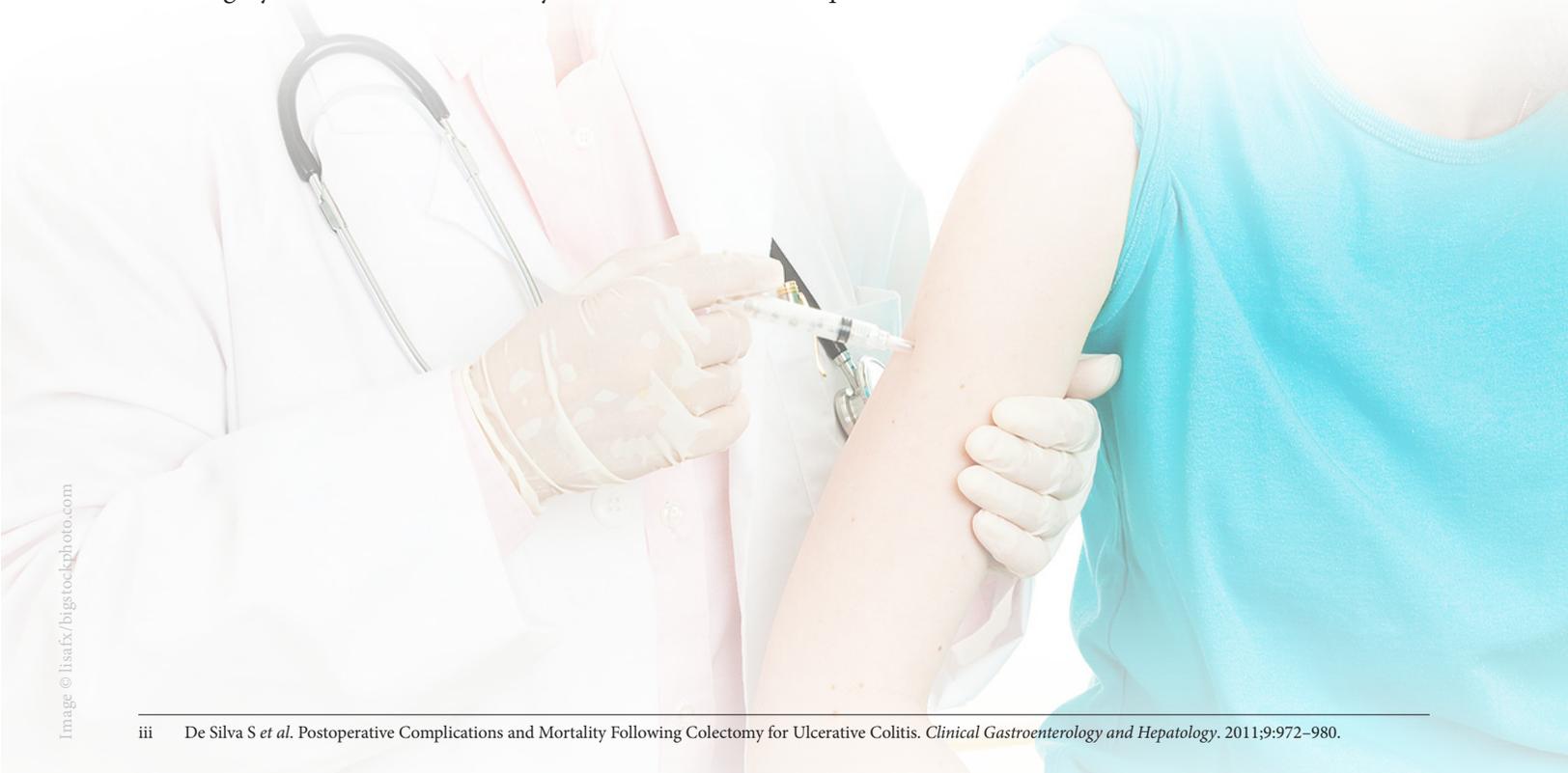
IBD can profoundly affect an individual's life at home, at school, or in the workplace – physically, emotionally, socially, and financially. Having to go to the washroom more than 10 times a day, or even talking about your bowels, is challenging at any age, but perhaps particularly so for a young person, when this disease commonly strikes.

Why Surgery is NOT a Solution for UC

The colon's primary function is to extract water from bowel contents, so when it is surgically removed, elimination remains frequent and is mostly liquid. Afterward, patients could face cramping and as many as 20 bowel motions a day. Extra-intestinal complications include continual, debilitating disease symptoms, secondary illnesses such as arthritis, skin lesions, depression and anxiety disorders, and loss of family/social interactions.

Surgery has a 1.5% mortality rate and a 27%

morbidity rate and leads to unnecessary usage of health care resources (e.g., additional hospital stays, further surgeries, diagnostic procedures, other medications) and a ripple effect of financial burden on the patient, government, and taxpayers (e.g., through inability to work, long-term disability claims, biologic-related debt, and even bankruptcy). 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.ⁱⁱⁱ



iii De Silva S *et al.* Postoperative Complications and Mortality Following Colectomy for Ulcerative Colitis. *Clinical Gastroenterology and Hepatology*. 2011;9:972–980.

TABLE 1: PROVINCIAL & FEDERAL DRUG PLAN COVERAGE OF BIOLOGICS FOR CROHN'S DISEASE

JURISDICTION	COVERAGE?		CRITERIA ¹	EFFICACY ASSESSMENT ² / AND RENEWAL PERIOD	GRADE	CANADIAN IBD EXPERTS RECOMMEND
	R	H				
BC PHARMACARE	Yes	Yes	5-ASA ³ glucocorticoids immunosuppressants	on treatment HBI <5 or HBI decrease >4; renewal 1 yr	B	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Clarify dosing optimization policy⁴
ALBERTA HEALTH	Yes	Yes	glucocorticoids immunosuppressants	HBI decrease >3; renewal 1 yr	C	<ul style="list-style-type: none"> Provide dosing optimization for Humira[®] Optimize coverage for fistulizing disease
SASKATCHEWAN PHARMACARE	Yes	Yes	5-ASA glucocorticoids immunosuppressants	evidence of efficacy; renewal 6 months.	C	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Increase approval period to 1 year and extend renewal period to 1 year Optimize coverage for fistulizing disease
MANITOBA PHARMACARE	Yes	Yes	5-ASA corticosteroids immunomodulators	evidence of efficacy; renewal 1 yr	B+	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion
ONTARIO PUBLIC DRUG PROGRAMS	Yes ⁵	Yes ⁵	glucocorticoids immunosuppressants	50% reduction in HBI and no steroids required; renewal 1 yr then 2 yrs	C-	<ul style="list-style-type: none"> Simplify entire biologics coverage criteria and process Shorten approval wait times, which are 100% to 500% times longer than other jurisdictions Provide dosing optimization Cover patients transitioning from private insurance⁶
RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC	Yes	Yes	corticosteroids immunosuppressants	evidence of efficacy; renewal 1 yr	B	<ul style="list-style-type: none"> Optimize coverage for fistulizing disease
NEW BRUNSWICK PRESCRIPTION DRUG PROGRAM	Yes	Yes	5-ASA corticosteroids immunosuppressants	evidence of efficacy; renewal 1 yr	C	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Provide dosing optimization Optimize coverage for fistulizing disease
NOVA SCOTIA PHARMACARE	Yes	Yes	5-ASA corticosteroids immunosuppressants	evidence of efficacy; renewal 1 yr	B	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Optimize coverage for fistulizing disease
PEI PHARMACARE	Yes	Yes	5-ASA glucocorticoids immunosuppressants	HBI decrease >3; renewal 1 yr	C	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Provide dosing optimization
NEWFOUNDLAND AND LABRADOR PRESCRIPTION DRUG PROGRAM	Yes	Yes	5-ASA (Humira [®] only) corticosteroids immunosuppressants	on treatment HBI <5 or HBI decrease >4; renewal 1 yr	D	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion for Humira[®] Provide dosing optimization Increase initial assessment from 4 to 12 weeks
NIBB ⁷ , NUNAVUT ⁸	Yes	Yes	5-ASA glucocorticoids immunosuppressants	evidence of efficacy; renewal variable, up to 1 yr	D	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Provide dosing optimization Optimize coverage for fistulizing disease Create a new application process to simplify and facilitate appropriate access that aligns with other jurisdictions
NWT ⁹	Yes	Yes	5-ASA glucocorticoids immunosuppressants	evidence of efficacy; renewal variable, up to 1 yr	C	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Provide dosing optimization Provide clarity in formulary for initial renewal times Optimize coverage for fistulizing disease
YUKON	Yes	No	5-ASA glucocorticoids immunosuppressants	evidence of efficacy; renewal 1 yr	D	<ul style="list-style-type: none"> Eliminate 5-ASA trial criterion Provide dosing optimization Provide clarity in formulary to include coverage of Humira[®] for Crohn's disease Optimize coverage for fistulizing

 R= Remicade[®] (infliximab) | H= Humira[®] (adalimumab)

TABLE 2: PROVINCIAL & FEDERAL DRUG PLAN COVERAGE OF BIOLOGICS FOR ULCERATIVE COLITIS

JURISDICTION	COVERAGE?			CRITERIA ¹	EFFICACY ASSESSMENT ²	RENEWAL PERIOD	GRADE	CANADIAN IBD EXPERTS RECOMMEND
	R	H	S					
BC PHARMACARE	No ¹⁰	No	No				D	<ul style="list-style-type: none"> Provide formal listing with criteria for all biologics with UC indication rather than case-by-case review
ALBERTA HEALTH	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication
SASKATCHEWAN PHARMACARE	Yes	No	No	unresponsive to high dose intravenous steroids	evidence of efficacy	6 months	B	<ul style="list-style-type: none"> Provide formal listing for UC for Humira® and Simponi®
MANITOBA PHARMACARE	Yes	No	No	5-ASA corticosteroids and immunomodulators	evidence of efficacy		B	<ul style="list-style-type: none"> Provide formal listing for UC for Humira® and Simponi®
ONTARIO PUBLIC DRUG PROGRAMS	Yes	No	No	corticosteroids and immunomodulators	Mayo score of <6 /= 50% reduction in prednisone	1 yr then 2 yrs (if off corticosteroids)	B-	<ul style="list-style-type: none"> Simplify biologic UC coverage criteria and process Reduce approval wait time Provide formal listing for UC for Humira® and Simponi®
RÉGIE DE L'ASSURANCE MALADIE DU QUÉBEC	No ¹¹	No	No				D	<ul style="list-style-type: none"> Provide formal listing with criteria for all biologics with UC indication rather than case-by-case review
NEW BRUNSWICK PRESCRIPTION DRUG PROGRAM	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication
NOVA SCOTIA PHARMACARE	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication
PEI PHARMACARE	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication
NEWFOUNDLAND AND LABRADOR PRESCRIPTION DRUG PROGRAM	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication
NIHB ⁷ , NUNAVUT ⁸ , & NWT ⁹ .	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication
YUKON	No	No	No				F	<ul style="list-style-type: none"> Provide formal listing for all biologics with UC indication

R= Remicade® (infliximab) | H= Humira® (adalimumab) | S= Simponi® (golimumab)

- A patient must fail (or not tolerate) these medications before being eligible to apply for coverage of a biologic medication.
- All jurisdictions require assessment with Harvey Bradshaw Index (HBI) with moderate to severe disease severity.
- Research suggests that in cases of Crohn's disease, 5-ASA should not be considered a front-line treatment and that use of these medications must be at the discretion of the prescribing gastroenterologist.
- This recommendation arises because in this particular jurisdiction, the dosing escalation is either not allowed, regardless of physician recommendation, or the jurisdiction permits it only for some medications.
- Every other provincial jurisdiction has an approval wait time that is between 3-13 days; wait times in Ontario range from about 7-41 days, creating a critical access delay for the patients who need these medications.
- For patients on biologics who are transitioning from private insurance, and for continuity of care between physicians.
- The Non-Insured Health Benefits (NIHB) program provides coverage for approximately 831,090 eligible registered First Nations and recognized Inuit with a limited range of medically necessary health-related goods and services not provided through private, provincial, or territorial health insurance plans. The process to apply for coverage is convoluted, time-consuming, unfair to patients, and does not have a feedback loop to inform physicians regarding approval or denial of coverage.
- Nunavut = Nunavut Extended Health Benefits. Nunavut uses the NIHB criteria, which the NIHB administers.
- NWT = Northwest Territories Extended Health Benefits for non-Natives and Métis >60 years of age. NWT uses NIHB criteria, which Alberta Blue Cross administers.
- BC PharmaCare does not list Remicade®, but will review applications on case-by-case basis for coverage.
- Although, in February 2013, *l'Institut national d'excellence en santé et en services sociaux* (INESSS) concluded that Remicade® should not be covered for UC; *Régie de l'assurance maladie du Québec* (RAMQ) will review applications on a case-by-case basis for coverage.

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