REPORT CARD

BIOLOGIC COVERAGE FOR INFLAMMATORY BOWEL DISEASE IN CANADA, 2016

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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 Gastrointestinal Society is a registered Canadian charity that, in collaboration 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.

THIS REPORT

We assembled this report card in association with gastroenterologists and other IBD medical experts living throughout the country. We formed recommendations using the most current evidence-based research on the appropriate management of IBD and on their clinical practices.

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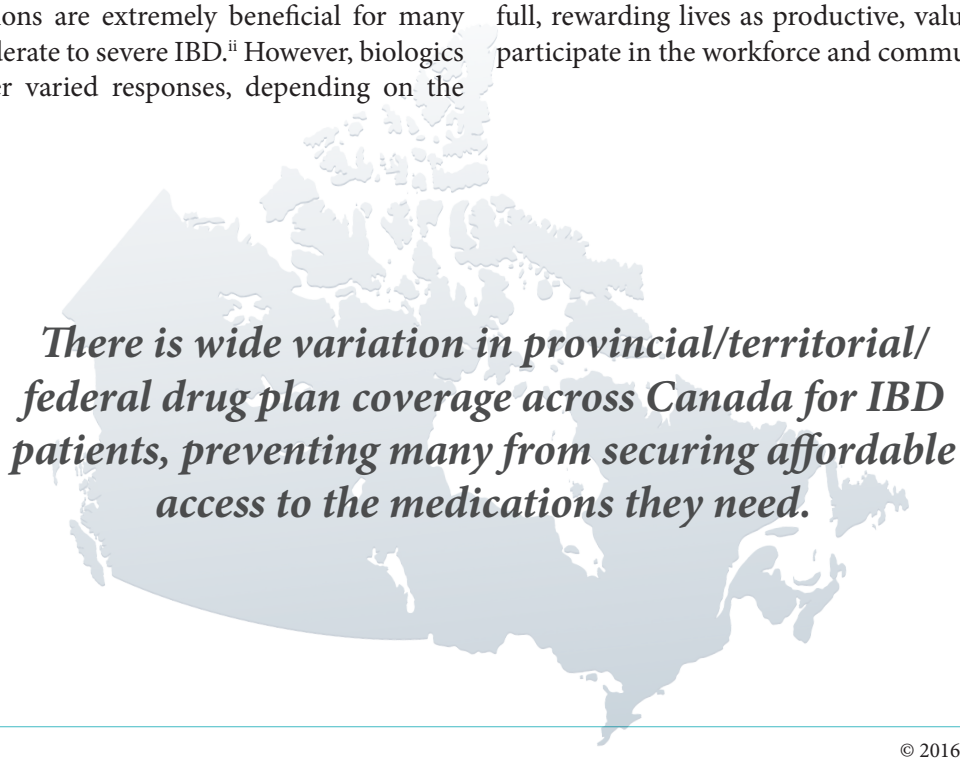
WHY AN IBD REPORT CARD?

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 one of 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.



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.

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:

- Research suggests that in cases of Crohn's disease, 5-ASA should not be considered a frontline treatment and that use of these medications should only be at the discretion of the prescribing gastroenterologist. Additionally, early azathioprine therapy is no more effective than placebo for newly diagnosed Crohn's disease and early azathioprine was not more effective in achieving a sustained steroid free remission than placebo. Furthermore, Health Canada Warning "IMURAN® (azathioprine) or PURINETHOL® (mercaptopurine) monotherapies are not authorized by Health Canada for the treatment of inflammatory bowel disease."[vii]
- 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® (golimumab), and Humira® (adalimumab) received approval in the fall of 2013, and Entyvio® (vedolizumab) in early 2015.

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**

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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)
• 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)	• 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 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)	• inflammation only involves the inner mucosa, which is the inner colon lining
Shared Symptoms might include: • 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
CD-Specific Symptoms • nutritional deficiency • delayed growth in children • weight loss • nausea & vomiting • weakness, fatigue • perianal infection or abscess • anal & perianal ulceration • fistulising disease	**UC-Specific Symptoms** • 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.[i] There is a slightly increased risk for those who have a family member with the condition.[i]

For an interesting, visual explanation of IBD, we encourage you to view our collaborative IBD video at www.badgut.org.

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[iii] 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 expenditures, 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]

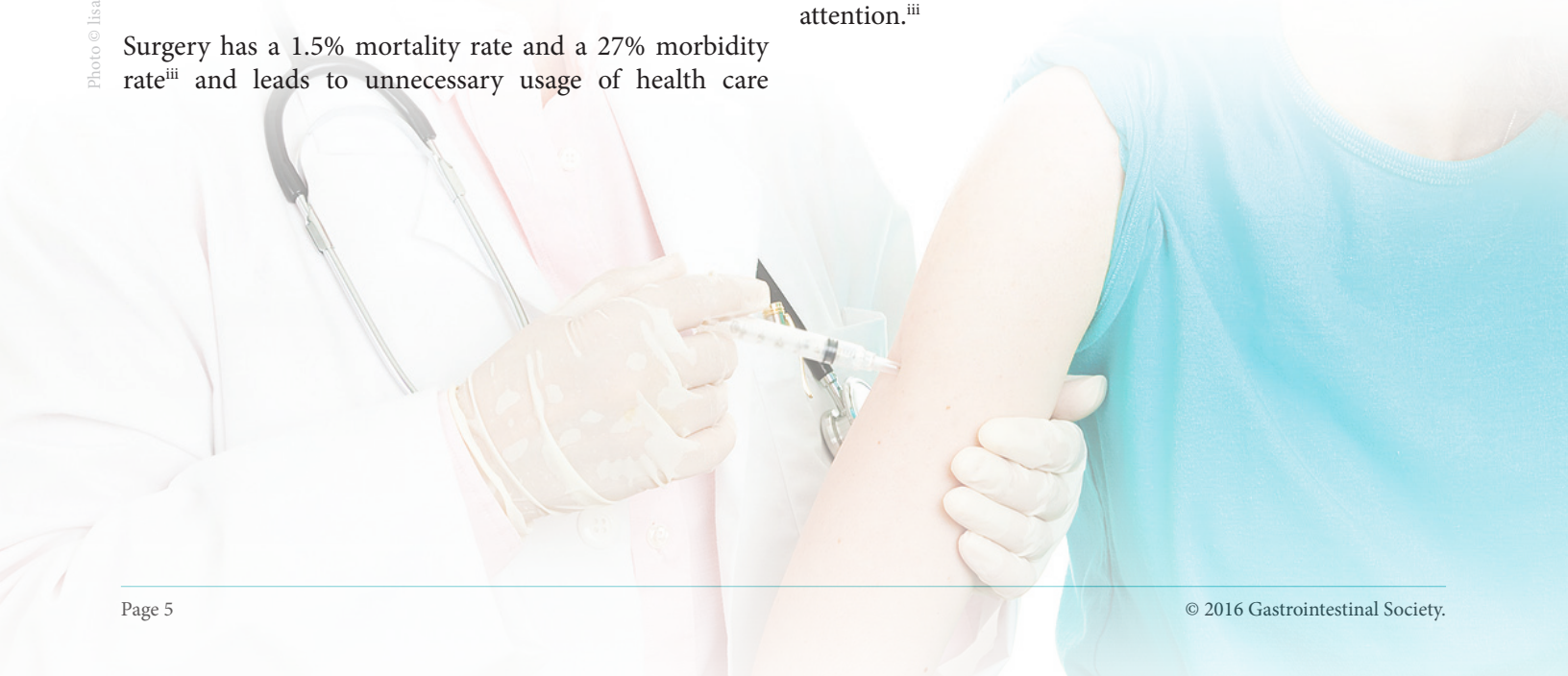

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TABLE 1 – CROHN'S DISEASE

REPORT CARD - PROVINCIAL & FEDERAL DRUG PLAN COVERAGE OF BIOLOGICS FOR CROHN'S DISEASE

Jurisdiction	Coverage?		Criteria[iv]	Efficacy Assessment[v]; Renewal Period	Grade	Canadian IBD Experts Recommend
	R	H				
BC PharmaCare	Yes	Yes	corticosteroid trial and either dependant, resistant, or intolerant Current HBI≥8	on treatment HBI <5 or HBI decrease >4; renewal -1 yr	A-	• clarify dosing optimization policy[vi]
Alberta Health	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants HBI ≥7	HBI decrease >3; renewal 1 yr	C+	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization for Humira®[vi] • optimize coverage for fistulizing disease
Saskatchewan Drug Plan	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants	evidence of efficacy; renewal 6 months	C+	• eliminate 5-ASA and immunosuppressant requirements[vii] • increase approval period to 1 yr and extend renewal period to 1 yr • optimize coverage for fistulizing disease
Manitoba Pharmacare	Yes	Yes	5-ASA[vii] corticosteroids immunosuppressants	Evidence of efficacy; renewal 1 yr	C+	• eliminate 5-ASA and immunosuppressant requirements[vii]
Ontario Public Drug Programs	Yes[viii]	Yes[viii]	glucocorticoids tried at least 2 weeks at maximum dose AND immunosuppressants tried for at least 3 months HBI ≥7 (HBI <7 will be considered on case-by-case basis)	50% reduction in HBI and no steroids required; initial approval is for 3 months 1st renewal 1 yr 2rd renewal 2 yrs	C-	• eliminate 5-ASA and immunosuppressant requirements[vii] • simplify entire biologics coverage criteria and process • shorten approval wait times • provide dosing optimization[vii] • provide initial approval for 6 months • cover patients transitioning from private insurance[ix] • use consistent application of criteria
Régie de l'assurance maladie du Québec	Yes	Yes	corticosteroids immunosuppressants	evidence of efficacy; renewal 1 yr	C+	• eliminate immunosuppressant requirements[vii] • optimize coverage for fistulizing disease
New Brunswick Prescription Drug Program	Yes	Yes	5-ASA[vii] corticosteroids immunosuppressants	evidence of efficacy; renewal 1 yr	C+	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization[vi] • optimize coverage for fistulizing disease
Nova Scotia Pharmacare	Yes	Yes	5-ASA[vii] corticosteroids immunosuppressants	evidence of efficacy; renewal 1 yr	C+	• eliminate 5-ASA and immunosuppressant requirements[vii] • optimize coverage for fistulizing disease
PEI Pharmacare	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants HBI ≥7	HBI decrease >3; renewal 1 yr	C+	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization[vi]
Newfoundland and Labrador Prescription Drug Program	Yes	Yes	5-ASA[vii] (Humira® only) corticosteroids immunosuppressants	on treatment HBI <5 or HBI decrease >4 or 100 point reduction in CDAI; renewal 1 yr	C	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization[vi] • increase initial assessment from 4 to 12 weeks
NIHB[x]	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants	evidence of efficacy; renewal variable, on treatment HBI <5 or HBI decrease >4, up to 1 yr	C	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization[vi] • optimize coverage for fistulizing disease • decrease approval delays

HBI= Harvey-Bradshaw Index, CDAI= Crohn's Disease Activity Index

TABLE 1 - CROHN'S DISEASE (CON'T)

REPORT CARD - PROVINCIAL & FEDERAL DRUG PLAN COVERAGE OF BIOLOGICS FOR CROHN'S DISEASE

Jurisdiction	Coverage?		Criteria[iv]	Efficacy Assessment[v]; Renewal Period	Grade	Canadian IBD Experts Recommend
	R	H				
NUNAVUT[xi]	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants	evidence of efficacy; renewal variable, up to 1 yr	C-	• eliminate 5-ASA and immunosuppressant requirements[vii] • create a new application process to simplify and facilitate appropriate access that aligns with other jurisdictions
NWT[xii]	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants	evidence of efficacy; renewal variable, up to 1 yr	C	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization[vi] • provide clarity in formulary for initial renewal times • optimize coverage for fistulizing disease
YUKON	Yes	Yes	5-ASA[vii] glucocorticoids immunosuppressants HBI >7	evidence of efficacy; renewal 1 yr	C	• eliminate 5-ASA and immunosuppressant requirements[vii] • provide dosing optimization[vi] • optimize coverage for fistulizing disease

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

MEASURING CROHN'S DISEASE

The Harvey-Bradshaw Index consists of a few questions that allow physicians to quickly categorize the severity of Crohn's disease and detect remission. This index is especially useful for data collection. Harvey and Bradshaw first published the index in *The Lancet*, in 1980, as a shorter, simpler alternative to the standard categorization technique called the Crohn's Disease Activity Index. Patients answer the following five questions, and are given a score based on the severity of their symptoms.

HARVEY-BRADSHAW INDEX QUESTIONS

1. Patient's general well-being (for the previous day)
(0 = very well, 1 = slightly below par, 2 = poor, 3 = very poor, 4 = terrible)

2. Abdominal pain (for the previous day)
(0 = none, 1 = mild, 2 = moderate, 3 = severe)

3. Number of liquid stools per day (for the previous day)
(score 1 per movement)

4. Abdominal mass
(0 = none, 1 = dubious, 2 = definite, 3 = definite and tender)

5. Complications (score 1 per item)
- joint pain (**arthralgia**)
- inflammation of the middle layer of the eye (**uveitis**)
- inflammation of fat cells that results in tender red nodules on shins (**erythema nodosum**)
- ulcers in the mouth (**aphthous ulcers**)
- condition that causes tissue to become necrotic (**pyoderma gangrenosum**)
- tear in the tissue that lines the anus (**anal fissure**)
- a newly formed channel between the end of the bowel and the skin around the anus (**fistula**)
- swollen tissue with an accumulation of pus (**abscess**)

HARVEY-BRADSHAW INDEX SCORE

Remission: <5
Mild Disease: 5-7
Moderate Disease: 8-16
Severe Disease: >16

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TABLE 2 – ULCERATIVE COLITIS

REPORT CARD - PROVINCIAL & FEDERAL DRUG PLAN COVERAGE OF BIOLOGICS FOR ULCERATIVE COLITIS

Jurisdiction	Coverage?				Criteria[iv]	Efficacy Assessment[v]; Renewal Period	Grade	Canadian IBD Experts Recommend
	R	H	S	E				
BC PharmaCare	No[xiii]	No	No	No			D	• provide formal listing for all biologics with UC indication
Alberta Health	Yes	No	No	No	mesalamine corticosteroids partial Mayo score >4	partial Mayo score decrease of ≥2 points 6 weeks after initiation then every 12 months; 6 weeks after initiation then every 12 months	C-	• provide formal listing for all biologics with UC indication
Saskatchewan Pharmacare	Yes	No	No	No	unresponsive to high dose intravenous steroids	evidence of efficacy; 6 months	C-	• provide formal listing for all biologics with UC indication
Manitoba Pharmacare	Yes	No	No	No	5-ASA corticosteroids and immuno-suppressants	evidence of efficacy	C-	• provide formal listing for all biologics with UC indication
Ontario Public Drug Programs	Yes	No	No	No	corticosteroids and immuno-suppressant	Mayo score of between 6-10 and endo sub score of 2; /Mayo <6 AND = /= 50% reduction in prednisone after loading; for 2nd renewal steroid free; 3 months and then 1 yr then 2 yrs (if off corticosteroids)	C-	• simplify biologic UC coverage criteria and process • reduce approval wait time • provide formal listing for all biologics with UC indication
Régie de l'assurance maladie du Québec	No[xiv]	No[xiv]	No[xiv]	No[xiv]			C	• provide formal listing with criteria for all biologics with UC indication
New Brunswick Prescription Drug Program	No	No	No	No			F	• provide formal listing for all biologics with UC indication
Nova Scotia Pharmacare	No	No	No	No			F	• provide formal listing for all biologics with UC indication
PEI Pharmacare	No	No	No	No			F	• provide formal listing for all biologics with UC indication
Newfoundland and Labrador Prescription Drug Program	No	No	No	No			F	• provide formal listing for all biologics with UC indication
NIHB	No	No	Yes	No	5-ASA immunosuppressants Corticosteroids partial Mayo score >4	partial Mayo score decrease of ≥2 points and 50% reduction prednisolone dose 3 months after initiation then every 12 months (with patients off steroids at 12 months); 3 months after initiation then every 12 months	C-	• provide formal listing for all biologics with UC indication

TABLE 2 – ULCERATIVE COLITIS (CON'T)

REPORT CARD - PROVINCIAL & FEDERAL DRUG PLAN COVERAGE OF BIOLOGICS FOR ULCERATIVE COLITIS

Jurisdiction	Coverage?				Criteria[iv]	Efficacy Assessment[v]; Renewal Period	Grade	Canadian IBD Experts Recommend
	R	H	S	E				
Nunavut[xi] & NWT[xii]	No	No	No	No			F	• provide formal listing for all biologics with UC indication
Yukon	Yes	No	No	No	prednisone immunosuppressants; evidence of efficacy partial Mayo score >6 & endoscopic sub-score ≥2	evidence of efficacy at 1 yr; 1 yr	C-	• provide formal listing for all biologics with UC indication

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

PARTIAL MAYO SCORING INDEX

ASSESSMENT FOR ULCERATIVE COLITIS ACTIVITY

The Partial Mayo Scoring Index is similar to the Harvey-Bradshaw Index, but instead of measuring Crohn's disease it measures ulcerative colitis. The Partial Mayo Scoring Index consists of a few questions for the patient to answer, and one question for the physician to answer. The numerical results provide a score that represents an estimate of ulcerative colitis disease severity.

PATIENTS COMPLETE THESE QUESTIONS:

Number of daily bowel movements you have when in remission/number of daily bowel movements you had before your diagnosis or symptoms of ulcerative colitis began (this number will be Your Normal):

1. **Stool Frequency** (based on the past 3 days)
   - normal number of stools = 0
   - 1-2 stools more than normal = 1
   - 3-4 stools more than normal = 2
   - 5 or more stools more than normal = 3

2. **Rectal Bleeding** (based on the past 3 days)
   - no blood seen = 0
   - streaks of blood with stool less than half the time = 1
   - obvious blood with stool most of the time = 2
   - blood alone passed = 3

PHYSICIAN COMPLETES THIS QUESTION:

3. **Physician's Global Assessment***
   - normal (sub scores are mostly 0) = 0
   - mild disease (sub scores are mostly 1) = 1
   - moderate disease (sub scores are mostly 1 to 2) = 2
   - severe disease (sub scores are mostly 2 to 3) = 3

*The physician's Global Assessment acknowledges the sub scores, the daily record of abdominal discomfort and functional assessment and other observations such as physical findings, and the patient's performance status.

TOTAL PARTIAL MAYO INDEX SCORE

Remission: 0-1
Mild Disease: 2-4
Moderate Disease: 5-6
Severe Disease: 7-9

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ECONOMIC BENEFITS OF BIOLOGICS IN IBD

OVERVIEW

Canada has the highest prevalence and incidence rates of IBD in the world.[i] There are close to 233,000 Canadians living with IBD: 129,000 with CD and 104,000 with UC. Physicians diagnose more than 10,200 new cases of IBD each year, comprising approximately 5,700 cases of CD and 4,500 cases of UC.

BURDEN OF IBD

Health economists estimated the direct medical costs for individuals with IBD to be $1.2 billion in Canada in 2012.[i] However, there are many other costs associated with IBD, and these indirect costs are higher than the direct medical costs.[i] Excluding disability leaves, IBD patients take 7.2 days off work per year on average, because of their illness.[xv] In addition, 28.9% of IBD patients report labour force nonparticipation.[xvi] This leads to a vast lack of productivity from people who wish they could be fruitful. We can reduce or eliminate these burdens by ensuring that individuals with IBD receive proper treatments.

BIOLOGICS INCREASE PRODUCTIVITY

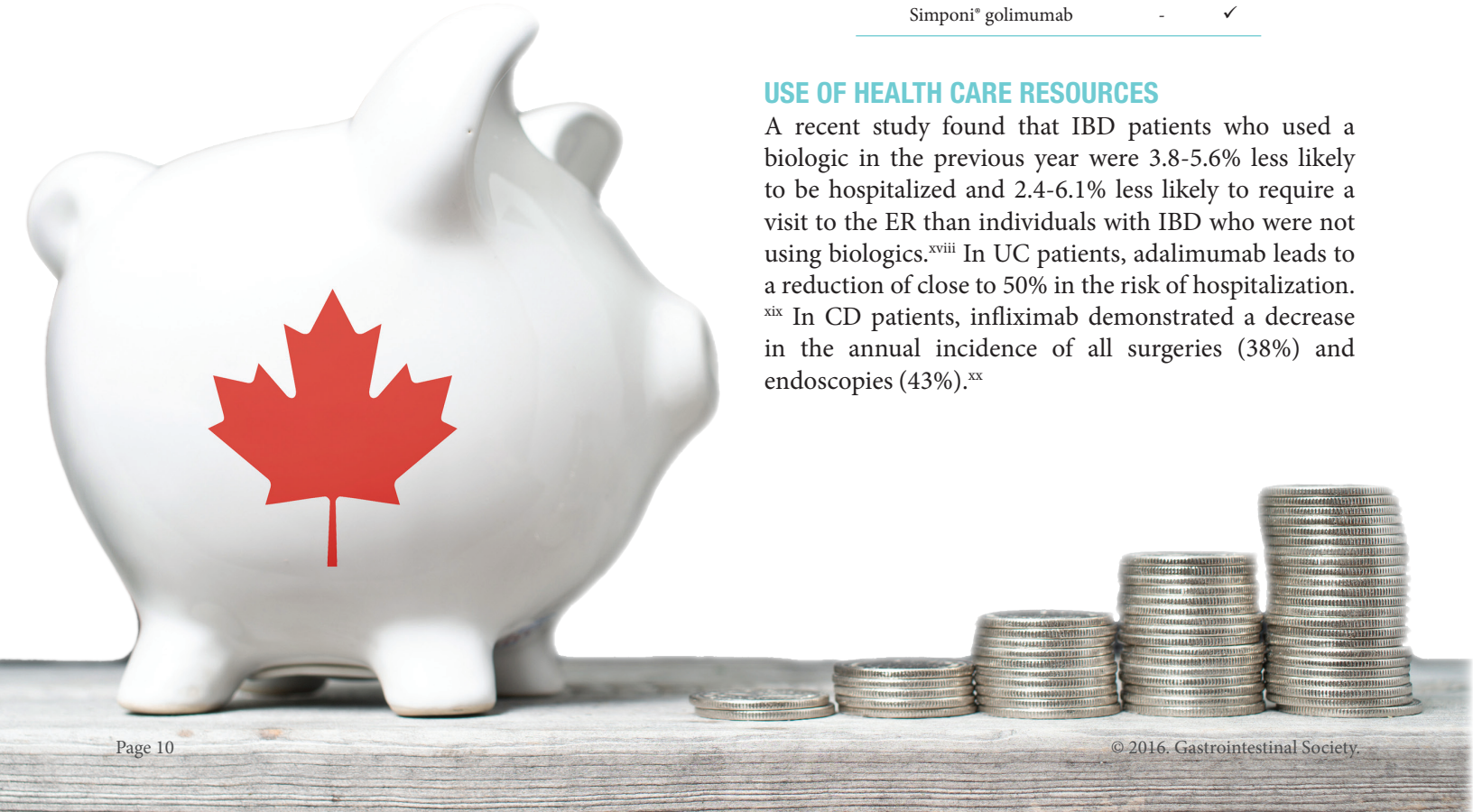
The productivity of individuals with IBD increases greatly when they receive biologic medications to manage their disease. A systematic review of 8 studies for work-related outcomes in CD and UC patients with biologics found that biologics had a positive effect on employment status after 24 weeks of treatment. 64% of UC patients were employed at baseline, and that number grew to 69% after treatment. In individuals with CD, after 54 weeks, 31% of patients who experienced remission were employed and only 16% of those who did not reach remission were employed. In addition, they found that patients treated with biologics significantly improved their productivity. The amount of absenteeism reduced by 7-15%, presenteeism reduced by 15-20%, and total work productivity impairment reduced by 19-21%.[xvii]

Biologics per Indications in Canada

Drug	CD	UC
Entyvio® vedolizumab	✓	✓
Humira® adalimumab	✓	✓
Remicade® infliximab	✓	✓
Simponi® golimumab	-	✓

USE OF HEALTH CARE RESOURCES

A recent study found that IBD patients who used a biologic in the previous year were 3.8-5.6% less likely to be hospitalized and 2.4-6.1% less likely to require a visit to the ER than individuals with IBD who were not using biologics.[xviii] In UC patients, adalimumab leads to a reduction of close to 50% in the risk of hospitalization.[xix] In CD patients, infliximab demonstrated a decrease in the annual incidence of all surgeries (38%) and endoscopies (43%).[xx]



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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.

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

iv A patient must fail (or not tolerate) these medications before being eligible to apply for coverage of a biologic medication.

v All jurisdictions require assessment with Harvey Bradshaw Index (HBI) with moderate to severe disease severity.

vi 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.

vii Research suggests that in cases of Crohn's disease, 5-ASA should not be considered a frontline treatment and that use of these medications should only be at the discretion of the prescribing gastroenterologist. Additionally, early azathioprine therapy is no more effective than placebo for newly diagnosed Crohn's disease and early azathioprine was not more effective in achieving a sustained steroid free remission than placebo. Furthermore, Health Canada Warning "IMURAN® (azathioprine) or PURINETHOL® (mercaptopurine) monotherapies are not authorized by Health Canada for the treatment of inflammatory bowel disease." Panés J *et al*. Early azathioprine therapy is no more effective than placebo for newly diagnosed Crohn's disease. *Gastroenterology*. 2013;45(4):766-74.

viii 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.

ix For patients on biologics who are transitioning from private insurance, and for continuity of care between physicians.

x 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.

xi Nunavut = Nunavut Extended Health Benefits. Nunavut uses the NIHB criteria, which the NIHB administers.

xii NWT = Northwest Territories Extended Health Benefits for non-Natives and Métis >60 years of age. NWT uses NIHB criteria, which Alberta Blue Cross administers.

xiii BC PharmaCare does not list Remicade®, but will review applications on case-by-case basis for coverage. Will cover if company provides first dose and patient improves.

xiv *Régie de l'assurance maladie du Québec* (RAMQ) will review applications on a case-by-case basis for coverage for all indicated biologics in UC, which are routinely approved.

xv Fedorak RN *et al*. Canadian Digestive Health Foundation Public Impact Series. Inflammatory bowel disease in Canada: Incidence, prevalence, and direct and indirect economic impact. *Canadian Journal of Gastroenterology*. 2010;24(11):651-5.

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xviii David G *et al*. Variations in care: a retrospective database analysis of healthcare utilization patterns for patients with inflammatory bowel disease. *Journal of Medical Economics*. 2014;30:1-8.

xix Feagan BG *et al*. Adalimumab therapy reduces hospitalization and colectomy rates in patients with ulcerative colitis: data from controlled trials. Results presented at: United European Gastroenterology Week (UEGW); 23-27 October, 2010; Barcelona, Spain.

xx Rubenstein JH et al. Infliximab decreases resource use among patients with Crohn's disease. *Journal of Clinical Gastroenterology*. 2002;35:151-6.