crohn's colitis

Name of Clinical Care Pathway

Induction of Advanced Therapy

Objective

Ensure a safe start to advanced therapy

Patient Population

Adult patients (>18 years) with a known diagnosis of inflammatory bowel disease (IBD)

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These clinical decision support tools were developed by Canadian experts in IBD based on their interpretation of current evidence and considerations specific to Canadian healthcare. International guidelines from Europe and the United States are available. However, these may reflect regional factors not directly applicable in Canada.

Abbreviations

CD	Crohn's disease
EKG	Electrocardiogram
HBI	Harvey Bradshaw Index
HBsAb	Hepatitis B surface antibody
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HBI	Harvey Bradshaw Index
HIV	Human immunodeficiency virus
IBD	Inflammatory bowel disease
IL	Interleukin
IV	Intravenous
JAK	Janus kinase
MMR	Measles, mumps, and rubella
NYHA	New York Heart Association
PACE	Promoting Access and Care through Centres of Excellence
pMayo	Partial Mayo
QPIs	Quality Performance Indicators
SC	Subcutaneous
S1P	Sphingosine 1-phosphate
TB	Tuberculosis
TNF	Tumor necrosis factor
UC	Ulcerative colitis

Highlights from this CCP

Pretherapy workup should be considered for all patients.

Introduction

IBD provider:

1. Prior to starting therapy, the patient should have the following completed:

   - Take history for hypertension/hyperlipidemia/heart failure, multiple sclerosis, diabetes, venous thromboembolism, current or past history of cancer and consider the age of the patient. If there is a known history of congestive heart failure, a baseline echocardiogram is recommended (at the physician's discretion).

     Note: Anti-TNF therapy is contraindicated for patients with congestive heart failure NYHA Class III and IV and multiple sclerosis.

   - HBsAg, HBsAb, HCV (HIV may also be considered if a patient is at high risk or high local prevalence) (PACE QPIs 6, 30).

   - Routine IBD follow-up labs as indicated/appropriate:

     Complete blood count, electrolytes and creatinine, annual ferritin, vitamin D and vitamin B12, liver biochemistry, and lipid profile at baseline for initiating JAK inhibitor therapy.

   - Chest x-ray and TB skin test, if immunosuppressed QuantiFERON –TB gold test recommended.

   - If considering an S1P receptor modulator, a baseline EKG is mandatory, and an eye exam by an optometrist or ophthalmologist should be performed if the patient has a history of eye disease, diabetes, or uveitis.

   - Vaccinations up to date.

     Recommended: Covid*, influenza*, pneumococcal*, MMR*, varicella zoster*, shingles* (non live vaccine preferred), hepatitis A* and B*
     *Optional

   - Consider arranging a fecal calprotectin kit prior to initiation of advanced therapy.

2. Review insurance options and provide the patient with appropriate start-up and Information sheets.
3. Depending on the choice of therapy, send a message to support staff to arrange a reassessment visit at 2-4 months to assess for primary response. As part of the assessment, report Harvey Bradshaw Index (HBI) if the patient has Crohn's disease or Partial Mayo (pMayo) if the patient has ulcerative colitis.

Support staff:

4. Arrange a clinic appointment for the patient every 2-4 months during induction and 4-6 months during the maintenance phase in the first year of therapy. Once safety and effectiveness are established beyond 12 months of therapy, follow up every 6-12 months.

   Provide an IBD follow-up blood requisition form and a fecal calprotectin kit or requisition for them to complete prior to their appointment (you may need to consider the turnaround time for testing results).
5. See Health Maintenance (Link) protocol for monitoring of adverse effects and prevention of other diseases.

Table 1: Dosing and monitoring of advanced therapies

Agent generic name	Indication	Target	Dose and frequency
Class: Anti-TNF			
Adalimumab	Moderate to severe CD and UC	Tumor necrosis factor (TNF)	**Induction:** 160mg SC at week 0, 80mg at week 2 **Maintenance**: 40mg SC every other week starting at week 4
Infliximab	Moderate to severe CD and UC	Tumor necrosis factor (TNF)	**Induction:** 5mg/kg IV at weeks 0, 2, and 6 **Maintenance**: 5mg/kg IV every 8 weeks starting at week 14 or 120mg SC injection every 2 weeks
Golimumab	Moderate to severe UC	Tumor necrosis factor (TNF)	**Induction:** 200mg SC at week 0, 2 **Maintenance**: 50mg-100mg SC every 4 weeks

Agent generic name	Indication	Target	Dose and frequency
Class: Anti-integrin			
Vedolizumab	Moderate to severe CD and UC	α-4-β-7 integrin	**Induction:** 300 mg IV at 0, 2 and 6 weeks **Maintenance**: 300mg IV every 8 months or 108mg SC every 2 weeks
Class: Cytokines			
Risankizumab	Moderate to severe CD and UC	IL-23 receptors	**Induction:** For CD: 600mg IV infusion at week 0, 4, 8 For UC: 1200 mg IV infusion at week 0,4,8 **Maintenance:** For CD: 360mg SC (on-body) injection every 8 weeks For UC: 180 mg or 360mg SC injection every 8 weeks
Ustekinumab	Moderate to severe CD and UC	IL-12 and IL-23 receptors	**Induction**: IV, dosing based on weight: • ≤55 kg: 260 mg as a single dose • >55 kg to 85 kg: 390 mg as a single dose • >85 kg: 520 mg as a single dose **Maintenance:** SC, begin maintenance dose (90 mg) 2 months after IV induction, then continue 90 mg every 2 months
Mirikizumab	Moderate to severe UC and CD	IL-23 receptor p19 antagonist	**Induction:** For UC: 300 mg IV at weeks 0, 4, and 8 For CD: 900 mg IV infusion for at least 90 minutes at Week 0, 4, and 8 **Maintenance:** For UC: 200 mg SC at week 12 and q4 weeks thereafter For CD: 300 mg SC at week 12 and q4 weeks thereafter
Guselkumab	Moderate to severe CD	IL 23 receptor and CD64	**Induction:** 200 mg IV infusion over a period of at least one hour at Week 0, 4 and 8 **or** 400 mg SC at Week 0, 4 and 8. **Maintenance:** 100 mg SC at Week 16 and every 8 weeks thereafter **or** 200mg SC at week 16 and every 4 weeks thereafter

Version: January 21, 2026

Agent generic name	Indication	Target	Dose and frequency
Class: Small molecules			
Ozanimod	Moderate to severe UC	Sphingosine 1-phosphate (S1P) receptors	**Induction:** 1mg/day of oral ozanimod for 10 weeks **Maintenance**: 1mg/day of oral ozanimod
Etrasimod	Moderate to severe UC	Sphingosine 1-phosphate (S1P) receptors	**Induction**: 2mg/day of oral etrasimod for 12 weeks **Maintenance**: 2mg/day of oral etrasimod
Tofacitinib	Moderate to severe UC	Janus kinase (JAK)	**Induction:** 10 mg twice daily for 2 months **Maintenance:** 5mg or 10mg twice daily
Upadacintinib	Moderate to severe CD and UC	Janus kinase (JAK)	**Induction:** 45mg once daily for 8 weeks (patients with UC) or 12 weeks (patients with CD) **Maintenance**: 15mg once daily or 30mg once daily

Please see the Loss of Response (Link) protocol in case of loss of response or partial response to advanced therapy.

References

Mitrev et al. Review article: consensus statements on therapeutic drug monitoring of anti-tumour necrosis factor therapy in inflammatory bowel diseases. Aliment Pharmacol Ther 2017; 46(11-12):1037-1053. https://doi.org/10.1111/apt.14368

Papamichael et al. Appropriate Therapeutic Drug Monitoring of Biologic Agents for patients with inflammatory bowel diseases. Clin Gastroenterol Hepatol. 2019; 17(9):1655-1668. https://doi.org/10.1016/j.cgh.2019.03.037