



# 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 IBD

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PACE Inflammatory Bowel Disease Clinical Care Pathways

## Highlight Box

Pretherapy workup should be considered for all patients

## Introduction

IBD Provider:

1. Prior to starting therapy, the patient should have the following completed:
  - a. 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.
  - b. HAV IgG, HBsAg, HBsAb, HCV (HIV may also be considered if patient at high risk or high local prevalence) ([PACE QPIs 6.30](#))
  - c. Routine IBD follow-up labs as indicated/appropriate (CBCD, FER, B12, Random glucose, ALB, ALP, ALT, TBIL, LPS, GGT, TSH, Vit D, CRP, AST, Fe, TIBC, ESR\*)
  - d. Chest x-ray
  - e. TB Skin test, if immunosuppressed QuantiFERON -TB gold test recommended
  - f. EKG if considering S1P receptor modulator.
  - g. Vaccinations up to date (recommended: COVID, Influenza, Pneumococcal, MMR and Varicella zoster, Shingrix, Hepatitis A\*) \*optional
  - h. Arrange a fecal calprotectin kit prior to initiation of Advanced Therapy
2. Review insurance options and provide appropriate start-up sheets and Information sheets to the patient.
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 \(HBI\)](#) or [Partial Mayo \(pMayo\)](#)

Support Staff:

4. Arrange a clinic appointment for the patient at 2-4 months during induction and 3-6 months during the maintenance phase. Provide IBD follow-up blood requisition form and a fecal calprotectin kit or requisition to complete prior to their appointment (you may need to take into account the turnaround time for testing results). \*applicable to pediatrics

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See [Health Maintenance protocol](#) for monitoring of adverse effects and prevention of other diseases.

## Notes:

### a. Dosing and monitoring of Advanced Therapies

Agent Generic name	Indicated for	Target	Dose and frequency
Class: Anti-TNF			
Adalimumab + biosimilars	Moderate to severe CD and UC	Tumor necrosis factor (TNF)	Induction: 160mg at week 0, 80mg at week 2 Maintenance: 40mg every other week starting at week 4
Infliximab + biosimilars	Moderate to severe CD and UC	Tumor necrosis factor (TNF)	Induction: 5mg/kg at week 0, 2, and 6 Maintenance: 5mg/kg every 8 weeks starting at week 14 (escalate to 10mg/kg if inadequate response)
Golimumab	Moderate to severe UC	Tumor necrosis factor (TNF)	Induction: 200mg at week 0, 2 Maintenance: 50mg-100mg every 4 weeks
Class: Anti-integrin			
Vedolizumab	Moderate to severe CD and UC	$\alpha$ -4- $\beta$ -7 integrin	Induction: 300 mg IV at 0, 2 and 6 weeks Maintenance: 300mg IV every 8 months OR 108mg subcutaneous injection every 2 weeks
Class: Cytokines			
Risankizumab	Moderate to severe CD and UC	IL-23 receptors	Induction: 600mg IV infusion at week 0, 4, 8 Maintenance: 360mg subcutaneous (on-body) injection every 8 weeks

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Ustekinumab	Moderate to severe CD and UC	IL-12 and IL-23 receptors	<p>Induction: IV, dosing based on weight:</p> <p>≤55 kg: 260 mg as single dose</p> <p>&gt;55 kg to 85 kg: 390 mg as single dose</p> <p>&gt;85 kg: 520 mg as single dose</p> <p>Maintenance: subcutaneous, begin maintenance dose (90 mg) 2 months after IV induction then continue 90 mg every 2 months</p>
Class: Small molecules			
Ozanimod	Moderate to severe UC	Sphingosine 1-phosphate (S1P) receptors	<p>Induction: 1mg/day of oral Ozanimod for 10 weeks</p> <p>Maintenance: 1mg/day of oral Ozanimod</p>
Tofacitinib	Moderate to severe UC	Janus kinase (JAK)	<p>Induction: 10 mg twice daily for 2 months Maintenance: 5mg twice daily (or 10mg twice daily in selected patients)</p> <p>If remission is not achieved and patient is at low risk of cardiovascular disease or thromboembolism: increase to 10 mg twice daily, then decrease to 5mg twice daily.</p>
Upadacitinib	Moderate to severe CD and UC	Janus kinase (JAK)	<p>Induction: 45mg once daily for 8 weeks (patients with UC) or 12 weeks (patients with CD)</p> <p>Maintenance: 15mg once daily or 30mg once daily (30mg once daily may be more effective for patients with more severe disease)</p>

Please see the [Loss of response/Partial response 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>