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

Dr. Neeraj Narula MD, MPH, FRCPC (McMaster University)
Dr. Yvette Leung MD, MSc, FRCPC (University of British Columbia)

PACE Inflammatory Bowel Disease Clinical Care Pathways

crohn's colitis

Highlight Box

Pretherapy workup should be considered for all patients

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.

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. If considering S1P receptor modulator, baseline EKG is mandatory and eye exam by optometrist/ophthalmologist should be performed if history of eye disease, diabetes, or uveitis.
    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 4-6 months during the maintenance phase in the first year of therapy. Once safety and effectiveness is established beyond 12 months of therapy follow-up every 6-12 months.

   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).

5. See Health Maintenance protocol for monitoring of adverse effects and prevention of other diseases.

Notes:

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 SC at week 0, 80mg at week 2 Maintenance: 40mg SC every other week starting at week 4
Infliximab + biosimilars	Moderate to severe CD and UC	Tumor necrosis factor (TNF)	Induction: 5mg/kg IV at week 0, 2, and 6 Maintenance: 5mg/kg IV every 8 weeks starting at week 14 (escalate to 10mg/kg IV if inadequate response), 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
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

Agent Generic name	Indicated for	Target	Dose and frequency
Class: Cytokines			
Risankizumab	Moderate to severe CD and UC	IL-23 receptors	Induction: 600mg IV infusion at week 0, 4, 8 Maintenance: 360mg SC (on-body) 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 single dose >55 kg to 85 kg: 390 mg as single dose >85 kg: 520 mg as 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	IL-23 receptor p19 antagonist	Induction: 300 mg IV at Weeks 0, 4, and 8 Maintenance: 200 mg SC, at Week 12, and q4Weeks thereafter
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 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

SC: Subcutaneous IV: Intravenous

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