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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PACE Inflammatory Bowel Disease Clinical Care Pathways

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:
    - 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
    - Arrange 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) or Partial Mayo (pMayo).

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 protocol for monitoring of adverse effects and prevention of other diseases.

Notes: 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 (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	Indication	Target	Dose and frequency
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: 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 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 (given as two consecutive SC injections of 100 mg and 200 mg in any order) every 4 weeks starting at Week 12 upon completion of induction dosing
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. Each 400 mg dose is given as two injections of 200 mg Maintenance: 100 mg SC at Week 16 and every 8 weeks thereafter or 200mg SC at week 16 and every 4 weeks thereafter

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 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 UC: Ulcerative colitis CD: Crohn's disease

Please see the Loss of 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

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