crohn's colitis

Induction of Advanced Therapy

Objective

Ensure a safe start to advanced therapy.

Patient Population

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

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)

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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

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	α-4-β-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

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			Maintenance: 360mg subcutaneous (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: subcutaneous, begin maintenance dose (90 mg) 2 months after IV induction then continue 90 mg every 2 months
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
Tofacitinib	Moderate to severe UC	Janus kinase (JAK)	Induction: 10 mg twice daily for 2 months Maintenance: 5mg twice daily (or 10mg twice daily in selected patients) **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.
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 (30mg once daily may be more effective for patients with more severe disease)

Please see the Loss of response/Partial response protocol in case of loss of response or partial response to Advanced Therapy.

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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

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