

Initiation of Immunomodulators

(Thiopurines and Methotrexate)

Objective

Appropriate initiation and use of immunomodulators (Thiopurines and Methotrexate).

Patient Population

Individuals with a known diagnosis of IBD.

Highlight Box

Methotrexate should not be used in females wanting to become pregnant (discuss alternate therapy prior to family planning).

Imuran and 6MP can be continued as ordered throughout pregnancy and breastfeeding.

Introduction

This care protocol provides a general guideline for initiating immunomodulators (also called immunosuppressants) in adults with inflammatory bowel disease.

IBD Provider:

- Prior to starting an immunomodulator, consider TPMT testing, EBV IgG screening. It is
 important to remember that patients may need to switch to a different immunomodulator or
 require biologic therapy. Refer to the IBD PATIENTS STARTING BIOLOGIC INDUCTION
 REGIME protocol for pre-biologic work-up.
- 2. At the time of the medication initiation appointment, the patient is to be given:
- ➤ A patient information sheet and instructions for taking the medication Thiopurines (Azathioprine or 6-mercaptopurine for IBD, Azathioprine Patient Instructions, 6-Mercaptopurine Patient Instructions); Methotrexate (Methotrexate Information sheet, Methotrexate Patient Instructions) (PACE QPI 22,23)
- Bloodwork requisitions:
 - A new start immunomodulator lab requisition to be done **every week** for 1 month (<u>Thiopurine Labs New start</u>), monthly for the first 6 months, then 3-monthly thereafter. This should include CBC, CRP, liver biochemistry, +/- albumin electrolytes and creatinine (<u>Thiopurine Labs Monthly</u>). (<u>PACE QPI 12</u>)
 - 6-TG and 6-MMP levels to be done at 3 months (physician discretion) (6TG & 6MMP Therapeutic Levels)





- Collection kit for fecal calprotectin at baseline, 3 months, 6 months, and then 6-monthly thereafter.
- 3. After the patient has been on an immunomodulator for 3 months, assess for clinical, and biochemical (including fecal calprotectin response). (<u>Harvey Bradshaw Index</u>) (<u>Partial Mayo Scoring Index</u>). (<u>PACE QPI 15</u>)
- 4. If there is inadequate response (including the inability to wean corticosteroids), consider dose optimization (+/- with the assistance of 6-TG, 6-MMP levels), or switch to an alternative therapy. **See Therapy decision protocols**
- 5. Skin cancer surveillance is to be performed by a family physician or dermatologist on an annual basis.

Support Staff:

1. Arrange a follow-up assessment (phone/clinic visit/telehealth) clinic appointment in 3-4 months.

