

Name of Clinical Care Pathway

Initiation of Immunomodulators (Thiopurines and Methotrexate)

Objective

Appropriate initiation and use of immunomodulators (thiopurines and methotrexate)

Patient Population

Individuals with a known diagnosis of inflammatory bowel disease (IBD)

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PACE Inflammatory Bowel Disease Clinical Care Pathways



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.

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

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

IBD provider:

- 1. Prior to starting an immunomodulator, consider thiopurine methyltransferase (TPMT) testing and Epstein-Barr virus (EBV) IgG screening. It is important to remember that patients may need to switch to a different immunomodulator or require advanced therapy. Refer to the <u>Induction of Advanced therapy</u> 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 (PACE QPI 22,23):
 - Thiopurines (azathioprine or 6-mercaptopurine, azathioprine patient instructions, 6-mercaptopurine patient instructions).
 - Methotrexate (methotrexate information sheet, methotrexate patient instructions).
 - Bloodwork requisitions:
 - A new start immunomodulator lab requisition is to be done every week for 1 month monthly for the first 6 months, then 3 months thereafter. This should include complete blood count, c-reactive protein, liver biochemistry, ± albumin electrolytes and creatinine (PACE QPI 12).
 - 6-thioguanine nucleotides (6-TGN) and 6-methylmercaptopurine (6-MMP) levels to be done at 3 months (physician discretion).
 - Collection kit for fecal calprotectin (FCP) 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, biochemical (including FCP response), <u>Harvey Bradshaw Index</u> and <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 level) or switch to an alternative therapy. See <u>Induction of Advanced Therapy</u> protocol.
- 5. Skin cancer surveillance is to be performed by a family physician or dermatologist annually.

Support staff:

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





