Treatment Algorithm for Inflammatory Bowel Disease
TREATMENT ALGORITHM
ULCERATIVE COLITIS
**Proctitis/Left Sided Colitis** *(mild to moderate disease)*

**INDUCTION THERAPY**
- Mesalazine suppositories 1g nocte (proctitis) or Mesalazine enemas 1g nocte (left sided colitis) ±
- Mesalazine oral 2-4g/day

**MAINTENANCE THERAPY**
- Mesalazine suppositories 1g (2-3 times/week) or Mesalazine enemas 1g (2-3 times/week) and/or Mesalazine oral 1-2g/day
- Assess with endoscopy/faecal calprotectin 3-12 monthly for mucosal healing or during flares not responding to therapy

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**Assess response 2-4 weeks Clinical remission?**

- **Yes**
  - Frequent relapse
    - Induction therapy as above
    - Increase maintenance dose for mesalazine eg Mesalazine suppositories 1g od or Mesalazine enemas 1g od and/or Mesalazine oral 3-4g/day
    - OR
    - Add azathioprine 1.5-2.5mg/kg/day or as per drug levels

- **No**
  - Refer to algorithm for severe disease
**Proctitis / Left Sided Colitis** *(severe disease)*

**INDUCTION THERAPY**
- Prednisolone 30-40mg/day ±
- Mesalazine oral 2-4 g/day
- Mesalazine suppositories 1g bd (proctitis)
  Mesalazine enemas 1g bd ± mesalazine suppositories 1g bd (left sided colitis)
- Calcium 1g/day + Vitamin D 1000 units/day

**MAINTENANCE THERAPY**
- Taper Prednisolone 5mg/week
- Mesalazine oral 1-2g/day ±
- Mesalazine suppositories (2-3 times /week) or Mesalazine enemas (2-3 times/week)
- Calcium and Vitamin D as above
- Assess with endoscopy/faecal calprotectin
  3-12 monthly for mucosal healing or during flares not responding to therapy

- Yes: Assess response 2-4 weeks
- Clinical remission?

- No: Frequent relapse/ Steroid dependent
  - Induction therapy as above
  - Increase maintenance dose for mesalazine eg
    Mesalazine suppositories 1g OD or Mesalazine enemas 1g OD and / or Mesalazine oral 3-4g/d
    OR
  - Add azathioprine 1.5-2.5mg/kg/day or as per drug levels

- Frequent relapse/ Steroid dependent
  - Add infliximab 5mg/kg 0,2,6 weeks followed by 8 weekly OR
  - Adalimumab 160mg/80mg at 0,2 weeks followed by 40mg every 2 weeks
  - Azathioprine as above

- Frequent relapse/ Steroid dependent
  - Other rescue therapy
  - Surgery
  - Tertiary referral
  - Dose escalation
**Extensive Colitis (mild disease)**

**INDUCTION THERAPY**
- Mesalazine oral 3-4 g/day
- Mesalazine suppositories 1g/day or Mesalazine enemas 1g/day

**MAINTENANCE THERAPY**
- Mesalazine oral 2g/day ±
- Mesalazine suppositories (2-3 times /week) or Mesalazine enemas (2-3 times/week)
- Assess with endoscopy/faecal calprotectin 3-12 monthly for mucosal healing or during flares not responding to therapy

**Frequent relapse**
- Induction therapy as above
- Increase maintenance dose for mesalazine eg
  - Mesalazine oral 3-4g/day ±
  - Mesalazine suppositories 1g od or Mesalazine enemas 1g od and/or
- Add azathioprine 1.5-2.5mg/kg/day or as per drug levels

**Assess response 2-4 weeks Clinical remission?**

Yes

No

Refer to algorithm for Extensive colitis (moderate to severe disease)
Extensive Colitis *(moderate to severe disease)*

**INDUCTION THERAPY**
- Prednisolone 30-40mg/day
- ± Mesalazine oral 3-4 g/day
- Mesalazine suppositories 1g/day or Mesalazine enemas 1g/day
- Calcium 1g/day + Vitamin D 1000 units/day

**MAINTENANCE THERAPY**
- Taper Prednisolone 5mg/week
- Mesalazine oral 2-4g/day ±
- Mesalazine suppositories (2-3 times /week) or Mesalazine enemas (2-3 times/week)
- Calcium and Vitamin D as above
- Assess with endoscopy/faecal calprotectin 3-12 monthly for mucosal healing or during flares not responding to therapy

Yes  Assess response 2-4 weeks Clinical remission? No  Refer to algorithm for acute severe colitis

Frequent relapse/ Steroid dependent

- Induction therapy as above
- Increase maintenance dose for mesalazine eg
  - Mesalazine oral up to 4g/day ±
  - Mesalazine suppositories 1g od or Mesalazine enemas 1g od
  OR
- Add azathioprine 1.5-2.5mg/kg/day or as per drug levels

Frequent relapse/ Steroid dependent

- Add infliximab 5mg/kg 0,2,6 weeks followed by 8 weekly OR
- Adalimumab 160mg/80mg at 0,2 weeks followed by 40mg every 2 weeks

Frequent relapse/ Steroid dependent

- Tertiary referral
- Dose escalation
- Other rescue therapy
- Surgery
Extensive Ulcerative Colitis
(acute severe/fulminant disease)

- Hospital admission
- Plain abdominal radiograph/plain CT abdomen to assess disease severity (colonic diameter >5.5cm, mucosal islands)
- Unprepared flexible sigmoidoscopy with biopsies to assess severity, confirm diagnosis and rule out coexisting CMV infection
- Stool culture and microscopy, Clostridium difficile toxin assay

Surgical intervention needed? (Toxic megacolon (colonic dilatation with signs of systemic toxicity)/perforation/severe bleeding)*

- Yes
  - Surgical intervention
- No
  - Medical treatment
    - Intravenous hydrocortisone 100mg qds or methylprednisolone 40mg bd
    - DVT prophylaxis (eg enoxaparin 40mg/day)
    - Intravenous antibiotics if coexisting sepsis
    - Adequate hydration
    - Assess 3 days
      - Inadequate response
        - Dose escalation
        - Tertiary referral
        - Surgery
      - Adequate response
        - Combined medical and surgical assessment
          - Adequate response
            - Convert IV steroids to oral prednisolone 40mg od, then taper down 5mg/week
            - Azathioprine 1.5-2.5mg/kg/day or as per drug levels
            - Continue infliximab 8-weekly or
            - Convert cyclosporin to oral 5mg/kg/day bd for 3 months then stop
            - Assess with endoscopy/faecal calprotectin 3-12 monthly for mucosal healing or during flares not responding to therapy
          - Inadequate response
            - Assess 4-7 days
              - Frequent relapse/Steroid dependent
              - Tertiary referral
              - Dose escalation
              - Other rescue therapy
              - Surgery
        - Assess 4-7 days
          - Inadequate response
            - Frequent relapse/Steroid dependent
            - Tertiary referral
            - Dose escalation
            - Other rescue therapy
            - Surgery
        - Adequate response
          - Convert to oral Prednisolone 40mg od then taper down down 5mg/week
          - Calcium 1g/day + Vitamin D 1000 units/day
          - Azathioprine 1.5-2.5mg/kg/day or as per drug levels
          - Assess with endoscopy/faecal calprotectin 3-12 monthly for mucosal healing or during flares not responding to therapy

* Frequent relapse/Steroid dependent

- Add infliximab 5 or 10 mg/kg 0,2,6 weeks followed by 8 weekly OR
- Adalimumab 160mg/80mg at 0,2 weeks followed by 40mg every 2 weeks

- Frequent relapse/Steroid dependent
- Tertiary referral
- Dose escalation
- Other rescue therapy
- Surgery
DEFINITIONS:

**Disease activity**

**Mild disease:** Mayo score 2-5  
**Moderate disease:** Mayo score 6-9  
**Severe disease:** Mayo score 10-12  

**Clinical remission:** Partial Mayo score <2 with no rectal bleeding.  
**Flares** – recurrence of symptoms in a patient in clinical remission.  
**Frequent relapse:** ≥2 episodes flares/year requiring steroids.  
**Steroid dependent:** Relapse of symptoms on steroid tapering.

**Acute severe/fulminant ulcerative colitis (Truelove and Witt’s criteria):**

- ≥6 bloody stools/day WITH  
- Fever (temp >37.8°) or  
- Tachycardia (pulse >90bpm) or  
- Anaemia (Hb <10.5g/dl)or  
- ESR (>30mm/h) or raised CRP  

**Adequate response:** <3 stools/day or 3-8 stools/day with CRP<45mg/L  
**Inadequate response:** >8 stools/day or 3-8 stools/day and CRP>45mg/L

* Careful intensive medical therapy jointly with surgeons may be option in selected patients.

**Endoscopic assessment**

**Mucosal healing**

**Adequate:** Endoscopic Mayo score 0,1  
**Inadequate:** Endoscopic Mayo score 2,3

Consider stepping up therapy regardless of symptoms in patients with inadequate mucosal healing.

Faecal calprotectin <150mg/kg may be used as a surrogate marker for mucosal healing.

**Relapse investigation protocol**

In patients with flares not responding to therapy, send stools for microscopy and culture and Clostridium difficile toxin as well as biopsies to look for coexisting CMV colitis.
Footnotes

THERAPY:

5-aminosalicylates
- Sulphasalazine (SSZ) can be considered as an alternative to mesalazine but higher risk of side effects (Steven Johnson syndrome, oligospermia) and higher doses less well tolerated.
- SSZ may provide better symptom relief than mesalazine in patients with IBD related arthropathy.

Thiopurines / Immunomodulators
- Azathioprine usually used, 6MP 1-1.5mg/kg/day, can be used if patient develops nausea.
- Start azathioprine at low dose, typically in increments of 50mg every 6-8 weeks to a dose of 1.5-2.5 mg/kg/day if no biochemical/haematological abnormalities or side effects.
- FBC & LFT’s weekly for 4 weeks then 2 weekly for 4 weeks, at initiation or following dose increase. Once the dose is stable, reduce to 3 monthly.
- TPMT levels and metabolite monitoring 6-TGN and 6-MMP(R) recommended in all patients if possible but should particularly be considered in patients who are intolerant/have significant side effects to the drug or in patients who have frequent relapses despite standard weight based regime.

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<tbody>
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<td>TDM</td>
<td>Low/absent 6-TGN and Low/absent 6-MMP (R)</td>
<td>Low 6-TGN and Low 6-MMP(R)</td>
<td>Low 6-TGN and High 6-MMP(R)</td>
<td>High 6-TGN and Low 6-MMP(R)</td>
</tr>
<tr>
<td>Risk</td>
<td>Inefficacy (false resistance)</td>
<td>Inefficacy or poor response</td>
<td>Poor response and/or hepatotoxicity</td>
<td>Myelotoxicity</td>
</tr>
<tr>
<td>Cause</td>
<td>Poor compliance to treatment</td>
<td>Underdosing</td>
<td>Very high TPMT activity i.e. pharmacologic resistance to thiopurines</td>
<td>Deficient TPMT activity</td>
</tr>
<tr>
<td>Action</td>
<td>Therapeutic patient education</td>
<td>Increase thiopurine dosage</td>
<td>Add allopurinol 100mg/day and decrease thiopurine dosage (25-50% of original dose)</td>
<td>Decrease thiopurine dosage according to TPMT phenotype</td>
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• At present, data for use of methotrexate still limited but can be considered in thiopurine intolerant individuals.
• Methotrexate can be given as a loading dose 25mg/week subcutaneously or intramuscularly for 12-16 weeks with oral folic acid 5mg stat on Day 3 after administration. This is followed by maintenance of 15mg/week either orally or sc/im. Blood monitoring similar as for thiopurines.

Anti-TNF therapy
• Although generally used as long-term maintenance therapy, can consider stopping biologic in 6 months to one year with thiopurine maintenance if complete mucosal healing achieved.
• Drug and antibody monitoring not available at present.

Screening pre biologic therapy:
• Latent TB: CXR or CT chest AND Tuberculin skin test (TST) or Interferon-gamma release assays (IGRA) such as Quantiferon Gold and T-SPOT. TB test.
• For current or previous chronic hepatitis B: Hep B sAg, IgG HBc Ab.

Vaccinations
• Consider all vaccinations especially in the elderly population.
• Main vaccines should include varicella, HPV, influenza, pneumococcal, Hepatitis B.
• Live vaccines should not be given within three weeks before commencing anti-TNF and within three months after last dose.

Steroids
• Taper prednisolone therapy as soon as clinical remission achieved, ideally patient should be steroid free within 3 months.
• Always prescribe with calcium/vitamin D supplements as per algorithm.

Rescue therapy in acute severe ulcerative colitis
• Infliximab preferred in thiopurine refractory patients.
• Cyclosporin best reserved in thiopurine naïve patients as long term side effects of cyclosporin limits its use as maintenance therapy.
• Sequential use of infliximab followed by cyclosporin or vice versa not recommended unless in specialized centres.
• Other rescue medications such as tacrolimus, leucocyte apheresis mainly used in Japan.
<table>
<thead>
<tr>
<th>MAYO SCORE</th>
<th>Stool frequency</th>
<th>Rectal bleeding</th>
<th>Physician global assessment</th>
<th>Endoscopic findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal number of stools for patient</td>
<td>No blood seen</td>
<td>Normal</td>
<td>Normal or inactive disease</td>
</tr>
<tr>
<td>1</td>
<td>1 to 2 stools per day more than normal</td>
<td>Streaks of blood with stool less than half the time</td>
<td>Mild</td>
<td>Mild erythema, decreased vascular pattern, mild friability</td>
</tr>
<tr>
<td>2</td>
<td>3 to 4 stools more than normal</td>
<td>Obvious blood with stool most of the time</td>
<td>Moderate</td>
<td>Marked erythema, absent vascular pattern, friability, erosions</td>
</tr>
<tr>
<td>3</td>
<td>&gt;= 5 stools more than normal</td>
<td>Blood alone passes</td>
<td>Severe</td>
<td>Spontaneous bleeding, ulcerations</td>
</tr>
</tbody>
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CROHNS’ DISEASE
**Crohn’s Disease (Luminal) (mild to moderate)**

**INDUCTION THERAPY**
- Prednisolone 30-40mg od
- Calcium 1g/day + Vitamin D 1000 units per day
- Enteral therapy (ileal and proximal small bowel disease)
- ± Mesalazine oral 3-4g/day ± topical mesalazine 1-3g/day (colonic disease)
- Proton pump inhibitor (upper GI disease)
- Smoking cessation

**MAINTENANCE THERAPY**
- Taper prednisolone 5mg/week
- Azathioprine 1.5-2.5mg/kg/day or as per drug levels
- Calcium and Vitamin D as above
- Proton pump inhibitor (upper GI disease) ± mesalazine/enteral nutrition
- Assess with endoscopy/faecal calprotectin/radiologically 3-12 monthly for mucosal healing or during flares not responding to medical therapy

Assess response 2-4 weeks

Clinical response?

- Yes
- No

Frequent relapse / steroid dependent

- Refer to maintenance therapy for severe disease

Refer to algorithm for severe disease
**Crohn’s Disease (Luminal) (severe)**

- Hospital admission
- Exclude surgical abdomen (bowel obstruction, perforation)
- Assess extent of disease (CT/MRI enterography if suspected small bowel involvement)

**INDUCTION THERAPY**
- Intravenous hydrocortisone 100mg qds/methylprednisolone 40mg bd OR
- Infliximab 5 or 10 mg/kg 0,2,6 weeks OR
- Adalimumab 160mg/80mg at 0,2 weeks
- Enteral nutrition and/or parenteral nutrition in extensive small bowel disease/fistulae
- Proton pump inhibitor in upper GI disease
- DVT prophylaxis eg enoxiparin 40mg od
- Intravenous antibiotics if coexisting sepsis

**MAINTENANCE THERAPY**
- Convert to oral Prednisolone 30-40mg od then taper 5mg/week OR
- Infliximab 5mg/kg 8 weekly OR
- Adalimumab 40mg every 2 weeks
- Azathioprine 1.5-2.5mg/kg/day or as per drug levels
- Smoking cessation
- Calcium 1g/day + Vitamin D 1000 units per day
- Proton pump inhibitor (upper GI disease)
- ± mesalazine/enteral nutrition
- Assess with endoscopy/faecal calprotectin/radiologically 3-12 monthly for mucosal healing or flares not responding to standard therapy

**Frequent relapse/steroid dependent**
- Tertiary referral
- Dose escalation
- Other rescue therapy
- Surgery

**Switch to Anti-TNF if on steroids**
- Tertiary referral
- Surgery
Crohn’s Disease *(perianal fistula)*

- Define anatomy and disease severity (Pelvic MRI/EUA anorectal ultrasound)
- Assess extent and activity of luminal disease (Colonoscopy)

**Simple fistula**
- Antibiotics ± local surgical management

**Complex fistula**
- Seton insertion
- Antibiotics (Ciprofloxacin 500mg bd and/or Metronidazole 400mg tds for 3-4 months)
- Azathioprine 1.5-2.5mg/kg/day or as per drug levels
- Infliximab 5mg/kg 0, 2, 6 weeks followed by 8 weekly
  OR
  Adalimumab 160mg/80mg at 0,2 weeks followed by 40mg every 2 weeks
- **Avoid steroids** if isolated fistulising disease (i.e. no luminal disease)
- Remove seton (4-6 weeks)

**Adequate closure**
- Continue infliximab/adalimumab
- Azathioprine 1.5-2.5mg/kg/day or as per drug levels

**Assessment 8-12 weeks**
- Check compliance
- Reassess with MRI

**Inadequate closure**
- Inadequate response after 12 weeks
- Consider infliximab/adalimumab dose escalation
- Surgery
- Continue azathioprine
DEFINITIONS:

**Disease activity - luminal**

**Mild disease:** Harvey Bradshaw Index (HBI) 5-7  
**Moderate disease:** HBI 8-16  
**Severe disease:** HBI >16

Clinical remission is Harvey Bradshaw index <5

Flares – recurrence of symptoms in a patient in clinical remission.  
Frequent relapse: ≥2 episodes flares/year requiring steroids.  
Adequate response: A ≥3 point decrease in HBI score from baseline.  
Steroid dependent: Relapse of symptoms on steroid tapering.

**Fistula**

Simple - superficial/low, without signs of abscess formation or anorectal stricture.  
Complex - high/multiple openings with abscesses; rectovaginal fistula; anorectal stricture with rectal inflammation.  
Adequate response - Closure of fistula based on clinical symptoms and external examination.

**Endoscopic Assessment**

Mucosal healing - Although no clear definition exists, generally defined as absence or almost complete absence of ulcers and erosions.  
Stepping up therapy to achieve mucosal healing should be considered in all patients with Crohn’s disease regardless of symptoms in patients to avoid long term complications and surgery.

Faecal calprotectin <150mg/kg may be used as a surrogate marker for mucosal healing.
**Footnotes**

**Enteral nutrition**
Polymeric formula (e.g., Ensure) or dipeptide-based formula (e.g., Peptamen) 30kcal/kg/day can be used as exclusive enteral nutrition for 4-6 weeks or as a supplement to normal diet.

**5 Aminosalicylates**
Limited evidence for mesalazine except for in mild colonic disease.

**Thiopurines/Immunomodulators**
- Azathioprine usually used, 6MP can be used if patient develops nausea.
- Start azathioprine at a low dose, typically in increments of 50 mg every 6-8 weeks to a dose of 1.5-2.5 mg/kg/day if no biochemical/haematological abnormalities or side effects.
- FBC & LFT’s weekly for 4 weeks then 2 weekly for 4 weeks, initially or during dose increase. Once the dose is stable, reduce to 3 monthly.
- TPMT levels and metabolite monitoring 6-TGN, 6-MMP(R) recommended in all patients if possible but should particularly be considered in patients who are intolerant/have significant side effects to the drug or in patients who have frequent relapses despite standard weight based regime.

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<td>Switch to another drug if active disease</td>
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• Although generally used as long-term maintenance therapy, can consider stopping biologic in 6 months to one year with thiopurine maintenance if complete mucosal healing achieved.
• Drug and antibody monitoring not available at present.

Screening pre biologic therapy:
• Latent TB: CXR or CT chest AND Tuberculin skin test (TST) or Interferon-gamma release assays (IGRA) such as Quantiferon Gold and T-SPOT.TB test.
• For current or previous chronic hepatitis B: Hep B sAg, IgG Hbc Ab.

Vaccinations
• Consider all vaccinations especially in the elderly population.
• Main vaccines should include varicella, HPV, influenza, pneumococcal, hepatitis B.
• Live vaccines should not be given three weeks before commencing anti-TNF and three months after last dose.

Steroids
• Taper prednisolone therapy as soon as clinical remission achieved, ideally patient should be steroid free within 3 months.
• Always prescribe with calcium/vitamin D supplements as per algorithm.
• Budesonide not available in Malaysia at this present time so not included in algorithm.
<table>
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<tr>
<th>Indices</th>
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<tr>
<td>General well-being (Yesterday)</td>
<td></td>
</tr>
<tr>
<td>(0 = very well, 1 = slightly below average, 2= poor, 3 = very poor, 4 = terrible)</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain (Yesterday)</td>
<td></td>
</tr>
<tr>
<td>(0 = none, 1 = mild, 2 = moderate, 3 = severe)</td>
<td></td>
</tr>
<tr>
<td>Number of liquid stools per day (Yesterday)</td>
<td></td>
</tr>
<tr>
<td>Abdominal mass</td>
<td></td>
</tr>
<tr>
<td>(0 = none, 1 = dubious, 2 = definite, 3 = tender)</td>
<td></td>
</tr>
<tr>
<td>Complications (1 point for each)</td>
<td></td>
</tr>
<tr>
<td>– Arthralgia</td>
<td></td>
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<tr>
<td>– Uveitis</td>
<td></td>
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<tr>
<td>– Erythema Nodosum</td>
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<tr>
<td>– Aphthous Ulcers</td>
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<tr>
<td>– Pyoderma Gangrenosum</td>
<td></td>
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<tr>
<td>– Anal Fissure</td>
<td></td>
</tr>
<tr>
<td>– New Fistula</td>
<td></td>
</tr>
<tr>
<td>– Abscess</td>
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Reference (adapted from)
Conventional Medical Management of Inflammatory Bowel Disease. Burger and Travis. Gastroenterology 2011;140:1827–1837
Inflammatory Bowel Disease – An Evidence-Based Practical Guide. Ailsa L. Hart and Siew C. Ng

The algorithms are intended as a treatment guide for standard adult patients with IBD. They may not be suitable for special groups (e.g., children, pregnant/breastfeeding women, older adult patients) or special situations such as in the post operative setting.
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