South East London Area Prescribing Committee:

Primary & Secondary Care Inflammatory Bowel Disease Pathway July 2019

Developed by: South East London IBD Pathway Development Group

Contents:

- **Pathway 1**: Presenting with symptoms
- **Pathway 2**: Ulcerative colitis (mesalazine pathway)
- **Pathway 3**: immunosuppressant progression to biologic therapy
- **Pathway 4**: Biologic therapy
- **Pathway 5**: Iron deficiency treatment pathway for patients with IBD

Approved: June 2019

Review date: June 2020 or sooner if evidence/practice changes

Not to be used for commercial or marketing purposes. Strictly for use within the NHS
IBD pathway 1: Presenting with symptoms

Patient presenting with lower GI symptoms suggestive of IBD

Use of steroids only as a last resort. If ≥ 2 courses in a year, refer 2º care.

Known IBD?

YES

LPs and review in 1-2 weeks

NO

GP comfortable with IBD management?

YES

Pt under 'active' FU in 2º care?

YES

Return to 1º care FU

NO

Symptoms controlled?

YES

Pt under 'active' FU in 2º care?

YES

Refer for 'urgent walk-in IBD' OPA via hotline (to be seen <1-2/52)

NO

Refer for 'new IBD' OPA via hotline (to be seen <2-6/52)

Known IBD?

YES

FBC, ESR, Calprotectin, Coeliac screen, TFTs, (stool MCS)

NO ie. subtle symptoms

Bloody diarrhoea?

YES

Repeat FCALP in 4 weeks from first test; Consider IBS advice in meantime (with proviso of re-test)

Bloods normal and FCALP 50-150

NO

Bloods abnormal and/or FCALP >150

Refer if high index of suspicion

FCALP rising >150?

YES

Equivocal FCALP results can be monitored over a longer period every 4-6w

NO

Repeat FCALP in 4 weeks from first test; Consider IBS advice in meantime (with proviso of re-test)

Referral pathway

IBS pathway

Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)

Contact encouraged to inform 2º care of episode

If 2 cycles of advice fail then refer for urgent OPA

Return to 1º care FU

KCH: kch-tr.IBDhelpline@nhs.net
Tel: 0203 299 1606 / 6044
GSTT: ibdhelpline@gstt.nhs.uk
Tel: 020 7188 2487
LGT: LG.IBD@nhs.net
Tel: 020 8333 3000 Ext 8167
PRUH: kch-tr.IBDnurse@nhs.net
Tel: 01689863189
**Patient with known UC** with flare of symptoms
Taking mesalazine only

**CHECK / ENCOURAGE ADHERENCE**
- Typically 55% are adherent -

**Newly diagnosed patient**

2 flares in last 6/12?

≥ 2 flares in last 6/12? **NO**

Severity of this flare?

**CONTACT SECONDARY CARE AT ANY STAGE IN THIS PATHWAY**

**MILD**
- BO 1-3x per day +/ - blood
- No systemic symptoms

- On rectal 5asa therapy alone (enema or supps)
- Add oral 5asa at maximum dose and strength

**MODERATE**
- BO 4-6x per day with blood
- No systemic symptoms

- On zero or maintenance dose (2.4g Octasa™/Mezavant™, 1.5g Salofalk™, 2g Pentasa™)
- Increase to maximum dose 5asa; Consider adding rectal therapy

**SEVERE**
- BO >6 per day with blood
- Fever, tachycardia, hypotension

- On maximum dose (4.8g Octasa™/Mezavant™, 3g Salofalk™, 4g Pentasa™)
- Consider adding Clipper (beclometasone) 5mg OD for max 4 weeks

2/52 review if Rx changed. Symptoms controlled?

Any steroids in last 12 months?

**WILL NEED DISEASE-MODIFYING THERAPY**

**EG. AZATHIOPRINE**

Advice from IBD helpine and/or refer for urgent OPA via helpline(<2/52)

**Call Gastro SpR on-call**
Admit via Medical team
Seen by IBD Cons within 48h

**Mesalazine – choice of oral preparation**
The 1st line oral mesalazine preparation is Octasa™ MR. Nb: Oral Asacol™ MR is not included in the SEL Joint Medicines Formulary and should usually be switched to Octasa™ MR. Other oral preparations should not be considered interchangeable and should not normally be switched in primary care.

**Rectal (‘topical’) therapies can be sole treatment**
- Enema added for ‘left-sided’
- Suppository for ‘proctitis’
- Enema can be added if ‘pancolitis’

**Prescribe prednisolone**
40mg OD reducing by 5mg per week to zero with Ca+vitD suppl OD

**Yearly faecal calprotectin tests are useful for monitoring disease activity. Faecal calprotectin > 250 should prompt discussion with secondary care.**

**Patients with Crohn’s disease experiencing flare-ups should be discussed with secondary care. Entocort (Budesonide MR) 9mg od for 4-6/52 may be used for mild or moderate Crohn’s if ileocaecal location.**

http://www.nice.org.uk/guidance/cg76/chapter/key-principles
IBD pathway 3: IMMUNOSUPPRESSANT progression to BIOLOGIC THERAPY

**VACCINATION AND VIRAL SCREEN**
Should be performed at this stage

Mercaptopurine may be used in AZA intolerant cases. Tioguanine is a 3rd line option
See SEL APC recommendation 074

**INITIAL AZA MONITORING**
Fortnightly FBC, LFTs for 6 weeks
Then at 8 weeks and 12 weeks
Three-monthly thereafter

TGN level at least at 12/52
Recheck if failing therapy

---

**Start point 1**
Patient requiring therapy despite pathway 2

Start AZA based on TPMT result

**High risk IBD?**

**Optimised AZA monotherapy**

Response at 12-16 weeks?

**SUITABLE FOR ENTRY INTO CLINICAL TRIAL?**

Virtual / telephone/ nurse-led F2F follow-up

---

**Start point 2**
Hospitalised patient

“Acute severe” UC

**Chronic active CD**

--

**Chronic active” UC**

**High risk or Complex IBD**
- Young patients (<40 years); Fulminant disease
- Previous surgery for Crohn’s disease / early recurrence
- Fistulising/penetrating Crohn’s disease at presentation
- Unable to use steroids as bridge to immunosuppression
- Already on immunosuppression (and adequate dosing)

**Biologic Pathway (#4)**

Methotrexate (MTX) can be considered if Crohn’s

**Response at 12 weeks?**

---

**Biologics**

**Ciclo should not be started if already on AZA**

Start CICLOSPORIN. If inappropriate, INFLIXIMAB (add AZA if naïve)

In-hospital response?

---

**Offer of shared care**

Shared care can only start after 3/12 and only if patient stable

**Primary care**

**Secondary care**

PROBIOTICS are not recommended for treatment of IBD, except for pouchitis, when use should be directed by secondary care. Probiotics are not available on NHS prescription and patients will normally need to purchase these themselves.
There are Acute Trust guidelines available for ciclosporin dosing and monitoring; in general therapy is a bridge to immunosuppressant and is inappropriate for maintenance >6/12.

**Acute severe UC from pathway 3**

**UC**

**Chronic active UC from pathway 3**

**CD**

**Patient requiring biologic therapy from pathway 3**

**Consider Clinical Trial**

Commissioning is not sought for experimental therapy

- The most appropriate and cost-effective biologic will be selected according to NICE guidance for CD
- Expect 20% of local population of CD in this arm
- The proportion of patients will be higher in tertiary care (population outside LSLBGB)

**CICLOSPORIN**

Max 6/12 3 infusions

Inducing remission may require 10mg/kg infusions, but will not continue as routine maintenance

- Remission once stable on AZA?
  - YES
  - NO

- Remission for acute severe UC defined by Mayo <2 when steroid-free

- If on ciclosporin, switch to alternative biologic as above

- If on IFX, give one further scheduled dose

- Choice should take into account cost (including service related) and informed patient preference, unless clinically inappropriate

**ADALIMUMAB**

**TOFACITINIB**

**GOLIMUMAB**

**INFIXIMAB**

**VEDOLIZUMAB**

Choice should take into account cost (including service related) and informed patient preference, unless clinically inappropriate

- Dose optimisation or drug-switching must be discussed in IBD MDM;
  - Consider surgery. Consider if a clinical trial would be suitable at each point of the pathway prior to switching drug. If patients are optimised, respond, de-escalated and relapse in the future, this section ‘re-sets’. Where patients are dose escalated they will be subject to regular review so that de-escalation of dose can be considered.

- Possible to dose-optimise based on drug/Ab level/clinical response?
  - YES
  - NO

- Possible to dose-optimise based on drug/Ab level/CR?
  - YES
  - NO

- Switch drug (see notes above)
  - YES
  - NO

- Remission at 12 months?
  - YES
  - NO

- Remission for biologic cessation is defined as asymptomatic and biochemical and/or endoscopic and/or radiologic evidence of healing

- Consider stopping or de-escalating biologic therapy

- Virtual / telephone/ nurse-led F2F follow-up

- Continue scheduled Rx

- Response at 12-16 weeks?
  - YES
  - NO

- Remission at 12 months?
  - YES
  - NO

- Steroid-free

- If on ciclosporin, switch to alternative biologic as above

IBD pathway 4: BIOLOGIC THERAPY
Pathway 5: Iron deficiency treatment pathway for patients with Inflammatory Bowel Disease (IBD)

Key:
- Management in Primary care
- Management in Secondary care

Confirmed iron deficiency
- Ferritin < 20 g/L or
- Iron saturations < 15%
- For active disease, ferritin < 100 g/L
- Iron saturations < 15%

**Hb**

- **Hb <70g/L**
  - Iron infusion urgently +/- blood transfusion
  - Repeat Hb (not ferritin or iron studies) in 2 weeks

- **Hb 70-100g/L**
  - Iron infusion (or blood transfusion in selected patient group)
  - Repeat Hb (not ferritin or iron studies) in 8 weeks

- **Hb >100 g/L**
  - Commence one of the following oral iron supplements:
    - Ferrous fumarate start at 210mg OD, increase up to TDS
    - Ferrous sulphate start at 200mg OD, increase up to TDS
    - Ferrous gluconate start at 300mg BD, increase up to 600mg TDS
  - Titrate to maximum dose tolerated for 12 weeks

- **Hb >100 g/L**
  - If intolerant trial of sodium feredetate start at 5 ml BD, increase up to 10 ml TDS
  - Titrate slowly to maximum dose tolerated

- **Hb >100 g/L**
  - If intolerant commence ferric maltol 30mg BD, first prescription from Gastro specialist
  - If intolerant organise iron infusion

- **Hb >100 g/L**
  - If intolerant organise iron infusion

**Advice to patients to improve adherence to oral iron treatment**

- Adverse effects usually settle down with time.
- Iron preparations can be taken after food to reduce gastro-intestinal side-effects.
- Reduce the dose frequency to one or two tablets daily
- Oral iron should be taken 2 hours apart from other medication
- Further information can be found on SEL APC recommendation

**Pathway 5: Iron deficiency treatment pathway for patients with Inflammatory Bowel Disease (IBD)**

- **Hb <70g/L**
  - Iron infusion urgently +/- blood transfusion
  - Repeat Hb (not ferritin or iron studies) in 2 weeks

- **Hb 70-100g/L**
  - Iron infusion (or blood transfusion in selected patient group)
  - Repeat Hb (not ferritin or iron studies) in 8 weeks

- **Hb >100 g/L**
  - Commence one of the following oral iron supplements:
    - Ferrous fumarate start at 210mg OD, increase up to TDS
    - Ferrous sulphate start at 200mg OD, increase up to TDS
    - Ferrous gluconate start at 300mg BD, increase up to 600mg TDS
  - Titrate to maximum dose tolerated for 12 weeks

- **Hb >100 g/L**
  - If intolerant trial of sodium feredetate start at 5 ml BD, increase up to 10 ml TDS
  - Titrate slowly to maximum dose tolerated

- **Hb >100 g/L**
  - If intolerant commence ferric maltol 30mg BD, first prescription from Gastro specialist
  - If intolerant organise iron infusion

An additional check of Hb after 2–4 weeks of iron supplement treatment can be carried out to assess clinical response and adherence. If Hb in normal range and iron stores replenished, consider discontinuing treatment after 12 weeks, and check 3 monthly for recurrence of anaemia for first year, then 6 monthly. Note that lowest effective dose has been documented and should be uptitrated as tolerated.