South East London Area Prescribing Committee:
Primary & Secondary Care Inflammatory Bowel Disease Pathway July 2019

Developed by: South East London IBD Pathway Development Group

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Approved: June 2019

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South East London Area Prescribing Committee. A partnership between NHS organisations in South East London: Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark Clinical Commissioning Groups (CCGs) and GSTFT/KCH/SLaM/Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust
IBD pathway 1:
Presenting with symptoms

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

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Patient presenting with lower GI symptoms suggestive of IBD

**Known IBD?**

- **YES**: 
  - **Known IBD?**
    - **NO**: 
      - **Bloods abnormal and/or FCALP >150**: 
        - **YES**: Refer for 'new IBD' OPA via hotline (to be seen <2/52)
        - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w
    - **YES**: Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)
  - **NO**: Bloods normal and FCALP 50-150
    - **YES**: Repeat FCALP in 4 weeks from first test; Consider IBS advice in meantime (with proviso of re-test)
    - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w

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**Bloody diarrhoea?**

- **YES**: Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)
- **NO**: 
  - **ie. subtle symptoms**: 
    - **YES**: 
      - **Cs4, ESR, Calprotectin Coeliac screen, TFTs, (stool MCS)**
      - **YES**: Refer for 'urgent walk-in IBD' OPA via hotline (to be seen <1-2/52)
      - **NO**: Rx and review in 1-2 weeks
    - **NO**: 
      - **ie. Seen in OPD in last 12 months?**
        - **YES**: Refer for 'new IBD' OPA via hotline (to be seen <2-6/52)
        - **NO**: Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)

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**Pt under ‘active’ FU in 2º care?**

- **YES**: 
  - **Known IBD?**
    - **NO**: 
      - **Bloods abnormal and/or FCALP >150**: 
        - **YES**: Refer for 'new IBD' OPA via hotline (to be seen <2-6/52)
        - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w
    - **YES**: Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)
  - **YES**: 
    - **Fx normal and FCALP 50-150**: 
      - **YES**: Repeat FCALP in 4 weeks from first test; Consider IBS advice in meantime (with proviso of re-test)
      - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w

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**GP comfortable with IBD management?**

- **YES**: Rx and review in 1-2 weeks
- **NO**: 
  - **Known IBD?**
    - **NO**: 
      - **Bloods abnormal and/or FCALP >150**: 
        - **YES**: Refer for 'new IBD' OPA via hotline (to be seen <2-6/52)
        - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w
    - **YES**: Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)
  - **YES**: 
    - **Bloods normal and FCALP 50-150**: 
      - **YES**: Repeat FCALP in 4 weeks from first test; Consider IBS advice in meantime (with proviso of re-test)
      - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w

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**Symptoms controlled?**

- **YES**: Patient or GP to contact IBD helpline for Rx advice
- **NO**: 
  - **Known IBD?**
    - **NO**: 
      - **Bloods abnormal and/or FCALP >150**: 
        - **YES**: Refer for 'new IBD' OPA via hotline (to be seen <2-6/52)
        - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w
    - **YES**: Refer urgently for flexible sigmoidoscopy (one-stop clinic if exists)
  - **YES**: 
    - **Fx normal and FCALP 50-150**: 
      - **YES**: Repeat FCALP in 4 weeks from first test; Consider IBS advice in meantime (with proviso of re-test)
      - **NO**: Equivocal FCALP results can be monitored over a longer period every 4-6w

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**Contact encouraged to inform 2º care of episode**

If 2 cycles of advice fail then refer for urgent OPA

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**Return to 1º care FU**

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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

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Patient with known UC with flare of symptoms
Taking mesalazine only

CHECK / ENCOURAGE ADHERENCE
- Typically 55% are adherent -

http://www.nice.org.uk/guidance/cg76/chapter/key-principles

MAY NEED DISEASE-MODIFYING THERAPY
EG. AZATHIOPRINE

≥ 2 flares in last 6/12?

NO

Severities of this flare?

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

Increase to maximum dose 5asa; Consider adding rectal therapy

2/52 review if Rx changed. Symptoms controlled?

YES

NO

CONTINUE MAXIMAL THERAPY FOR 8/52 THEN REDUCE TO MAINTENANCE UNLESS EVIDENCE OF DISEASE ACTIVITY

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 ™)

On maximum dose (4.8g Octasa ™/Mezavant ™ 3g Salofalk ™, 4g Pentasa ™)

Consider adding Clipper (beclometasone) 5mg OD for max 4 weeks

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

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

On rectal 5asa therapy alone (enema or supps)

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

MAY NEED DISEASE-MODIFYING THERAPY
EG. AZATHIOPRINE

≥ 2 flares in last 6/12?

YES

NO

CONTACT SECONDARY CARE AT ANY STAGE IN THIS PATHWAY

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.

Yrly 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.

MAY NEED DISEASE-MODIFYING THERAPY
EG. AZATHIOPRINE

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

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

Primary or secondary care

Secondary care
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

Virtual / telephone/ nurse-led F2F follow-up

Start point 1
Patient requiring therapy despite pathway 2

Optimised AZA monotherapy

Response at 12-16 weeks?

High risk IBD?

Start point 2
Hospitalised patient

“Acute severe” UC

Chronic active CD

“Chronic active” UC

Biologic Pathway (#4)

Ciclo should not be started if already on AZA

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

Offer of shared care

Secondary care

Primary 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.

Ciclo should not be started if already on AZA

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

In-hospital response?

YES

NO

Colectomy

NO

YES

SUITABLE FOR ENTRY INTO CLINICAL TRIAL ?

Response at 12 weeks?

YES

NO

SUITABLE FOR ENTRY INTO CLINICAL TRIAL ?

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)

Methotrexate (MTX) can be considered if Crohn’s

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

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**

**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**
  - Remission for acute severe UC defined by Mayo <2 when steroid-free
- **NO**
  - If on IFX, give one further scheduled dose
  - If on ciclosporin, switch to alternative biologic as above

**Chronic active UC from pathway 3**

**Adalimumab**
**Infliximab**
**Golimumab**
**TOFACITINIB**
See MHRA advice (May 2019)

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

**Response at 12-16 weeks?**

- **YES**
  - Continue scheduled Rx Virtual / telephone / nurse-led F2F follow-up
- **NO**
  - Possible to dose-optimise based on drug/Ab level/clinical response?
    - **YES**
    - **NO**

**Remission at 12 months?**

- **YES**
  - Remission for biologic cessation is defined as asymptomatic and biochemical and/or endoscopic and/or radiologic evidence of healing
- **NO**
  - **Switch drug (see notes above)**
    - **YES**
    - **NO**

**Consider stopping or de-escalating biologic therapy**

**Consideration of 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.**

**Patient requiring biologic therapy from pathway 3**

**CD**

Commissioning is not sought for experimental therapy

**ADALIMUMAB**
**Infliximab**
**Golimumab**
** vedolizumab**

"Biosimilar available"

Dose optimisation or drug-switching must be discussed in IBD MDM;

- 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)

**Remission once stable on AZA?**

- **YES**
  - TOFACITINIB
    - See MHRA advice (May 2019)
- **NO**
  - If on IFX, give one further scheduled dose
  - If on ciclosporin, switch to alternative biologic as above

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

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

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

**Inducing remission**

- **YES**
  - Remission for acute severe UC defined by Mayo <2 when steroid-free
- **NO**
  - If on IFX, give one further scheduled dose
  - If on ciclosporin, switch to alternative biologic as above

**Consider**

**Possible to dose-optimise based on drug/Ab level/clinical response?**

- **YES**
  - Remission at 12 months?
    - **YES**
    - **NO**
  - Possible to dose-optimise based on drug/Ab level/CR?
    - **YES**
    - **NO**
- **NO**
  - **Switch drug (see notes above)**
    - **YES**
    - **NO**

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

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
- If intolerant commence ferric maltol 30mg BD
  - First prescription from Gastro specialist
- If intolerant trial of sodium feredate start at 5 ml BD, increase up to 10 ml TDS
  - Titrate slowly to maximum dose tolerated

Hb > 100 g/L
- If intolerant organise iron infusion
- If intolerant commence ferric maltol 30mg BD
  - First prescription from Gastro specialist
- If intolerant trial of sodium feredate start at 5 ml BD, increase up to 10 ml TDS
  - Titrate slowly to maximum dose tolerated

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

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

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.