

# NHS Lanarkshire Outpatient IBD Treatment Pathway Ulcerative Colitis

TARGET AUDIENCE	All clinical staff working in the Gastroenterology service in	
	Secondary Care	
PATIENT GROUP	Adult patients diagnosed with Ulcerative Colitis	

# **Clinical Guideline Summary**

- This guideline describes a pathway for the medical management of adult patients with a confirmed diagnosis of Ulcerative Colitis in the outpatient secondary care setting in NHS Lanarkshire.
- The pathway provides a stepwise approach to the management of Ulcerative Colitis, including a description of the factors to consider when choosing a Biologic or Immunosuppressive therapy.
- This pathway has been re-produced with thanks to the Gastroenterology Team at the Western General Hospital, NHS Lothian.

Lead Author	Mr Michael Smith	Date approved	March 2023
Version	1.1	Review Date	March 2024

### NHS Lanarkshire Outpatient IBD Treatment Pathway Ulcerative Colitis If Acute Severe Ulcerative Colitis admit to hospital Active Ulcerative Colitis Step 1 - Assess severity and extent<sup>a</sup> Consider surgical management at all Mild – Bowel output - 1-3/day. No systemic symptoms stages of treatment escalation Lanarkshire Moderate – Bowel output - 4-6/day. No systemic symptoms Step 6a Treatment Escalation 1st Line Severe – Bowel output - >6/day with systemic symptoms Infliximab S/C (or IV\*) Step 7 - Assess response 8-14 weeks<sup>t</sup> +/- immunomodulator OR Bloods, FCP, clinical response and Step 2a - Optimise oral and/or Step 2b - Consider oral therapeutic drug levels where JAK inhibitor corticosteroid if 5-ASA therapy topical 5-ASA therapy appropriate Filgotinib<sup>c</sup> or Tofacitinib<sup>c,d</sup> already optimised depending on severity and Cortiment 9mg once daily for 8 Step 6bTreatment Escalation 1st Line Step 8b Primary Non-Step 8a Clinical response Prescribe by brand name. weeks (mild to moderate only) Response – all step 6a/b Thiopurine<sup>b</sup> monotherapy in steroid Salofalk® (tablets/granules) are OR 1st line options exhausted dependent patients if appropriate the preferred brand for new Prednisolone 40mg once daily for patients in NHSL. Where Azathioprine or Mercaptopurine 7 days, reducing by 5mg/week. Step 9 - Ongoing assessment of responses Salofalk® is unsuitable Octasa® Co-prescribe PPI and and Pentasa® are alternatives. At least 3-6 monthly bloods, FCP and Step 6cTreatment Escalation 1st Line Calcium/Vitamin D supplement. review of clinical response +/-1st Line conditional use ONLYe: Consider FRAX score and need reactive/proactive TDM where indicated for bisphosphonate treatment. Vedolizumab S/C (or IV\*) ONLY use 1st line for patients where step Step 9a 6a/b 1st line treatment options are not Step 9b Secondary Step 3 - Assess clinical response and faecal calprotectin (FCP) clinically appropriate Immunogenic Non-Response - all failure step 6a/b 1st line Step 6d Treatment Escalation 2nd Line options exhausted (Infliximab only) Step 4a - FCP and clinical Step 4b - Treatment Escalation Adalimumab S/C improvement. If no response, steroid dependent or more Continue 5-ASA than one course of steroids per year, Step 6e Treatment Escalation 2nd/3rd consider escalation of medical treatment Step 10 - Duration of therapy: options but also consider surgery. Annual review of therapy Vedolizumab S/C (or IV\*) Consider de-escalation where appropriate OR \*Reserve IV therapy in responding patients Ustekinumab S/C for those who need Step 5 - Pre-Escalation Considerations it for individual Ensure pre-immunosuppression Step 11 1st, 2nd and 3rd line options failed or contraindicated circumstances ONLY screening complete, counselling and relevant vaccinations Consider surgical management

### Re-produced with permission from NHS Lothian WGH Gastroenterology Team

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Version	1.1	Review Date	March 2024

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### Prescribing Notes

The 1<sup>st</sup> line route of administration choice for Infliximab and Vedolizumab should always be S/C.

This is to ensure capacity for the Aseptic Pharmacy Department and Planned Investigation Unit at University Hospital Monklands is sustainable. This will ensure availability for those patients who absolutely need to be maintained on intravenous therapy e.g. compliance reasons, manual dexterity issues, patient intolerance of S/C therapy (not exhaustive).

### Factors to consider when choosing a Biologic or Immunosuppressive drug in IBD

- 1. Route of administration
- 2. Speed of response
- 3. Potential immunogenicity and need for combination therapy
- 4. Side effects including cancer
- 5. Persistence of drug therapy
- 6. Availability of infusion facilities and therapeutic drug monitoring
- 7. Overall cost

### **Footnotes**

- a) Endoscopic assessment should ideally be done before treatment, an appropriate endoscopy scoring (UCEIS) is mandatory. However, this should not delay the start of therapy in those with a confirmed diagnosis of IBD.
- b) The evidence for the use of a thiopurine in ulcerative colitis is for the treatment of steroid dependent UC. Those unsuitable for a thiopurine include (but not limited to) EBV negative young males, history of lymphoma, skin cancer, cervical neoplasia and those over the age of 50 years.
- c) Avoid JAKi's in pregnancy and breastfeeding. If female of childbearing potential, ensure adequate contraception in place. If contraception use cannot be guaranteed, avoid JAKi use.
- d) The MHRA/CHM advice about the use of tofacitinib with regard to venous thrombo-embolism, major adverse cardiovascular events and malignancies should be adhered to and discussed with patients. It should only be used in those over 65 years old if no other alternative exists. https://bnf.nice.org.uk/drug/tofacitinib.html
- e) Vedolizumab could be considered as first line therapy in the elderly, those with a past history of cancer or significant co-morbidity that would make other first line options unsuitable.
- f) Define treatment goals at the start of treatment which for most patients should be steroid free, clinical and biochemical remission. Non-response should precipitate treatment change.
- g) The subsequent drug choice should take in to account any initial response to existing treatment including symptoms and objective markers of response together with therapeutic drug monitoring where available. Primary non-response is often best addressed by moving treatment to a different class of drug. These treatment decisions are best supported by the IBD MDT.

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# **Appendices**

## 1. Governance information for Guidance document

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Endorsing Body:	Gastroenterology (IBD) Medicines Governance Group
Version Number:	1.1
Approval date	March 2023
Review Date:	March 2024
Responsible Person (if different from lead author)	N/A

CONSULTATION AND DISTRIBUTION RECORD		
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Distribution	Consultant Gastroenterologists UHH, UHM and UHW IBD Clinical Nurse Specialists UHH, UHM and UHW Specialist Clinical Pharmacists Gastroenterology UHM and UHW Heads of Pharmacy UHH, UHM and UHW Homecare Medicines Service, NHSL Aseptic Pharmacy Department, NHSL	

CHANGE RECORD			
Date	Lead Author	Change	Version
January 2023	Mr Michael Smith	Initial version.	1.0
February 2023	Mr Michael Smith	Minor changes based on comments from ADTC.	1.1

Lead Author	Michael Smith	Date approved	March 2023
Version	1.1	Review Date	March 2024