

Advanced Therapies for the Treatment of Outpatients with Inflammatory Bowel Disease Standard Operating Procedure

V1.0

June 2026

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Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

- 1.1. This Standard Operating Procedure (SOP) outlines the process of identifying patients with Inflammatory Bowel Disease (IBD) who require escalation to advanced therapies and the essential steps required to ensure appropriate drug choice, safe initiation of advanced therapies and ongoing monitoring, including staff roles and documentation.
- 1.2. IBD is an umbrella term used primarily to cover Crohn's Disease (CD) and Ulcerative Colitis (UC) but can include a wide range of gastrointestinal illnesses. IBD is a chronic condition that causes inflammation within the gastrointestinal tract, characterised by periods of remission and exacerbation.
- 1.3. Advanced Therapies refers to a range of immunomodulating therapies including biologic agents and targeted oral small molecule drugs which have been approved for use in moderate – severe IBD by NICE.
- 1.4. This version supersedes any previous versions of this document.
- 1.5. This SOP should be read in conjunction with the following documents:
- 1.6. Endoscopy Unit Outpatient Department Standard Operating Procedure - [Link](#)

2. Purpose of this Standard Operating Procedure

- 2.1. The purpose of this Standard Operating procedure is to standardise practice within gastroenterology for initiating Advanced Therapies, thereby minimizing risk, and maintaining compliance with BSG guidelines and IBD standards.
- 2.2. This SOP will outline the process for identifying patients requiring advance therapies, pre-treatment screening, counselling, initiation, ongoing monitoring and documentation.
- 2.3. This SOP will outline guidance, evidence base and assessment tools to assess patients and ensure treatment continues to be safe, effective, appropriate and evidence based.

3. Ownership and Responsibilities

3.1. The following responsibilities apply to this SOP:

- Oversight of the identification of patients on advanced therapies is managed by the IBD lead nurse and the named gastroenterologist.
- The lead IBD nurse will be supported with service needs by the Service Manager for Gastroenterology.
- The Lead IBD nurse will be supported clinically by the Gastroenterology consultants and Clinical Matron for Gastroenterology.

3.2. Role of the Service Manager

The service manager is responsible for:

- Being familiar with this SOP.
- Being a point of escalation regarding service provision.
- Supporting the IBD lead nurse with monitoring and co-ordinating capacity and demand of service.

3.3. Role of the Clinical Matron

The Clinical Matron is responsible for:

- Being familiar with this SOP.
- Being a point of escalation regarding the service.

3.4. Role of Gastroenterologist

Gastroenterologists are responsible for:

- Being familiar with this SOP.
- Identifying patients who require escalation and referring to the IBD nursing team to initiate the advanced therapies prescribing procedure.
- Supporting the IBD team to provide advance therapies safely and accordance with National guidance.
- Ensuring decisions regarding patient care and treatment with advanced therapies are clearly documented and in line with National guidance, during clinic reviews.
- Overseeing the care of IBD patients receiving advanced therapies, including providing clinical review when indicated and providing advice and guidance to the IBD team regarding deranged bloods, loss of response or contraindications for treatment.
- Attendance at IBD MDT to discuss complex cases and those that fall out of the prescribing guidelines.

3.5. Role of the IBD Pharmacist

The IBD pharmacist is responsible for:

- Being familiar with this SOP.
- Prescribing of established, ongoing advance therapies for IBD patients both via the Medical Day Unit and homecare prescriptions.
- Clinically checking prescriptions for initiation of advance therapies via homecare.

- Monitoring blood results of IBD patients established on advanced therapies and identifying/discussing any anomalies with the responsible gastroenterology consultant.
- Undertaking post induction and ongoing reviews of patients receiving advanced therapies alongside the IBD nurses.
- Support the IBD nurses when needed in prescribing advanced therapies for new patients.

3.6. Role of the IBD Lead Nurse

The IBD Lead Nurse is responsible for:

- Being familiar with this SOP.
- Ensuring that the standards and practices detailed within this SOP are shared with the appropriate clinicians.
- Ensure standards are adhered to.
- Ensure colleagues are appropriately trained for the roles and responsibilities outlined in the SOP.
- Support the IBD team in provision of service, escalating issues and managing prescriptions and reviews.
- Monitor and co-ordinate safety, capacity and demand of the service.

3.7. Role of the IBD Specialist Nurse

The IBD Specialist Nurse is responsible for:

- Being familiar with this SOP.
- Ensuring standards are adhered to and appropriate competencies are maintained.
- Identifying patients who require escalation and referring to the IBD administrator to book counselling appointments or referring to the IBD MDT if a patient falls outside of National guidelines for commencement or switch of advanced therapies.
- Request and review pre-screening bloods and chest x-ray (if able) for new patients starting advanced therapies.
- Prescribe advanced therapies via Medical Day Unit and homecare for new patients starting advanced therapies.
- Support the IBD pharmacist with ongoing prescriptions for patients established on advanced therapies.

- Support the IBD support nurses with reviewing patients at post-initiation and annually, with any queries or concerns, and to aid in decision-making related continuing treatment.

3.8. Role of the IBD Support Nurse

The IBD support nurse is responsible for:

- Being familiar with this SOP.
- Ensuring standards are adhered to and competencies maintained.
- Providing up to date and in-depth counselling for IBD patients starting advanced therapies, including risk VS benefit, side effects and safety netting and documenting this in a standardised clinic letter for the patient, GP and gastroenterology consultant.
- Providing patient information leaflets and further resources for the patients.
- Highlighting any contraindications or concerns raised during counselling to the IBD specialist nurses and the consultant.
- Requesting pre-screening bloods.
- Completing onward referral to medical unit and / or homecare registration forms.
- Undertaking post induction and annual review of patients on advanced therapies and discussing any concerns raised with the IBD specialist nurses / consultant.

3.9. Role of The IBD Administrator

The IBD administrator is responsible for:

- Being familiar with this SOP.
- Ensuring standards are adhered to.
- Listing patients for the IBD MDT and outcoming the meeting.
- Booking and outcoming counselling and review clinics in a timely manner.
- Sending patient information leaflets about the medications prior to the counselling clinic.
- Assist with monitoring and co-ordinating capacity and demand of service.

4. Standards and Practice

4.1. Service

- 4.1.1. The IBD nursing service is available Mon-Fri 8am -17.30pm and are accessible to patients via the advice line Mon-Fri 9am – 11.30am or via email (excluding Bank Holidays).
- 4.1.2. Contact Details; advice line 01872 252 178 email rch-tr.IBDNurse@nhs.net
- 4.1.3. Patient care will be overseen by the IBD nursing team, IBD pharmacist and gastroenterologist.

4.2. Patient Pathway – identifying patients for escalation

- 4.2.1. Patients can be identified as needing escalation via Consultant or Specialist nurse review.
- 4.2.2. Once identified, the consultant will complete an IBD nurse referral via electronic patient record (EPR). If identified by an IBD nurse, they will include patient identifiers in an email to the biologic nurses and IBD administrator for assessment of eligibility and to book into Advanced Therapies counselling clinic.
- 4.2.3. Eligibility for escalation will be assessed by the IBD nursing team in accordance with NICE guidelines, using recognized assessment tools (Harvey Bradshaw Index, Simple Colitis Activity Index, Truelove and Witt severity score), or investigations (colonoscopy, faecal calprotectin - FCP, CT abdomen, small bowel MRI) and documented.
- 4.2.4. Eligibility is defined as moderate – severely active IBD which has not responded to conventional therapies.
- 4.2.5. If a patient falls outside of NICE guidelines for initiation of advanced therapies, they will be referred to the IBD radiology MDT for discussion with the wider team, which will then be documented on the electronic patient record using the MDT outcome template.
- 4.2.6. Appropriate drug choice should be documented with rationale for choice on the electronic patient record.

4.3. Patient Pathway Pre-screening and counselling

- 4.3.1. Once eligibility is confirmed then patients will be booked into counselling clinic by the IBD administrator (as per Endoscopy Unit Outpatient Department SOP). The IBD administrator will send appropriate drug information to the patient (CCUK patient information leaflets) via email or post for the patient to review prior to the appointment.

- 4.3.2. Counselling clinic will take place in the Endoscopy Unit Outpatient Department with pre-screening bloods to be taken on the day including baseline CRP, FBC, eGFR, LFT's, Hepatitis B and C Blood and culture, EBV, Varicella, HIV and QuantiFERON Gold (Q gold) for ALL advanced therapies and recorded on PRE-BIOLOGIC assessment on EPR.
- 4.3.3. All patients commencing advanced therapies need a Tuberculosis (TB) risk assessment in the form of Q Gold blood test and chest x-ray, in the event of indeterminate Q Gold, assessment of TB risk factors should be undertaken (as per NICE CKS Topic Tuberculosis, July 2023). Commencement of therapy can be considered if clear chest x-ray and steroids are the likely cause for indeterminate results, if patient has been counselled for red flag symptoms of TB and the conversation is documented.
- 4.3.4. All patients should be encouraged to take part in national cancer screening programs; all female patients should be encouraged to engage with cervical screening. Patients with increased risk of skin cancers should have skin mapping surveillance by GP with specialist interest or dermatology team.
- 4.3.5. Patients starting on JAK inhibitors will need baseline fasting lipids which may need to be requested via GP if appointment timing is not appropriate. Where possible, patients starting a JAK inhibitor should be booked into the earliest appointment to facilitate fasting lipids.
- 4.3.6. Patients starting on JAK inhibitors should have a cardiovascular risk assessment undertaken using a Q Risk 3 score (Cardiovascular risk assessment calculator tool available at: [QRISK3](#)) which should be documented in the patient letter. Any patients with a Q Risk score of 10% or above or patients under the age of 25 with identified risk factors should be discussed at MDT prior to starting and have outcome documented on EPR. Cardiovascular adverse events should be discussed during counselling and documented in the counselling letter.
- 4.3.7. Patients starting on S1P receptor modulators will require an initial ECG prior to commencing clinic which should be reviewed by the requesting consultant for any pre-existing arrhythmia and a heart rate >55 BPM. For Etrasimod patients require an eye test with macular review prior to commencing treatment, if a patient has a history of uveitis or macular degeneration a pre-treatment eye test is required for Ozanimod. Treatment should be stopped if macular oedema occurs.
- 4.3.8. After counselling patient's clinic's outcomes should be completed; accordingly, if starting treatment, FAIFR/TNT PL for biologic review, or back to consultant for review if not commencing treatment.
- 4.3.9. After the counselling clinic appointment, a letter should be completed sent to the patient, the GP and the gastroenterology consultant which documents; advanced therapy drug choice including rationale, diagnosis, co-morbidity, other medications, drug information, blood monitoring information, follow up plan and patient consent to start medication and adhere to monitoring requirements as outlined.

- 4.3.10. The biological counselling nurses will check for pre-screening blood results on a weekly basis to review pre-screening and move onto initiating treatment.

4.4. Patient Pathway Initiating treatment

- 4.4.1. Once advanced therapy has been selected and pre-screening results are negative, if the patient requires infusions they will be referred to the Medical Day Unit via Maxims referral.
- 4.4.2. Medical Day Unit administrators will book patients as per maxims referral and send an appointment letter to the patient. The MDU administrators send a weekly TCI list to IBD nurses, IBD pharmacist and general pharmacy to arrange prescriptions and medications.
- 4.4.3. For all advanced therapy loading doses coming to MDU, IBD Nurse prescriber to check pre-screening and pre-infusion bloods (FBC,CRP,LFT's, eGFR), complete BlueTeq form for initiation and continuation of high-cost drugs (biosimilar biologics do not require a BlueTeq) and prescribe treatment. IBD nurse prescriber to check patient is on FAIFR/TNT (biologic review) pending list for appropriate timeframe.
- 4.4.4. For all advanced therapies which are initiated through a homecare company, IBD nurse prescriber to check pre-screening and pre-infusion bloods (FBC,CRP,LFT's, eGFR), complete BlueTeq form for initiation and continuation of high-cost drugs (biosimilar biologics do not require a BlueTeq) and prescribe treatment using appropriate prescription and registration forms. New start homecare scripts will be screened by the IBD pharmacist and sent to healthcare at home company. IBD nurse prescriber to check patient is on FAIFR/TNT (biologic review) pending list for appropriate timeframe.
- 4.4.5. Ongoing and routine prescriptions can then be prescribed by the IBD pharmacist or other prescriber for IBD in the absence of an IBD pharmacist for both MDU patients and homecare patients providing patients have up to date bloods (within the last 6 months for homecare, 2 months for MDU).

4.5. Patient Pathway Review and Monitoring

- 4.5.1. A post induction review will be booked by the IBD administrator from FAIFR/TNT PL at 12-14 weeks for biologic medications and 7-8 weeks for JAK inhibitors and S1P receptor modulators in accordance with the British Society of Gastroenterology (BSG) guidelines, individual medication Summary of Product characteristic's (SPC) and IBD standards.
- 4.5.2. Post induction review will be undertaken by the IBD support nurse, the patient will be assessed using a standardised assessment tool (HBI, SCCAI), routine blood and faecal calprotectin. These assessments are then documented in a clinic letter and a decision documented whether to continue biologic therapy based on the outcome of the assessments, with support of the IBD clinical nurse specialist. If the patient has not shown

convincing evidence of improvement, then they will be referred back to the gastroenterologist for further input. As per BSG guidelines (2025) therapeutic drug monitoring is indicated at initial review for patients started on anti-TNF therapy, however not for non-anti-TNF therapies.

- 4.5.3. If a clinical response is demonstrated following review, the patient will then be outcomed for review with gastroenterology consultant in 6 months and IBD biologic review clinic in 12 months to ensure regular routine review (IBD standards, 2019).
- 4.5.4. At the annual review, assessment using a standardised assessment tool (HBI, SCCAI), routine bloods and faecal calprotectin will be undertaken and documented in a clinical letter. If, following discussion with the gastroenterologist, therapy is to be continued, a blueteq should be completed by the IBD nurse / pharmacist if indicated and patient outcome for review with named gastroenterologist in 6 months / IBD nurse in 12 months.
- 4.5.5. If loss of response to therapy is identified, further investigation should be discussed with gastroenterologist and medication optimised if appropriate or biologic switch discussed at IBD MDT.
- 4.5.6. Patients receiving ongoing intravenous treatments require bloods prior to each infusion as discussed with them during counselling, to include FBC, LFT's, eGFR, CRP which will be reviewed prior to prescribing of each infusion by the prescriber. Bloods for the next infusion will be requested when current results are reviewed. Patients will be reviewed at the point of infusion by the infusion unit nursing team for signs of infection or recent antibiotic use using the assessment tool on Maxims. If there are any discrepancies identified, these are to be discussed with the IBD clinical specialist nurses and documented on the discharge summary.
- 4.5.7. Patients receiving therapy via homecare require blood every 3 months as discussed and documented during counselling clinic appointment and documented in the clinic letter. The prescriber should ensure the patient has had bloods done and had a clinical review in the last 6 months before generating an ongoing prescription. If patient bloods are overdue by one month, a short prescription can be generated and a blood monitoring reminder sent to the patient. If bloods are overdue by >6 months, the prescriber can inform the patient in writing that no further prescriptions will be generated until up-to-date blood results are available. Bloods for subcutaneous injections include: FBC, LFT's, eGFR, CRP. JAK inhibitors require routine bloods and a lipid profile at post initiation review, routine bloods three monthly and then lipids monitored either 3 monthly or 6 monthly dependents on risk factors which will be clearly documented in counselling and review letters. The prescriber should ensure that the next set of blood has been requested on ICE when the most recent results are reviewed.
- 4.5.8. If patients DNA appointments, then the prescriber should hold the prescription and inform the patient that the prescription is on hold until a clinical review has taken place.

5. Dissemination and Implementation

- 5.1. This SOP will be available on the Trust Document Library.
- 5.2. A hard copy will be available in the IBD nurse office.
- 5.3. The IBD lead nurse will be responsible for ensuring that clinicians have been orientated to this SOP to ensure safe initiation of advance therapies for all IBD patients requiring escalation.
- 5.4. This SOP will be emailed to specialty colleagues and highlighted at the specialty business and governance meeting.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Blueteq completion. Patient Experience. Clinic outcomes / patient numbers.
Lead	Francesca Fairhurst, IBD Lead Nurse.
Tool	Blueteq reports. Patient experience. RADAR / clinic outcome audit.
Frequency	Ongoing monitoring through localised Business and governance. Annual audit of patient numbers for service projection to be shared with the speciality.
Reporting arrangements	Performance reports through Speciality Business and Governance Meetings into Care Group Care Board.
Acting on recommendations and Lead(s)	Speciality Triumvirate Team leading in recommended actions with IBD lead nurse and IBD lead consultant.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within a negotiated time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

7. Updating and Review

This SOP will be reviewed every three years, or earlier as updated National Guidelines are available or local audit identifies a need.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the [Equality Diversity And Inclusion Policy](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Advanced Therapies for the Treatment of Outpatients with Inflammatory Bowel Disease Standard Operating Procedure V1.0
This document replaces (exact title of previous version):	New Document replacing: Biological medications for the treatment of patients with Inflammatory Bowel Disease (archived).
Date Issued / Approved:	21 May 2026
Date Valid From:	June 2026
Date Valid To:	June 2029
Author / Owner:	Amber Wynn – IBD Pharmacist. Francesca Fairhurst – IBD Clinical Lead Nurse.
Contact details:	01872 253 403. rch-tr.IBDNurse@nhs.net
Brief summary of contents:	Identification, initiation and ongoing management of IBD patients who require advance therapies.
Suggested Keywords:	Biologic, Irritable Bowel Disease, JAK.
Target Audience:	RCHT: Yes CFT: No CIOB ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Business and Governance Meeting. Senior Management Team Meeting. Care Board Meeting.
Manager confirming approval processes:	Roz Davies.
Name of Governance Lead confirming consultation and ratification:	Natasha Andrews.
Links to key external standards:	None

Information Category	Detailed Information
Related Documents:	None
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Gastroenterology

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
May 2026	V1.0	Initial issue.	Francesca Fairhurst, IBD Clinical Lead Nurse.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Quality and Equality Impact Assessment (QEIA) Form

The QEIA process allows RCHT to monitor the impact of changes to its policies and services, ensuring that nobody is unduly disadvantaged.

Please ensure you have completed a Quality and Equality Impact Assessment (QEIA) using this link to complete the form:

[E11 QEIA Policy](#).

For guidance, please see the [QEIA Essentials – Quick Reference Guide](#) or contact as required below:

Equality, Diversity and Inclusion guidance, please contact: rcht.inclusion@nhs.net.

Quality Governance guidance, please contact Jillian Tozer: jillian.tozer3@nhs.net

Appendix 3. Pre-screening investigations

Class of treatment	Pre-screening required													
	FBC	CRP and electrolytes	Liver function test	HIV	HBV	HCV	EBV	Varicella	Q gold for TB	X ray for TB	Q Risk	ECG	Eye test	Lipids
Anti-Tumour necrosis factor (TNF) (eg. Adalimumab, infliximab, golimumab)	X	X	X	X	X	X	X	X	X	X				
IL-23 (eg. Ustekinumab, guselkumab, risankizumab, mirikizumab)	X	X	X	X	X	X	X	X	X	X				
Integrin antagonist (eg. Vedolizumab)	X	X	X	X	X	X	X	X	X	X				
Sphingosine-1-phosphate (S1P) modulator (eg. Ozanimod, etrasimod)	X	X	X	X	X	X	X	X	X	X		X	X	
Janus Kinase (JAK) inhibitor (eg. Upadacitinib, tofacitinib, filgotinib)	X	X	X	X	X	X	X	X	X	X	X			X