# Document Control

## Title

**Protocol for the Use of Biologics Therapy in Adult Inflammatory Bowel Disease (IBD)**

## Author

| Author's job title | Clinical Nurse Specialist- IBD Gastroenterology |

## Directorate

**Unscheduled care**

## Department

**Gastroenterology**

## Version | Date Issued | Status | Comment / Changes / Approval |
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tr>
<td>0.1</td>
<td>Jan 2019</td>
<td>Draft</td>
<td>For initial consultation</td>
</tr>
<tr>
<td>0.2</td>
<td>Feb 2019</td>
<td>Draft</td>
<td>Feedback from Dr Byron Theron, Consultant Gastroenterologist, changes made</td>
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<td>Feedback from Dr Alex Moran, Consultant Gastroenterologist, changes made</td>
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<td>Feedback from Natalie Kemp, Homecare and Cancer Services Pharmacist, changes made</td>
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<tr>
<td>1.0</td>
<td>Mar 2019</td>
<td>Final</td>
<td>DTC review 16/05/19, changes made</td>
</tr>
<tr>
<td>1.1</td>
<td>May 2019</td>
<td>Revision</td>
<td>Reviewed by Drugs and Therapeutics Committee</td>
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## Main Contact

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Tel: Direct Dial – Tel: Internal – Email:

## Lead Director

Lead IBD Clinician

## Superseded Documents

Prescribing, Dispensing and Administering Biological Medicines Standard Operating Procedure

## Issue Date | Review Date | Review Cycle |
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>May 2019</td>
<td>May 2022</td>
<td>Three years</td>
</tr>
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</table>

## Consulted with the following stakeholders: (list all)

- Consultant Gastroenterologists
- Clinical Nurse Specialist- IBD Gastroenterology
- Homecare and Cancer Services Pharmacist

## Approval and Review Process

- Drugs and Therapeutics committee

## Local Archive Reference

G:\ Gastroenterology-IBD folder

**Local Path**

Gastroenterology-IBD folder
<table>
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<th>Policy categories for Trust’s internal website (Bob)</th>
<th>Tags for Trust’s internal website (Bob)</th>
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<tr>
<td>Gastroenterology</td>
<td>Crohn’s disease, ulcerative colitis, IBD, Gastroenterology, advice line, biologics, infliximab, adalimumab, vedolizumab, ustekinumab, ibd medications, ibd protocol</td>
</tr>
</tbody>
</table>

Filename
Protocol for the Use of Biologics Therapy in Adult Inflammatory Bowel Disease (IBD) v1.0
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1. **Introduction**

Inflammatory bowel disease (IBD) is the term given to Crohn’s disease and Ulcerative colitis. These are chronic lifelong conditions which cause inflammation within the gastrointestinal tract. It is estimated that approximately 620,000 people in the UK have IBD (IBD Standards, 2013).

“Biological drugs (also known as biotherapeutics or biopharmaceuticals) are a form of treatment for Crohn’s Disease and Ulcerative Colitis (the two main forms of Inflammatory Bowel Disease - IBD). In general they are prescribed for people with moderate to severe IBD when other treatments have not worked.” (CCUK, 2018)

2. **Purpose**

2.1. The purpose of this document is to detail the process for the use of biological therapies for IBD patients under the care of the Northern Devon Healthcare NHS Trust.

2.2. The policy applies to the service provided by the IBD Clinical Nurse Specialist, and supported by the IBD Gastroenterology Team.

2.3. This policy also applies to the different clinical areas where biological therapies for IBD are provided and administered.

2.4. Implementation of this policy will ensure that there is:

- A safe and efficient nursing follow-up for IBD patients on biologics
- Access to information, support and education for those who are to commence on a biologic treatment
- A monitoring service for IBD patients on biologic therapy

3. **Definitions**

- IBD- Inflammatory Bowel Disease
- CD- Crohn’s disease is a form of IBD
- UC- Ulcerative colitis is another form of IBD. It can affect all or part of the large bowel.
- EIM- Extraintestinal manifestations
- CNS- Clinical nurse specialist
- MDT- Multi-disciplinary team
4. Responsibilities

This protocol will be carried out in accordance with agreed departmental and multidisciplinary protocol, and in collaboration with the medical supervisors.

This protocol is to be updated 3-yearly in accordance with the Trust policy. The Clinical Nurse Specialist is responsible for updating this protocol.

5. Scope of the service

Authority to undertake this service is given by the Northern Devon Healthcare NHS Trust’s Chief Executive, Chief Nurse, Medical Director and Consultant Gastroenterologists.

The nursing team will at all times act within the NMC code- Professional standards of practice and behaviour for nurses, midwives and nursing associates (NMC, 2018)

5.1. Service access

Biologic therapies that are given intravenously are administered in the Seamoor Unit. Subcutaneous preparations are arranged via the Homecare Team, and appropriate patient self-injection training is initiated at home.

For inpatients, biological therapy is prescribed and administered according to the local prescribing policy.

5.2. Funding

Funding for biological therapy is applied for via blueteq, and must be secured prior to starting therapy.

Access to blueteq is via this link: https://www.blueteq-secure.co.uk/trust/
6. **Pre-treatment screening**

All patients requiring biological therapy must have a pre-treatment screen completed and documented in the medical notes. (Appendix 1)

Pre-treatment counselling is also vital and patient consent documented.

Pre-treatment screening, must include the following: (dated within the last 6 months)

- Chest X-Ray
- TB Quantiferon Test (if indeterminate, discuss with Consultant)
- Viral screen (HIV, Hep B, Hep C, Varicella)
- Baseline routine bloods (Full blood count, CRP, liver and renal profile)
- Baseline faecal calprotectin/ endoscopy/ biopsy result
7. **Biological Therapies and Standard Dosing**

Therapy must be initiated with the lowest cost suitable product (taking into account administrative costs, dosage, and price per dose).

The following biologic therapies are available for Inflammatory Bowel Disease, and must be prescribed by brand name as per Prescribing, dispensing and Administering Biological Medicines Standard Operating Procedure:

7.1 **Infliximab (Intravenous)- for Crohn’s disease and Ulcerative Colitis**

- **Loading dose:** 5mg/kg at Week 0, 2 and 6

- **Maintenance dose**: 5mg/kg 8-weekly

  *This is sometimes escalated e.g. to 10mg/kg (unlicensed). SPC states: Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation.

For dose escalation, dosage and frequency must be clearly documented and agreed by Consultant Gastroenterologist.

7.2 **Adalimumab (Subcutaneous)- for Crohn’s disease and Ulcerative Colitis**

- **Loading dose options:**
  
  - Week 0: 80mg, Week 2: 40mg, Week 4: 40mg
  
  - Week 0: 160mg, Week 2: 80mg, Week 4: 40mg

  *SPC states ‘for adult patients with moderately to severely active Crohn’s disease 80 mg at week 0 followed by 40 mg at week 2. In case there is a need for a more rapid response to therapy, the regimen 160 mg at week 0 (given as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), 80 mg at week 2 (given as two 40 mg injections in one day), can be used with the awareness that the risk for adverse events is higher during induction.’

- **Maintenance dose:** 40mg fortnightly

7.3 **Vedolizumab (Intravenous)- For Crohn’s disease and Ulcerative Colitis**

- **Loading dose:** 300mg at Week 0, 2 and 6

Note: For Crohn’s disease, patient may benefit from a Week 10 dose if there is minimal response.
**Maintenance dose:** 300mg 8-weekly

### 7.4 Golimumab (Subcutaneous)- for Ulcerative Colitis

**Weight <80kg:**

- **Loading dose:** Week 0: 200mg, Week 2: 100mg, Week 6: 50mg
- **Maintenance:** 50mg every 4 weeks

*Note: Patients with inadequate response may benefit from 100mg at Week 6 and maintenance 100mg 4-weekly.*

**Weight >80kg:**

- **Loading dose:** Week 0: 200mg, Week 2: 100mg, Week 6: 100mg
- **Maintenance:** 100mg every 4 weeks

### 7.5 Ustekinumab (Intravenous + Subcutaneous)

Treatment should be initiated (Week 0) with a single IV induction dose using a weight based dose specified in the table below:

<table>
<thead>
<tr>
<th>Body Weight of Patient at the time of dosing</th>
<th>Recommended Dose</th>
<th>Number of 130 mg Ustekinumab Vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 55 kg</td>
<td>260 mg</td>
<td>2</td>
</tr>
<tr>
<td>&gt; 55 kg to ≤ 85 kg</td>
<td>390 mg</td>
<td>3</td>
</tr>
<tr>
<td>&gt; 85 kg</td>
<td>520 mg</td>
<td>4</td>
</tr>
</tbody>
</table>

**Week 8:** 90mg subcutaneous injection

**Maintenance:** 90mg subcutaneous 8- or 12- weekly

### 8. Post-induction Review

A clinical assessment review should be conducted post-induction to assess response and/or management of reported side-effects. (Appendix 2)
The post-clinical review is to be arranged **10-12 weeks after starting biological therapy.** This can be done via the IBD nurse-led clinic (telephone or face-to-face).

In the case of inadequate response, discussion with Consultant Gastroenterologist must be made and management plan to be documented.

In the case of no response after 14-16 weeks, consideration to stopping or switching treatment may be necessary.

Response of biological therapy is measured by a reduction in HBI or SCCAI score by >3, reduction in faecal calprotectin results, or improvement on endoscopic assessment.

9. **Annual Review**

Patients on biological therapy for Inflammatory Bowel Disease must have a Consultant clinical review every 12 months. Plan should be clearly documented (Appendix 2) if the patient is to continue treatment as per NICE criteria, and funding renewal secured via blueteq as appropriate.

10. **Prescribing and Administration**

Please refer to NDHT Administering Biological Medicines Standard Operating Procedure:


11. **Assessment and Monitoring**

IBD patients requiring intravenous biological therapy are reviewed by the Clinical Nurse Specialist on the day of their appointments, as needed.

An IBD assessment (Appendix 3) nursing proforma is completed in each visit.

Patients on biological treatment require 2-3 monthly blood tests for monitoring. This is to ensure safety in the use of biologics. Blood tests requires are: Full blood count, liver profile, renal profile, and CRP.
Faecal calprotectin testing is also useful to monitor treatment response and disease activity. This can be arranged prior to post-induction review, and 12-month review.

12. Monitoring Compliance with and the Effectiveness of the protocol

Monitoring of the implementation, effectiveness and compliance with these guidelines will be the responsibility of the IBD Service Lead Clinician.

13. Audit

The biologics service will be audited annually to ensure the aims of the service are being met. The audit will also review if the proposed benefits are being met. Patient and end-user feedback is encouraged via the Care Opinion platform or by email (ndht.ibdnurse@nhs.net).

14. Associated Documentation

- Northern Devon Healthcare NHS Trust Medicines Policy
- North & East Devon Formulary and Referral Site. Accessible at www.northeast.devonformularyguidance.nhs.uk
- Northern Devon Healthcare NHS Trust Injectable Medicines Policy
- Northern Devon Healthcare Trust Prescribing, Dispensing and Administering Biological Medicines Standard Operating Procedure

15. Equality Impact Assessment

15.1. The author must include the Equality Impact Assessment Table and identify whether the policy has a positive or negative impact on any of the groups listed. The Author must make comment on how the policy makes this impact.

Table 1: Equality impact Assessment

<table>
<thead>
<tr>
<th>Group</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
<th>No Impact</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Gender Reassignment</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Human Rights (rights to privacy, dignity, liberty and non-</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>degrading treatment), marriage and civil partnership</td>
<td></td>
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<tr>
<td>-----------------------------------------------</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pregnancy</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternity and Breastfeeding</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race (ethnic origin)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Religion (or belief)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td>X</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

16. References

BNF (2016) Infliximab https://doi.org/10.18578/BNF.394829790

BNF (2016) Vedolizumab https://doi.org/10.18578/BNF.810107746

BNF (2017) Ustekinumab https://doi.org/10.18578/BNF.438135001


Crook, K et al (2018) ‘Protocol for Infliximab in Patients (Adult and Paediatric) with Inflammatory Bowel Disease (IBD) London: St. Mark’s Hospital

IBD Standards; ‘Standards for the Healthcare of People who have Inflammatory Bowel Disease (IBD) Update’ (2013), London: Oyster Healthcare Communications Ltd.

## 17. Appendix 1

**Biologics Therapy for Inflammatory Bowel Disease: Pre-treatment Checklist**

<table>
<thead>
<tr>
<th>Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

### Pre-treatment screening:

<table>
<thead>
<tr>
<th>Test</th>
<th>Date</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest X-Ray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB QuantiFERON / Mantoux</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B &amp; C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBC, CRP, Renal and Liver Profile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fecal occult blood test</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Questions:

- Previous TB/ Contact with TB?
- Country of birth
- BCG Vaccine
- Any recent travels? (within last 6 months)
- Cardiac and/or Respiratory issues
- Pregnant? Breastfeeding?
- Smoking? (Sticks/day)
- Any recent vaccinations?
- Previous biologics?
- Routine screening:
- Information pack/ sheet given?
- Counselling regarding:
- Side-effects
- What to do if unwell/ has infection

**Notes:**

For Homecare, have the relevant forms been completed and sent? **YES** / **NO**

Completed by: ____________________  Date: ________________

## 18. Appendix 2

**Gastroenterology**
Biologics therapy protocol

Biological Therapy for Inflammatory Bowel Disease: Treatment Review

<table>
<thead>
<tr>
<th>Patient details:</th>
<th>Drug and dose:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication:</td>
<td>Start date:</td>
</tr>
</tbody>
</table>

Any reported side-effects/ adverse reactions to treatment:

Monitoring bloods:

Disease activity:

<table>
<thead>
<tr>
<th>Harvey Bradshaw Index (HBI)</th>
<th>Simple Colitis Activity Index (SCCAI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well Being (for the previous day)</td>
<td>Bowel Frequency (daily):</td>
</tr>
<tr>
<td>Very well</td>
<td>1-3</td>
</tr>
<tr>
<td>Slightly decreased</td>
<td>1</td>
</tr>
<tr>
<td>Poor</td>
<td>2</td>
</tr>
<tr>
<td>Very poor</td>
<td>3</td>
</tr>
<tr>
<td>Terrible</td>
<td>4</td>
</tr>
<tr>
<td>Abdominal Pain (for the previous day)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1</td>
</tr>
<tr>
<td>Mild</td>
<td>2</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
</tr>
<tr>
<td>Severe</td>
<td>4</td>
</tr>
<tr>
<td>Bowel movements</td>
<td>Score 1 point for each bowel movement</td>
</tr>
<tr>
<td>Abdominal Mass</td>
<td>None</td>
</tr>
<tr>
<td>Dubious</td>
<td>2</td>
</tr>
<tr>
<td>Definite</td>
<td>3</td>
</tr>
<tr>
<td>Definite and Tenderness</td>
<td>4</td>
</tr>
<tr>
<td>Complications (score 1 point for each complication)</td>
<td></td>
</tr>
<tr>
<td>Arthritis, ulcers, mouth ulcers, erythema nodosum, afferent, new tissue, abscess.</td>
<td></td>
</tr>
<tr>
<td>Remission 0, Mild 1-3, Moderate 4-5, Severe &gt;5</td>
<td></td>
</tr>
</tbody>
</table>

Notes:

Post-induction review [ ] Annual review [ ]

Completed by: __________________________ Date: __________________________
<table>
<thead>
<tr>
<th>Patient details</th>
<th>IBD Assessment Sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug:</td>
<td></td>
</tr>
<tr>
<td>Allergies:</td>
<td></td>
</tr>
</tbody>
</table>

**Diagnosis:**

**Co-morbidities:**

**Please ensure pre-treatment screen has been completed prior to 1st dose.**

|------|--------------------|-------------|------------|------------------|----------------|---------------|----------|--------|--------|---------------|--------|-----------------------|-----------|-------------------|---------------------|-----------|---------------|------------------------|------------|-------------------|------------------------|----------|-----------------|-----------------------|-------------|----------------|---------------------|

If there are any signs of infections, abnormal observations, concerns or queries over the patient’s health, please contact the consultant gastroenterologist/ specialist registrar/ IBD nurse before preparing and administering the infusion.