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# Infliximab

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## Guideline for the prescribing, administration and monitoring of Infliximab in adult patients with Inflammatory Bowel Disease (IBD)

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Approved by:

Issue date: April 2020

Review date: April 2023

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## **INDICATION:**

Infliximab is a chimeric human-murine monoclonal antibody which binds and inhibits both released and membrane-bound tumour-necrosis factor alpha (TNF- $\alpha$ ). By inhibiting the cytokine TNF- $\alpha$ , infliximab has an anti-inflammatory and immunosuppressant action, which allows it to be clinically used for IBD patients – including Crohn's disease and Ulcerative Colitis.

Infliximab is recommended as a treatment option for adult patients with:

- Severe active Crohn's disease
- Active fistulising Crohn's disease
- Acute exacerbation of severely active Ulcerative Colitis

## **DOSAGE:**

The recommended dose of infliximab for all indications for IBD is: **5mg/kg by intravenous infusion at weeks 0, 2 and 6 and then every 8 weeks.**

## **PATIENT SELECTION:**

The prescribing of infliximab for IBD patients should be on the recommendation or request of a consultant gastroenterologist ONLY.

Inpatients – All inpatients should be located on the gastroenterology ward under the care or joint care of a consultant gastroenterologist.

Outpatients – Patients to be admitted to dedicated unit for administration of infliximab (under the care of or at request of consultant gastroenterologist)

### ELIGIBILITY FOR

The use of infliximab in IBD has been subject to three NICE technology appraisals:

1. [NICE Technology Appraisal guidance 187](#): Infliximab (review) and adalimumab for the treatment of Crohn's disease
2. [NICE Technology Appraisal guidance 163](#): Infliximab for acute exacerbations of ulcerative colitis
3. [NICE Technology Appraisal guidance TA329](#): Infliximab Adalimumab and Golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy

## **MODERATE TO SEVERE ACTIVE CROHN'S DISEASE:**

Infliximab is recommended, within its licensed indication, for patients with severe active Crohn's disease:

- Whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatment) OR
- Who are intolerant of conventional therapy OR
- Where conventional therapy is contraindicated

Severe active Crohn's disease is defined as very poor general health and one or more symptoms such as weight loss, fever, severe abdominal pain and usually frequent (3–4 or more) diarrhoea stools daily.

People with severe active Crohn's disease may or may not develop new fistulae or have extra-intestinal manifestations of the disease. This clinical definition normally, but not exclusively, corresponds to a Harvey-Bradshaw score of 8 to 9 or above (Appendix 4) or Crohn's Disease Activity Index (CDAI) score of 300 or more (Appendix 5).


## **ACTIVE FISTULISING CROHN'S DISEASE:**

Infliximab is recommended, within its licensed indication, for patients with active fistulising Crohn's disease:

- Whose disease has not responded to conventional therapy (including antibiotics, drainage and immunosuppressive treatments) OR
- Who are intolerant of conventional therapy OR
- Where conventional therapy is contraindicated

## **ULCERATIVE COLITIS:**

Infliximab is recommended, within its licensed indication:

- for use in patients with moderate to severe ulcerative colitis where disease has not responded to conventional therapy (including 5-aminosalicylates(5-ASA), immunosuppressive and/or corticosteroid treatment)
- In Acute Severe Ulcerative Colitis (ASUC) where patients are failing to respond by Day 3 to IV hydrocortisone or methylprednisolone (BSG, 2019) as judged by a suitable scoring system, should be treated with rescue therapy in the form of intravenous infliximab or ciclosporin for patients who have not previously failed thiopurine therapy. (Please see link for management of acute severe colitis . Please left click to open link). Infliximab is also recommended for patients in whom ciclosporin is contraindicated or clinically inappropriate, based on a careful assessment of the risks and benefits of treatment in the individual patient (NICE, 2008).

- Acute severe colitis [ASUC] is best defined by Truelove and Witt's criteria (Appendix 6). People with bloody diarrhoea 6 or more times a day with signs of systemic toxicity, should be admitted to hospital for intensive treatment.

The Mayo Score is used to assess the disease activity in patients who have ulcerative colitis. It is used to provide an assessment of the severity of the disease and can be used to monitor patients during therapy. The score can range from 0-12 with the higher the score indicating a worse severity of the disease (Appendix 7).

## **CONTRA-INDICATIONS:**

- Patients with a history of hypersensitivity to infliximab or other anti-TNF $\alpha$  inhibitors
- Current sepsis or infection
- Abscess (CT or USS to exclude)
- Pregnancy or breastfeeding
- Moderate to severe heart failure (NYHA III/IV)
- Tuberculosis (active or latent)

## **PRE-SCREENING:**

All patients should undergo a full clinical history, physical examination and further investigations as required, with particular reference to the known toxicity profile of the agent being considered. This should include a symptom enquiry regarding infection, tuberculosis, demyelination, lupus, heart failure and malignancy.

It is vital that ALL patients are screened and assessed for suitability and eligibility of infliximab therapy prior to initiation. (see proforma in Appendix 1)

### **1. Baseline Bloods required:**

- FBC, U&Es, LFTs, CRP

### **2. Infection screening**

Send stool sample for C.difficile and culture. Complete following blood results prior to starting treatment:

- HIV serology, Hepatitis B and C serology, Varicella-Zoster serology & Herpes Simplex serology

### **Tuberculosis**

- Full TB history (check family history, travel history and profession)
- Quantiferon Gold blood test/ T spot test
- Reported Chest X-Ray (within 6 weeks)

Further information available in [BTS guideline](#).

### **3. Vaccination history:** Prescriber must confirm vaccination history (where applicable):

- No live vaccines in the last four weeks preceding the infusion.



- VZV varicella vaccine (if there is no medical history of chicken pox, shingles or VZV vaccination)
  - Human papilloma virus (in women)
  - Influenza (trivalent inactivated vaccine) once a year
  - Pneumococcal polysaccharide vaccine (3 years)
  - Hepatitis B vaccine in all HBV seronegative patients
4. **Echocardiogram** – for patients with suspected heart failure.
  5. **Urine pregnancy test** (for women of childbearing age)

**PATIENT CONSENT:**

All patients should receive full verbal and written information (Appendix 3) on the risks and benefits of infliximab therapy to help them make an informed decision about their healthcare. This must be documented in the patient’s medical notes.

**PRESCRIBING:**

Prescribe infliximab on the fluids side of the All-Wales medication chart at a dose of 5mg/kg. It is administered as an intravenous infusion in 250ml of Sodium Chloride 0.9% over 2 hours:

INTRAVENOUS AND SUBCUTANEOUS INFUSIONS														
INFUSIONS TO BE ADMINISTERED ONCE ONLY, UNLESS THE PRESCRIBER SPECIFIES THEY ARE TO BE CONTINUOUS*														
DATE & START	INFUSION FLUID		ROUTE	MEDICINE ADDED		INFUSION RATE OR DURATION	PRESCRIBER'S SIGNATURE	PHARM	TIME			VOL GIVEN	GIVEN BY	CHKD BY
	TYPE / STRENGTH	VOLUME		APPROVED NAME	DOSE				DATE	START	STOP			
Date	SODIUM CHLORIDE 0.9%	250ml	IV	INFLIXIMAB	5mg /kg	2 hours	Signed							
Batch No.	Device No.		*Prescriber to initial if continuous →			bleop No.								
Batch No.	Device No.		*Prescriber to initial if continuous →			bleop No.								

All patients prescribed infliximab should also be prescribed the following on the when required side of the All-Wales medication chart:

- IV hydrocortisone 100mg (unless already prescribed for acute treatment)
- IV chlorphenamine 10mg
- IV or PO paracetamol 1g

**MANUFACTURING:**

Where possible, infliximab should be aseptically prepared in the Pharmacy Aseptic Unit (Morriston: 34015; Singleton: 35517). Please contact ward Pharmacist who will advise and provide information.

If required to be prepared at ward level, please follow the guidelines below:

- Reconstitute each 100mg vial of infliximab with 10ml of Water for Injection using a 21-gauge (0.8mm) or smaller needle.
- Do not use the vial if the vacuum is not present.
- Gently swirl the solution by rotating the vial to dissolve the powder. Avoid prolonged or vigorous agitation. Do not shake to avoid foam formation.
- Allow reconstituted solution to stand for 5 minutes – should be colourless to light yellow and opalescent.
- Dilute the total volume of the reconstituted solution dose to 250ml with sodium chloride 0.9%.
- Withdraw required volume of infliximab for required dose using a luer-lock syringe.
- Withdraw from the 250ml Sodium Chloride 0.9% bag a volume equal to the volume of reconstituted infliximab.
- Slowly add the total volume of reconstituted infliximab to the 250ml bag. Gently mix.
- The reconstituted solution should be used immediately. Should this be delayed, the reconstituted infusion, if prepared on the ward, can be stored at 2°C - 8°C and administered within 24 hours.

**Administer infliximab using an infusion set with an in-line filter (pore size 1.2micrometer or less).**

## **ADMINISTRATION AND MONITORING:**

### **Monitoring of ward based patient**

- **Monitor baseline temperature, BP, pulse, Oxygen saturations and RR prior to starting treatment.**
- **15 Minutes** after starting the infusion record: full observations i.e. BP, pulse, oxygen Saturations RR and temperature. (Usually if a patient reacts to the drug, it will be within the first 10 minutes so close observation is advised)
- Once infusion is complete, record patient's full observations again including BP, pulse, oxygen saturations, RR and temperature. Further observations can then resume as previously completed for this patient depending on NEWS score.

### **Monitoring of medical day unit patients or patients in OPD settings**

- **Monitor baseline temperature, BP, pulse Oxygen saturations and RR prior to starting treatment.**
- **15 Minutes** after starting the infusion record: full observations i.e. BP, pulse, oxygen Saturations RR and temperature. (Usually if a patient reacts to the drug, it will be within the first 10 minutes so close observation is advised)

- Once the infusion is complete, record patient's full observations again including BP, pulse, oxygen saturations, RR and temperature. Further observations can be completed for this patient depending on NEWS score.

**If Patient is an in-patient, then cannula site should be monitored as per the IV cannula hospital policy. For OPD patients need their cannula site checked hourly until the cannula is removed.**

Patients need to be closely observed for infusion reactions during administration of infliximab. Nursing staff should be experienced in the recognition and management of infusion reactions and of anaphylaxis. Nursing staff should contact the ward doctor or the doctor on call if patient develops a hypersensitivity reaction. Resuscitation equipment should be available. If acute infusion reactions occur, infusion must be stopped immediately.

Hypersensitivity reactions reported include:

- Fever, Chills, Chest Pain, Hypo-/Hypertension, Dyspnoea, Pruritis/urticarial, Angioedema, Anaphylaxis

**Mild allergic reactions:** (occur most frequently during the first and second infusion):

Symptoms include: flushing, rash, urticaria, itching, nausea, fatigue, headache, fever, chills, and dizziness

**Action:**

- Slow down the rate of the infusion by half, or stop and restart after 30 minutes at a lower rate of half.
- Administer paracetamol 1g PO (if the patient has not received a dose within 4 hours previously)
- Administer chlorphenamine 10mg IV over 1 minute if a rash develops or if patient develops rash/itching.

Acute infusion-related reactions including anaphylactic reactions may develop during (within seconds) or within a few hours following infusion and are most likely to occur during the first and second infusion.

**Severe allergic reactions:**

Symptoms include: bronchospasm (cough/wheeze/dyspnoea), angioedema of upper airway, hypotension (systolic BP < 90mmHg or BP dropped more than 40mm Hg from baseline)

**Action:**

- STOP infusion immediately
- Get immediate medical assistance
- Lay patient flat with legs raised
- Administer oxygen

Follow the Resuscitation Council's recommendations for treatment

**Emergency trays, including adrenaline, antihistamines, corticosteroids and an artificial airway must be available.**

Patients may be pre-treated with chlorphenamine, hydrocortisone and/or paracetamol (prescribed on when required side of drug chart) to decrease the risk of infusion-related reactions, especially if reactions have occurred previously.

## **FOLLOW-UP**

Repeat FBC, U&E, LFT and CRP prior to each infusion.

Medical review at 4-6 weeks following induction regime of Infliximab or based on clinicians discretion.

# Appendix 1: Infliximab Prescribing Protocol



<b>Anti-TNF Proforma</b>	Affix patient label
<b>Indication for Infliximab therapy</b>	
Severe active Crohn’s disease not responsive to standard immunosuppressive disease	
Fistulating Crohn’s Disease	
Moderate to severe Ulcerative Colitis	

<b>Contraindications to Infliximab therapy</b>	Yes	No
<b>Discuss with referring doctor if any contraindications present</b>		
TB or other severe infections such as sepsis, abscesses and opportunistic infections		
Moderate or severe heart failure (NYHA class III/IV)		
Hypersensitivity to infliximab, other murine proteins or any of the excipients		
History of malignancies, including lymphomas		
Demyelinating CNS disorders (risk of exacerbation)		
Female patients who may be / may become pregnant*		
For urine pregnancy test if any possibility of pregnancy		

\* Patients should not become pregnant within 6 months of last dose – give contraceptive advice if needed

<b>Medication</b>	<b>Y/N</b>	<b>Dose</b>
Azathioprine/6-Mercaptopurine (delete as appropriate)		
Methotrexate		
Budesonide		
Prednisolone		



**Checks prior to starting anti-TNF therapy:**

	Dates
Hb	
WCC	
Platelets	
Neutrophils	
Lymphocytes	
Sodium	
Potassium	
Urea	
Creatinine	
Albumin	
Bilirubin	
Alk Phos	
ALT	
CRP	
ESR	
Weight	
Stool (C.diff)	
Stool MS+S	

Viral serology		Result	Date
Hepatitis B serology	HbsAg		
	Anti-Hbs		
	Anti-HbcAg		
Varicella Zoster serology			
Herpes Simplex serology			
Quantiferon Gold			
HIV serology			
Hepatitis C serology			



**Vaccination history:**

In view of risk of opportunistic infections all patients should be offered vaccination for the following (no live vaccines) – tick if offered/administered:

- VZV vaccination if no past history of shingles/chickenpox and negative serology
- HPV vaccination for women

Note: Give advice regarding regular screening for cervical cancer / if extensive warts or condylomata, consider discontinuing treatment

- Influenza (trivalent inactivated influenza vaccine) – once a year
- Pneumococcal polysaccharide vaccine – once every 3 years
- Hepatitis B vaccine if seronegative for Hep B

(measure serological response after completion of vaccination)

**Smoking**

- Current  /day
- Ex-smoker
- Non-smoker

Smoking cessation advice given Y / N

**Patient consent**

- Patient has received information on the risks and benefits of infliximab therapy

Patient has received the NACC Patient Information Leaflet (Appendix 3)



**On the day of Booking:**

Date: .....

Wt in Kg: .....

**Pre-biological Harvey Bradshaw Index (HBI) - Disease activity on day of booking**  
(For Crohn's disease)

Date	Number of stools	Well being	Extra-intestinal manifestations	Abdominal Mass	Abdominal Pain	Score

Date: .....

Wt in Kg: .....

**Check list for signs or history of current/ recent infection**

Date	Temperature Y/N	Sore Throat/ Cough Y/N	Urinary Symptoms Y/N	Tooth Abscess Y/N	Visit to GP/ Dentist Y/N	Comments

## **Appendix 2: Nursing Protocol for Infliximab Administration**



Aseptic non-touch technique should be used at all times when administering the drug and accessing the patient's intravenous cannula/catheter.

### **Administration procedure:**

1. On receipt of drug from pharmacy – check label for correct patient name and drug dosage according to the prescription chart and patient's weight (5mg/kg)
2. Prime an administration set & **1.2micron filter** (dispensed from pharmacy with the drug) with the infusion solution. Attach to patient after checking patency of peripheral cannula
3. Give infusion **over 2 hours**.
  - If, for any reason the infusion is not given immediately after reconstitution, it should be stored in the drug refrigerator and the infusion commenced within 3 hours of reconstitution, or discarded.

**Infusion 0- 4 (number 4):** Infuse over 2 hours and observe 2 hours post infusion

Vital observations-temperature, blood pressure, oxygen saturations, pulse and respiratory rate recorded pre infusion, then 15 minutes after infusion has started. All vital observations then to be recorded once infusion has been completed. Then hourly observations for 2 hours post infusion. Further observations can then resume as previously completed for this patient depending on NEWS score.

**Infusion number 5 to 8:** Infuse over 1 hour vital observations- temperature, blood pressure, oxygen saturations, pulse and respiratory rate recorded pre infusion, then 15 minutes after infusion has started. All vital observations then to be recorded once infusion has been completed. Observe for 1-hour post infusion with 1 further set of observations.

**Infusion number 9+:** Infuse over 30 minutes vital observations- temperature, blood pressure, oxygen saturations, pulse and respiratory rate recorded pre infusion, then 15 minutes after infusion has started. All vital observations then to be recorded once infusion has been completed. Observe for 30 minutes post infusion with 1 further set of observations.

**IV access must remain in-situ for each patient for the appropriate post infusion period.**

### **Indication for reduced infusion**

A reduced infusion time of 1 hour is now licensed for IBD (MSD 2013): Patients who have tolerated at least 4 infliximab infusions over 2 hours without any hypersensitivity or reaction

### **Exclusion Criteria Reduced Infusion**

- Patients who have less than 4 previous Infliximab infusions
- Patients who have had previous infusion reactions at other hospital other than in Swansea Bay University Hospitals
- Patients who have either hypersensitivity or delayed hypersensitivity reaction including those who tolerated subsequent infusions
- Patients with known cardiac history

### **Monitoring of patient**

- Monitor baseline temperature, BP, pulse and RR **prior to starting treatment.**
- After starting the infusion, the BP, pulse and RR should be recorded after **15 minutes for the infusion starting.** (Usually if a patient reacts to the drug, it will be within the first 10 minutes so close observation is advised)
- Vital observations: BP, pulse, temperature and RR should then be monitored at **end of infusion and hourly for 2 hours after the infusion.**
- Conduct observations for a minimum of 1 hour after the infusion is finished.
- Temperature and cannula site should be monitored hourly.

Patients need to be closely observed for infusion reactions during administration of infliximab. Nursing staff should be experienced in the recognition and management of infusion reactions and of anaphylaxis. Nursing staff should contact the ward doctor or the doctor on call if patient develops a hypersensitivity reaction. Resuscitation equipment should be available. If acute infusion reactions occur, infusion must be stopped immediately.

Hypersensitivity reactions reported include: • Fever, Chills, Chest Pain, Hypo-/Hypertension, Dyspnoea, Pruritis/urticarial, Angioedema, Anaphylaxis

**Mild allergic reactions:** (occur most frequently during the first and second infusion): Symptoms include: flushing, rash, urticaria, itching, nausea, fatigue, headache, fever, chills, and dizziness

#### **Action:**

- Slow down rate of infusion, or stop and restart after 30 minutes at a lower rate
- Administer paracetamol 1g PO (if the patient has not received a dose within 4 hours previously)
- Administer chlorphenamine 10mg IV over 1 minute

#### **Severe allergic reactions:**

Symptoms include: bronchospasm (cough/wheeze/dyspnoea), angioedema of upper airway, hypotension (systolic BP < 90mmHg or BP dropped more than 40mm Hg from baseline)

#### **Action:**

- STOP infusion immediately
- Get immediate medical assistance
- Lay patient flat with legs raised
- Administer oxygen
- Follow the Resuscitation Council's recommendations for treatment of anaphylaxis

## Appendix 3: Patient Information Leaflet

(Please right click to open hyperlink)



## Appendix 4: Harvey Bradshaw Index Score

Harvey-Bradshaw Index of Crohn’s disease activity (HBI)		
Criteria	Points	Score
General well-being in the last 24 hours	0=well, 1=below par, 2=poor, 3=very poor, 4=terrible	
Abdominal pain in the last 24 hours	0=none, 1=mild, 2=moderate, 3=severe	
Abdominal mass in the last 24 hours	0=none, 1=possible, 2=definite, 3=definite and tender	
Extra intestinal manifestations	1 point for each of the following: arthralgia, uveitis, aphthous ulcers, erythema nodosum, anal fissure, new fistula, pyoderma gangrenosum, abscess.	
No. of liquid stools in the last 24 hours	1 point for each stool	
<b>Total:</b>		

A HBI score of <5 correlates with clinical remission, a score of 8-9 or above indicates severe disease.

## Appendix 5: Crohn's Disease Activity Index (CDAI)

Crohn's Disease Activity Index (CDAI)		
Criteria	Points	Score
Average number of liquid or soft stools per day over 7 days	14 points per stool	
Using loperamide or diphenoxylate for diarrhoea	30 points	
Average abdominal pain rating over 7 days	0=none, 35=mild, 70=moderate, 105=severe	
General well being each day over 7 days	0=well, 49=below par, 98=poor, 147=very poor, 196=terrible	
Complications	Arthritis or arthralgia (20 points), Iritis or uveitis (20 points), Erythema nodosum, pyoderma gangrenosum or aphthous stomatitis (20 points), Anal fissure, fistula or abscess (20 points), Other fistula (20 points), temperature over 100 °F (37.8 °C) in the last week (20 points)	
Finding of an abdominal mass	0=none, 20=possible, 50=definite	
Anaemia - Absolute deviation of hematocrit from 47% in males or 42% in females	6 points per percent deviation (e.g. a male patient with a hematocrit of 40% has an absolute deviation of 7)	
Weight change - Percentage deviation from standard weight	1 point for each percent deviation (1 - weight/standard weight) * 100, thus positive percent deviation represents weight loss, adding points to the CDAI	
<b>Total:</b>		

0-149 points:	Asymptomatic remission
150-220 points:	Mildly to moderately active Crohn's disease
221-450 points:	Moderately to severely active Crohn's disease
≥ 451points:	Severely active to fulminant disease

Note: The definition of severe Crohn's disease normally corresponds to a CDAI score of more than 300; however results should be interpreted in the light of the specific clinical situation.

## **Appendix 6:**

### **Truelove and Witt's criteria for severity of colitis**

	<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>
Bloody Stool Frequency	<4	4-6	>6
Pulse rate	Normal	Between mild & severe	>90
Temperature	Normal	Between mild & severe	>37.8
Haemoglobin	Normal	Between mild & severe	<10.5
ESR	Normal	Between mild & severe	>30

### **Simple clinical colitis activity index**

<b>Features</b>	<b>Scores</b>
Bowel frequency [day]	1-3= 0, 4-6=1, 7-9=2, >9=3
Bowel frequency (night)	1-3= 1, 4-6=2
Urgency of defecation	Hurry = 1, Immediately = 2, Incontinence = 3
Blood in stool	Trace = 1, occasional Frank = 2, Usually frank = 3
General well being	0= very well, 1=slightly below par, 2=poor, 3= very poor, 4= terrible
Extracolonic features	1 per manifestation

## **Appendix 7: Mayo Score/ Disease Activity Index (DAI) FOR Ulcerative colitis**

Criteria	Point Value
<b>Stool Frequency</b>	
<b>Normal</b>	<b>0</b>
<b>1-2 stools/day more than normal</b>	<b>+1</b>
<b>3-4 stools/day more than normal</b>	<b>+2</b>
<b>&gt;4 stools/day more than normal</b>	<b>+3</b>
<b>Rectal bleeding*</b>	
<b>None</b>	<b>0</b>
<b>Visible blood with stool less than half the time</b>	<b>+1</b>
<b>Visible blood with stool half of the time or more</b>	<b>+2</b>
<b>Passing blood alone</b>	<b>+3</b>
<b>Mucosal appearance at endoscopy</b>	
<b>Normal or inactive disease</b>	<b>0</b>
<b>Mild disease (erythema, decreased vascular pattern, mild friability)</b>	<b>+1</b>
<b>Moderate disease (marked erythema, absent vascular pattern, friability, erosions)</b>	<b>+2</b>
<b>Severe disease (spontaneous bleeding, ulceration)</b>	<b>+3</b>
<b>Physician rating of disease activity</b>	
<b>Normal</b>	<b>0</b>
<b>Mild</b>	<b>+1</b>
<b>Moderate</b>	<b>+2</b>
<b>Severe</b>	<b>+3</b>



**Swansea Bay University Health Board**

**Authorisation Form for Publication onto COIN**

PLEASE ENSURE THAT ALL QUESTIONS ARE ANSWERED – IF NOT APPLICABLE PLEASE PUT N/A

COIN ID.	3488
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Name and Signature of Lead Pharmacist.	CRISTINA AL-MOKHTAR
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Please sign to confirm that the document has been authorised by an approved governance process in a speciality or delivery unit.	DR SAUMAN JAFRE
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Is the document relevant to the GP Portal?	NO
Equality Statement (Mandatory for Policies). (1)	
Please specify keywords to assist with searching. (2)	Infliximab, IBD ULCERATIVE COLITIS, CROHN'S DISEASE
Published.	September 2020
Last Review.	October 2020
Next Review/Expiry Date.	April 2023

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