CLINICAL GUIDELINE

Burton Hospitals
NHS Foundation Trust

INFLIXIMAB PRESCRIBING AND ADMINISTRATION GUIDELINES

Approved by:	**Trust Management Team**
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Burton Hospitals NHS Foundation Trust

POLICY INDEX SHEET

Title:	**Infliximab Prescribing & Administration Guidelines**
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Date of Last Review:	**New Policy**
Responsibility:	**Medical Director's Office**
Stored:	**Intranet**
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Linked Trust Policies:	
Equality Impact assessed?	
Consulted	**Dermatology Consultants, Gastroenterology Consultants, Rheumatology Consultants, Pharmacy, Drugs & Therapeutics Committee**

REVIEW AND AMENDMENT LOG

Version	Type of change	Date	Description of Change
1	New Policy	January 2015	New Policy

INFLIXIMAB PRESCRIBING AND ADMINISTRATION GUIDELINES

CONTENTS PAGE

BURTON HOSPITALS NHS FOUNDATION TRUST

INFLIXIMAB PRESCRIBING AND ADMINISTRATION GUIDELINES

1. INTRODUCTION

Infliximab is an anti-tumour necrosis factor-α (Anti-TNF) antibody. It is from a group of drugs called cytokine inhibitors. Cytokines are small protein molecules, which occur in the body and are involved in inflammatory conditions. Infliximab binds to these molecules and inhibits the inflammatory response.

Infliximab is currently used within the NICE Technology Appraisals to treat a number of inflammatory conditions. This includes Ulcerative Colitis, Crohn's Disease, Rheumatoid Arthritis and Psoriasis.

For full guidance the NICE Technology Appraisals can be found at: www.nice.org.uk

2. DEFINITIONS

Infliximab

Monoclonal antibody used in the treatment of Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis and Psoriasis

Infusion reaction

Adverse symptoms occurring within 1-2 hours of infusion

3. DUTIES AND RESPONSIBILITIES

Gastrointestinal and Rheumatology clinicians

- Assessing patients and carrying out pre-treatment investigations
- Prescribing for in-patients and day case patients

Gastrointestinal and Rheumatology nursing staff

- Carrying out dose calculations
- Carrying out baseline observations and interpreting results
- Administering infliximab
- Monitoring patients

4. PRESCRIBING

4.1 Prescribing for Inpatients

- Prescribe infliximab on the ONCE ONLY section of the inpatient drug chart

- Complete all details on the drug chart. This includes patients' name, DOB, address and hospital number
- Complete the allergy section of the chart and document the patient's weight
- **Dose** - usually ranges from 3mg/kg to 5mg/kg depending on indication. Refer to specialist literature for further dosing information
- The prescriber is responsible for calculating the infliximab dose and prescribing in mg
- Specialties requiring IV hydrocortisone prior to infliximab must prescribe 100mg IV stat on the ONCE ONLY section of the drug chart
- Patients should continue treatment on the brand they have been commenced on. New patients should start on biosimilar infliximab.

4.2 Prescribing for Day Case Patients

Note: Infliximab Day Case Prescription Charts are valid for 6 months only.

- Prescribe infliximab on the Infliximab Day Case Prescription Chart
- Complete all details on the chart. This includes patients' name, DOB, address and hospital number
- Complete the allergy section of the chart must be completed and document the patient's weight
- **Declaration** – the Consultant or Registrar is responsible for completing the declaration for treatment. He / She must indicate if treatment is in line with the appropriate NICE Technology Appraisal by adding the technology appraisal reference number and countersigning. If treatment is outside the NICE criteria but has been agreed by PCT, tick the Intervention Not Normally Funded column and countersign the chart. The use of infliximab must be approved with the commissioners using the Prior approval scheme (ie Bluteq)
- **Dose** - usually ranges from 3mg/kg to 5mg/kg depending on indication. Refer to specialist literature for further dosing information
- **New patients** - Patients not previously treated with infliximab require initial loading, where an infusion is given at weeks 0, 2 and 6 weeks. Complete and sign the relevant section of the chart for patients new to infliximab. Prescribe dose as mg/kg, complete indication column and sign chart
- **Maintenance treatment** - administer infliximab every 8 weeks. Complete and sign the relevant section of the chart. Prescribe dose as mg/kg, complete indication column and sign chart
- **Dose review** – in some cases the frequency of administration may be altered following consultant review
- Nursing staff carry out dose calculation on admission based on current patient weight
- **Adjunctive drugs** - Sign the reverse of the prescription chart for Paracetamol, oral and IV chlorphenamine and IV hydrocortisone in the case of an infusion reaction
- Specialties requiring IV hydrocortisone 100mg IV prior to each infliximab infusion must complete and sign the preprinted section of the prescription chart
- Pharmacy will be unable to dispense infliximab for charts which are out of date, incorrectly completed or where the declaration is incomplete.

5. DOSE CALCULATION (FOR DAY CASE PATIENTS)

- Nursing staff on the ambulatory day units are responsible for making dose calculations on admission
- Weigh Patient upon **each** admission and document on the chart
- Dose calculations are made in the following way
- Multiply the dose prescribed in mg/kg x patient weight
  e.g. for a patient weighing 70kg prescribed a dose of 5mg/kg, **dose is 70 x 5 = 350mg**
- Round doses to the nearest 5mg, e.g. **323mg → to 325mg**
- Document dose on the prescription chart and ensure a second calculation check is carried out by another staff nurse or healthcare professional.

6. PATIENT PREPARATION AND PRE-TREATMENT INVESTIGATIONS

The following investigations must be performed prior to administration of the first infusion:

- Medical History to exclude Tubercle Bacillus (TB)
- FBC
- CXR to exclude active TB
- Urinary pregnancy test as appropriate
- For subsequent infusions, take bloods (for FBC, U&E's, LFT's and CRP) 2 weeks prior to date of infusion
- Carry out baseline observations (Blood Pressure (BP), Pulse (P), Temperature and Weight) when patient arrives on the unit.
- Check blood results
- Ensure no evidence of sepsis or clinically manifested infection.
- Cannulate patient according to Trust policy.

7. PREPARATION OF INFUSION

- Calculate the number of infliximab vials needed. Each infliximab vial contains 100mg of infliximab e.g. a dose of 350mg will require reconstitution of 4 x 100mg infliximab vials
- Reconstitute each infliximab vial with 10 mL of water for injections, using a syringe equipped with a blue needle
- Remove flip-top from the vial and wipe the top with a 70% alcohol swab. Insert the syringe needle into the vial through the centre of the rubber stopper and direct the stream of water for injections to the glass wall of the vial. Do not use the vial if the vacuum is not present
- Gently swirl the solution by rotating the vial to dissolve the lyophilised powder. Avoid prolonged or vigorous agitation. DO NOT SHAKE. Foaming of the solution on reconstitution is not unusual
- Allow the reconstituted solution to stand for 5 minutes. Check that the solution is colourless to light yellow and opalescent. The solution may develop a few fine translucent particles, as infliximab is a protein
- Do not use if opaque particles, discoloration, or other foreign particles are present
- See section 7 for storage instructions of reconstituted vial

- Withdraw the volume of the reconstituted infliximab (e.g. 300mgs of infliximab is reconstituted with 30mLs of water) from the 250mLs bag/bottle of 0.9% Sodium Chloride
- Slowly add the total volume of reconstituted infliximab solution to the 250mL infusion bottle or bag. Gently mix
- Check the infusion with another trained member of staff and label the bag using a white sticker.

8. ADMINISTRATION OF INFUSION

- Use an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 1.2 micrometer or less) obtained from stores
- For patients new to infliximab administer the infliximab infusion intravenously over a period of 2 hours
- Patients who have tolerated at least 4 initial 2 hour infliximab infusions, may be considered for shortened infusion times as below:
    - Infusions 1-4 → Administered over 2 hours and the patient must wait for 2 hours after infusion
    - Infusions 5-9 → Administered over 1 hour and the patient must wait for 1 hour after infusion
    - Infusion ≥ 10 → Administered over 30 minutes and the patient does not need to wait
- It is recommended that the administration of the solution for infusion is started as soon as possible and within 3 hours of preparation
- Do not infuse infliximab in the same intravenous line as any other agents.

9. VIAL SHARE

- The Ambulatory Day Units are authorised to carry out vial sharing of infliximab
- Unused reconstituted solution must be stored at 2°C to 8°C in the fridge for a **MAXIMUM of 24 hours**
- Label the vial with time and date of reconstitution
- After 24 hours any unused reconstituted solution must be discarded as per local policy
- Set aside any unused/saved vials must be set aside in Ambulatory Day Unit fridge in tray labelled “Vial Sharing Returns”. Designated pharmacist will personally collect stock to return to pharmacy.

10. MONITORING OF INFUSION

- Infliximab has been associated with acute infusion-related reaction, including anaphylactic shock and delayed hypersensitivity reactions
- Acute infusion reactions including anaphylactic reactions may develop within seconds or within a few hours following infusion
- Vital signs must be monitored **every 30 mins** during the infusion
- If acute reactions occur, stop the infusion **immediately**
- Patient must be made to wait post infusion for monitoring (depending on infusion number)
    - For patients on infusion 1 – 4 2 hours post infusion
    - For patients on infusion 5 – 9 1 hour post infusion
    - For patients on infusion ≥ 10 does not require to be monitored post infusion

11. TREATMENT OF INFUSION REACTION

An infusion reaction is any reaction occurring during or within 1-2 hours of an infusion. This can be classified into mild, moderate and severe.

Treat all infusion reactions according to the table below:

Reaction	Symptoms	Treatment
Mild	Palpitations, headache, nausea, dizziness	Stop infusion Give PO Paracetamol 1g and/or Chlorphenamine 4mg PO or Chlorphenamine 5-10mg IV Monitor vital signs every 10mins Restart infusion after 20mins at a slower rate (10mls/hr increasing rate every 15 mins)
Moderate	Hypo/hypertension, mild chest discomfort, shortness of breath and elevated temperature	Stop infusion Give PO Paracetamol 1g and/or Chlorphenamine 5-10mg IV Give IV Hydrocortisone Monitor vital signs every 10mins Restart infusion after 20mins at a slower rate (10mls/hr increasing rate every 15 mins)
Severe	Hypo/hypertension, stridor, chest discomfort or shortness of breath, bronchospasm, angiooedema of upper airway	STOP infusion immediately Obtain medical assistance Treat as per anaphylaxis protocol

The decision to retreat a patient with infliximab who has had a reaction to it will be made by the consultant responsible for that patient's care.

12. TRAINING

Staff involved in the administration of infliximab must have completed the IV drug administration and read the policy prior to administering the medication.

13. MONITORING OF COMPLIANCE

Compliance guidelines to be monitored using audit, responsibility being with the Specialty Consultant.

14. REFERENCES

Electronic Medicines Compendium (2012). Summary of Product Characteristics for *Remicade* ®
http://emc.medicines.org.uk (the Trust is not responsible for the content of external websites)
National Institute of Clinical Excellence (NICE). Clinical guidelines NICE TA187 – Crohns Disease;
NICE TA134 – Psoriasis; NICE TA163 – Ulcerative Colitis; NICE TA130 – Rheumatoid Arthritis.