Gloucestershire Hospitals
NHS Foundation Trust

Infliximab IV infusion: Prescribing and Administering

1. Background:

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 at GHNHSFT 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

Infliximab is available as a number of brands, including the originator infliximab, Remicade® and a number of biosimilar brands such as Inflectra®, Remsima® and Flixabi®. A biosimilar medicine is a biological medicine that is highly similar to another biological medicine already licensed for use. It is a biological medicine that has not been shown to have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy.

Biosimilar medicines are not considered generic equivalents to their originator biological medicines because the two products are similar but not identical. However, they will have met regulatory requirements in terms of comparative quality, safety and efficacy.

In line with MHRA guidelines, biological medicines, including biosimilars, must be prescribed by brand name to support on-going pharmacovigilance of the individual products.

At the time of dispensing, an originator biologic should not be automatically substituted for a biosimilar or vice versa.

2. Prescribing

Prescribing for in-patients

Infliximab must be prescribed on Sunrise as a ONCE ONLY prescription by **brand name e.g. Remsima® 100mg powder for concentrate for infusion (infliximab)**

The dose of infliximab usually ranges from 3mg/kg to 10mg/kg depending on indication. Refer to specialist literature and the relevant biologic pathway for further dosing information.

Infliximab dose must be calculated by the prescriber and the dose must be prescribed in mg.

IV hydrocortisone is not routinely administered as a pre-medication

Prescribe rescue medicines PRN for use by nursing staff in the event of a reaction – refer to relevant part of policy.

Prescribing for Day Case Patients

All infliximab must be prescribed on the Infliximab Day Case Prescription chart with the specific brand required entered into the appropriate space. It is vital that the brand required is clear for the dispensing pharmacist.

All details on the chart must be completed. This includes patients' name, DOB, address and hospital number. An addressograph is sufficient.

The allergy section of the chart must be completed and patients' weight must be documented on the chart.

Declaration
All infliximab prescription charts must have the declaration for treatment completed by the prescriber. They 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 as an Individual Funding Request., this box must be ticked and the chart countersigned.

The dose of infliximab usually ranges from 3mg/kg to 10mg/kg depending on indication. Refer to specialist literature and the relevant biologic pathway for further dosing information.

Patients not previously treated with infliximab require initial loading, where an infusion is given at weeks 0, 2 and 6 weeks (or 0 and 2 weeks if transitioning to SC infliximab). If the patient is new to infliximab complete the relevant section of the chart. Prescribe the dose as mg/kg, complete the indication column and sign the chart.

Patients on maintenance treatment with infliximab are administered doses every 8 weeks. In some cases, the frequency of administration of infliximab may be altered. When prescribing for a maintenance patient complete the relevant section of the chart. Prescribe the dose as mg/kg, complete the indication column and sign the chart.

The actual dose for administration is calculated by nursing staff upon patient admission based on their current weight.

The reverse of the prescription chart must be signed for paracetamol, oral and IV chlorphenamine and IV hydrocortisone in the case of an infusion reaction.

IV hydrocortisone is not routinely administered as a pre-medication.

Infliximab Day Case Prescription charts are valid for 6 months only.

Pharmacy will be unable to dispense infliximab for charts which are out of date, incorrectly completed to include brand details or where the declaration is incomplete.

3. Dose Calculation (For Day Case Patients)

Dose calculation is carried out on admission by nursing staff on the Medical Day Unit.

Patient must be weighed upon admission. The weight must be documented on the chart for each admission.

Calculate the dose required by multiplying the dose prescribed in mg/kg by patient weight e.g. for a patient weighing 70kg prescribed a dose of 5mg/kg, dose is 70 X 5 = 350mg.

The dose must be rounded to the nearest 5mg e.g. 323mg → rounded to 325mg

The dose must be documented on the prescription chart and a second calculation check must be carried out by another registered nurse or healthcare professional.

4. Patient Preparation and Pre-Treatment Investigations

Prior to administration of the first infusion, the following investigations must be performed:

- Medical History, chest X ray and T spot test to exclude tuberculosis
- HIV, Hepatitis B and C serology
- History to confirm previous exposure to Varicella Zoster or serology test

For subsequent infusions bloods must be taken (for FBC, U&E's, LFT's and CRP) 2 weeks prior to date of the infusion

On admission, carry out baseline observations: blood pressure (BP), heart rate (HR), temperature and weight when patient arrives.

Check the patient's blood results and contact the relevant clinical team if any abnormality is found.

Ensure there is no evidence of sepsis or clinically manifested infection.

Cannulate the patient.

5. Preparation of the infusion

Calculate the number of infliximab vials needed. Each 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 21 gauge (0.8mm) or smaller 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. This is a 100mg in 10ml (10mg in 1ml) solution.

Do not use if opaque particles, discoloration, or other foreign particles are present.

See section 7 for storage instructions of reconstituted vial.

<u>For doses up to and including 1000mg: Add to 250ml 0.9% sodium chloride infusion bag</u>

The recommended concentration of infliximab once in an infusion bag is 0.4-4mg/L. 250ml bags have an additive tolerance of up to 100ml. Therefore it is not necessary to remove any fluid from the 250ml infusion bag before adding infliximab for doses up to and including 1000mg.

Slowly add the total volume of reconstituted infliximab solution to the 250ml 0.9% sodium chloride infusion bag. Gently mix.

Check the infusion with another trained member of staff and label the bag using a white sticker.

For doses greater than 1000mg: Add to 500ml 0.9% sodium chloride infusion bag

The recommended concentration of infliximab once in an infusion bag is 0.4-4mg/L. 500ml bags have an additive tolerance of up to 200ml. Therefore it is not necessary to remove any fluid from the 500ml infusion bag before adding infliximab for doses greater than 1000mg.

Slowly add the total volume of reconstituted Infliximab solution to the 500ml 0.9% sodium chloride infusion bag. Gently mix.

Check the infusion with another trained member of staff and label the bag using a white sticker.

6. Administration of Infusion

Use an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 1.2 micrometre 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 a shortened infusion and no post dose observation period as below:

Infusion number	Infusion time	Waiting periods afterwards for observation
1-4	2 hours	15 minutes
5-9	1 hour	No wait
10 and over	30 minutes	No 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.

7. Vial Sharing

Vial sharing of infliximab vials on the Medical Day Unit has been authorised by GHNHSFT.

Any unused reconstituted solution must be stored at 2°C to 8°C in the fridge for a MAXIMUM of 24 hours.

The vial must be clearly labelled with the time and date of reconstitution.

After 24 hours any unused reconstituted solution must be discarded as per local policy. Any vials unused/saved from vial sharing must be set aside in the Medical Day Unit fridge in tray labelled “Vial Sharing Returns”. Designated Pharmacist will collect stock to return to Pharmacy.

8. 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 30mins during the infusion.

If acute reactions occur, the infusion must be stopped immediately.

9. 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.

Mild reactions include: Palpitations, headache, nausea, dizziness

If patient has mild reaction:

- Stop infusion
- Monitor vital signs every 10mins
- Restart infusion after 20mins at a slower rate (10mls/hr increasing rate every 15 mins)
- Consider giving PO paracetamol 1g for headaches/or chlorphenamine 4mg PO or chlorphenamine 5-10mg IV as required for urticaria

Moderate reactions include: Hypo/hypertension, mild chest discomfort, shortness of breath and elevated temperature

If patient has a moderate reaction:

- Stop infusion
- Monitor vital signs every 10mins
- Restart infusion after 20mins at a slower rate (10mls/hr increasing rate every 15 mins)
- Give PO Paracetamol 1g for headaches and/or chlorphenamine 5-10mg IV for urticarial reactions
- Consider giving IV Hydrocortisone

Severe reactions include significant hypo/hypertension, stridor, chest discomfort or shortness of breath, bronchospasm, angiooedema of upper airway

If a patient has a severe reaction:

- 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.

References:

1. Summary of Product Characteristics for Remsima® Last updated on the Electronic Medicines Compendium 04/10/2016. Accessed via the Electronic Medicines Compendium http://emc.medicines.org.uk on 21/01/2025
2. Medusa NHS Injectable Medicines Guide, Infliximab monograph. Accessed on 17/09/2025 Injectable Medicines Guide - Display - Infliximab - Intravenous - Version 9 - IVGuideDisplayMain.asp
3. National Institute of Clinical Excellence (NICE) www.nice.org