

**WAHT-KD-019  
Treatment of Inflammatory Bowel Disease with Biologics (in patients over  
15 years of age)**

**INPATIENT BIOLOGICS**

<b>Key Document code:</b>	Treatment of Inflammatory Bowel Disease with Biologics (In patients over 15 years of age)	
<b>Key Document Owner:</b>	Helen Osinski	Senior IBD CNS
<b>Approved by:</b>	Medicines Safety committee	
<b>Date of Approval:</b>	04 <sup>th</sup> November 2019	
<b>This is the most upto date and should be used until a revised version is in place:</b>	4 <sup>th</sup> November 2021	

**Key Amendments**

<b>Date</b>	<b>Amendment</b>	<b>Approved by</b>

**To be initiated by consultant gastroenterologist only, can be prescribed by consultant, registrar, IBD CNS or gastroenterology pharmacist only**

Inform IBD CNS when the patient has been given a biologic on the ward as she will arrange further doses, either bleep on 469 or 228, leave a message on extension 33554 or email to helen.osinski@nhs.net

**PATIENT SCREENING REQUIREMENTS PRE TREATMENT**

- TB quantiferon t-spot test (Please click on this link for more information on the TB screening), NB this test must be taken first thing in the morning as it has to get to the laboratory to be processed on the same day . This test can take a week or two to be processed. If the patient is felt to have severe disease the consultant must consider the risks and benefits of giving the biologic without these results and the patient should be counselled as to the risks involved. A chest x-ray should be obtained and reviewed prior to giving infusion to rule out any infection/active TB
- If not done within last 12 months, obtain blood for HIV, Hepatitis B and C serology – if positive discuss with patients consultant
- If not done previously, obtain blood for Measles and Varicella immunity status (you do not need to wait for these results before starting treatment)
- Rule out any active infection or possible abscess/sepsis
- Have they received any LIVE vaccinations? If yes, you must wait 3 weeks before commencing treatment
- Any history of malignancy? If yes it must be discussed with consultant
- Is the patient pregnant? If yes, it must be discussed with consultant

Patient must be registered as a new patient on Blueteq CCG approval system for high cost drugs) via, <https://www.blueteq-secure.co.uk/Trust/default.htm> (for Worcestershire CCGs only)

**INFLIXIMAB INDUCTION REGIME(REMSIMA,REMICADE,INFLECTRA)**

Infusions are given at week 0, 2 and 6 (from the first date) to induce remission. Dose is 5mg/kg in 250ml Sodium chloride 0.9% over 2 hours . Use pre-printed prescription where ever possible code 2149 on EZ notes or you can prescribe on a fluid prescription chart. Before each induction dose 200mg hydrocortisone I.V should also be given, (evidence suggests this reduces antibody formation and thus the risk of anaphylaxis). If the patient is already receiving regular I.V hydrocortisone an extra dose is NOT needed.

Please note that the key documents are not designed to be printed, but to be used on-line. This is to ensure that the correct and most up-to-date version is being used. If, in exceptional circumstances, you need to print a copy, please note that the information will only be valid for 24 hours and should be read in conjunction with the key document supporting information page

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If patient improves and is discharged please ensure you have informed the IBD CNS so that she can arrange further doses, if she is not available please ask gastroenterology secretaries to arrange next two doses at the intervals stated above in medical daycase.

**How to reconstitute infliximab.**

You may receive a premade infusion bag which you can administer straight away.

If you receive vials, follow these instructions

Add 10mls water for injection to each vial taking care to aim the stream of water at the side of the vial to prevent damage to the antibody.

DO NOT shake or agitate the vial, rotate each vial gently between the palms of the hands (excess foaming will result in drug wastage, shaking will destroy the antibody and may render the infusion inactive).

Leave to stand for 5 minutes.

Check solution for discoloration or foreign particles. Discard if any present.

(You will have to remove the equivalent amount of saline from the 250ml bag as you are going to add, so the total volume after reconstituting is 250mls).

For example, if the infliximab dose is 150mg, it would equal 15mls once reconstituted, so you would have to remove 15mls of sodium chloride from the bag before adding the infliximab.

Carefully withdraw solution from the vial using a green needle and sterile syringe, and add to a bag of Sodium Chloride 0.9% for infusion, to a **total volume of 250mls**

The reconstituted and diluted Infliximab solution should be infused using a volumetric pump through a filter (<1.2 microns, supplied by pharmacy with Infliximab).

Commence infusion within 24 hours of reconstitution.

How to administer Infliximab

Commence infusion at 60ml/hour for the first 10 minutes, and then re-check patient observations.

If observations satisfactory and patient reporting no side effects, increase rate to 125ml/hour for remainder of infusion.

Check observations every half hour throughout infusion.

If the patient reports any side effects please manage as per instructions on the reverse of the pre-printed prescription sheet.

Storage of Infliximab

Store in a refrigerator (2°C - 8°C) before reconstitution. After reconstitution the infusion should be used within 3 hours

**ADALIMUMAB RAPID INDUCTION REGIME (HUMIRA)**

Subcutaneous injection, 40mg strength pre-filled syringe or pen supplied.

Give 80mg on day one and 80 mg on day two, then 80mg two weeks later.

If patient improves and is discharged ensure you have informed the IBD CNS so that she can arrange the week 2 dose, if she is not available please ask gastroenterology secretaries to arrange the next dose in two weeks time in medical daycase.

Storage of Adalimumab

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the pen/syringe in its outer carton to protect from light. A single syringe/pen may be stored at temperatures up to a maximum of 25°C for a period of up to 14 days. The pen/syringe must be protected from light and discarded if not used within this period.

**VEDOLIZUMAB INDUCTION REGIME (ENTYVIO)**

Infusions are given at week 0, 2 and 6 (from the first date) to induce remission.

Dose is 300mg IV, in 250ml Sodium Chloride 0.9% over 30minutes.

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**Storage**

Store in a refrigerator (2°C - 8°C) before reconstitution. Keep vial in outer carton to protect from light.

**How to reconstitute vedolizumab**

Add 4.8ml of water for injection to vial, taking care to aim the stream of water at the side of the vial to prevent excessive foaming.

DO NOT shake or agitate the vial, rotate each vial gently between the palms of the hands (excess foaming will result in drug wastage, shaking will destroy the antibody and may render the infusion inactive).

Check solution for discoloration or foreign particles. Discard if any present. Let sit for 20 minutes or until any foam has settled.

Add the 5ml reconstituted Vedolizumab to a 250ml bag of Sodium Chloride 0.9% for infusion.

The solution should be infused using a volumetric pump.

Commence infusion within 24 hours of reconstitution. Store at room temperature once reconstituted.

**How to administer Vedolizumab**

IV infusion over 30minutes, perform full set of observations once infusion is finished.

**USTEKINUMAB INDUCTION (STELARA)**

One intravenous dose dependant on weight, see table below, next dose is a s/c injection at week 8

I.V infusion in 250ml Sodium Chloride 0.9 given over 1 hour. <b>Body weight at time of dosing</b>	<b>Recommend ed dose</b>	<b>Number of Ustekinumab 130mg vials</b>	<b>Volume to be removed from 250mL 0.9% NaCl Bag</b>
≤55kg	260mg	2	52mLs
>55kg to ≤ 85kg	390mg	3	78mLs
85kg	520mg	4	104mLs

**How to administer Ustekinumab**

Via IV infusion over 1 hour, perform full set of observations once infusion is finished.

If patient improves and is discharged please ensure you have informed the IBD CNS so that she can arrange further doses. If she is not available please email her the details so she can arrange on her return

**Storage**

Store in a refrigerator (2°C - 8°C) before reconstitution.

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