WAHT-KD-019

Treatment of Inflammatory Bowel Disease with Biologics, (in patients over 15 years of age)

Worcestershire Acute Hospitals NHS Trust

Patient Screening Requirements Pre Treatment

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

Key Amendments

Date	Amendment	Approved by

Contraindications to treatment TNFa

- Patients with sepsis, or with clinically apparent opportunistic infection.
- Patients who are hypersensitive to the drug or any active substance.
- Patients with Congestive Heart Failure (CHF), NYHA Class III/IV.

(Treatment should be discontinued in those whose CHF is worsening.)
 Active or previously untreated Tuberculosis (TB)

CAUTION should be taken for patients with:

- Female patients who may be pregnant
- Persistent or recurrent infection
- Chronic leg ulcers
- Indwelling urinary catheters
- Demyelinating disease
- Malignancy less than 10 years ago
- Hepatitis B
- Latex allergy as the needle cover of Ustekinumab contains latex

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- TB quantiferon tspot test

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.
If the result is equivocal then repeat it. If it remains equivocal refer to the respiratory team for assessment.
If the result is positive refer to the respiratory team for assessment.

- If not done within last 12 months, obtain blood for HIV, Hepatitis B and C serology – if positive discuss with the 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 if deemed urgent). If patient is not immune and treatment is urgent you may proceed. Patient will be given written advice by IBD CNS how to manage any contact with these diseases.
- 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 (they cannot have LIVE vaccinations whilst on biologics)
- Any history of malignancy? If yes it must be discussed with consultant

- Is the patient pregnant? If yes, it must be discussed with consultant

After this screening the patient and GP are written to by the IBD CNS to ask that their vaccination history is checked and if it is unclear or incomplete the person be vaccinated against Diptheria, polio, tetanus, pneumococcal polysaccharide (PPV23) and given the yearly flu jab. If under the age of 25 they should also have Meningitis C. If female and in the age brackets of the national programme they should receive HPV. Hepatitis B is only indicated in those considered in a high risk category (as detailed in a letter to the patient). All of the above can be given in an inactivated form and treatment with biologic does not need to be delayed.

Tuberculosis Assessment and Exclusion Guidelines

In patients receiving a Biologic there is an increased risk of clinical tuberculosis (TB) developing or latent disease being reactivated.

- Patients should be screened for active or latent TB infection **before** receiving a Biologic. This should be through the completion of a detailed patient history to determine previous TB or recent contact with the disease before the **first** infusion, in conjunction with T-Spot blood test.

- If the T-Spot is equivocal it should be repeated, if it remains equivocal or is positive advice should be sought from the Respiratory physicians.

- Any patient with active TB will generally require 6 months of chemotherapy with minimum of 2 months full chemotherapy before consideration of Biologic therapy.

- In patients with previous TB, if past treatment is considered to have been adequate by respiratory consultant they may start Biologic treatment but will require careful monitoring with chest x-ray every 3 months and sputum cultures if respiratory symptoms develop.

- Patients of Black African ethnicity aged over 15 years and **all** patients born in the Indian Sub-continent should be considered for chemoprophylaxis with isoniazid for 6 months.

- For inpatients requiring rescue Infliximab the T-Spot should still be taken. However if it is deemed imperative to start the Infliximab and the patient agrees after adequate counselling (as to the possible consequences if the T-Spot then turns out to be positive) the infusion can be given.

References:

Rampton, D.S. (2005) Preventing TB in patients with Crohn's disease needing Infliximab or other anti-TNF therapy. **GUT.** 54:1360-1362.
British Thoracic Society Standards of Care Committee (2005) BTS recommendations for assessing risk and for managing Mycobacterium tuberculosis infection and disease in patients due to start anti-TNF- ά treatment. **Thorax** 60:800-805
NICE guideline (2016) Tuberculosis NG33. https://www.nice.org.uk/guidance/ng33