WAHT-KD-019

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

Adalimumab prescribing information and dosing schedule

Mode of action of Anti TNFα

Adalimumab is an anti TNFα monoclonal antibody, which binds to Tumour Necrosis Factor alpha (TNFα). TNFα is an inflammatory cytokine and is found at relatively high concentrations in patients with Inflammatory Bowel Disease. There is evidence that treatment with Anti TNFα reduces the infiltration of inflammatory cells into diseased parts of the intestine and also reduces inflammatory markers.

Adalimumab is administered as a subcutaneous injection, either via preloaded pen or syringe containing 40mg of Adalimumab (one injection per device). It is managed via a home care agency in the community, who arrange delivery of the drug and a nurse visit to educate the patient on administration, storage etc. Patients are also offered the opportunity to receive a tailored support package to help them achieve the best results from the medication called Abbvie care.

The consultant should inform the IBD CNS of the patient who will then organise registration and prescriptions, these go to the hospital pharmacy who liaise with the homecare agency.

Dosing schedule

Standard dosing schedule to induce remission

Week 0 – 160mg (4x40mg injections spread over two days)
Week 2 – 80mg (2x40mg injections on the same day)
Week 4 – 40mg (1x40mg injection)
Then 1x40mg injection every 2 weeks thereafter as maintenance treatment.

Reduced dosing schedule to maintain remission

This is generally only used if the patient is relatively symptom free and we are changing Anti TNFα agent due to side effects etc.

Week 0 – 80mg (2x40mg injections on the same day)
Week 2 – 40mg (1x40mg injection on the same day)
Then 1 injection every 2 weeks thereafter as maintenance treatment.

Managing loss of response

Ensure symptoms are due to active disease by performing faecal calprotectin or other investigations such as endoscopy, MRI, CT or VCE.

Obtain Adalimumab trough levels and antibodies. Manage patient as per table below.

DRUG LEVEL	ANTIBODY	POSSIBLE ACTION
Low (<5 mg/L)	Negative	Intensify regime by decreasing interval to weekly injections. If low levels persist, consider changing to another Anti TNFα or out of class.
Low (<5 mg/L)	Positive, low level titre (<57AU/ml)	Intensify regime as above. Also consider adding in or optimising immunosuppression. If low levels persist, consider changing to another Anti TNFα or out of class.
Low (<5 mg/L)	Positive, high level titre (>58 AU/ml)	Switch to another Anti TNFα or out of class.
Therapeutic (>5 mg/L)	Negative	Switch to another biologic out of class.

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Evidence on interpreting Adalimumab drug levels is at present based on observational studies only and so the above is intended as guidance only, some patients may require higher levels to achieve therapeutic response.

The effectiveness of any changes should be assessed regularly and when possible the dosage or interval returned to the standard maintenance schedule.

Pregnancy and breast feeding

Several studies have shown that treatment with anti-TNFα does not increase the risk of adverse pregnancy outcomes. The drug does cross the placenta in the third trimester and so where possible Adalimumab should be stopped by week 24-26 of gestation, with timing of the last dose as close to this as possible. If the patient has severe disease treatment can be continued throughout pregnancy after discussion with the patient with regards to the unknown long term risks.

As Infliximab has been detected in infants up to 6months after birth and Adalimumab is in the same class as this, the infant should not receive any LIVE vaccinations until it is 6months of age. With the normal vaccine programme, this should only affect the rotovirus vaccine, which cannot be given. They can receive all non-live vaccines as per the normal vaccination strategy. This information should be given to the patient and their GP in writing.

There is currently limited data on the safety of treatment with Anti-TNFα whilst breastfeeding, but it is probably low risk. Patients should be informed of this.

Blood monitoring requirements

U&Es, LFTs, CRP, FBC and ESR are checked one month after starting the treatment, then two months after that and then every 3 months for the duration of treatment. The results are reviewed before each new prescription is issued.

Storage

Store in a refrigerator (2°C-8°C). Do not freeze. Keep the pre-filled syringe or pen in its outer carton in order to protect from light.

A single pre-filled syringe or pen may be stored at temperatures up to a maximum of 25°C for a period of up to 14 days. The syringe or pen must be protected from light and discarded if not used within the 14 day period.