WAHT-KD-019

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

VEDOLIZUMAB (Entyvio) PRESCRIBING AND SCHEDULE INFORMATION

Mode of action

Vedolizumab is a humanised monoclonal antibody that binds specifically to the α4β7 integrin, which is a protein preferentially expressed on a subset of lymphocytes. These lymphocytes migrate to the GI tract and cause inflammation that is characteristic of ulcerative colitis and crohn's disease. Vedolizumab binds to the integrin and inhibits their ability to cross into the GI tract and cause inflammation.
Vedolizumab is given as an intravenous infusion in either the medical daycase unit for patients over 18 years of age, or in the childrens clinic for patients aged 15-17years.
Prescribers should prescribe on an intravenous fluid prescription chart.
Induction regime

Infusions are given at week 0, 2 and 6 (from the first date) to induce remission, followed by an observation period. Crohn's patients may benefit from an extra dose at week 10. All infusion dates are arranged by the IBD clinical nurse specialist or if unavailable the consultants secretary. **Week number**	**Dose to be given**	**Duration of infusion**	**Observation period**
0	300mg in 250ml Sodium Chloride 0.9%	30 minutes	2 hours
2	300mg in 250ml Sodium Chloride 0.9%	30 minutes	2 hours
6	300mg in 250ml Sodium Chloride 0.9%	30 minutes	1 hour
10 (crohns patients only)	300mg in 250ml Sodium Chloride 0.9%	30 minutes	1 hour
14	300mg in 250ml Sodium Chloride 0.9%	30 minutes	1 hour
22 and all subsequent doses	300mg in 250ml Sodium Chloride 0.9%	30 minutes	30minutes

Maintenance regime

Treatment in patients with ulcerative colitis should be stopped if no benefit is seen after 10 weeks.
Patients with crohns disease who have had an inadequate response should get an extra dose at week 10. Treatment in patients with crohns disease should be stopped if no benefit is seen after 14 weeks
Maintenance infusions are then given at a 300mg dose every 8 weeks.
Managing symptom relapse
Ensure symptoms are due to active disease by performing faecal calprotectin or other investigations such as endoscopy, MRI, CT or VCE.
The dose interval can be decreased to 4-6 weekly, the dose cannot be increased.

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

Blood monitoring requirements

Patients will have blood tests for U&Es, LFTs, CRP, FBC and ESR before each infusion, no longer than 4 days prior for induction doses and 7 days prior for maintenance doses.

For outpatients, if abnormal these blood tests must be reviewed by the IBD CNS (or Team D doctor) before the infusion can be commenced.

For patients in the childrens clinic, these blood tests must be reviewed by the nurse in charge, if they have any concerns they will discuss this with either the IBD CNS, Team D doctor or paediatrician.

- All patients to be asked before each infusion if they have any signs of active infection, if they do they must be discussed with IBD CNS or Team D doctor before the infusion can be commenced
- Full set of observations to be taken, any concerns to discuss with IBD CNS or Team D doctor before the infusion can be commenced (in particular any pyrexia)
- Female patients pre or peri menopause to have pregnancy test before each infusion, if positive IBD CNS to be informed

Clinic staff to complete form A and file in patient notes for each infusion, to be printed from eZ notes, or biological daycase checklist.

Pregnancy and Breastfeeding

There is no adequate data on the use of Vedolizumab in pregnancy and therefore women should be advised to use contraception during treatment and for 18 weeks after treatment finishes. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Vedolizumab is to be used during pregnancy only if the benefits clearly outweigh any potential risk to both the mother and foetus. Patients should be advised that the potential effects are unknown.

Vedolizumab has been detected human milk. The effect of Vedolizumab on infants is unknown. The use of vedolizumab in lactating women should take into account the benefit of therapy to the mother and potential risks to the infant.

Reconstitution and administration of Vedolizumab

How to reconstitute vedolizumab

Add 4.8ml of sterile 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.

How to administer Vedolizumab

Administer via I.V infusion over 30 minutes, patient to stay for an observation period following infusion.

Timing of observation period as per table above.

Storage

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