NHS
Fylde and Wyre
Clinical Commissioning Group

Vedolizumab (Entyvio ®▼)
for Crohn's Disease

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed **not** to fund Vedolizumab for Crohn's Disease.

This is an interim policy recommendation and will be reviewed following the publication of the NICE single technology appraisal of vedolizumab in Crohn's disease. The anticipated date of publication is May 2015.

This medicine is classified as BLACK for this indication

Summary of supporting evidence:

There are insufficient data to justify the greater acquisition costs of vedolizumab compared to infliximab and adalimumab which are both NICE approved for the treatment of Crohn's disease.

- GEMINI II study reported that significantly more patients with moderate to severely active Crohn's disease treated with vedolizumab, an α4β7 integrin antibody, were in clinical remission (CDAI-score of ≤ 150) at week 6 than those given placebo, but there was no significant difference between groups in the proportion with a CDAI-100 enhanced clinical response. Patients treated with vedolizumab were more likely to be in clinical remission at week 52 but this maintenance trial population included both the double blind induction phase and open label induction phase patients (cohorts 1 and 2 respectively), which may overestimate the true effect of vedolizumab due to the potential for selection bias.
- In the induction phase of GEMINI II, although the primary efficacy end-point (proportion of patients who achieved clinical remission at week 6) was met, the gain over placebo was a modest 7.7% (NNT = 13) at week 6 and lower than expected (21%) due to a high placebo response rate.
- In the supporting induction study, GEMINI III, there was no statistically significant difference between vedolizumab and placebo for the primary end-point of clinical remission in the TNF alpha inhibitor failure population.
- For the maintenance phase of GEMINI II, the primary end-point of clinical remission was statistically significant in favour of vedolizumab compared with placebo. Two out of the three secondary endpoints (CDAI-100 response and corticosteroid-free clinical remission) at week 52 were also statistically significant in favour of vedolizumab, but durable clinical remission was not.
- There is extensive clinical experience with TNF alpha inhibitors in Crohn's disease and the side effect profile for vedolizumab is less well established than for TNF alpha inhibitors.

For further details around the evidence, cost effectiveness and for an explanation of the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/

Policy date: February 2015
Review date: February 2018