Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Drug Name: Vedolizumab for Ulcerative Colitis

Brand Name: Entyvio® 300 mg

Form: Powder for concentrate for solution for infusion

Administration Route: IV Infusion

Dose: 300mg at zero, two and six weeks and then every eight weeks* thereafter.

Licensed Indication: Treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF-α) antagonist. (http://www.medicines.ie/medicine/16097/SPC/Entyvio+300+mg+powder+for+concentrate+for+solution+for+infusion/)

Reimbursed Indication: As per licence.

Reimbursement Mechanism: Hospital

Ex-manufacturer price: €2,347 (ex VAT)

Alternative price in place: Yes commercial in confidence discount in place. Please contact the company (Takeda) for pricing information.

Cost-effectiveness: Not found to be cost effective at the original price submitted. Please see NCPE website for summary report (http://www.ncpe.ie/wp-content/uploads/2014/10/Summary-ulcerative-colitis.pdf)

Comparator drugs for ulcerative colitis: corticosteroids, infliximab, adalimumab, golimumab.

Other Information:

- This medicine is under additional monitoring. This means that it is being monitored even more intensively than other medicines. All suspected adverse events should be reported to the Health Products Regulatory Agency.
- The main clinical trial[1] (GEMINI 1) of vedolizumab demonstrated a consistent benefit over placebo albeit somewhat lower in patients who had experienced TNF-α antagonist failure compared with patients who were TNF-α antagonist naïve. Comparative efficacy data with TNF-α antagonist therapy was lacking and indirect comparisons were limited by critical differences in clinical trial design.

[1] GEMINI 1 study was a phase 3, randomised, placebo-controlled, blinded study evaluating the efficacy and safety of vedolizumab as induction and maintenance treatments in the licensed population (n=374). doi: 10.1056/NEJMoa1215734

- Continued therapy for patients with ulcerative colitis should be carefully reconsidered if no evidence of therapeutic benefit is observed by Week 10. Therapeutic benefit is defined as reduction in complete Mayo score of ≥ 3 points and ≥ 30% from baseline with an accompanying decrease in rectal bleeding subscore of ≥ 1 point or absolute rectal bleeding subscore of ≤ 1 point.

*There was no difference in clinical trial results between the 4 weekly administration and 8 weekly administration for the maintenance phase however there is a significant increase in cost.