### HMMC Recommendation:

**Vedolizumab is the commissioning responsibility of CCGs.**

**NOT RECOMMENDED FOR PRESCRIBING IN PRIMARY CARE.**

**RECOMMENDED FOR USE IN SECONDARY CARE. PLACE IN PATHWAY AGREED WITH LOCAL SPECIALISTS:**

Vedolizumab is commissioned at the following positions in the Crohn’s disease treatment pathway:

- **a. Adult patient**
- **b. Moderate to severely active Crohn’s disease where disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine or where these treatments are not tolerated or there are clinical contraindications to such therapies.**
- **c. Active Crohn’s disease equating to an HBI \( \geq 8 \) and confirmed with endoscopy/radiological evidence and faecal calprotectin**

**AND**

- **d. Where one of the following applies:**
  - I. After disease has failed to respond to at least one TNF\(\alpha\) antagonist (primary or secondary failure) and for secondary failure, where dose escalation of TNF\(\alpha\) antagonist has failed to recapture disease response OR
  - II. Where TNF\(\alpha\) antagonist intolerance has led to discontinuation of both adalimumab and infliximab treatment OR
  - III. Where TNF\(\alpha\) antagonist is clinically contraindicated (both adalimumab and infliximab)

- **e. In line with discontinuation criteria stated in NICE TA352, and in line with SPC, response to vedolizumab will be assessed at week 10. Patients who have not shown a response may receive a further dose at week 10. Therapy will be continued every eight weeks from week 14 in responding patients only. Treatment must not be continued if there is no evidence of therapeutic benefit by Week 14. Response is defined in the following manner:**
  - i. **a decrease in HBI score of \( \geq 2 \) points at week 14.**
  - f. **At 12 months, vedolizumab treatment is to be reviewed and a trial without treatment should be considered for patients in complete clinical remission (HBI \( \leq 4 \)).**

In line with NICE TA187, the current Hertfordshire routine commissioning pathway for biologics in Crohn’s disease recommends prescribing the least costly biologic that is clinically appropriate as the first choice treatment.

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### Table: NICE TAG 352 – Vedolizumab for treating moderately to severely active Crohn’s disease after prior therapy, August 2015

<table>
<thead>
<tr>
<th>Name: generic (trade)</th>
<th>What it is</th>
<th>Indication</th>
<th>Date decision last revised</th>
<th>Decision status</th>
<th>NICE / SMC Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vedolizumab (Entyvio (^\circledast))</td>
<td>Humanized monoclonal antibody that binds specifically to ( \alpha_4 \beta_7 ) integrin</td>
<td>Treatment of adults with moderate to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF(\alpha)) antagonist.</td>
<td>December 2015</td>
<td>Final</td>
<td>NICE TA 352—recommended SMC – accepted for use</td>
</tr>
</tbody>
</table>
Taking into account drug and activity costs, vedolizumab is usually significantly more costly than the subcutaneous adalimumab, Remicade® and the two infliximab biosimilar treatment options in most patient groups (using local prices and national PAS schemes, assuming average patient weight and including VAT and infusion costs where appropriate).

The position of vedolizumab in the biologics pathway for Crohn’s disease will be reviewed on specialist request when further clinical experience is available, and/or when evidence of comparative efficacy and cost effectiveness is published.

NICE Recommendation:
1.1 Vedolizumab is recommended as an option for treating moderately to severely active Crohn’s disease only if:
   - a tumour necrosis factor-alpha inhibitor has failed (that is, the disease has responded inadequately or has lost response to treatment) or
   - a tumour necrosis factor-alpha inhibitor cannot be tolerated or is contraindicated.

Vedolizumab is recommended only if the company provides it with the discount agreed in the patient access scheme.

1.2 Vedolizumab should be given as a planned course of treatment until it stops working or surgery is needed, or until 12 months after the start of treatment, whichever is shorter. At 12 months, people should be reassessed to determine whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to decide whether continued treatment is justified.

Reference: NICE TAG 352 – Vedolizumab for treating moderately to severely active Crohn’s disease after prior therapy
https://www.nice.org.uk/guidance/ta352