East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG, Surrey Heath CCG, Crawley CCG, Horsham & Mid-Sussex CCG

NICE Technology Appraisal Briefing Paper for Prescribing Clinical Network: November 2015

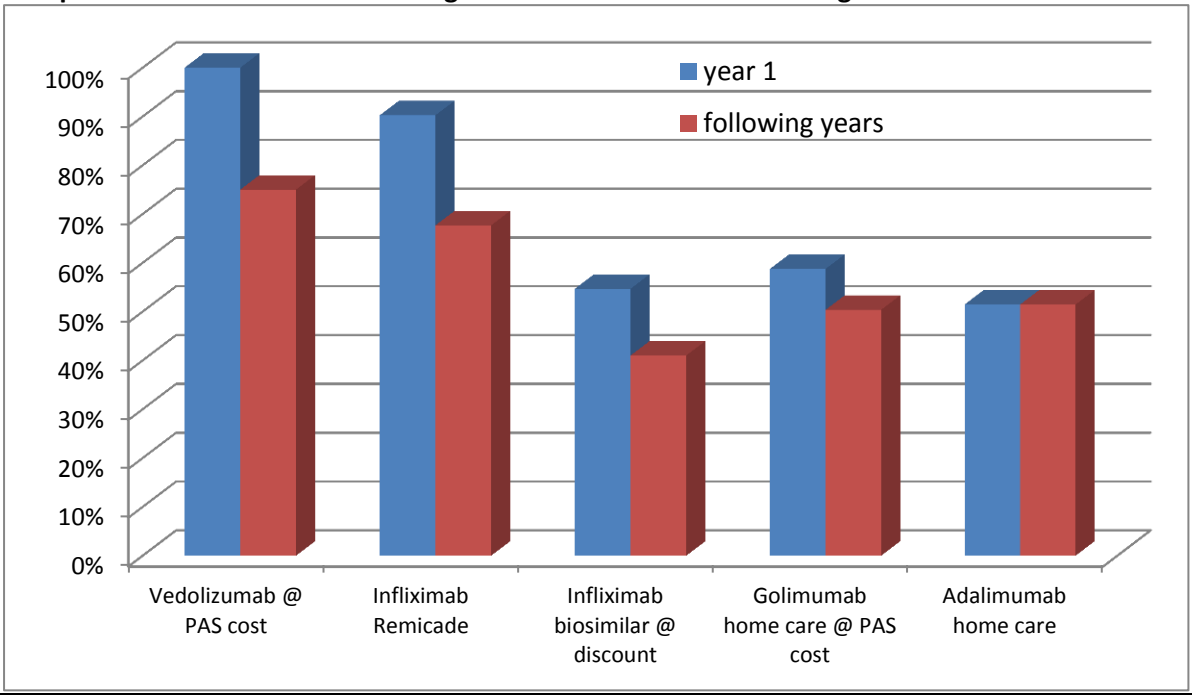
NICE TA Guidance	Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [TA352]
Date of issue	August 2015
Available at	http://www.nice.org.uk/guidance/ta352
Medicine details	
Name, brand name and manufacturer	Vedolizumab (Entyvio, Takeda UK) is a humanised IgG1 monoclonal antibody derived from a newly engineered cell line. It is targeted against α4β7 integrin, which is expressed on certain white blood cells. α4β7 integrin is responsible for recruiting these cells to inflamed bowel tissue. It is administered by intravenous infusion.
Licensed indication, formulation and usual dosage	Vedolizumab has a marketing authorisation in the UK for 'the treatment of adult patients with moderately 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 antagonist'. The summary of product characteristics states that the recommended dosage of vedolizumab for treating Crohn's disease is 300 mg at 0, 2 and 6 weeks, then every 8 weeks thereafter. It further notes that people who have not shown a response may benefit from a dose at week 10. If no evidence of therapeutic benefit is seen by week 14, vedolizumab should not be continued.
Disease and potential patient group	
Brief description of disease	Crohn's disease is a long-term condition that causes inflammation of the lining of the digestive system. Inflammation can affect any part of the digestive system, from the mouth to the back passage, but most commonly occurs in the last section of the small intestine (ileum) or the large intestine (colon). Common symptoms can include: • diarrhoea • abdominal pain • fatigue (extreme tiredness) • unintended weight loss • blood and mucus in faeces (stools)
Potential patient numbers per 100,000	NICE estimates 7,340 people in the prevalent population and around 400 people in the incident population in England may be eligible for treatment with vedolizumab for Crohn's disease each year. This equates to 14 people per 100,000 in the prevalent population and 1 per 100,000 in the incident population. Local clinicians (Gastroenterology Network October 2015, hosted at SD CCG) said that initial experience with vedolizumab had not been very positive and expected numbers for treatment would be low.

SUMMARY

Guidance
From Section 1 of NICE TA. 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. 1.3 People whose treatment with vedolizumab is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.
Cost implications
Cost: vedolizumab, net price 300-mg vial = £2050 (Accessed BNF online Oct 2015) **Annual cost per patient:** At list price: Year 1 8 injections £16400 Year 2 6 injections £12300 NB need to add cost of appointment for infusion service (variable between Trusts) **Availability of PAS and details (if appropriate):** The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of vedolizumab. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS. Any enquiries from NHS organisations about the patient access scheme should be directed to Ross.Selby@takeda.com. **Availability of homecare service (if appropriate):** N/A Infusion administration

Alternative treatments and cost per patient per year

Comparative costs of available biologics in Crohn's Disease - including PAS discounts



Impact to patients

NICE concluded that a further drug treatment that improves symptoms or brings the disease into remission would be highly valued by patients.

Impact to primary care

None

Impact to secondary care

Availability of an additional treatment for people whose treatment options are limited, such as those whose disease has either failed to respond to, or lost response to TNF-alpha inhibitors, or for whom they are contraindicated.

Impact to CCGs

Cost pressure – CCG funded PbRe drug

Implementation

- Revision of Crohn's disease pathway, (attached)
- Blueteq forms developed (attached)

Recommendation to PCN

Adopt revised Crohn's disease pathway and Bueteq forms for CCG funding as PbRe

Traffic light status: **Red**

Additional comments: