NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Costing report:
Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy (TA352)

Published: August 2015

Summary

Vedolizumab is recommended as an option for treating moderately to severely active Crohn's disease only if:

- a tumour necrosis factor (TNF)-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or
- a TNF-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.

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.

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.

This statement is supported by a local costing template, due to the list price of vedolizumab having a discount which is commercial in confidence. Once the cost of the drug is obtained from the manufacturer, the user needs to input this cost into the light blue blank cells on the Unit costs worksheet in the local costing template.

This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts.

1 Introduction

1.1 The guidance states that:

- Vedolizumab is recommended as an option for treating moderately to severely active Crohn's disease if:
  - a tumour necrosis factor (TNF)-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or
  - a TNF-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.

- 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.
- 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.

1.2 The Department of Health and Takeda have agreed that vedolizumab will be available to the NHS with a patient access scheme which makes vedolizumab available with a discount. The size of the discount is commercial in confidence. It is the

responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to **Ross.Selby@takeda.com**.

1.3 This report is supported by a costing template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance.

2 Background

2.1 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.

2.2 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.

2.3 The number of people eligible for treatment in England is estimated in table 1.

Table 1 Estimated number of people eligible and uptake for treatment in England

Population	Proportion	Number of people in the prevalent population	Number of people in the incident population
Adult population of England		41,766,418	41,766,418
Prevalence of Crohn's disease	0.20%	83,533	
Incidence of Crohn's disease	0.01%		4,500
Adults with moderate or severe Crohn's disease	40%	33,413	1,800
People in whom conventional treatment is ineffective or where they cannot tolerate it	50%	16,707	900
Adults with moderate or severe Crohn's disease who have infliximab or adalimumab	95%	15,871	855
Adults who have infliximab or adalimumab treatment that is ineffective	41%	6,508	351
Adults who cannot tolerate infliximab or adalimumab, or for whom this type of treatment is contraindicated	5%	835	45
Total number of people eligible for treatment with vedolizumab		7,343	396
Estimated total uptake	80%	5,874	317

2.4 It is assumed the prevalent population will treated by year 5 and thereafter the incident population will require treatment. An

estimated profile of the uptake is set out in appendix A, with detailed working contained within the costing template.

3 Resource impact

3.1 The guidance might have resource implications at a local level. Therefore, we encourage organisations to evaluate their own practices against the recommendations in the NICE guidance and assess costs using the local costing template.

3.2 The local costing template contains two assumptions input sheets and two costing template sheets, this is to allow the user to input separate assumptions for the prevalent and incident populations.

3.3 The following assumptions have been made in the local costing template:

- The population eligible for treatment with vedolizumab has been calculated based on the number of people with moderate and severe Crohn's disease in whom a tumour necrosis factor-alpha inhibitor is ineffective, or in whom it is contraindicated or not tolerated.
- It is assumed that currently no one in the eligible population takes vedolizumab.
- In future the proportion of people in the eligible population who will take vedolizumab in the prevalent population is estimated to be 80% (5,874) by the end of year 5. In the incident population it is also estimated to be 80% (317). These estimates should be changed to reflect local estimates.
- Detailed uptake estimates for the prevalent population over years 1-5 are provided in the local costing template 'future uptake' worksheet.
- 53% are expected to stop treatment after 14 weeks as a result of vedolizumab being ineffective; this proportion was taken from the GEMINI II study.

- 47% are expected to be treated for 52 weeks; this proportion was taken from the GEMINI II study.
- Remission rates are estimated to be 51.5% based on results from the GEMINI II study, in the population who had not had a TNF-alpha inhibitor before, and the same proportion for in the population in whom TNF-alpha inhibitors had failed taken from the GEMINI LTS study.
- For the 49.5% who did not experience remission it is estimated that they will continue with vedolizumab treatment for a further 2 years.
- Units cost are detailed in the costing template

4 Savings and Benefits

4.1 Vedolizumab provides a further option for people with Crohn's disease when existing treatments are ineffective or unsuitable.

4.2 A small number of adverse events can be reduced by using vedolizumab these include serious infections, lymphoma, acute hypersensitivity reactions and melanoma skin cancer.

4.3 Vedolizumab can lead to remission when used to treat Crohn's disease in the eligible population.

About this costing statement

This costing statement accompanies the NICE technology appraisal guidance on vedolizumab for treating moderately to severely active Crohn's disease after prior therapy and should be read in conjunction with it. See terms and conditions on the NICE website.

This statement is written in the following context

This statement represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The statement is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the statement are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.

Appendix A

	Year								
Population	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**2023/24**
Prevalent population	**441**	**1,980**	**2,706**	**2,700**	**1,896**	**1,240**	**509**	**218**	**-**
Incident population	**-**	**-**	**-**	**-**	**-**	**79**	**356**	**513**	**630**
Total people treated	**441**	**1,980**	**2,706**	**2,700**	**1,896**	**1,319**	**865**	**731**	**630**