NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Vedolizumab for treating moderately to severely active ulcerative colitis [ID691]

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name*:* [redacted]

Name of your organisation: ***The Newcastle Upon Tyne Hospitals NHS Foundation Trust, RVI, Newcastle Upon Tyne***

Are you (tick all that apply):

☑ a specialist in the treatment of people with the condition for which NICE is considering this technology?

a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?

- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?

- other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

Ulcerative colitis is currently treated with a combination of Mesalazine based oral and topical products, short courses of steroids (up to 12 weeks) and immunosuppression with Azathioprine or 6-MP if required. More severe disease may also be treated with biological agents such as anti TNF antibodies, Infliximab and Adalimumab or patients may choose to go for surgery.

Patients whose disease is resistant to treatment with Mesalazine and immunosuppression, such as Azathioprine, are the patients whose treatment is most controversial as the anti TNF antibodies such as Infliximab are licensed for this but NICE approval has not been granted and long term funding within the health service is difficult to obtain.

The fact that the management of the more severe end of the ulcerative colitis disease is controversial, actually indicates the need for further treatment options. Vedolizumab certainly appears to offer an attractive new treatment technology in this disease setting.

Vedolizumab treatment will be used exclusively in secondary care, be delivered by IV infusions and used within licensed indications.

The use of Vedolizumab in ulcerative colitis is not yet incorporated into our guidelines but will be when they are revised over the next few years.

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The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Vedolizumab uses a novel mechanism of action and therefore adds a useful treatment option for selected patients with ulcerative colitis.

Vedolizumab is administered by IV infusion every 4 – 8 weeks and this is similar to Infliximab administration which is widely used for Crohn's disease.

The advantage of Vedolizumab is in the potential to be specific to the gut and therefore reduce the level of systemic immunosuppression. The disadvantage of Vedolizumab is the relative novelty with the inevitable implication that there is much less clinical experience available regarding safety and possible adverse drug reactions.

The GEMINI trials using Vedolizumab have been designed to predict long term outcome and they appear to show that serious adverse drug reactions are quite rare and certainly would be consistent with the hypothesis that anti integrin drugs, by being gut specific, may turn out to be safer than anti TNF antibodies. To really identify the relative safety of future trials we will need to compare these two types of treatment.

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Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

As yet there are no additional sources of evidence giving further information about Vedolizumab beyond the published papers Feagan et al "Vedolizumab as Induction and Maintenance Therapy for Ulcerative Colitis" NEJM 2013, volume 369, 669-2710

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

The resources required to adopt Vedolizumab as technology in this setting are very similar to those that are already available for the current use of Infliximab in Crohn's disease there would really not be any additional training issues involved, although the cost of delivering the drug does require a hospital visit and is therefore additional to the drug cost itself.

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Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

No