Royal College of Nursing

National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

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

Appraisal consultation document

Royal College of Nursing

Introduction

The Royal College of Nursing (RCN) was invited to review the Appraisal Consultation Document (ACD) for **Vedolizumab for treating moderately to severely active ulcerative colitis [ID691]**

Nurses caring for people with active ulcerative colitis reviewed the documents on behalf of the RCN.

Appraisal Consultation Document – RCN Response

The Royal College of Nursing welcomes the opportunity to review this document. The RCN's response to the questions on which comments were requested is set out below:

Has the relevant evidence has been taken into account?

NICE have recommended the use of Vedolizumab within its licensed indication which is positive in terms of care for UC patients. However we are concerned that the current recommendation implies we can use Vedolizumab first line, but will not be allowed for those who have failed anti-TNF, yet we have evidence for Vedolizumab in this setting (in Gemini 1) but no evidence for anti-TNF in Vedolizumab failures.

We feel clinicians will be hesitant to use Vedolizumab first line until there is real time clinical experience and evidence. This means we will use anti-TNF first but then cannot use

Vedolizumab if they fail. We have no studies to support using antiTNF following failure of Vedoluzima.

Therefore we are concerned that in clinical practice the recommendations within the ACD are not workable as most clinicians will continue to use anti-TNF first due to safety/experience issues. Surgery will then be the only available option, at least until there is evidence of using anti TNF after Vedolizumab failure.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

We would ask that the summaries of the clinical and cost effectiveness of this appraisal be aligned to the clinical pathway followed by patients with Ulcerative Colitis. The preliminary views on resource impact and implications should be in line with established standard clinical practice.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

We think that the committee should re think their wording in regards to these particular clauses

1.1 would benefit from the removal of;

'The person has not had a TNF-alpha inhibitor' **or**

1.2 Proposed wording:

Vedolizumab is not endorsed for treating moderately to severely active ulcerative colitis in people who have not had a response to, or have lost response to, treatment with a TNF-alpha inhibitor, due to poorer response rates but could be considered with careful pre-treatment counselling and early review.

There is evidence for vedolizumab after anti TNF failure, in one study of 895 patients, 32% of the ITT population had prior anti-TNFα failure. Maintenance therapy with VDZ every 8 weeks was significantly more effective than placebo in achieving clinical remission (37%), durable clinical response (46.5%) and remission, mucosal healing, and corticosteroid-free remission in UC patients with a high rate of prior anti-TNF failure (Feagan et al 2012).

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Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

Are there any equality-related issues that need special consideration that are not covered in the appraisal consultation document?

We are not aware of any specific issue at this stage. We would ask that any guidance issued should show that an equality impact analysis has been considered and that the guidance demonstrates an understanding of issues relating to all the protected characteristics where appropriate.

While we broadly welcome these recommendations as access to biologics for patients with ulcerative colitis is important. However, we have concerns that it will effectively be a first line therapy although TNF alpha inhibitors have been commercially available for many years and there is significant clinical experience with these. Those patients who have previously received TNF alpha inhibitors as rescue therapy, as part of standard management or within the context of a clinical trial will be precluded from receiving Vedolizumab, which appears unfair and illogical in terms of current practice.

Reference:

Feagan B, Rutgeerts P, Sands B, Sandborn W, Colombel J, Hanauer S, Van Assche G, Axler J, Kim H, Danese S, Fox I, Milch C, Sankoh S, Wyant T, Xu J, Parikh A, (2012) Vedolizumab Maintenance Therapy for Ulcerative Colitis: Results of GEMINI I, a Randomized, Placebo-Controlled, Double-Blind, Multicenter Phase 3 Trial Volume 107, supplement 1, October 2012 American Journal of Gastroenterology, American College of Gastroenterology. www.amjgastro.com