Vedolizumab for treating moderately to severely active Ulcerative Colitis (UC)

NICE Appraisal Consultation Document, December 2014

Response on behalf of the UK Clinical Pharmacy Association (UKCPA)

We welcome the proposed recommendation to use vedolizumab in UC particularly as the drug has of a different mode of action in comparison to the available biologic treatment for UC.
We can particularly see the use of vedolizumab in the elderly patient with a higher risk of infection [1].

However we are concerned that the guidance excludes patients previously exposed to anti-TNFs.

Current practice uses infliximab (IFX) as rescue therapy in acute sever colitis but has an overall efficacy rate of about 40-50% only. Once failed on anti-TNFs recapturing remission with a second anti-TNF only works in a minority of patients.
We feel that the current evidence support the use of vedolizumab in patients previously exposed to anti-TNFs even if the numbers in the trials were not powered enough to show significance (Gemini I)[2]. From the trial data it is clear that vedolizumab is not suitable to treat acute severe colitis and IFX needs to be use as a rescue therapy due to its faster response. It is likely that patients who loose response to anti-TNFs would then respond to vedolizumab as a maintenance treatment avoiding life changing surgery.
This would keep it in line with the current draft guidance of anti-TNFs in moderate to severe UC which potentially allows for switching between anti-TNFs although it would make more sense to change class once failed on anti-TNFs.
In addition we are currently able to measure antibodies to anti-TNFs to guide therapy decisions which makes for a more individualised optimisation of therapy.
Vedolizumab would be a valuable tool in maintaining remission in patients producing antibodies against anti-TNFs avoiding surgery and the following consequences of living without colon (see evidence by Crohn's and Colitis UK and their patients' reports).

It is currently not clear if the anti-TNF failure group is different to patients that respond but this should not be a reason to exclude access to an effective treatment for these patients. We are currently in the process of trying to stratify patients according to disease picture and response to treatment, but so far the evidence has been elusive. There are patient reports of effectiveness of vedolizumab after anti-TNF failure with life changing results to their condition (see evidence by Crohn's and Colitis UK and their patients' reports).

We have serious concerns that these patients would be denied an effective treatment based on unclear evidence. There is a cohort of patients who had IFX in the past and having active disease would benefit from this novel therapeutic class as pulse treatment produces a higher risk of antibody formation.

We would like to urge the committee to review the decision to exclude patients previously exposed to anti-TNFs from vedolizumab therapy as this may be the only medical alternative to surgery with its life changing impact on the patient.

References:

1. Cottone K et al. Age is a risk factor for severe infections and mortality in patient given anti-TNF therapy for IBD. Clinical Gastroenrerol Hepatol.2011;9:30-35
2. Feagan BG, Rutgeerts P, Sands BE, Hanauer S, Colombel JF, Sandborn WJ, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2013;369(8):699-710.