Healthcare Improvement Scotland

NICE Health Technology Appraisal - Assessment Report On Infliximab, Adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA14 and TA262)	
TO: NICE 05 August 2014	FROM: Healthcare Improvement Scotland

1. It is important that the Executive Summary is clear and easily understood when read on its own. On page 17 it refers to patients classified as responders at the end of the induction phase and also patients classified as being in remission at the end of the induction phase. The Executive Summary needs to state clearly what is meant by responders versus those being in remission at the end of the induction phase.

2. On page 17, what is meant by the sentence "For patients classified as responders at the end of the induction phase, treatment effects were not statistically significant".

3. It would also be useful in the Executive Summary to explain what happened to the other treatment the patients were receiving before being randomized to the biological therapy of placebo. When patients come in to these studies, they are classified as failure or conventional therapy. Presumably, the conventional therapy was largely steroids and Azathioprine. Was the conventional therapy discontinued as it was not working, or was it continued in part or whole?

4. In the Executive Summary and several other points in the document, the term "dominance" is used. For example, in the sentence "ruled out due to dominance". What does this mean? It sounds like some special epidemiological or economic analysis term. It is important that those words are not used without clear explanation as to their meaning.

5. On page 28, it states "Treatment using immune-modulatory therapy will be started at the same time as oral corticosteroids". I do not think this is the case. Patients with ulcerative colitis will often receive an initial course of steroids and sometimes one or two further courses of steroids before being commenced on maintenance Azathioprine. The two are not necessarily started together.

6. In the economic analysis, it seems to be assumed that biologic treatment will be life-long but evidence in Crohn's disease suggests patients may be successfully maintained in remission after a period of biological therapy and on withdrawal. There is clearly no evidence regarding this in ulcerative colitis, which makes predictions of long-term costs inaccurate.

5. I think the prevalence of pouchitis following IPAA is under-estimated – they state 5% but some data suggests up to 50%.

6. There will be a group of patients who may not consider surgery acceptable. The document does not offer solution for these patients.

7. The document provides useful information on the costs of the biologics versus other treatments but does not seem to come to any conclusion as to whether the biological therapy should be approved for use or not. In order to come to a conclusion on that, it would be helpful to include a comparison of the cost-effectiveness of the biological therapy in ulcerative colitis contained in this document with that already calculated for its use in Crohn's disease. This would help see the cost-effectiveness in perspective.

Comment provided to Healthcare Improvement Scotland by;

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