

30 November 2009.

Dear Dr Longson,

Re: Health Technology Appraisal: Infliximab (review) and adalimumab for the treatment of Crohn's disease (including a review of the technology appraisal guidance 40).

Many thanks for giving us the opportunity to respond to this new appraisal consultation document. Taking your questions in turn:

1. Do you consider that all of the relevant evidence has been taken into account?

Yes

2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?

Yes.

3. Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

Not without modification.

There are two main problems and two minor ones:

- (i) The statements in 1.1 and 1.3 regarding stopping treatment at 12 months are not workable as they currently stand and we are puzzled that the qualifications of these statements that were in the previous version of the appraisal have now been removed. The evidence base (GETAID study) only supports the cessation of treatment in patients who (a) have not required corticosteroids in the previous 6 months and (b) have no evidence of ongoing mucosal ulceration on colonoscopy (including ileoscopy).

To address this we would strongly recommend reinsertion in both 1.1 and 1.3, in each case after "whichever is shorter" the following sentence: "The person's disease should then be reassessed.

Maintenance treatment should only then be continued if there is clear evidence of ongoing active disease, as determined by clinical

symptoms and/or need for corticosteroids within the previous 6 months and investigations, including endoscopy if necessary”.

(ii) An additional statement should be inserted:

“In persons who have had a good initial response to infliximab but have subsequently become non-responsive or intolerant a trial of adalimumab is reasonable providing this is discontinued if there has been no response within 8 weeks”.

(iii) 1.5 – “one or more of” should be inserted before “weight loss and sometimes fever ...”. Patients should not all be expected to have lost weight before becoming eligible for anti-TNF therapy.

(iv) As we stated previously: The CDAI is cumbersome for use in clinical practice, requiring a one week patient diary and laboratory tests – we would recommend an insert (in italics) in para 1.5 last sentence: “This clinical definition normally but not exclusively corresponds to a Crohn’s Disease Activity Index (CDAI) score of 300 or more (*or to an equivalent Harvey-Bradshaw Score of 9 or more*).

We are pleased to see that access to both infliximab and adalimumab for adults with severe Crohn’s disease will be equivalent.

4. Are there any equality related issues that may need special consideration?

No

We do hope that these issues get resolved quickly as the IBD community, patients and clinicians alike, are becoming increasingly anxious about the current geographical variations in access to treatment that are resulting from lack of up-to-date guidance. We remain very grateful to the NICE Committee members for the attention that they have paid to the concerns about the previous inappropriate use of low relapse rates from the Silverstein cohort in economic modelling and to the scientific and medical concerns about the poor efficacy of episodic anti-TNF treatment.

Many thanks,

Yours sincerely,


(on behalf of Royal College of Physicians)


(on behalf of British Society of Gastroenterology)