NACC Response to the Draft Appraisal Document – September 2009

Summary

NACC very much welcomes the recommendation of the Appraisal Committee that patients who meet the eligibility criteria should have access to maintenance treatment with an antiTNF therapy.

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

The various assessment reports have indicated that the evidence base for assessment of these technologies is incomplete. We are not aware of any additional relevant published evidence that has not been considered.

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?

The summaries fairly reflect the reports and discussions of the committee that we have read or heard. The limitations of the evidence make the judgements on cost-effectiveness particularly vulnerable to the assumptions applied to the modelling, but the overall interpretation seems reasonable.

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?

- We have some reservations about these and would like to see the following issues addressed in the recommendations:
- a) The criterion for use of infliximab which is expressed as 'intolerance to adalimumab' is too restrictive. We would wish to see some consideration given to patient preference and professional judgement about home-based therapy involving self-administration. Whilst home administration would we feel normally be the preferred choice of patients, there may be some who would find this difficult.

e.g "After full discussion between the doctor and patient, a decision is made that the patient is unable to manage home-based treatment

b) It is recognised that a proportion of patients who lose response to one anti-TNF may respond successfully to another. This possibility is not referred to in the recommendations. To avoid such cases being referred individually through PCT approval

procedures, we would like to see a specific statement in the FAD that switching from one antiTNF to another fro a trial period under such circumstances is approved.

As a more general point the recommendations appear to acknowledge that the cost assumptions used to produce the ICERs on which the committee based its recommendations might be affected by local procurement discounts (cf. para 3.6); however, the recommendations contain no reference to the possibility either that the treatment costs of an individual patient may differ substantially from the assumptions inherent in the FAD or that purchasing costs may change over the period to which the FAD will apply.

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

We believe strongly that all patients who meet the eligibility criteria in terms of severity of their Crohn's Disease should have access to anti-TNF therapy. Without the change we have proposed to the criteria for access to infliximab, we believe some patients may be denied access. If PCTs rigidly apply the restrictions as set out in the draft appraisal, then treatment would be restricted to adalimumab unless there is clinical intolerance. This may lead to some patients being effectively excluded from antiTNF therapy because they are considered by their health professionals to be unable to reliably sustain maintenance treatment in an unsupervised setting.

NACC 5th October 2009