From:

Sent: 21 August 2008 20:05

To:

Cc:

Subject: Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF-a Inhibitor

Importance: High

21 August 2008

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Dear

Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for the treatment of rheumatoid arthritis after failure of a previous TNF-α Inhibitor

Thank you for your letter of 1 August, lodging NRAS's appeal against the above Final Appraisal Determination (FAD).

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.
- Ground 2: The Institute has prepared a FAD which is perverse in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point is referred on to the Appeal Panel.

Initial View

You have raised two points of appeal, one under Ground 2 and one under Ground 3.

Your first appeal point is that the Institute has prepared guidance which is perverse in the light of the evidence submitted. This assertion appears to be based in part upon the findings of some research presented to a meeting of the European League

against Rheumatism in June of this year. However, it would seem that this is new data not before the Appraisal Committee at the time of its appraisal and, as such, inadmissible in evidence at this stage. You also refer to the availability of the drugs elsewhere in Europe and the USA, but those are not matters which the Appraisal Committee or the Appeal Panel can take into account. I am not therefore minded to allow this appeal point to continue, though please let me know if I have misunderstood the status of the new data or if you wish to elaborate on why you think the Appraisal Committee has been perverse in its approach to economic modelling.

Your second appeal point alleges that the Institute has breached Articles 1 and 2 of the European Convention on Human Rights and the Disability Discrimination Act. The articles you cite appear to be from the UN convention on the rights of people with disabilities and not from the ECHR. This convention is not part of the law of the United Kingdom. Nor do you specify the basis on which you consider the Institute to have breached the Disability Discrimination Act. My difficulty is that at present I cannot see why being sero-negative as opposed to sero-positive should be considered a disability. (I accept that having RA is or will usually lead to a disability, but cannot see how distinctions within the RA patient population, all of whom for the sake of argument are disabled, constitute discrimination on the grounds of disability.)

Further, sero-negative and sero-positive patients are not distinguished in the recommendation.

I am therefore minded to conclude that your second appeal point, as framed, is invalid.

Preliminary Conclusion

My initial view, therefore, is that neither of your appeal points are valid. I would, however, be happy to consider any further comments you may wish to make; any correspondence should be sent to the Institute within two weeks of the date of this letter.

[redacted]

[redacted]