From:

Sent: 21 August 2008 19:54

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 ARMA's appeal against the above Final Appraisal Determination (FAD). I have also seen the letters of support from Arthritis Care, British Society for Rheumatology and British Professionals in Rheumatology.

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. Since, however, I consider all your points of appeal to be valid, you may take it that they will all 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 may my final decision as to whether each appeal point is referred on to the Appeal Panel.

Initial View

You have raised three points of appeal (1, 2 and 3) all under Ground 2.

Your first appeal point is that the Appraisal Committee was perverse in failing to apply critical assessment of the BRAM model

and accepting the conclusions of this model to the exclusion of other analyses. You put forward three arguments in support of this point, a, b and c, all of which I consider to be valid.

Your second appeal point is that the Appraisal Committee was perverse in giving insufficient consideration to the alternatives for patients failing a first anti-TNF therapy. I consider this be largely outside the scope of the appraisal and am not therefore minded to allow this appeal point to continue.

Your third appeal point is that the Appraisal Committee was perverse in concluding that there were significant limitations in the evidence base for this appraisal. Apart from drawing attention to patient numbers, you have not really explained why and, unless you can provide further explanation, I am not minded to allow this appeal point to continue.

Preliminary Conclusion

My initial view, therefore, is that your appeal point 1 is valid. I presently consider appeal points 2 and 3 to be invalid, but would 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.

As I am minded to rule that at least one of your appeal points is valid, an appeal hearing will take place. The Institute will contact you to arrange this in due course.

Yours sincerely

Mark Taylor
Appeals Committee Chair
National Institute for Health and Clinical Excellence