From:

Sent: 21 August 2008 19:50

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 email of 1 August, lodging Abbott Laboratories Limited'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 may 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 under Ground 1 (paras 3.1 to 3.5 and 3.6 to 3.8) and one point of appeal under Ground 2 (paras 4.1 to 4.4).

Ground 1

1.1 Exclusion of cost offsets from the economic modelling

You argue that the Appraisal Committee failed to attach sufficient weight to the impact of joint replacement costs, costs of outpatient visits and inpatient stays on the estimates of the cost effectiveness of sequential TNF inhibitor use. I regard this point to fall more appropriately within Ground 2 than Ground 1 in that it is directed more towards perversity than procedural unfairness. If you would like to reformulate the point under Ground 2, I would be happy to consider it again.

1.2 Refusal to supply economic model in fully executable form

The Court of Appeal's decision in the Eisai –v- NICE case is currently under appeal to the House of Lords. Nevertheless, it seems to be me appropriate that the Appeal Panel should consider this point in case there are considerations applying to the release of the model in this case that were not present in the Eisai case. I therefore consider this point to be valid.

Ground 2

2 Data Inputs for HAQ Multipliers

I consider this point to be valid.

Preliminary Conclusion

My initial view, therefore, is that your appeal points 1.2 and 2 are valid. If you would like to reformulate appeal point 1.1 as a Ground 2 point, I would be pleased to consider it again. In addition, I 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 some of your appeal points are 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