From:

Sent: 21 August 2008 20:03

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

National Institute for Health and Clinical Excellence

Midcity Place
71 High Holborn
London
WC1V 6NA

Tel: 0845 003 7780
Fax: 0845 003 7784

Sent via email

www.nice.org.uk

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 the Royal College of Nursing'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. 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 two points of appeal under Ground 2 and two points of appeal under Ground 3.

Ground 2

Your first appeal point under Ground 2 is that the FAD is perverse in failing adequately to take into account the offset costs.

Your second appeal point is that the recommendations are arbitrary and perverse. I consider both these points to be valid.

Ground 3

Your first appeal point under Ground 3 is that the Institute has breached the Race Relations Act 1976 ("RRA"), the Disability Discrimination Act 1995 ("DDA") and the European Convention on Human Rights ("ECHR"). I am minded to refer your arguments in relation to the RRA to the Appeal Panel, but I am struggling to understand your argument under the DDA and ECHR. Under the DDA, could you explain which group of patients it is are being discriminated against on the grounds of their disability? At first sight all patients with RA are being treated alike. Under the ECHR Article 8 ECHR does not give any entitlement to particular medical treatment. If Article 8 is not engaged, Article 14 is not engaged. Article 14 only applies where another Article of the ECHR is engaged. I am not therefore minded to allow this argument to go forward, except as it relates to the RRA.

Your second appeal point under Ground 3 argues that the FAD has the effect of acting as an unlawful restriction on the prescription of these drugs contrary to the Transparency Directive. Since the Institute's Appeal Panel has consistently ruled that such arguments are bad as a matter of law, I am not minded to allow this point to continue.

Preliminary Conclusion

My initial view, therefore, is that both your appeal points under Ground 2 are valid points of appeal. I presently consider your first appeal point under Ground 3 to be partially valid and your second appeal point under Ground 3 to be invalid. 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 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