Dear [Name]

Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for the treatment of Ankylosing Spondylitis (AS)

Thank you for lodging Schering-Plough'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 at 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 guidance 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 under Ground 1 (1.1 and 1.2), two points of appeal under Ground 2 (2.1 and 2.2) and one point of appeal under Ground 3 (3.1).

Your appeal point 1.1 is that in failing adequately to consider evidence of the clinical effectiveness of Infliximab, the FAD is inconsistent with previous guidance for TNF-α inhibitors, with the Institute's published procedures and unfair.

To the extent that this point of appeal alleges inconsistency with previous guidance, I regard it to be invalid. The Appraisal Committee is obliged to conduct appraisals in accordance with the Institute's published procedures. The procedures do not, however, mandate consistency between appraisals, although it would be open to appellants to argue that an absence of consistency is perverse in light of the evidence submitted. If you would like to reformulate this aspect of your first appeal point as a Ground 2 argument, I would be happy to reconsider it.

You then go on to allege that the Committee failed to act in accordance with the Institute's Guide to the Methods of Technology Appraisal, in particular with paragraph 5.4.2.4 thereof. I understand your argument to be that the Committee has failed adequately to consider the clinical effectiveness of Infliximab on its own (as distinct from its consideration of the clinical effectiveness of Infliximab in comparison with Adalimumab and/or Etanercept).
If I have interpreted your argument correctly, I regard the point to be valid. I would be grateful if you could confirm that my interpretation of your appeal point is correct.

In making this argument, you go on to present what appears to be new data relating to cost effectiveness of Infliximab based on the parameters preferred by the Decision Support Unit and the Committee. Unfortunately, the Institute's appeal process is not designed or intended to constitute a re-hearing of the appraisal nor is the Appeal Panel able to consider new evidence relating to an appraisal. While I appreciate the work that you have undertaken to prepare these figures, the Appeal Panel will not be able to take this data into account in considering your appeal point.

At present, I am minded to consider your appeal point 1.2 (the Committee's failure to consider the effectiveness of Infliximab on the basis of an 8 week dosing schedule is inconsistent with the Institute's published procedures and unfair) to be invalid. You argue that the Committee's failure to consider the data in support of the 8 week dosing schedule and to assess the cost effectiveness of Infliximab in the relevant sub-group of patients is inconsistent with the scope for the appraisal. However, having read the final scope for the appraisal, I have not been able to ascertain where this inconsistency arises. I would be grateful if you would indicate with which part of the scope the FAD is inconsistent. I would then be happy to reconsider your appeal point.

You also argue that the Committee's alleged failure is inconsistent with the Institute's procedures. However you have provided no evidence in support of your argument, nor do you indicate which of the Institute's procedures have not been complied with. If you would like to substantiate this element of your argument, I would be happy to reconsider it.

I regard your appeal point 2.1 (the Committee's failure to assess the effectiveness of Infliximab on the basis of an 8 week dosing schedule is perverse in the light of the evidence submitted) to be valid. However, I note that the Institute is not obliged automatically to publish guidance that is
consistent with the recommendations of the Committee for Medicinal Products for Human Use.

I regard your appeal point 2.2 (the effect of the Committee's recommendation is to force those who can't self-inject Adalimumab or Etanercept to attend a clinic or rely on home delivery nurses, thereby increasing the cost of those drugs, which is perverse) to be valid.

Your appeal point 3.1 is that, in making a recommendation that reduces patient choice, the Committee has effectively discriminated against those with mental or physical disabilities that prevent them from self-injecting Adalimumab or Etanercept. You argue that this alleged discrimination is contrary to section 19(1)(b) of the Disability Discrimination Act 1995 ("the 1995 Act").

Firstly, I should note that I do not believe section 19(1)(b) of the 1995 Act to be relevant as the Institute is not itself providing services to patients. However, I acknowledge that section 21B of the 1995 Act obliges public authorities (including the Institute) not to discriminate against a disabled person in carrying out its functions and that section 49A imposes a general duty on public authorities (again including the Institute) to have due regard to, among other things, the need to eliminate unlawful discrimination and to promote equality of opportunity between disabled persons and other persons.

Having read your appeal point and paragraph 4.3.18 of the FAD, however, I do not understand the basis on which you contend that discrimination on the grounds of disability arises in this instance. Your argument appears to be that those patients who cannot self-inject Adalimumab or Etanercept as the result of a disability will have to obtain assistance in order to take their treatment and that, were those patients instead given access to Infliximab, any discrimination on the basis of that person's disability will be avoided. I note, however, that paragraph 4.3.18 of the FAD states that Infliximab is administered by intravenous infusion which 'can only be administered over a period of time in a medical environment.' My understanding is that if paragraph 4.3.18 is correct
and if your proposal were to be implemented, patients with a disability would require medical assistance to take their treatment whether they were given Adalimumab, Etanercept or Infliximab.

I would be grateful if you could either confirm that I have understood your appeal point correctly or, if I have not, provide me with further explanation of your argument.

**Preliminary Conclusion**

My initial view, therefore, is that appeal points 1.1 (in part and subject to clarification/confirmation), 2.1 and 2.2 are valid. I consider your appeal point 1.2 to be invalid, however, if you would like to provide additional evidence and clarification in support of it, I would be pleased to consider your arguments again. I would appreciate clarification of your appeal point 3.1. 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 three 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