Dear Sirs

Final Appraisal Determination: Belimumab for the treatment of systemic lupus erythematosus

Thank you for lodging your appeal against the above Final Appraisal Determination. As feels she would have a conflict of interest in participating in this appeal, I will be conducting the initial scrutiny.

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
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified 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 should be referred on to the Appeal Panel.

I can confirm that there will be an oral hearing of the appeal.

**Ground 2**

2.1-2.10. [The institute is premature in issuing its decision.] It should ensure that it has all relevant data necessary before it makes a final decision and ... by making a decision at this point it will leave some lupus patients who have the most difficult manifestations of the illness paying a very heavy physical price, without effective treatment.

I am taking these paragraphs as one appeal point, summarised as above, and I agree that it is a valid ground two appeal point. I expect the appeal panel will also consider your paragraphs 5.1-5.3 when considering this point.

2.11 LUPUS UK also consider that the comments which the FAD has made on Rituximab have caused considerable confusion and increased the uncertainty about treatment of lupus patients. A direct comparison with this drug cannot be made as is frequently referred to (paras...........) because the measured outcomes are different from the BLISS trials.

I am taking this as a second valid ground two appeal point, that Rituximab could not reasonably be used as a comparator in this appraisal and/or that the conclusions drawn from that comparison are unreasonable.

**Ground 3**

**Paragraphs 3.1-3.3**

As you acknowledge, Rituximab was outside the scope of this appraisal, and while any "postcode lottery" for Rituximab may be undesirable it is difficult to see how this could be addressed by the appraisal committee in an STA for a different treatment. I would not presently be minded to refer this point to the appeal panel.

**General**

I do not think you intended me to consider paragraphs 4.1-4.2 as appeal points as such, and I have drawn the appeal panel's attention to your paragraphs 5.1-5.3 under ground 2 above.
Conclusion

As I agree some of your appeal points are valid I will pass them to an appeal panel for consideration. If you wish to comment on my approach to your paragraphs 3.1-3.3 (or indeed 2.1-2.11), you should do so by 1 June 2012, whereupon I will make my final scrutiny decision.

Yours sincerely

Chair
National Institute for Health and Clinical Excellence