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. We consider that one of the main flaws to the guidance is the prominence given in the
decision making process, to a comparison of Rituximab with Belimumab.

This is a valid ground two appeal point, although as guidance to help you prepare for the
appeal, I suggest you should focus on the FAD and the appraisal documentation. Sir
Andrew will not have been part of the appraisal committee and his comments represent his
opinion. The appeal panel will be more concerned to understand the appraisal committee's
approach to the appraisal, and will want to form its own view as to the reasons for the
guidance drafted.

2.2. The NICE guidance, which indicates that there is no advantage of "licensed" Belimumab
compared to "unlicensed" Rituximab, will potentially lead doctors into a situation which
conflicts with advice issued by the General Medical Council (2008) and the MHRA (2009).

As you note, were NICE to recommend the use of an unlicensed treatment, particularly one
not included in the scope of the STA, it would be arguable that it had exceeded its powers
rather than that the guidance was unjustified. I agree this is a valid appeal point, but that it is
valid under ground three rather than under ground two.

2.3. The NICE guidance, which indicates that there is no advantage of "licensed" Belimumab
compared to "unlicensed" Rituximab, will potentially lead to severe adverse unintended
consequences for lupus patients.

I do not think that this point and point 2.2 can both be valid at the same time. Point 2.2
argues that the effect of the guidance may be to encourage unlicensed use of Rituximab.
Point 2.3 argues that the effect will be to make it more difficult for patients to have access to
Rituximab, ie to reduce its use. I might have been minded to agree that either one of these
points was valid at this stage, but I cannot logically agree that both are valid at the same
time. At present I am minded to refer appeal point 2.2, but not 2.3, to the appeal panel. (You
may wish to know that another appellant is advancing a similar argument to your appeal point 2.2)

If you would rather I referred 2.3, or wish to argue that both points could be considered in the same appeal, then I would be willing to consider any further arguments you may make before reaching a final decision.

Ground 3

I have agreed that appeal point 2.2 is a ground 3 appeal. Appeal point 2.3 would fall under ground 3, but for the reservation I have set out 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 grounds 2.2 and 2.3 above, you should do so by 1 June 2012, whereupon I will give a final scrutiny decision.

Yours sincerely

Chair
National Institute for Health and Clinical Excellence