From:

Sent: 16 September 2008 16:52

To:

Cc:

Subject: Appeal : Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for treatment of rheumatoid arthritis after failure of a previous TNFa inhibitor

Importance: High

16 September 2008

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Dear

Final Appraisal Determination: Adalimumab, Etanercept and Infliximab for treatment of rheumatoid arthritis after failure of a previous TNFa inhibitor

Thank you for your letter of 3 September. This letter represents my final decision on the initial admissibility of your appeal points.

Ground 2

I note your expectations as regards reappraisal of new information. However I also note that, following the appeal in June 2007, the appraisal committee clearly decided to issue guidance on use of a first anti-TNF before carrying out the reconsideration of sequential use required by the appeal decision. In itself that seems to me to have been a reasonable and responsible step to have taken, in as much as patients did not have to wait for the completion of the reappraisal of sequential use to benefit from the recommendation for first use.

However it does seem to me that both the published guidance and this guidance flow from the same underlying appraisal, and must, therefore, be based on the same evidence. Therefore I think it would be correct for the appraisal committee not to have looked at new evidence after the publication of the recommendation for first use. Nor do I think that the appeal panel decision required them to do so.

In any case it still seems to me that the data referred to was presented after the re-appraisal was complete, even if the re-appraisal had considered new evidence. I take the point that the meta analysis was based on information which would have been within the timeframe for consideration, but the meta analysis is a separate piece of work and cannot have been considered before it was out into the public domain.

Therefore it remains my view that this is not a valid ground of appeal.

Ground 3

I am afraid we are slightly at cross purposes. The ECHR is part of UK law by virtue of the Human Rights Act 1998, my point was that the UN convention is not part of UK law. However article 14 of the ECHR is not a freestanding prohibition on discrimination, it is a prohibition on discrimination in enjoyment of any other ECHR right. I do not believe that any other ECHR right is in play here, so Art 14 does not apply.

Thank you for further detail on your discrimination argument. I now understand that the point is that sero-negative patients are less likely to benefit from rituximab, and that the argument is that those patients should have been given different treatment options.

I remain fundamentally concerned that being sero-negative is not a disability. All patients with RA (who for these purposes at least I assume are all disabled) are treated alike. I do understand your concern but I have difficulty in seeing that it can amount to disability discrimination in Disability Discrimination Act terms.

With some hesitation though I feel that this issue should be considered by an appeal panel for determination after an appeal hearing, and therefore I agree it is a valid ground of appeal. By way of guidance I would urge you to look carefully at how your concern amounts to discrimination on the grounds of disability.

You may on reflection prefer to argue simply that it is perverse not to make special provision for sero-negative patients. I will leave this to your judgement, but if you do prefer to have the issue considered under ground 2 the appeal panel will allow this.

Yours sincerely

Mark Taylor
Appeals Committee Chair
National Institute for Health and Clinical Excellence