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[redacted]
National Rheumatoid Arthritis Society
[redacted]
[redacted]
Maidenhead
SL6 [redacted]
By email to: [redacted]

25 September 2015

Dear [redacted]

FAD: Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed

Thank you for lodging NRAS' appeal against the above Final Appraisal Determination. I am replying on [redacted] behalf as [redacted] considers she has a potential conflict of interest in connection with the subject matter of your appeal. I am a non-executive Director of NICE and will be succeeding [redacted].

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:

- 1(a) NICE has failed to act fairly,[1] or
- 1(b) NICE has exceeded powers;[2]

[1] Formerly ground 1
[2] Formerly ground 3

- (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

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 will 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.

Initial View

Ground 1 (a)

1. **In making the assessment that preceded the recommendation to only include those with severe disease, NICE has failed to act fairly**

You explain that new information was produced and circulated before the 21 May committee meeting. You did not have time to make a written submission on that information. However there was a further meeting on 22 July 2015 and it seems to me you did have a chance to make a proper response to the ACD and to make any points you wished.

Looked at in the round it does seem to me you had an opportunity to know and respond to all of the information in front of the committee. The committee clearly considered your points, even if they disagreed with them in drafting the FAD which you are now challenging substantively under Ground 2. I would not be minded therefore to refer this point to an appeal panel.

2: In terms of due process, it was unfair for the committee to arrive at a decision apparently influenced by the views of one member who had not read all the relevant scientific evidence.

For the purposes of this letter I assume that it is correct that the Vice Chairman had indeed read only the titles of the BSR referenced papers.

I am not minded to refer this point to an appeal committee. It is necessary to distinguish between the committee, and its members. An appeal is an appeal against a decision of the committee as a whole. I would accept that the Vice Chairman is likely to be a fairly influential member of the committee, and I would also accept that there might be some cases where the actions of one committee member might taint the decision of the committee as a whole. Even so I would not accept that this is such a case for the following reason.

There is a difference between a committee being unaware of evidence before it, and a committee deciding not to review evidence in detail or at all. A committee which is unaware of relevant evidence will usually have acted unfairly. A committee which judges even on brief inspection that relevant evidence is in fact unlikely to assist it and need not be reviewed in detail is unlikely to have acted unfairly. The appeal panel takes the view that questions of weight and use of evidence are for the committee, and it is not the role of the panel to review those judgements. In this case the Vice Chairman clearly was aware of the existence of the referenced papers, which themselves were I assume cited in support of the BSR submission which he clearly had read, and it would seem felt able from the titles of the papers and/or the content of the submission to be confident he did not need to read further. That is a matter for his judgement and fairness does not require more of him.

I would not be minded to refer this point to an appeal panel.

Ground 1(b)

No points raised

Ground 2

It is unreasonable to conclude that treatment for moderately active RA is not cost effective when the ICERs presented were within the range defined by NICE as cost effective.

A valid appeal point.

As I agree some of your appeal points are valid they will be passed to an appeal panel for consideration. There will be an oral hearing. I will be happy to consider any further comment

you may have on the two grounds which I am not minded to regard as valid before making a final decision. Any such comments should be received within 14 days of the date of this letter.

Yours sincerely

[redacted]

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