

British Society for Rheumatology
Bride House
18-20 Bride Lane
London EC4Y 8EE

By email to [REDACTED]

19 October 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 your letter dated 8 October 2015. This is my final decision on initial scrutiny.

Ground 1 (a) 1 NICE failed to act fairly by not giving the BSR an opportunity to make written representation regarding new important information in the assessment report prior to the second appraisal committee.

I am still unpersuaded that this is a valid appeal point. As I understand it, the Assessment Group altered the assumptions used in their modelling and presented those figures to the 21 May meeting of the Appraisal Committee. Those updated figures were more favourable to treatment than the Assessment Group's previous modelling, although not overall more favourable than manufacturers' modelling. The updated figures were broadly accepted by the Committee and appear in the ACD.

There are three reasons I do not consider there has been any unfairness. First, the new figures were available during the consultation period and seem to have been part of the guidance consulted on. You say that "The first opportunity to refer the committee to published scientific data [on the identification of certain subgroups of patients] was in response to the ACD". If so, that would be a fair process. The essential point is that you

were given that opportunity, and even if it might have been "better" if you had had that opportunity sooner, (as to which I have no view) that is not the same as there having been unfairness. The conduct of the committee and the assessment group also seems reasonable, and the figures were simply not available much before 21 May. In the context of an appraisal which has been running for some time I could understand any reluctance to delay an ACD to allow you to comment, when the publication of the ACD would itself give you that opportunity.

The second reason is that it is apparent that a range of models and a range of ICERs had been in play prior to 21 May 2015 and I am not persuaded that the ICERs in question were so out of keeping with all of the possible values that had been under consideration that a further pause before publishing an ACD was necessary.

The third reason is that the Appraisal Committee considered the question of whether patients with moderately active disease should have access to the DMARDS. They concluded in the ACD that they should not. You challenged this in your response to the ACD, referring to the 'new' ICERs and presenting evidence to show that it was possible to identify patients with moderate disease with the fastest progression. The Committee considered this but did not change their conclusion in the FAD. I find it hard to see any unfairness here: the issue was included in the ACD, you commented on it in writing during consultation and at a subsequent Committee meeting, and the Committee considered your comments. This is the standard process. A second ACD would normally only be issued if there was a substantial change and it was thought right to consult again before proceeding to a FAD.

Ground 1a) 2 It was procedurally unfair for the committee to reach a decision when it was apparent that not all members had read the relevant material.

I am still unpersuaded that this is a valid appeal ground under this heading. If "the conclusions of the committee reflect the fact that the committee did not review the evidence in detail" then I would expect the appeal panel to be able to address that concern under your ground 2 appeal, if the result is that the recommendations cannot reasonably stand in the light of the evidence. My view is that these issues are better explored under ground 2, and if it should transpire that the committee really have not considered relevant evidence at all, I would imagine your arguments under that ground would be greatly strengthened.

Ground 1(b)

No points raised.

Ground 2

It is unreasonable to conclude that treatment for moderately active rheumatoid arthritis is not cost effective when the ICERs were in the range accepted by NICE.

Already accepted as a valid appeal point

There will be an oral hearing to consider your appeal ground 2

Yours sincerely



National Institute for Health and Care Excellence