NICE National Institute for Health and Care Excellence

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Merck Sharp Dohme
Hertford Road
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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 MSD's appeal against the above Final Appraisal Determination. I am replying on [redacted]'s 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 taking over her responsibilities.

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)

1.1(a) The FAD unfairly discriminates against Remicade

I am unpersuaded that this is a valid ground of appeal. It seems to me that the concept of beginning treatment with the least expensive drug was transparently consulted on, as was the existence and relevance of biosimilars. I can see that the committee expanded its reasoning on this issue between the ACD and FAD but I cannot see any procedural unfairness.

I do not myself see the inference from paragraphs 4.88 and 4.99 that you assert, nor do I think that would be a ground of appeal. However as you may be aware NICE's guidance executive can edit draft guidance to correct factual inaccuracies or to clarify (but not change the substance of) guidance. If the guidance is passed to the guidance executive for publication (which will depend on the outcome of the appeal) I would suggest they would be the appropriate body to consider whether the guidance might be misunderstood as you suggest.

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

1.2(a) the FAD lacks transparency

A valid appeal point. I am not sure that the substance of the point you present is very accurately summarised as the FAD lacking transparency, rather than an alleged failure to follow process which led to unfairness, or a failure to allow proper comment on the issue of biosimilars, but the appeal panel will consider the substance of the complaint made.

Grounds 1(b) and 2

No points raised

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]

National Institute for Health and Care Excellence