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2 October 2015

MSD
Hertford Road
Hoddeson
Hertfordshire
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Dear [redacted],

FAD: Ankylosing spondylitis and axial spondyloarthritis (non-radiographic) adalimumab etanercept infliximab and golimumab (inc rev TA 143 and TA 233) ID 694

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 succeeding her.

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

[1] formerly ground 1
[2] formerly ground 3

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 NICE has inappropriately used contract prices in analyses

I agree this is a valid appeal point, save in respect of your observation that "there is no transparency on how the "highest NHS Contract price"...was determined." FAD 4.46 seems to state clearly that assessment group took the cheapest of the biosimilar products, and then used the highest price that might need to be paid for that product as a result of the tendering process. I am not sure how you argue that that description is so unclear as to cause unfairness?

Subject to that observation this point will proceed.

1.2 The FAD lacks transparency

There are several subpoints here. The first is your complaint that contract prices were not used for remicade (or for the other products) but were used for biosimilar infliximab.

So far as products other than infliximab is concerned, I do not understand the alleged unfairness in light of the fact that their use is recommended. I fully appreciate that it is usually sufficient to identify an unfairness without also needing to show that it would have made a difference to the outcome, but in a case where use of the products is recommended already, I am not sure how it can be said to have been unfair in any meaningful sense not to have used their contract prices. Presumably that would only have strengthened the case for their use.

I have a similar concern as regards infliximab. I can understand, (for the purposes of initial scrutiny at least,) that the use of contract prices for some forms of infliximab and not others might call for comment. But all forms of infliximab are recommended for use. The caveat that treatment should be started with the least expensive product does not single out any product by brand, and which product might be least expensive might vary from time to time and place to place, a point your letter itself makes. So while I can appreciate the point that on the face of it there might be a question to investigate as to the treatment of your particular product, in fact it does not seem to have had any impact on the recommendation to use infliximab of which your product is one example.

At present I would not be minded to allow this point to proceed.

There are then two suggestions for the wording of the guidance. I take the suggestion that paragraphs 4.46 and 4.67 should be deleted to be a consequence of your argument under heading 1.1 above, and it seems to me it stands or falls with it. Your suggestion as to the wording of paragraph 1.1 of the guidance does not seem to fall within a ground of appeal. Your wording elaborates on the committee's wording, and seems to be consistent with it, but I do not understand how it can be said to be unfair that the committee expressed themselves as they did? (For transparency, I note that the wording you are suggesting is similar to the wording actually used in ID537 which I was also not minded to regard as unfair. My view is that either form of wording could fairly be used.)

I would not be minded to allow these points to proceed.

Finally there is the point that biosimilars are not mentioned in the appraisal scope. I agree that that is 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 sub-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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