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Director
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21 August 2017

Dear [redacted]

Final Appraisal Determination: Naltrexone-bupropion for managing overweight and obesity

Thank you for lodging Orexigen's appeal against the above Final Appraisal Determination.

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, or
- 1(b) NICE has exceeded powers;
- (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.

I can confirm that there will be an oral hearing of the appeal.

Initial View

Ground 1(a)

1a.1 NICE presented an ICER for the first time only in the FAD, which means that the company has not had the opportunity to comment meaningfully on the Institute's view of the cost-effectiveness of Mysimba. This is inconsistent with NICE's procedures and unfairly prejudiced Orexigen

A valid ground one appeal point. I note your reference to paragraph 3.7.31 of the Guide to the Process for Technology Appraisal. This states that a further ACD should be considered in particular circumstances; however, it does not require an ACD to be issued. You will need to persuade the Panel that the decision not to issue a second ACD was unfair.

1a.2 NICE's failure to give Orexigen an opportunity to consult on any proposed ICER, or to provide any justification, means that the process has also lacked transparency.

My initial view is that the FAD does give an explanation of the basis for the ICER figure in paragraphs 3.10-3.15 and there is no lack of transparency. Therefore my initial view is that this is not a valid appeal point. To the extent that your argument is that it was unfair for the Committee to rely on this figure within the FAD without there being a second ACD for consultation, those arguments can be made under 1.1 above.

1a.3 NICE's assumption that treatment with Mysimba must inevitably involve long-term and recurrent treatment is counter to the product's approved summary of product characteristics (SmPC), which is inconsistent with NICE's procedures and unfairly prejudices the company.

My initial view is that this is not a valid appeal point. I do not agree that the assumptions made about long-term and recurrent treatment are inconsistent with the SmPC. Based on your description of the SmPC it is possible to have long-term or recurrent treatment within the scope of the SmPC. Treatment could continue if a 5% reduction in weight is achieved. Further courses of treatment are also possible. I also note the comments of the clinical expert recorded at paragraph 3.5 of the FAD, that long-term treatment is likely to be

necessary for many people. I do not think it was unfair of the Committee to take this into account.

1a.4 The Appraisal Committee has allowed the NHS's failure to offer tier 3 services in accordance with NICE clinical guidelines to influence its approach to this HTA, which is procedurally unfair and prejudices the company.

My initial view is that this is not a valid ground one appeal point as it is about how the Committee took the provision of tier 3 services into account rather than whether a fair procedure has been followed. I note that you have made similar arguments under Ground 2.4, which I have found to be a valid appeal point.

Ground 1(b) NICE has exceeded its powers by making a determination based wholly or mainly on budget impact.

My initial view is that this is not a valid appeal point. It is clear from the FAD that the Committee has taken many different factors into account when making its decision. In my view it is not the case that the Committee's determination is based wholly or mainly on budget impact. I do not think that the Committee's approach is incompatible with the Institute's general duty under section 233 to have regard to *"the broad balance between the benefits and costs of the provision of health services or of social care in England".*

I note your comments regarding the ongoing judicial review. If you wish to clarify or elaborate on the arguments you are making under this appeal point you should do so in response to this letter within the deadline given. As set out at paragraph 4.5 of the *Guide to the technology appraisal and highly specialised technologies appeal process*[1] the Appeal Panel only considers the exact grounds and arguments as set out in the appeal letter, and appellants should prepare their appeal letters accordingly.

Ground 2

2.1 The Appraisal Committee's conclusion that the relevant clinical trials are too short to eliminate uncertainty is unreasonable

[1] https://www.nice.org.uk/process/pmg18/chapter/making-an-appeal

My initial view is that this is not a valid appeal point. I do not think that the Committee expresses this view in the FAD. It notes at paragraph 3.7 that the trials were "*of short duration"*. This is one of the factors that contributes towards uncertainty around the ICER. I do not think that it was unreasonable for the Committee to take into account the length of the trial when making its deliberations.

2.2 NICE's assumption with Mysimba must inevitably involve long-term and recurrent treatment is inconsistent with the product's approved summary of product characteristics (SmPC), and is therefore unreasonable in light of the evidence before it.

My initial view is that this is not a valid appeal point. I have explained above that I do not think that the Committee's approach is inconsistent with the SmPC.

2.3 The Committee's over-cautious assessment of uncertainty was unreasonable in light of the evidence before it.

My initial view is that this is not a valid appeal point. The FAD clearly sets out the Committee's reasoning on the issue of uncertainty. It also deals with the question of innovation at paragraph 3.19. It is not enough that you disagree with the Committee's findings, as reasonable people may reach different conclusions.

2.4 It is unreasonable to prejudice the company on the basis of budget impact where the potential budget impact is a result of a failure of CCGs to implement a treatment pathway for obese patients consistent with NICE clinical guidelines.

A valid appeal point.

2.5 Given that the evidence before the Appraisal Committee is that the level of care offered at tier 3 is patchy and diminishing, it is unreasonable for the Committee to conclude that the introduction of Mysimba into tier 3 would have a large impact on NHS budgets.

My initial view is that this is not a valid appeal point. Given the prevalence of obesity in the overall population (30%) it would be possible for even patchy provision of Mysimba to have a significant impact on health budgets. Therefore, my view is that it was not unreasonable for the Committee to require more robust evidence of cost effectiveness, in accordance with paragraph 6.2.14 of the Methods Guide.

As I agree some of your appeal points are valid it will be passed to an appeal panel for consideration.

If you wish to make any further comment on the points that I have indicated that I do not, at this preliminary stage, view as valid, please provide to me this within 10 working days from the date of this letter, no later than **Tuesday 5 September 2017**. I will then reach a final decision on the validity of those points.

Yours sincerely

Dr Rosie Benneyworth
Vice Chair
National Institute for Health and Care Excellence