NICE National Institute for Health and Care Excellence

10 Spring Gardens
London
SW1A 2BU
United Kingdom

+44 (0)300 323 0140

sent by email: [redacted]

[redacted]
[redacted]
Orexigen Therapeutics Ireland Limited
2nd Floor Palmerston House
Fenian Street
Dublin 2, Ireland

13 September 2017

Dear [redacted],

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

Thank you for your letter of 4 September. This is my final decision on initial scrutiny.

Ground 1 (a)

1(a).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.

Already accepted as valid.

1(a).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.

You have not made any further arguments under this ground, other than to reserve your position and acknowledge the point made in my earlier letter that *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.*

My final decision is therefore that this is not a valid ground of appeal.

1(a).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.

You have not made any further arguments under this ground, other than to reserve your right to raise the failure of stopping rules and related aspects (which you argue could have been addressed as part of a proper consultation) under point 1(a).1. As I stated in my previous letter, your arguments under that ground will need to focus on why you consider that the decision not to issue a second ACD was unfair.

1(a).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.

You have agreed that your arguments can be made under Ground 2.4. This ground 1 argument is not a valid point of appeal.

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

In my last letter I numbered this ground 1.5. As it is a ground 1(b) point it should have been numbered 1(b).1. Please accept my apologies for this oversight. This letter adopts the correct numbering.

You have not made any further arguments under this ground but have explained that you will make your point about budget impact under ground 1(a).1. As set out above, your arguments under ground 1(a).1 should focus on the fairness of the decision not to issue a second ACD.

This is not a valid ground of appeal.

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

I have considered the further representations made in your letter. I have concluded that your point that the FAD does not adequately explain the reason why the committee concluded that the trials were of short duration given the CHMP guidance you have quoted is a valid ground of appeal. I consider that this could be argued either as a ground 1 or a ground 2 point but that it would more comfortably be argued as a ground 1(a) point as arguments about transparency are usually made under ground 1(a). I will leave it to you to decide which ground you wish to make these arguments under.

Ground 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.

You have not made any further arguments under this point. I note that you again say that you intend to discuss the point under ground 1(a).1. I refer to my earlier comments about the focus of arguments under that ground – the Appeal Panel is unlikely to find reasonableness arguments made "by the back door" under ground 1(a) helpful.

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

I have carefully considered the additional points that you have made. It is not enough to argue that there was another way of conducting the appraisal that would have been reasonable. That does not by itself make the way the appraisal was conducted unreasonable, as there can be more than one reasonable approach.

My view remains that this is not a valid ground of appeal, for the reasons set out here and in my previous letter.

Ground 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.

Already accepted as a valid appeal point.

Ground 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.

You have not made any further arguments in relation to this point. I note your intention to make arguments under ground 1(a).1 and refer to my comments above on this. My final decision is that this is not a valid ground of appeal.

There will be an oral hearing to consider your appeal grounds 1(a).1, 2.1 (this is limited to your point about the approach of the Committee compared with that of the CHMP; you may prefer to argue this as a ground 1(a) point), 2.4.

Yours sincerely

Rosie Benneyworth
Vice Chair
National Institute for Health and Care Excellence