­Sent by email to: xxxxxxxx@ITS.JNJ.com

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Director of Health Economics, Market Access, Reimbursement, Patient Engagement & Government Affairs

Janssen-Cilag Ltd UK

10 August 2020

Dear xxxxxx

**FINAL APPRAISAL DOCUMENT FOR ABIRATERONE FOR HIGH-RISK HORMONE-SENSITIVE METASTATIC PROSTATE CANCER**

Thank you for your letter of 3 August 2020, responding to my initial scrutiny views. This is my final decision on initial scrutiny.

**Ground 1(a): In making the assessment that preceded the recommendation, nice has failed to act fairly**

*1.1. Ground 1(a).1:The Appraisal Committee has failed to consider whether and, if so, to what extent the change in health-related quality of life associated with use of abiraterone has been adequately captured (a) capture of benefits in the QALY for abiraterone (b) Aspects of the technology that relate to non-health objectives of the NHS*

Your subpoint (a) above is already agreed to be a valid appeal point.

Having considered your further explanation of the factors you say ought to have been considered under subpoint (b) (relating to broader benefits to the NHS i.e. “NHS efficiency” and “the ability of the service to treat other patients with other conditions”), I am prepared to refer this point to the appeal panel for consideration under ground 1(a).

While I remain mindful that technology appraisal guidance may not be the appropriate place for any adjustments to NHS practice in response to a pandemic, and while it would be unrealistic to require a Committee to update itself constantly on the detail of a rapidly changing global pandemic, I am also mindful of the high vulnerability of this particular patient group to COVID-19. In this context and given the specific subject matter of this particular appraisal, I will not exclude your argument within subpoint (b) that the Committee ought to have taken into account the impact of COVID-19.

*1.2. Ground 1(a).2: The Appraisal Committee’s conclusion that “there are no clear-cut clinical criteria to define who can have abiraterone in combination but not docetaxel in combination” does not: (a) provide adequate reasons for diverging from NHS England’s commissioning policy; (b) justify rejection of the criteria proposed by NHS England for determining access to abiraterone through the Blueteq management system; (c) provide reasons for deviating from its conclusions in the earlier appraisal of Radium-223; and (d) explained why it has adopted a different approach to that followed in the appraisal of lenalidomide*

Your subpoint (c) above is already agreed to be valid appeal point.

I remain unpersuaded that subpoints (a), (b) and (d) above are valid appeal points, for the same reasons explained in my initial scrutiny letter. Having considered your further arguments I still consider these three subpoints are unarguable. I note that the Committee refer to the NHS England commissioning policy so cannot be said to have failed to take it into account. In my judgement the case of Servier is distinguishable, as the body from which NICE departed in that case was the EMA exercising its regulatory function and the difference in opinion related to the reliability of clinical trial data. I do not accept that Servier is authority that any disagreement with NHS England calls for a particular level of reasoning.

*1.3. Ground 1(a).3: the Appraisal Committee has provided no reasons to explain its view that the benefits of abiraterone may be different in those patients who are unable to receive docetaxel*

Already agreed to be a valid appeal point.

*1.4. Ground 1(a).4: The conclusions of the Appraisal Committee in relation to the cost effectiveness of abiraterone in this appraisal are opaque*

On reflection I agree that this is a valid appeal point insofar as it relates to the failure to provide an ICER range.

For the reasons explained in my initial scrutiny letter I do not agree that there is a valid appeal point that the Committee was required to publish the specific ICER/s or disclose more detailed conclusions, save that as noted above I am willing to refer an appeal point for the panel to consider whether it ought to have published an ICER range.

I do not agree that it is unclear whether the ICERs involved a comparison with ADT alone or merely a comparison with docetaxel, as it seems to me clear that the Committee calculated both ICERs (see page 2 of the FAD which states “the cost-effectiveness estimates of abiraterone with prednisone or prednisolone plus ADT compared with both ADT alone and docetaxel plus ADT are higher than the range normally considered a cost-effective use of NHS resources”) but concluded (as explained at paragraph 3.2 of the FAD) that it was “not appropriate to consider separately the clinical and cost effectiveness of abiraterone in combination in people who currently have ADT alone”.

*1.5. Ground 1(a).5 The fact that NICE disclosed its preferred ICERs to NHS England for the purposes of negotiation of a commercial agreement, but not to Janssen is unfair*

I remain unconvinced the “imbalance” complained of as between NHS England and the company can have caused any unfairness whatsoever in the appraisal process, which is what the appeal is concerned with. I do not agree that the “imbalance” was a feature of the appraisal about which an appeal could validly be brought.

The commercial negotiation process and appraisal process are distinct. I understand your argument to be that that (1) the “imbalance” in information in the negotiation context was the reason that a commercial agreement was not reached (which is a matter on which I obviously cannot comment) and (2) the company was unfairly disadvantaged in the appraisal for failing to reach a commercial agreement (but that is true only to the extent that of course NICE could not take into account a commercial proposal not agreed by NHS England when exercising its function of assessing cost effectiveness).

You have not shown me that the company could have been or was in fact disadvantaged in the appraisal as a result of NHS England being aware of the ICERs.

*1.6. Ground 1(a).6: the Committee’s statement that “the clinical experts involved in STAMPEDE confirmed that post-progression survival was shorter after abiraterone in combination than after ADT in this trial” is based on unpublished data that have not been disclosed or confirmed.*

Already agreed to be a valid appeal point.

*1.7. Ground 1(a).7: The Appraisal Committee’s focus on number of subsequent treatment options rather than outcomes relies on an irrelevant consideration*

Already agreed to be a valid appeal point.

**Ground 1b: that NICE has exceeded its powers**

*1.8. Ground 1(b).8: the assertion by the Appraisal Committee that it is required to say whether abiraterone is “safe” in patients who cannot take docetaxel assumes the role of the regulatory authority*

Already agreed to be a valid appeal point.

**Ground 2: The recommendation is unreasonable in light of the evidence submitted**

*2.1. Ground 2.1: The Appraisal Committee’s conclusion that “there are no clear-cut clinical criteria to define who can have abiraterone in combination but not docetaxel in combination” is unreasonable in the context of the available evidence*

Already agreed to be a valid appeal point

*2.2. Ground 2.2: the Appraisal Committee’s conclusion that the benefits of abiraterone may be different in those patients who are unable to receive docetaxel is unreasonable in light of the evidence available*

Already agreed to be a valid appeal point.

Therefore the valid appeal points are your grounds 1(a).1(a), 1(a).1(b), 1(a).2(c), 1(a).3, 1(a).4 insofar as it relates to the failure to provide an ICER range, 1(a).6, 1(a).7, 1(b).8, 2.1 and 2.2.

Where there are multiple appellants, NICE shares the valid appeal grounds of each appellant with the other appellants to assist with preparation for the hearing.

NICE will be in contact with you regarding the administration of the appeal, which will be held orally.

Many thanks

Yours sincerely

Tim Irish

Vice-Chair

National Institute for Health and Care Excellence