­Sent by email to: [xxxxxxxx@ITS.JNJ.com](mailto:xxxxxxxx@ITS.JNJ.com)

xxxxxxxxxxxxxxxx

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

Janssen-Cilag Ltd UK

21 July 2020

Dear xxxxxx

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

Thank you for your letter of 10 July 2020, lodging Janssen’s appeal against the above Final Appraisal Document (FAD).

**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 its 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.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I will make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

**Initial View**

**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 in this appraisal*

I agree your subpoint (a) is a valid appeal point.

I am not presently persuaded that your subpoint (b) is a valid appeal point. First, I do not think the committee can be faulted for not taking account of the current pandemic, which is likely to be a temporary state of affairs. Second, I would expect the factors you raise (reduced administration cost and greater convenience of an oral at-home treatment and reduced immunosuppression) to be included in modelling in the form of costs of a comparator, improved quality of life, or fewer adverse incidents. Further I am not sure these are non-health objectives of the NHS, as they all seem to be health related.

*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*

I am not persuaded that subpoint (a) is a valid appeal point, because I do not think that the committee were required to take an NHS England commissioning policy as their starting point. That being so there is no obligation to give a reason for departing from it. For similar reasons I do not think that subpoint (b) is a valid appeal point (and additionally, I do not think the Blueteq criteria meet the Committee’s concern about a lack of clear cut clinical criteria, as they include patients who have made an informed choice not to receive docetaxel which is not a clinical criterion)

I agree that your subpoint (c) (erroneously labelled (b)) concerning the appraisal of Radium 223 is a valid appeal point.

I do not agree that your point (d) (labelled (c)) is a valid appeal point because I am not persuaded that the appraisal of lenalidomide has enough in common with this appraisal to be a meaningful guide.

*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*

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*

I am not persuaded this is a valid appeal point. The committee’s conclusion is clear, even if an ICER or a range of ICERs is not given. Further it seems to me that a reason for this is that the ICERs may indicate what level of confidential discounts may be given for other treatments, and that seems to me to be a reasonable concern. You will have developed the economic model yourselves and the committee have set out in the FAD and in the committee slides comments on the model, and on their preferred assumptions. It seems to me it is possible to understand their committee’s conclusion and the reasons for it in acceptable detail.

*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 am not convinced this can have caused any unfairness in the appraisal process, which is what the appeal is concerned with. Further as noted above it seems to me that the Committee had a valid reason for not disclosing precise ICERs, namely to protect the commercially confidential discounts offered by others.

*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.*

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*

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*

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*

And

*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*

Both valid appeal points.

In respect of the points or subpoints that I am not yet minded to refer you are entitled to submit further clarification and/or evidence to me within the next 10 working days, **no later than 5pm Monday 3 August 2020**,and I will then give a final decision on the points to put before an appeal panel. For the points I am already content to refer on, an oral appeal will be held, although under current circumstances this is likely to be held remotely.

Many thanks

Yours sincerely

Tim Irish

Vice-Chair

National Institute for Health and Care Excellence