­Sent by email to: [xxxxxxxxxx@rightangleuk.com](mailto:xxxxxxxxxx@rightangleuk.com)

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STAMPEDE Trial Chief Investigator

On behalf of the British Uro-Oncology Group

21 July 2020

Dear xxxxxxxxxxxxxx

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

Thank you for your letter of 9 July 2020, lodging the BUG 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.

You have not allocated your appeal points to a specific appeal ground, but I believe they would all fall to be considered under ground 2. If you disagree please would you make this clear in your reply to this letter.

**Initial View**

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

*1 The statement “There are concerns that the trials may overestimate the effectiveness of abiraterone. This is because the treatments offered in the trials after the disease progresses do not reflect those offered in the NHS, where more people on standard care have effective treatments after their disease progresses than in the trials.” Is unreasonable*

A valid appeal point.

*2 The statement “The cost-effectiveness estimates without a commercial arrangement are higher than the range normally considered a cost-effective use of NHS resources.” Is unreasonable*

I am not persuaded this is a valid appeal point. It is possible for two groups to differ on an issue without either group’s conclusion being unreasonable. Further it is not possible for NICE to receive new information or analysis once an appraisal has been completed.

*3 The statement “It is not appropriate to consider separately the clinical and cost effectiveness of abiraterone in combination in people who currently have ADT alone” is unreasonable*

A valid appeal point.

*4 The statement “The clinical experts explained that people who have previously had docetaxel as first-line treatment in the hormone-sensitive setting can have docetaxel again (for up to an additional 10 cycles)” is unreasonable*

A valid appeal point.

5 *The statement “The comparison of abiraterone and docetaxel suggest that there may be no difference in overall survival” is unreasonable*

A valid appeal point.

*6 The statement “The magnitude of OS benefit for abiraterone may be over-estimated” (section 3.6) is unreasonable*

A valid appeal point.

*7 The statement “Neither STAMPEDE nor LATITUDE likely capture all the benefit on overall survival of follow-on treatments used in NHS clinical practice” is unreasonable*

A valid appeal point.

*8 The conclusions on Health Economic Modelling and costs are unreasonable*

I am not persuaded this is a valid appeal point for the reason given under point 2 above.

*9 The treatment of QOL is unreasonable*

I am not persuaded this is a valid appeal point because these data appear to have been presented very recently and I do not think they formed part of the evidence base of the appraisal.

*10 COVID-19 should have been taken into account*

I am not persuaded this is a valid appeal point. An appraisal has to give guidance to be used in the NHS at all times. If NHS practice needs to be adjusted to respond to a (hopefully) time limited event such as a pandemic then that should be done by way of time limited guidance addressing the circumstances of the event, and not by adjustments to individual appraisals.

Further the bulk of the appraisal predated the pandemic.

In respect of the points 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