Appendix 2. Request for submission of new evidence
Abiraterone for metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy [ID503]

June 2014

Overview

Janssen is requesting an opportunity to submit additional evidence that is relevant to and likely to affect the provisional recommendations in the ACD. Whilst we appreciate that a delay in the appraisal timelines is not ideal, we believe that this new evidence, which directly addresses a number of key concerns raised by the appraisal committee, will decrease the ICER and provide greater certainty in the base case cost-effectiveness analysis.

We strongly believe that this new evidence is of key significance to the Appraisal Committee's preliminary decision that abiraterone is not recommended for patients with metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy. Janssen are committed to providing NICE with the most relevant evidence on which to base their decisions, and regret that to do so would necessitate a delay to the appraisal process. The rationale for presenting this additional evidence and the likely impact it will have on the Committee's provisional recommendation is detailed below.

[redacted]

[redacted]

2. Submission of a revised economic model

Janssen is cognisant that the appraisal committee felt that the economic model, utilising a DES framework was not easy to understand. To address this concern, Janssen would welcome the opportunity to present a simplified version of the economic model that [redacted], addresses other key concerns outlined in the ACD, and which we believe may reduce the ICER. In the modified model, we are aiming to:

- [redacted],
- remove the prediction equations,
- incorporate further the impact of delaying chemotherapy on cost-effectiveness, in particular the utility benefit, which would lower the ICER, given the longer time to chemotherapy associated with abiraterone,
- Improve the characterisation of the important QoL benefits that abiraterone offers outside of that currently captured in EQ-5D, particularly those that are related to delay of chemotherapy, and importantly,
- incorporate the impact of avoiding chemotherapy altogether, i.e. comparison of two pathways which are currently not explored in the model:
    - 'ADT -> Abiraterone -> BSC -> Death' compared against,
    - 'ADT -> BSC -> Death'

Patients who are either unfit, elderly, frail, or simply do not want to receive chemotherapy, currently have no treatment options other than BSC, given that patients can only access novel treatments such as abiraterone or enzalutamide after docetaxel. Survival of these patients is therefore anticipated to be significantly lower, given that BSC is not associated with any survival benefit, and these patients do not benefit from survival gains either from chemotherapy or from novel therapy in the post-chemotherapy setting. By incorporating this patient population with more rapid progression and a shorter life expectancy, one can expect the ICER to reduce, given the incremental benefit associated with abiraterone over BSC (ie lower QALYs gained in the BSC arm leading to greater incremental QALYs gained with abiraterone).

3. Conclusion

Janssen firmly believes that the proposal outlined above, that is, a revised economic model that incorporates [redacted] the benefit of a delay to chemotherapy and those patients that never receive chemotherapy, merits further consideration in assessing the clinical and cost-effectiveness of abiraterone in the pre-chemotherapy setting. As such, in response to the issues raised in the ACD, we hope that the Appraisal Committee will afford us the opportunity to present this new evidence and a revised economic case, given the high clinical need for abiraterone in this setting.