**National Institute for Health and Care Excellence**

**Single Technology Appraisal (STA)**

**Abiraterone for treating newly diagnosed high risk metastatic hormone-naive prostate cancer**

**Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)**

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit**

| Section | Consultee/ Commentator | Comments [sic] | Action |
| --- | --- | --- | --- |
| Appropriateness | Tackle Prostate Cancer | Yes | Comment noted |
| Janssen | Janssen believes this is an appropriate topic to refer to NICE for appraisal | Comment noted |
| Wording | Tackle Prostate Cancer | Yes | Comment noted |
| Janssen | Janssen suggests that the wording of the remit should reflect the anticipated licence as added in italics below:  “To appraise the clinical and cost effectiveness of abiraterone within its marketing authorisation for treating newly diagnosed adults with high-risk, metastatic hormone-naive prostate cancer (mHNPC)” | Comment noted, ‘High-risk’ has been added to the remit to reflect the marketing authorisation. |
| Timing Issues | Tackle Prostate Cancer | There always are more pressing matters, but one of the drawbacks of the way these drugs are introduced is that they seem always to commence with trials with "moribund" patients I have always suspected that Abiraterone (and Enzalutamide, for that matter) would produce even more spectacular results with patients whose cancer is at an earlier stage. | Comment noted. NICE acknowledges the concern, however abiraterone can only appraised within its marketing authorisation. |
| Janssen | Commercial in confidence:  \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* | Comment noted. NICE aims to publish guidance published within 90 days of the marketing authorisation. |
| Additional comments on the draft remit | Janssen | No additional comments | Comments noted |

Comment 2: the draft scope

| Section | Consultee/ Commentator | Comments [sic] | Action |
| --- | --- | --- | --- |
| Background information | Tackle Prostate Cancer | Yes | Comments noted |
| Janssen | The statement “In England, there were over 40,000 people newly diagnosed with prostate cancer and over 9500 deaths from prostate cancer in 2013.” refers to a wider population than the one considered as part of this scope.  Based on the NPCA Annual report (2015), 13,102 of the 48,294 (21%) men new diagnosed with prostate cancer every year are diagnosed with an advance prostate cancer (i.e. metastatic). | Comments noted. NICE acknowledge that this figures states in the scope are for a wider population. |
| The technology/ intervention | Tackle Prostate Cancer | Yes | Comments noted. |
| Janssen | No comments | Comments noted. |
| Population | Tackle Prostate Cancer | Yes | Comments noted. |
| Janssen | The population should reflect the expected license for abiraterone:  Adults with newly diagnosed high-risk, metastatic hormone-naive prostate cancer (mHNPC) | Comment noted, ‘high-risk’ has been added to the remit to reflect the marketing authorisation. |
| Comparators | Tackle Prostate Cancer | These treatments are correct. I think that Zoladex should be described as ‘best supportive care. | Comment noted. NICE’s clinical guideline 175 recommends continuous luteinising hormone-releasing hormone agonist therapy (LHRH) as a treatment options. LHRH, which includes goserelin (Zoladex), is included as a comparator in the scope. |
| Prostate Cancer UK | Yes, the treatments mentioned are used as standard and those with which abiraterone should be compared. As indicated in NHS England Commissioning Policy Statement on Docetaxel in combination with androgen deprivation therapy, this would be described as ‘best alternative care’. Please also note that as identified in the docetaxel policy statement, ‘hormone naïve’ refers to where treatment with docetaxel is started within 12 weeks of commencing treatment with ADT.  However, earlier docetaxel has only recently become standard practice in England, and even more recently in Wales and as such we cannot be certain that its adoption equates to standard practice. | Comment noted. |
| Janssen | No Comments | Comment noted. |
| Outcomes | Tackle Prostate Cancer | As far as I can tell | Comment noted. |
| Janssen | Janssen suggest that “response rate” is not generally used as an outcome measure in advanced prostate cancer as prostate metastases, particularly bone metastases, generally do not show radiological responses to a treatment, even though overall the treatment may be working. | Comment noted. Response rate has been removed from the outcome measures. |
| Economic analysis | Tackle Prostate Cancer | None | Comment noted. |
| Janssen | No comment | Comment noted. |
| Equality and Diversity | Tackle Prostate Cancer | There are no equality considerations in this scoping document | Comment noted. |
| Janssen | No comment | Comment noted. |
| Other considerations | Tackle Prostate Cancer | As suggested earlier:  The implications for downstream treatment if and when Abiraterone fails need to be addressed | Comment noted. This will be a single technology appraisal focused on newly diagnosed patients. It would be beyond the appraisal remit to make recommendations for subsequent treatment. |
| Janssen | No comment | Comment noted. |
| Innovation | Tackle Prostate Cancer | As there is no data yet, it is difficult to say, but this could be a very significant development. It could give a very important new avenue for the treatment of advanced prostate cancer. | Comment noted. The potential innovative aspects of the technology will be considered in the appraisal. |
| Janssen | Abiraterone is the first novel agent to be licensed for the treatment of adults with newly diagnosed high-risk mHNPC.  Abiraterone is an oral medication with a unique mechanism of action, blocking testosterone production at three sites of androgen synthesis, which will provide an alternative therapy to patients who are willing to take their treatment at home.  Abiraterone is generally well tolerated and is likely to offer patient benefits such as not having to travel to hospital for treatment and not having to have undergo i/v infusions which are unlikely to be accounted for in the in the QALY calculation.  Assessment of these QALY benefits may be taken via patient interviews and/or a patient preference study.  Furthermore, although use of docetaxel is commission by NHS England, there is no health-related quality of life data (HRQoL) available to describe the impact of using docetaxel in combination with ADT in this population.  Assessment of newly diagnosed mHNPC patient’s HRQoL on docetaxel may be taken from an on-going utility study commissioned by Janssen. | Comment noted. The potential innovative aspects of the technology will be considered in the appraisal. |
| Questions for consultation | Tackle Prostate Cancer | None | Comment noted. |
| Prostate Cancer UK | Regarding all relevant comparators for abiraterone, we consider that these have been adequately covered.  Even though we don’t think degarelix is a comparator, we would consider that it is comparable with ‘androgen deprivation therapy alone’ as already mentioned in the ‘Comparators’ section of the draft scope. However we do note that the group of men with whom degarelix is used tend to be more advanced with widespread metastasis involving high risk of spinal cord compression or obstructive uropathy.  Based on the proposals in this consultation, we consider that abiraterone would fit alongside first-line hormone therapies (ADT) and docetaxel for the treatment of hormone naïve metastatic prostate cancer.  Use of abiraterone at this point in the pathway, as proposed, would potentially be innovative by providing patients with greater treatment choice.  This is important as it improves the ability for careful selection of the right treatment for the right patient. For example, for hormone resistant men there is the option of both abiraterone and enzalutamide. The side effect profile of each drug is different and has to be considered in order to determine the best treatment choice for the patient.  Taxanes such as docetaxel carry a risk of peripheral neuropathy - which can be life changing. If abiraterone was moved to earlier in the pathway for use alongside ADT, as with docetaxel, this would present a treatment option not associated with this risk. This would improve the current situation by enabling the clinician to make a treatment choice based on the best option for the patient.  However, without the ability to compare clinical benefit between abiraterone and current standard practice and without knowing details of the specific patient population that participated in the trial, it is difficult to be certain of comparators. As such our agreement that the comparator is docetaxel may be refined when more data becomes available | Comments noted. |
| Janssen | Janssen believes that degarelix could not be considered as a comparator, as it would imply that a comparison is made between abiraterone with prednisone or prednisolone + degarelix vs degarelix alone. However, there is currently no data regarding the combined use of abiraterone and degarelix in that specific population. | Comment noted. |
| Additional comments on the draft scope | Tackle Prostate Cancer | None |  |
| Prostate Cancer UK | We welcome the timely consideration of abiraterone, based on emerging clinical evidence, for use earlier in the treatment pathway of newly diagnosed metastatic hormone-naïve prostate cancer. Providing that the findings of the clinical trial demonstrate clinical and cost-effectiveness, this approach should enable speedy and uniform adoption of this new indication.  We would welcome this timely approach to horizon scanning being applied to those treatments both on and off-patent which demonstrate clinical and cost-effectiveness at another point in the treatment pathway, such as the case with docetaxel.  However we would also suggest that NICE be mindful of the next arm of the STAMPEDE trial (arm G), which is due to report in 2017, which looks at the same patient population as covered by this draft scope: abiraterone plus standard of care for men with hormone sensitive metastatic disease. This will likely broaden the evidence base for the treatment under consideration here, and therefore we suggest that NICE consider whether or not to delay appraisal for this indication, in light of this forthcoming trial data. | Comments noted. |
| Janssen | No additional comment | Comment noted. |

**The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope**

British Uro-oncology Group (BUG)