British Uro-oncology Group (BUG) Response to: NICE - ACD - prostate cancer - enzalutamide [ID600] (non-comp consultees)

We write in response to your ACD as titled above. We contest the inclusion of the statement regarding patient access to enzalutamide only if they have not had prior treatment with abiraterone.

The ACD published in October 2013 gave no indication that this caveat would be included or furthermore was even under any consideration. We strongly question the ethics of such a proposed clause in a second ACD. The opinion of stakeholders and the role of the consultation process during the first ACD appear to have been disregarded in this instance. Publicity around the first ACD means that patients and clinicians are now waiting expectantly to have access to enzalutamide regardless of prior therapy. We would strongly urge NICE to re-consider this proposed guidance.

The remit of the STA was to review post chemotherapy use of enzalutamide, with no consideration or stipulation as to other treatments the patient may have received prior to chemotherapy, as per the AFFIRM trial. If NICE starts implementing such changes in scope and limitations, this will have a huge impact on patient outcome, clinician freedom to prescribe, survivorship rates, and provision of medicines per se across all disease areas. Therefore, so long as the patient has received treatment with chemotherapy prior to enzalutamide, it is immaterial whether they may or may not have received abiraterone prior to chemotherapy. The STA seems to have subjectively focused in on one other therapy, for what can only be assumed are potential perceived cost issues.

There is no robust evidence for the sequencing of drugs for the management of metastatic castrate resistant prostate cancer (mCRPC) and we are surprised that NICE has made a decision on evidence from small retrospective studies that are not Level 1 evidence. Indeed, other retrospective studies are starting to consistently show a response to enzalutamide after abiraterone in a considerable proportion of men in the post chemotherapy setting and this has been the experience of many oncologists in the UK. There is a strong desire amongst clinicians to have the freedom to prescribe enzalutamide in the post docetaxel setting, irrespective of previous therapies, for patients that they believe will benefit from this treatment. The current ACD from NICE would deny some mCRPC patients the opportunity for optimal therapy.

This proposed ACD prejudices persons with, and all those affected by, prostate cancer. There is no precedent or ethical reason for NICE to adopt this approach.

The new PPRS scheme determines that overspend of the drugs budget will be refunded by the pharmaceutical industry. It is perverse therefore that a treatment be restricted in a group of patients in whom there remains a significant unmet clinical need, and in whom there remain limited therapeutic options.

We strongly urge you to remove the clause regarding abiraterone.

We look forward to hearing from you.

Yours sincerely

On behalf of the British Uro-oncology Group (BUG)

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