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c/o Jeremy Powell
Technology Appraisal Project Manager
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Dear Mr Powell

Re: Enzalutamide for the treatment of metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen [ID600] - Appraisal consultation document (ACD) 2

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 29,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

I write on behalf of the NCRI/RCP/RCR/ACP/JCCO with regard to the above ACD2 consultation. We are grateful for the opportunity to comment and would like to make the following joint submission.

We welcome the overall conclusion that enzalutamide is a cost-effective treatment for metastatic castration resistant prostate cancer patients whose disease has progressed despite prior docetaxel chemotherapy. However, restricting patient access to enzalutamide only if they have not had prior treatment with abiraterone is a new addition which was not included in the ACD published in October 2013.

Developments in treatment pathways are an on-going process and to pick up on one treatment as exclusion to a subsequent treatment is neither wise nor desirable. We would suggest that so long as the patient has received treatment with chemotherapy prior to enzalutamide then they should have the option of access to enzalutamide, if clinically appropriate, irrespective of whether they may or may not have received abiraterone prior to chemotherapy.

Whilst the optimum sequencing of treatment strategies in metastatic castrate resistant prostate cancer (mCRPC) remains to be determined, our experts do not believe it is prudent to base decisions on small retrospective series. Some retrospective series have suggested partial cross-resistance and equally some have suggested response rates of 38% [1] in this group of patients who have previously received abiraterone and docetaxel chemotherapy. Therefore, in the absence of any robust evidence, we believe that the restrictive clause in the current ACD from NICE is open to challenge and has the potential to compromise patient care with resultant implications on survival rates. At the very least, it would deny some men the option of the only effective therapy for their stage of disease in progressive MCRPC.

Despite significant progress in management of mCRPC there still remains a dearth of effective treatments in this setting and enzalutamide provides an effective treatment option with significant clinical benefits. We would therefore strongly recommend the removal of the restrictive clause regarding abiraterone treatment as an exclusion factor for subsequent enzalutamide.

Yours sincerely

Ref:
1. Clinical activity of enzalutamide against metastatic castration-resistant prostate cancer (mCRPC) in patients who have progressed on abiraterone acetate: The Princess Margaret experience. (Abstract 159, ASCO GU 2014). Presenting Author: Francisco Emilio Vera-Badillo