



██████████
Director, Centre for Health Technology Evaluation
NICE
c/o appeals@nice.org.uk

From The Registrar
██████████
██████████

23 May 2014

Dear ██████████

Re: Final Appraisal Determination (FAD): (Prostate cancer (hormone refractory) - Enzalutamide) [ID600]

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 close to 30,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP is grateful for the opportunity to consider the above FAD. In doing so, we have liaised with the National Cancer Research Institute (Prostate Clinical Studies Group), the Royal College of Radiologists, the Association of Cancer Physicians and the Joint Collegiate Council for Oncology and wish to submit the following appeal.

Grounds of Appeal

Ground 1a): In making the assessment that preceded the recommendation, NICE has failed to act fairly.

1.1: In the Final Appraisal Determination the guidance states in section 1.2 that:

'The use of enzalutamide for treating metastatic hormone-relapsed prostate cancer previously treated with abiraterone is not covered by this guidance.'

When our experts queried the interpretation of this statement from the NICE Committee, in specific reference to the question whether the use of Enzalutamide was being recommended in a patient with metastatic hormone-relapsed prostate cancer if they had previously received abiraterone, we received the following reply:

'The Committee felt that they had not seen sufficient evidence to allow them to make a recommendation regarding the use of enzalutamide in patients previously treated with abiraterone. Since there is no recommendation for this situation, commissioners would need to make their own decisions regarding funding. (Commissioners are required to make funding available where NICE recommends a treatment.)'

We believe this clearly represents an aspect of not ensuring fairness and uniform application of available treatment modalities across the country. As a result, this is likely to result in variation in local commissioning thereby jeopardising the very principle of ensuring uniformity of access based on NICE approval.

It would be our appeal that the Committee should therefore remove section 1.2 of the guidance. Instead, the final guidance should only include section 1.1 – *‘Enzalutamide is recommended within its marketing authorisation as an option for treating metastatic hormone-relapsed prostate cancer in adults whose disease has progressed during or after docetaxel containing chemotherapy, only if the manufacturer provides enzalutamide with the discount agreed in the patient access scheme.*

We believe that this change would prevent confusion in the interpretation of the guidance at local commissioning level and ensure that patients across the country have an equal access to the drug (enzalutamide).

We wish to be heard by a written appeal.

Yours sincerely



Registrar