Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Enzalutamide for the treatment of metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: British Uro-oncology Group (BUG)

Are you (tick all that apply):

√ a specialist in the treatment of people with the condition for which NICE is considering this technology?

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?
- other? (please specify)

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What is the expected place of the technology in current practice?
How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

The current management of men with metastatic hormone relapsed prostate cancer which has relapsed after docetaxel chemotherapy currently includes abiraterone acetate, 2nd line chemotherapy or best supportive care as described in the final scoping document. This stage is often associated with symptomatic disease both from uncontrolled local prostate cancer and also from bone and soft tissue metastases. If left untreated there is a high incidence of bone pain and the potential for other skeletal related events such as fracture or spinal cord compression. There is a significant impact on quality of life for the patient and his family.

Abiraterone is prescribed in combination with steroids and has shown to be effective in this group of patients. Mitoxantrone is less commonly used. In a recent survey of 63 specialist urological oncologists, only 13 (20%) stated that they would occasionally prescribe mitoxantrone in men with metastatic hormone relapsed prostate cancer who had failed docetaxel. The management of men with prostate cancer should be through a multidisciplinary team to include an oncologist and a urologist so that all patients have equal access to appropriate active therapy.

Enzalutamide has shown a significant 4.8 month improvement in overall survival when compared to placebo for this group of patients in the multicentre, randomised placebo-controlled AFFIRM study which included 1,199 men. The study also demonstrated significant improvements in important secondary endpoints for this group of patients including overall and radiographic progression free survival, time to first skeletal event,

improvements in quality of life and was effective for both bone and soft tissue disease. Enzalutamide has therefore been shown to significantly extend life and also improve symptoms including pain and overall quality of life. The toxicity profile is impressive with serious adverse events more common in the placebo group than with the active agent. It is extremely well tolerated with no need for additional monitoring visits or tests and can be taken with food. This makes it an easy drug to prescribe and receive and is accessible for patients without additional hospital visits.

Enzalutamide should be prescribed in the specialist clinic with patients attending routine visits without the need for additional monitoring as described above.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Enzalutamide will be easier to use than any current available technologies as it requires no additional monitoring and as above is extremely well tolerated with minimal toxicity. It should be avoided in men with known risks of seizure but this is a small proportion of patients. The fact that it was shown to have less serious adverse events than placebo means there will be significant advantages for patients in terms of additional intervention for complications of cancer and the need for supportive care for pain and skeletal related events. There is also a quality of life advantage.

There are a number of UK centres involved in the AFFIRM study. Our experience in prescribing enzalutamide within a clinical trial and in a patient

access scheme has been the same with excellent responses demonstrated and impressive tolerability. The population in the study are applicable to the group of patients seen in the UK who would be suitable for this technology. There is great enthusiasm from UK oncologists to be able to prescribe enzalutamide for men with hormone resistant prostate cancer who have progressive disease after docetaxel in view of its efficacy, tolerability and reduced toxicity and also the fact that there is no need for the burden of additional monitoring and appointments in over-subscribed and busy outpatient clinics.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

No additional information at the present time but recent surveys form the British Uro-oncology Group will be available at the time of the appraisal

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within
3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

As described above, enzalutamide is a well tolerated drug that will be prescribed in routine outpatient clinics without the need for additional expense or monitoring and has a significant improvement in lifestyle both in terms of the morbidity of cancer progression and quality of life. There is great enthusiasm to be able to prescribe this drug for men in the UK with advanced hormone relapsed prostate cancer who have progressive disease after docetaxel chemotherapy. It is considered to be a highly significant development for treatment of this disease. In a recent survey of 65 dedicated specialist urological oncologists, a question was asked how likely they would

be to prescribe enzalutamide in the future if it was available. Of the respondents to this question, 88% answered that they would like to prescribe and 70% stated that they were very likely or would definitely offer enzalutamide to their patients in the future.

Equality

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.