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] **submitting comments on behalf of:**

Name of your organisation: NCRI/RCP/RCR/ACP/JCCO

Comments coordinated by [redacted]
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)?
  Dr Bahl is Lead Doctor (Clinical Director) at Bristol Haematology and Oncology Centre; Executive Committee member of British Uro-oncology Group (BUG); Member of NCRI Prostate Clinical Studies Group

- 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.

In patients with metastatic prostate cancer (CRPC) the current NICE guidelines approve of Docetaxel chemotherapy. In the post-docetaxel setting there is approval for Abiraterone as per the NICE guidelines. This technology (Enzalutamide) has been licensed for use in the post-docetaxel setting after the results from the AFFIRM trial. In England, the CDF cohort policy now approves of Enzalutamide in the eligible patients in the post-docetaxel setting for patients who have never had abiraterone.

Enzalutamide use in the expanded access programme and also now through the Cancer Drug Fund (CDF) in England is always based on the licensed indication of this drug.

Treatment in the post-docetaxel setting in metastatic CRPC patients is evolving rapidly and Enzalutamide adds significantly to this. The reported overall survival benefit alongwith a very favourable safety profile with no routine monitoring specification makes this a very valuable modality of treatment in this setting. It also, has the advantage of being an oral medication and no interaction with food making it easier for patients to take this medication.

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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?

The currently available and licensed options in the post-docetaxel CRPC scenario are:

1. Abiraterone: NICE approved, oral medication, requires 2 weekly monitoring of blood tests, has interaction with food so needs to be taken on empty stomach, requires steroids (Prednisolone) to be taken along with it.
2. Cabazitaxel: Not approved by NICE. Intravenous chemotherapy, regular hospital visits atleast 3 weekly, associated side-effects of chemotherapy. Available through the CDF in England.
3. Radium 223- Not available in UK (has FDA approval). NICE is evaluating this in a single technology appraisal.

Enzalutamide has the following attributes:

1. Oral medication
2. No interaction with food so no requirement to take it on empty stomach and not have food for 2 hours after in contrast to abiraterone
3. Less side-effects than placebo in the Phase III AFFIRM trial
4. Not necessary to give steroids with it
5. No specific requirement for monitoring of blood tests for side-effects monitoring.

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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.

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)?

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This technology (if approved by NICE) would be implemented without any additional resource input in the current context. It would help in reducing number of patient visits/interaction with the uro-oncology teams in contrast to abiraterone which requires more monitoring.

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.