NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Patient/carer organisation submission (STA)

Enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy

Thank you for agreeing to give us your views on this treatment that is being appraised by NICE and how it could be used in the NHS. Patients, carers and patient organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of receiving NHS care for the condition
- the experience of having specific treatments for the condition
- the outcomes of treatment that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the acceptability of different treatments and how they are given
- expectations about the risks and benefits of the treatment.

To help you give your views, we have provided a questionnaire. You do not have to answer every question — the questions are there as prompts to guide you. The length of your response should not normally exceed 10 pages.

1. About you and your organisation

Your name: [redacted]

Name of your organisation: Tackle Prostate Cancer

Your position in the organisation: Trustee

Brief description of the organisation: Tackle Prostate Cancer is the only patient led prostate cancer charity in the UK. Tackle's role is to represent our affiliated member groups at a national level, on bodies such as NICE, NHS England as well as liaising with commercial organisations.

We are asking for your collective view as an organisation and will be asking patient experts for their individual input separately. If you have the condition, or care for someone with the condition, you may wish to complete a patient expert questionnaire to give your individual views as well. (For example: who funds the organisation? How many members does the organisation have?)

We have over 5000 affiliated members, all of whom are living with prostate cancer in all of it's stages. Our funds come from donations from a wide variety of businesses and affiliation fees from our members.

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2. Living with the condition

What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Living with advanced prostate cancer, particularly when it has progressed to the stage where it requires Enzalutamide can be very wearing. All patients are different in their state of health, but many live with the side effects of the treatments they have already been put through. Enzalutamide can enable you

to live a completely normal life, however, once a month, blood tests have to be taken to check on the progress of the disease. This can be an emotionally difficult time because the patient always wonders whether the disease has progressed and this is very stressful.

3. Current practice in treating the condition

Which treatment outcomes are important to patients or carers? (That is, what would patients or carers like treatment to achieve?) Which of these are most important? If possible, please explain why.

The important treatment outcomes are twofold. The very fact that the patient is still alive is self explanatory, but equally important is quality of life and the treatment should be capable of reducing pain and enable the patient to live as normal life as possible and to take a full and active roll in society.

What is your organisation's experience of currently available NHS care and of specific treatments for the condition? How acceptable are these treatments and which are preferred and why?

Current NHS practice for advanced prostate cancer is deeply flawed. As it stands, apart from some very strict circumstances Enzalutamide or Abiraterone cannot be given after each other. This restricts the treatment options for patients and for many will result in a premature end to life.

Radium 223 cannot be given with either Enzalutamide or Abiraterone.

Unlike other cancers, in the NICE treatment pathway, there is no provision for Bone Health. This is becoming even more important because patients are living longer with Enzalutamide and an increasing number are experiencing catastrophic spinal compression.

4. What do patients or carers consider to be the advantages of the treatment being appraised?

Benefits of a treatment might include its effect on:

- the course and/or outcome of the condition

- physical symptoms
- pain
- level of disability
- mental health
- quality of life (such as lifestyle and work)
- other people (for example, family, friends and employers)
- ease of use (for example, tablets rather than injection)
- where the treatment has to be used (for example, at home rather than in hospital)
- any other issues not listed above
- Few, if any side affects.

Please list the benefits that patients or carers expect to gain from using the treatment being appraised.

Enzalutamide has proved to be a highly successful treatment in the post chemotherapy setting. It produces all of the benefits listed above, even in very advanced patients. If it would be made available for pre-chemotherapy, the patient would be stronger and be in an even better place to take advantage of this remarkable drug. Not only would it save the patient all of the rigors of six months of chemotherapy, it would save on the cost of chemotherapy treatment, the outcome of which is doubtful anyway. Enzalutamide is easily taken in capsule form and administered daily at home.

Please explain any advantages that patients or carers think this treatment has over other NHS treatments in England.

Enzalutamide is very easy to take, just four tablets per day. It has very few side affects and is far less toxic than other treatments, which require prednisolone to be taken as well. It appears to be of benefit for a longer time than other treatments.

If you know of any differences in opinion between patients or carers about the benefits of the treatment being appraised, please tell us about them.

None that I no of.

5. What do patients and/or carers consider to be the disadvantages of the treatment being appraised?

Disadvantages of a treatment might include:

- aspects of the condition that the treatment cannot help with or might make worse Not applicable
- difficulties in taking or using the treatment (for example, injection rather than tablets) Tablets. Very easy to take
- side effects (for example, type or number of problems, how often, for how long, how severe. Please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate) This is a very personal question. This treatment does NOT cause any of these problems, but desease progression might. In which case, the patient might well want to come of treatment and let events take their course
- where the treatment has to be used (for example, in hospital rather than at home) The treatment is taken at at home and is self administered.
- impact on others (for example, family, friends and employers) The treatment can only have a positive benefit on others.
- financial impact on the patient and/or their family (for example, the cost of travel to hospital or paying a carer) As I said in the above, apart from monthly blood tests, the treatment is self administered at home and has no financial implications for the patient.
- any other issues not listed above. None

Please list any concerns patients or carers have about current NHS treatments in England.

As stated earlier in this document, the drug sequencing imposed by NHS England with Abiraterone and Enzalutamide is a life limiting and a disappointing situation, as the lack of bone health recommendations from NICE.

Please list any concerns patients or carers have about the treatment being appraised.

None

If you know of any differences in opinion between patients or carers about the disadvantages of the treatment being appraised, please tell us about them.

None to my knowledge

6. Patient population

Are there any groups of patients who might benefit more from the treatment than others? If so, please describe them and explain why.

None to my knowledge

Are there any groups of patients who might benefit less from the treatment than others? If so, please describe them and explain why.

None to my knowledge

7. Research evidence on patient or carer views of the treatment

Is your organisation familiar with the published research literature for the treatment?

✓Yes ☐ No

If you answered 'no', please skip the rest of section 7 and move on to section 8.

Please comment on whether patients' experience of using the treatment as part of their routine NHS care reflects the experiences of patients in the clinical trials.

On a personal level, my patient experience is far in excess of the timeline quoted for the length of time that the treatment continues to work.

Do you think the clinical trials have captured outcomes that are important to patients? Are you aware of any limitations in how the treatment has been assessed in clinical trials?

Clinical trials model much of the data employing tools recommended by NICE. Modelled data does always reflect real life and in many instances the survival is greater and the resultant cost of QALY less.

If the treatment being appraised is already available in the NHS, are there any side effects that were not apparent in the clinical trials but have emerged during routine NHS care?

Yes it is already available on the NHS and has exceeded the expectations of the clinical trials

Are you aware of any relevant research on patient or carer views of the condition or existing treatments (for example, qualitative studies,

surveys and polls)?

✓☐Yes A trial is being conducted in Guy's Hospital with post Abiraterone and Radium 223 patients being given Enzalutamide.

If yes, please provide references to the relevant studies.

This comes from a member who has been recommended for the trial.

8. Equality

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Protected characteristics are: age; being or becoming a transsexual person; being married or in a civil partnership; being pregnant or having a child; disability; race including colour, nationality, ethnic or national origin; religion, belief or lack of religion/belief; sex; sexual orientation.

Please let us know if you think that recommendations from this appraisal could have an adverse impact on any particular groups of people, such as:

- excluding from full consideration any people protected by the equality legislation who fall within the patient population for which the treatment is/will be licensed; No
- having 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 treatment; No
- any adverse impact on people with a particular disability or disabilities. No

Please let us know if you think that there are any potential equality issues that should be considered in this appraisal.

None

Are there groups of patients who would have difficulties using the treatment or currently available treatments? Please tell us what evidence you think would help the Committee to identify and consider such impacts.

None

9. Other issues

Do you consider the treatment to be innovative?

✓Yes ☐ No

If yes, please explain what makes it significantly different from other treatments for the condition.

Enzalutamide is highly affective. It not only prolongs life, it reduces pain, it does not have the toxicity issues of other treatments and has very few side affects.

Are there any other issues that you would like the Appraisal Committee to consider?

Bone Health. As patients live longer with these advance treatments, bone health becomes more important

10. Key messages

In no more than 5 bullet points, please summarise the key messages of your submission.

- Enzalutamide is a highly affective treatment and will be even more so in the pre-chemotherapy setting.
- Enzalutamide reduces pain and enables the patient to enjoy a near normal quality of life
- Enzalutamide has very few side affects. In most patients none that an advanced prostate cancer patient has not been living with for a long time
- Enzalutamide is very easy to take. Just four tablets per day.
- Enzalutamide will be even more successful in the pre-chemotherapy setting and this would increase the quality of life for the patient by not having to go through six months of debilitating and often unsuccessful chemotherapy.