Appendix G – Patient/carer organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: Prostate Cancer UK

Are you (tick all that apply):

√ an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)

Prostate Cancer UK is the UK's leading charity for men with prostate cancer and prostate problems. We support men and provide information, find answers through funding research and lead change to raise awareness and improve care. The charity is committed to ensuring the voice of people affected by prostate disease is at the heart of all we do.

We conducted an online survey of people affected by prostate cancer about their opinions on abiraterone for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy and access to the drug. 40 people replied to the survey and quotes from the respondents are included in this submission. Of the 40 respondents, 12 men said they had been treated with abiraterone before chemotherapy.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy

As demonstrated in a recent phase III trial[i] abiraterone was shown to increase the time before prostate cancer could be seen to progress in chemotherapy-naïve men with metastatic castration-resistant prostate cancer by an average of 8.2 months. It has also increased the time before men started to experience other symptoms such as pain and a decline in performance status.

Should NICE recommend abiraterone for use in this indication, it will help to extend standardised access to the drug, increase the range of clinically effective treatment options available to all patients for whom it is appropriate and provide them with greater choice and hope, possibly giving them more time with their families and improving their quality of life.

Prostate Cancer UK was delighted that NICE in 2012 approved the use abiraterone for men who had previously received chemotherapy. The results from the phase III clinical trial for pre-chemotherapy are very positive and we hope NICE will approve abiraterone for this indication also.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:
- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above

Of the 40 people affected by prostate cancer who responded to our survey, 30 people believe it is ‘very important’ (29) or ‘important’ (1) for abiraterone before chemotherapy to become a treatment option available to all men for whom it is clinically appropriate. 7 respondents were unsure. When asked about benefits of abiraterone before chemotherapy, 26 people said that it was important to extend life for as long as possible. 24 said that it improved long-term control of the disease. 21 said it could provide a better quality of life, including less pain. 11 said it provided another treatment option when other treatments have failed. 14 said that an advantage of abiraterone before chemotherapy is that it can be administered orally.

Quotes on advantages include:

“The prolonged survival is key. My dad is 62 and has so much he wants to do with the time left - even if it is just a few months, it would make a huge difference and allow him to maintain activities that are so important to his identity and sense of self before having the much more disruptive chemotherapy.”

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy

"My dear Dad died in September 2013 and I had asked for him to be given abiraterone several months before but he was not given it. Had he been given it before chemotherapy I think my Dad would still be here and not have died an agonising death."

"Chemo would usually be thought of as a last resort due to its extensive side effects so an additional treatment that is effective before chemo would be a huge improvement in the very limited number of options available for metastatic disease."

Abiraterone can help improve outcomes for men with this type of prostate cancer by delaying chemotherapy treatment, which often has debilitating side effects. These can include: nausea and vomiting, temporary bone marrow problems, fatigue, hair loss, loss of appetite, bowel problems (such as diarrhoea) and numbness of the hands and feet.

A further benefit of this treatment is that it can be administered orally at home by the patients and does not require frequent hospital visits for administration.

2. Disadvantages

Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

The side effects[ii] of abiraterone are generally mild and may be easily managed but can include symptoms such as build-up of fluids in the ankles, headaches, loss of appetite and diarrhoea.

When asked about possible side effects of abiraterone before chemotherapy, 4 people were very concerned; 13 were concerned, but expect the benefits to outweigh the side effects; 11 were concerned, but no more than any other standard treatment.

Some of the comments received were:

"Already suffering with neuropathic pain from secondary mets in the bones, the prospect of reducing pain outweighs the risk of side effects, especially if it delays chemotherapy which is much more disruptive and potentially unpleasant."

"The side effects do not sound anywhere near as bad as the side effects from chemotherapy which are horrendous."

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy

"All treatments carry some side effects but most would put up with them for extended life."

"Very stressful and upsetting taking the drug due to feeling sick and unwell."

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

As described above some respondents to our survey had side effects from taking abiraterone. However the overwhelming majority of respondents believe abiraterone for this indication should be made available on the NHS.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

This licensed indication (pre-chemotherapy) abiraterone will be of most benefit to men who have stopped responding to hormone therapy, but have yet to commence with chemotherapy. Given the side effects associated with chemotherapy, abiraterone could improve quality of life and increase progression-free survival.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Docetaxel.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:
- improvement of the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc)

See above comments made in response to question 2.

A further benefit of this treatment is that it can be administered orally at home by the patients and does not require frequent hospital visits for administration.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:
- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

The disadvantages identified are the mild side effects associated with the treatment.

Research evidence on patient or carer views of the technology
If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

See above comments.

Availability of this technology to patients in the NHS
What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

Comments from respondents to our survey included:

"Greater choice of treatment options. Possible feelings of greater control over one's condition."

"A good option instead of going straight on to chemotherapy."

"Chemo would usually be thought of as a last resort due to it's extensive side effects so an additional treatment that is effective before chemo would be a huge improvement in the very limited number of options available for metastatic disease."

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

Comments from respondents to our survey included:

"I would be very annoyed. This drug should already be available on the NHS. My Dad wanted it and didn't get it. I believe prostate cancer patients are getting a very bad deal from the NHS."

"Disappointed that the best options are not pursued giving people a better chance of a good quality of life."

"Distraught and annoyed as there is no reason why abiraterone is not just a effective before chemo as after, and I cant see why that rule was introduced apart from cost saving which is despicable."

By extending the use of abiraterone for this indication on the NHS, it would provide men with advanced disease another option and possibly provide increased progression free survival. If abiraterone was not approved for this indication then it would deny those men standardised access to the drug, limit treatment options available and decrease choice and hope.

Prostate Cancer UK believes men should be able to access that drug on the NHS if it has been prescribed by their doctor and they make an informed choice to take it. If the STA recommends this treatment for use it would provide hope and demonstrate to men and their carers that progress is being made in the treatment of prostate cancer, including for men with advanced disease.

Are there groups of patients that have difficulties using the technology?

No. Abiraterone is easily administered orally as a tablet and can be taken by the patient at home. The recommended dose is 1,000 mg (four 250 mg tablets) as a single daily dose that must not be taken with food.[iii]

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.

It will be important to ensure that access to this technology is equitable and discrimination does not occur on the basis of age, ethnicity or socio-economic status. Prostate cancer is more common in men aged over 60 and African Caribbean men are three times more likely to develop prostate cancer than white men of the same age in the UK.

Furthermore, men from lower socioeconomic backgrounds are less likely to survive prostate cancer than men from more affluent backgrounds. It will be important to ensure that eligible patients from these populations are not denied access to this technology (if approved) because of factors related to their age, ethnicity and socio-economic status. Information and communication strategies must also be considered and patients consulted to ensure that access can be as equitable as possible.

Other issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

It is important that health-related quality of life and adverse effects are considered with an equal standing to the other outcomes, such as patient-reported outcomes. Consideration of patient-reported outcomes will ensure that the agent is not only clinically effective but also improves outcomes of importance to this patient population.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy

---

[i] Abiraterone in Metastatic Prostate Cancer without Previous Chemotherapy. Charles J. Ryan, et.al The New England Journal of Medicine Vol 368 No 2 January 2013.
[ii] Abiraterone summary of product characteristics. Electronic Medicines Compendium 2013. http://www.medicines.org.uk/EMC/medicine/24976/SPC/Zytiga+250+mg+tablets/#UNDESIRABLE_EFFECTS (accessed February 2013)
[iii] Abiraterone summary of characteristics. Electronic Medicines Compendium 2013. http://www.medicines.org.uk/EMC/medicine/24976/SPC/Zytiga+250+mg+tablets/#POSOLOGY (accessed February 2013)