NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone for the treatment of metastatic castration resistant prostate cancer following previous cytotoxic therapy

About you

Your name: [redacted]

Name of your organisation: The Prostate Cancer Charity

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)

The Prostate Cancer Charity is the UK's leading charity working with people affected by prostate cancer. We fund research, provide support and information, and campaign to improve the lives of people affected by prostate cancer. The Charity is committed to ensuring that the voice of people affected by prostate cancer is at the heart of all we do.[i]

The Charity conducted a paper and online survey of people affected by prostate cancer about their opinions on abiraterone for the treatment of metastatic, castration-resistant prostate cancer and access to the drug. 101 people replied to the survey and quotes from the respondents are included in this submission. Of the 101 respondents, 7 were men with prostate cancer who are currently being treated with abiraterone. [ii]

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.

As demonstrated in a recent phase III trial[iii], abiraterone has been found to prolong the overall survival of men whose prostate cancer has spread to other parts of the body (advanced prostate cancer) and has stopped responding to other hormone therapy and chemotherapy treatments by an average of 3.9 months. Also, pain eased during the trial for a statistically significantly number of patients taking abiraterone than the placebo.

This treatment will make a significant difference to these men by offering the possibility of extending their lives, when there are only very limited treatment options are available, apart from palliative care.

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Should the STA recommend abiraterone for use for this indication, it will help to provide 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.

(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 101 people affected by prostate cancer who responded to our survey, 82 people (9 people did not answer this question) believe it is 'very important' for abiraterone to become a treatment option available to all patients for whom it is clinically appropriate. 39 respondents explained that this is because it is important for them to extend life for as long as possible. Increased survival was seen by some as an opportunity for these patients to be able to spend more time with family and friends.

"Additional time with friends and loved ones should be enormously beneficial and helpful in many different family scenarios e.g. enabling the pleasure of witnessing the birth of a grandchild which might otherwise not be possible. This is one example, but one could cite a very long list of others."

The comments made by 32 respondents also suggest that another benefit of having this drug available as a treatment option is that it will improve quality of life by increasing hope and mental well-being at a time when very limited treatment options are available.

" [It will] Give men who are currently on effective hormone therapy hope and optimism because there is another future treatment in the armoury available when the cancer becomes hormone resistant. This will be of tremendous psychological benefit."

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.

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

2. **Disadvantages**

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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 their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

The side effects[iv] of abiraterone are generally mild and may be easily managed but include:

- build up of fluid on the ankles
- a rise in blood pressure
- headaches
- loss of appetite
- tiredness (fatigue)
- hot flushes
- swelling or pain in the joints
- muscle aches
- diarrhoea
- urinary tract infections
- a cough, cold like symptoms
- an irregular heart beat
- passing urine more often
- heartburn

Out of the 71 respondents who answered a question about the disadvantages of abiraterone, the overwhelming majority (46) said they did not have any concerns relating to abiraterone. Many respondents believe that the side effects are milder than other treatments or, at worse, comparable to other treatments.

"From what I have read I have no major concerns with the side effects quoted as they are very much as can be expected with other [prostate cancer] treatment drugs and can be managed. However, I should imagine the side effects experienced will vary from patient to patient but the greater majority would tolerate them."

"Most of the side effects seem to be similar to what I have using Zoladex so I would not be unduly worried."

Only one respondent was concerned about whether abiraterone would be suitable for people with heart conditions. Three other respondents questioned whether the side effects outweighed a short extension of life.

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

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The overwhelming majority of people who we surveyed about abiraterone agreed that for men who were in the advanced stages of prostate cancer, and for whom chemotherapy had ceased to be effective, this drug could extend life and thus ensure quality time at the end of their lives.

Only a few respondents (4) commented that they thought that the clinical effectiveness of abiraterone is fairly limited, by only giving an average life extension of 4 months. One other respondent believed more emphasis should be placed on cure and prevention.

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?

In the licensed indication (post chemotherapy), it will perhaps be of most benefit to those who are not suitable for (e.g. cannot tolerate side effects/other health conditions) or cannot get access to cabazitaxel. For these men, abiraterone will be the only treatment that can offer the chance of extending life. It may also be of particular benefit to those who cannot attend hospital appointments as regularly as cabazitaxel would require.

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.

A chemotherapy drug called cabazitaxel has been found to extend the lives of men with metastatic castration resistant prostate cancer that no longer responds to hormone therapy or the chemotherapy agent docetaxel. It was found to extend life by an average of 2.4 months.

Cabazitaxel was recently licensed for use in the UK and is currently being appraised by NICE and the Scottish Medicines Consortium. It is not, therefore, currently widely available to men across the UK.

There is currently no data available comparing the effectiveness of abiraterone and cabazitaxel.

(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 in 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

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hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

There are currently no other treatments widely available on the NHS across the UK for men who have metastatic castration-resistant prostate cancer which has stopped responding to hormone therapy and chemotherapy. The only other options are palliative.

The findings from the phase III clinical trial demonstrate that abiraterone can prolong overall survival in men with metastatic castration-resistant prostate cancer who have previously received other hormone therapy and chemotherapy. Survival was prolonged, on average, by 3.9 months compared to a placebo.

When compared to the placebo group, patients taking abiraterone were also more likely to experience a significant drop in their PSA levels (which is the standard measure of prostate cancer activity), and they had more time before their PSA level started to rise again (10.2 months v 6.6 months). X-rays showed that, on average, tumour growth was delayed in men taking abiraterone (5.6 months v 3.6 months).[v]

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

The disadvantages identified are the mild side effects associated with the treatment. The majority of people (71) affected by prostate cancer who responded to this question stated that these disadvantages do not in any way outweigh the benefit of extending life.

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.

7 respondents to our survey said they were currently being given abiraterone.
The general consensus of opinion was that it had improved their quality of life and allowed them to extend their lives.

"Apart from extending the anticipated life expectancy which, is in my view is the main reason for subjecting yourself to the possible side effects, I would say the benefits are much the same as taking part in a trial, where you do feel you are at least taking up the fight to survive the disease and also improve your outlook on life!"

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

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No respondents who are currently taking abiaterone reported any major side effects.

"Hardly any side effects so far (hot flushes, raised blood pressure, fatigue). I have only been on it for three months but pains in stomach and lower back have gone. I am not taking any pain killers at all."

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?

Of the 101 people affected by prostate cancer that we surveyed, the most common benefits of making abiraterone available on the NHS were identified as extending the lives of men with advanced prostate cancer and providing an additional treatment option for these men.

There are currently no other non-palliative treatments available on the the NHS for men with this type of cancer. All men should be offered the choice of a life-extending agent that can allow them a few extra months to spend with family and friends and 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.

"[An STA recommendation would offer] Encouragement that the NHS is taking the issue of prostate cancer on an equal footing with breast cancer. A sign that real progress is being made in the NHS fight against this disease - these sort of thoughts make a big difference to men with prostate cancer and their families. The idea of having life extended by this treatment cannot really be quantified in terms of the benefit it would give to men and their families".

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

No. Abiraterone is easily adminstered orally as a tablet and can be taken by the patient at home. Four tablets are taken once a day on an empty stomach, plus one steroid tablet taken twice a day on a full stomach. There may be issues with compliance – especially for older men/men with memory/dementia problems. Therefore, clear messaging is needed.

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

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The main implication for these patients would be the loss of a chance to increase their survival and increased distress associated with not being able to access a clinically relevant drug.

"[I would be] Aggrieved. My disease is advanced - to what degree is not exactly known, but I have had chemo and radiotherapy so am running out of options."

Many respondents to our survey reported that that patients with prostate cancer would feel deprived and let down by the NHS if the treatment were not recommended.

"Personally, I would feel annoyed and frustrated. I would only have palliative radiotherapy, a deteriorating quality of life and ever-approaching death to 'look forward' to. Phase 3 trials have shown abiraterone to be effective and safe and it has been approved for use in the USA and Europe. I have been looking forward to abiraterone being made available for nearly a year and would feel that NICE had missed a great opportunity to enhance the quantity and quality of lives of many thousands of men in the UK - and to put the UK at the forefront of cancer treatment worldwide."

"If the results from other countries are encouraging, I would be unhappy if it were not available in UK"

"Devastated and angry with a Health Service that has turned its back on us men. 5 years ago we metastatic men had no hope now we can see a glimmer of light PLEASE don't extinguish that faint glimmer of light."

"10,000 men die each year from prostate cancer. It would be a matter of extreme disappointment if a cancer drug that could be of benefit to many men is not made available."

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

Equality

Are there any issues that require special attention in light of the NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others?

It will be important to ensure that access to this technology is equitable and discrimination does not occur solely 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

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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, such as the extension of life.

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[i] Transforming the future for prostate cancer: The Prostate Cancer Charity's 2020 goals and 2008-2014 strategy. The Prostate Cancer Charity 2008. Available at: http://www.prostate-cancer.org.uk/about-us/what-we-do/our-strategy

[ii] Between 25th August and 22nd September 2011, The Prostate Cancer Charity surveyed people affected by prostate cancer living in England and Wales for their views on abiraterone. 100 people responded to an online and paper survey. 92% of respondents had been diagnosed with prostate cancer (the others were relatives or friends of someone diagnosed with the disease) and 25% of respondents had advanced prostate cancer. 5 people said they were currently being treated with abiraterone.

[iii] Abiraterone and Increased Survival in Metastatic Prostate Cancer. Johann S. De Bono, et.al The New England Journal of Medicine Vol 364 No 21 May 2011.

[iv] Abiraterone Summary of Product Characteristics. Electronic Medicines Compendium 2011. Available from http://emc.medicines.org.uk (accessed September 2011)

[v] Ibid