NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy [ID503]

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:

I am a retired academic in the social sciences and an active volunteer with Prostate Cancer UK.

Are you (tick all that apply):

I was diagnosed and treated for prostate cancer in 2004. The cancer is currently in full remission. I have been nominated as a patient expert at a number of relevant NICE events by Prostate Cancer UK for whom I have been an active volunteer since 2007. My voluntary work for the charity includes awareness, support and campaigning work, including advocacy for men and their families who encounter the disease. Additionally, I am a committee member for the Research Ethics Service of the Health Research Authority.

While I fully identify myself with the submission (qv) to this STA by the Senior Policy Officer of my nominating organisation, I will also take the opportunity to make a personal statement, as follows.

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

1. Advantages

Abiraterone is successful in the treatment of advanced metastatic prostate cancer that proves resistant to chemotherapy, prolonging life and providing an improved quality of life for patients. *Prima facie* there seems to be no reason why it should not prove equally efficacious before chemotherapy. A recent Phase III trial (*) seems to confirm this assumption: the evidence shows that it prolongs life, delays the onset of distressing symptoms associated with advanced prostate cancer and improves the quality of life in a number of important respects.

The benefits of this drug taken before chemotherapy, as also experienced by men who have received it after chemotherapy, might well include:

- Managing effectively the worst symptoms of advanced metastatic prostate cancer.
- Extending life by a significant margin, enabling men to put their affairs in order, nurture their closest relationships and achieve important end-of-life objectives.
- Alleviating the pain and discomfort often associated with late-stage, metastatic prostate cancer.
- Restoring a positive state of mind and enhancing mental health in general for both the patient and his loved ones. For men still in employment, the treatment will enable them to retain their function and earning capacity. Similar benefits, too, might accrue to men who enjoy an active, physically demanding lifestyle.
- Giving men some sense of personal control over their condition since the drug is self-administered and requires limited hospital visits compared with other treatments.

2. Disadvantages

There are some unwanted side effects to this drug including build-up of fluids in the ankles, headaches, loss of appetite and diarrhoea. In general, these side effects are reported to be moderate and manageable. Men may well accept these inconveniences as a reasonable price to pay for the alleviation of more significant and distressing symptoms. I am aware (anecdotally and by informal report), however, that in some cases, problems with the liver can arise as an apparent consequence of taking the drug, leading to abandonment of the treatment and/or switching to an alternative drug, Enzalutamide, the latter having the same effects upon the underlying cancer without concomitant damage to the liver.

As far as I am aware, there would be no negative consequences for the patient's family, friends or employers, nor financial hardship for any party arising from its being prescribed: rather the contrary.

In discussion with persons directly affected by the disease at this stage, and receiving a range of alternative treatments, nearly all parties recognise that, amongst the limited options

available for treatment, the potential benefits of this drug far outweigh any likely disadvantages that it may entail.

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

I am aware personally of one patient who received Abiraterone following chemotherapy, who benefited enormously from it initially and spoke very positively of its profound and welcome effects upon the skeletal pain, fatigue and depression following a failing course of chemotherapy. He did, however, subsequently experience liver problems and was taken off the course of Abiraterone. Other patients, however, report only positive outcomes. It may well be that the drug will not be effective in all cases of the target indication, but continuing and further research will no doubt assess and thoroughly evaluate the incidence of the range of outcomes.

Given these differences in individual experiences, there is, I believe, a powerful argument for testing rigorously the potential value of this drug to men with advanced metastatic prostate cancer before they embark upon a course of chemotherapy. Chemotherapy has predictable, deleterious side effects upon the patient, notwithstanding its effectiveness in managing the underlying cancer. Abiraterone may prove a real and attractive alternative to existing standard treatments for the majority.

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?

Patients most likely to benefit from this technology are those whose advanced metastatic cancer is no longer responsive to hormone therapy, but who have not yet embarked upon chemotherapy, who are also asymptomatic or have not yet developed symptoms associated with this stage of the disease. It may be less advantageous to those patients who do not meet these criteria.

For patients, especially older patients and/ or those with mobility problems who live at some distance from hospitals, it will be highly advantageous to be able to be able to have effective treatment in tablet form that can be taken at home without medical supervision.

Since the technology requires that the patient doses himself at regular intervals and coordinated with meals, patients with reduced mental capacity, for example, may require the assistance and support of a carer to ensure correct use of the technology.

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Comparing the technology with alternative available treatments or technologies

(i) Chemotherapy regimes including Docetaxel are prescribed for patients with advanced metastatic prostate cancer that no longer responds to hormone therapy.

From what I have learnt at previous NICE events that I have attended, Enzalutamide appears to be an alternative technology for this subset of patients and has sometimes been administered in clinical practice where complications have arisen from treatment by Abiraterone.

I am not qualified to comment on the relative benefits and adverse effects of these technologies.

(ii) I refer you to my answer to (1) above: advantages of the technology.

(iii) I refer you to my answer to (2) above: disadvantages of the technology.

Equality and diversity

NICE should ensure that access to this technology is equitable, consistent and universal; and that 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 aggressive prostate cancer than white men of the same age in the UK. Men from lower socioeconomic backgrounds are less likely to survive prostate cancer than men from more affluent backgrounds.

If this technology is approved, it will be important to ensure that eligible patients from these populations are not denied access to it because of irrelevant factors related to age, ethnicity and socio-economic status. Effective information and communication strategies must also be implemented and patients consulted to ensure that access is as equitable as possible and that potential recipients of the technology are fully apprised of its effects and are thus able to make an informed choice to submit themselves to the treatment, or not.

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Research evidence on patient or carer views of the technology

I refer you to the details of the survey conducted by my sponsoring body, Prostate Cancer UK, and cited in the statement (qv) submitted to this STA by its Senior Policy Officer.

I have no further evidence to offer.

Availability of this technology to patients in the NHS

The availability of this technology would provide a further option for treatment in a somewhat limited range of alternatives for men with advanced prostate cancer that is proving resistant to hormone therapy.

It will likely extend life by a significant margin to the advantage of the patient himself, his carers, family, friends and – in some cases – employers. At the same time, it will measurably enhance the quality of life of patients, bringing relief from pain, restoration of optimism and good spirits, avoidance of the need for extensive or frequent hospital visits and it will empower patients in the management of their disease by putting the technology in their hands.

If it were not made available, all of the above advantages would be lost. Men and their families would be faced with limited options for treatment for their condition other than palliative care, or the predictable, dire side-effects of chemotherapy and an uncertain future for the progress of their already critical disease, depressed spirits and consequent distress amongst their loved ones.

The technology is easily and readily self-administered, requiring manageable dosages in tablet form at specified intervals during the day. It would not pose difficulties for the overwhelming majority of patients for whom it would be prescribed.

Other issues

While it is clearly important that NICE makes its decisions upon the basis of reliable and valid evidence gained from high quality research conducted by medical and health economic experts, it is equally important that the voice of ordinary patients is heard and accorded the respect and it deserves. In the strictest sense, its evidence may not be as rigorous as that secured by experts, but it is nonetheless authentic and addresses the human concerns at the

heart of illness, its treatment and consequences. It may well address the very real emotional aspects of health events that are not so easily measured and quantified, but are none the less real or important for that.

References:

**Saad F, Shore ND, Van Poppel H, et al. Abiraterone acetate in metastatic castration-resistant prostate cancer patients without prior chemotherapy: Interim analysis of the COU-AA-302 phase 3 trial. Presented at: the Annual Meeting of the American Urological Association; May 4-8, 2013; San Diego, California. Abstract 713.*