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Technology Appraisal Committee B
National Institute for Health and Care Excellence
10 Spring Gardens
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5th June 2014

Dear Jeremy,

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

Thank you for inviting Prostate Cancer UK to respond to the Appraisal Consultation Document (ACD) on abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy.

About us

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.

Prostate Cancer UK's view on the draft decision

Prostate Cancer UK is very concerned that this decision, if confirmed, will have a detrimental effect on men with prostate cancer. We urge NICE and the pharmaceutical company Janssen to work together so that men can access abiraterone on the NHS in England and Wales. As reported in the ACD document, albeit not capturing fully the true value to men with prostate cancer, delaying the use of chemotherapy can mean men are not faced with severe side effects of chemotherapy and therefore experience improved quality of life that abiraterone can offer earlier on in their treatment.

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.

Prostate Cancer UK is a registered charity in England and Wales (1005541) and in Scotland (SC039332). A company limited by guarantee registered number 2653887 (England and Wales). VAT 905 9415 18.

Clinical practice

The use of abiraterone before chemotherapy has been approved for use on the Cancer Drugs Fund (CDF) , but this is only a temporary measure and the CDF applies in England only. Between April 2013 and March 2014 abiraterone, for this indication, was the second most requested treatment with 3,023 notifications received[ii]. This means that abiraterone before chemotherapy is now part of standard practice in England; we do not believe the ACD reflects this. We have asked several clinicians about their current use of abiraterone for this indication, comments included:

"We are routinely using abiraterone before chemotherapy. Almost all patients, without exception."

Benefits of abiraterone before chemotherapy: "Fewer side effects. Easier for patients to receive. Easier for departments to administer."

"It is possible to use abiraterone in patients who would not have been otherwise fit for chemotherapy because of age, comorbidity and patient preference not to have chemotherapy."

Therefore it is essential that NICE approves its use in order for standardise access elsewhere.

Abiraterone pre-chemotherapy: what do men with prostate cancer say?

As the UK's leading prostate cancer charity, we are in a privileged position to be able to represent the views of men with prostate cancer. As highlighted in our earlier submission to NICE, we surveyed men with prostate cancer to find out their views on abiraterone before chemotherapy.

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. 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."

“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.

Since the ACD was published on NICE’s website, we have been asking people affected by prostate cancer to provide their views on the draft decision. Comments have included:

“Abiraterone should definitely be an option for men who haven’t had chemotherapy. Every man is different but just look at my results [PSA went from 500 to 0.05] – it turbo charged the effects of treatment and it was really heartening to see my PSA levels dropping. As far as my experience has been concerned it’s ticked all the boxes.”

“Sadly my dad was told that he was not suitable for chemotherapy, this then meant he was unable to have abiraterone. He passed away in October 2012. We must keep going to get this through, wouldn't want anyone else to be refused treatment.”

Conclusion

Prostate Cancer UK believes that NICE’s draft recommendation on abiraterone acetate for the treatment of metastatic hormone relapsed prostate cancer not previously treated with chemotherapy is unacceptable, as this will deny those men access to this vital treatment option, especially when it is becoming commonplace for men for whom hormone therapy is no longer effective.

Yours sincerely,

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Head of Policy and Campaigns

[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] Quarterly figures – including notifications and Individual Cancer Drug Fund Requests (ICDFRs). Report April 2013-March 2014. http://www.england.nhs.uk/ourwork/pe/cdf/