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Jeremy Powell
Technology Appraisal Committee B
National Institute for Health and Care Excellence
10 Spring Gardens
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18th February 2014

Dear Jeremy,

Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with docetaxel-containing regimen

Thank you for inviting Prostate Cancer UK to respond to the Appraisal Consultation Document (ACD) on Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with docetaxel-containing regimen.

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 detrimental effect on men with prostate cancer. The restriction around the use of enzalutamide is bad news for men with advanced prostate cancer who have limited treatment options. Until now, only abiraterone has been approved by NICE for men with this stage of prostate cancer. This decision complicates the situation for men who desperately need more treatment options. We therefore call on the Committee to remove this unfair, illogical restriction on the use of enzalutamide and allow men to access to every option when they are approaching the end of their lives. Furthermore, we do not believe the Committee has justified why the restriction is now proposed, when the first ACD in October 2013 did not make any reference to sequential use of abiraterone and enzalutamide.

Prostate Cancer UK is pleased that NICE are proposing to recommend enzalutamide for those men who have received one or more docetaxel containing chemotherapy, but we believe the

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restriction around abiraterone will see fewer men benefiting from enzalutamide. As demonstrated in a recent phase III trial[i], enzalutamide 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 4.8 months, although we are aware that the ERG analysis says 4.5 months. Nonetheless, we view enzalutamide as a highly important treatment option for men which should be available to men whether or not they have already had abiraterone.

Impact on clinicians

Prostate Cancer UK views the Committee's draft decision as creating unnecessary confusion, which if not overturned, will place an unnecessary burden on clinicians. At the point where a man has stopped responding to hormone therapy, the clinician now has a complicated decision to make, namely risk excluding a patient from ever having enzalutamide if they think abiraterone would be beneficial, but turns out not to work or to be poorly tolerated by that patient.

If the decision was confirmed by the Committee, we believe the draft decision would result in the following scenarios for patients:

- Trying abiraterone pre-docetaxel (currently available on the Cancer Drugs Fund in England) before going onto chemotherapy, but being then unable to access enzalutamide.
- Having chemotherapy first, then trying enzalutamide and then trying abiraterone if all else fails.
- Having chemotherapy first, then abiraterone, but again excluding enzalutamide.

Following publication of the ACD, we have consulted clinicians who are very concerned about the restriction will have on men.

Professor Roger S Kirby, Director Prostate Centre

"[I am] pleased the drug has been approved but disappointed and perplexed that the additional condition has been applied…It is best to let individual clinicians make a decision about drugs and as the two drugs have different mechanisms of action you may get an additional response from enzalutamide even with someone who has previous experience of abiraterone."

Professor David Neal Clinical Director of Surgical Oncology; Professor of Surgical Oncology; Honorary Consultant in Surgical Uro-oncology, Cambridge University Teaching Hospitals NHS Foundation Trust and Senior Research Group Leader at CRUK CI.

"NICE's decision that men with advanced prostate cancer should not be given enzalutamide if they have previously received abiraterone is not in my view based on good evidence that this approach

lacks effectiveness . The mechanism of action of enzalutamide (it blocks the androgen receptor) is quite different from that of abiraterone (it blocks the synthesis of androgens).

This decision of NICE will place doctors treating these men in a position of difficulty, they are therefore more likely to start with enzalutamide as first line treatment of hormone relapsed prostate cancer, which may not turn out to be the most cost-effective approach as abiraterone comes off patent".

Enzalutamide: what 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 enzalutamide.

As we stated in our response to the consultation in June 2013, Prostate Cancer UK conducted an online survey of people affected by prostate cancer to find out their opinions on enzalutamide for the treatment metastatic hormone-relapsed prostate cancer previously treated with docetaxel-containing regimen. 63 (46 who were men diagnosed with prostate cancer) people replied to the survey. Of these, 59 people (one person did not answer the question) believe it is 'very important' (53) or 'important' (6) for enzalutamide to become a treatment option available to all men for whom it's clinically appropriate. From those who responded to our survey, respondents saw the benefits of enzalutamide providing another treatment option and improving quality of life. Comments included:

"It gives an extra option when existing treatments stop working."

"[Enzalutmaide] another treatment option available which has proved successful and gives hope to increase life expectancy and quality of life."

"Anything that can extend and improve life must be a benefit."

"Maintain a better quality of life for those who feel all else has failed."

"Anything that gives people a better chance of a longer life with their loved ones is important."

Prostate Cancer UK believes that enzalutamide will make a significant difference to men whose prostate cancer has spread to other parts of the body and have stopped responding to other hormone therapy and chemotherapy. This treatment could make a significant difference to men by the possibility of extending their lives at a point when there are only very limited treatment options available. Currently, only abiraterone has been approved by NICE for men with this form of prostate cancer.

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. We have also launched an online and paper copy petition calling for the removal of the restriction on enzalutamide only recommended for those men who have not previously been given abiraterone. The petition says:

"I call on NICE to remove its unfair restriction on enzalutamide, which would only make the drug available for those men who haven't had the drug abiraterone. The restriction will mean that men and their doctors will have to make an agonising decision about which treatment to try at an already very difficult time. Men with advanced prostate cancer should have all options open to them, especially when they are limited to very few towards the end of their lives."

We currently have had 3,494 people sign up to our petition (as of 2pm 18th February 2014), this demonstrates the strength of feeling those affected by prostate cancer have, and supports our view that the Committee must remove the restriction on the use of enzalutamide. The names of signatories to our petition can be found in Annex A.

We have also heard from many people who are very angry and concerned about the proposed restriction on enzalutamide and the negative impact it will have on men and their families. Below are a selection of quotes which highlight the severity the proposed decision could have:

"I have lost a family member and a close friend to prostate cancer. We live in the United Kingdom so let's act like it and have fair rules for all! Family of victims and victims of prostate cancer would love the opportunity to extend their lives by 4 months!"

"My Dad has advanced Prostate Cancer, diagnosed in June 2013, at 54 years old. How dare NICE restrict the medications available for us as a family to spend as much time as possible together."

"My husband has advance prostrate cancer and was on abiraterone for 6 months, but the cancer has spread and he is now having chemo and the abiraterone was stopped, he chose to have the chemo on the understanding that enzalutamide would be available at a later time, this news has destroyed our hope as we all know this decision is down to cost, my husband loves life and has a wonderful supportive family this is so unfair and we are now thinking about moving to Scotland its bloody disgusting that this drug is not available, my husband has worked all his life the government needs to change this decision asap."

"My husband was offered abiraterone after chemotherapy, but it only held things for about four months. My husband now only has chance of enzalutamide to hold his cancer for a few more precious months but is denied access to this on the NHS as he lives in England. Our only option is to subscribe privately which will impact obviously in our lives causing further stress to my husband."

I was diagnosed with prostate cancer in January 2012 by the oncology department of the Royal United Hospital, Bath. The cancer was moderately aggressive and had spread to lymph nodes. Since then I have undergone docetaxel chemotherapy, palliative radiotherapy and have had a course of Abiraterone. Throughout this time I have been receiving hormone therapy and am currently undergoing cabazitaxel chemotherapy. I have been denied Enzalutamide because I have already had Abiraterone. The current chemotherapy is extremely unpleasant; enzalutamide would be much preferable, having no significant side effects. If this treatment fails there will be no further option available unless enzalutamide gets NICE approval."

"I have just commenced a cycle of Abiraterone as my prostate cancer has become resistant to standard hormone therapy. My PSA has begun doubling from Sept 2013 when it was down to 9 and is now over 200. I discussed treatment options with my oncologist and together we opted for abiraterone as an alternative to chemo as I am a symptomatic currently those have multiple bone deposits throughout my skeleton. I was aware that this would preclude the future use of enzalutamide but having read further on this I think it most unfair that this may be denied to me and other men in the future. I am aware of the high cost of both therapies but with no chance of a cure, I can only hope that if this fails I won't have to have chemo as the only future option. I urge NICE to reconsider their position and offer hope the men like me who at best can hope for an extended quality of life."

"My husband Kevin has advanced PC with metastatic spread and has just started on his first cycle of abiraterone. If this fails then he is facing chemotherapy. This decision by NICE to exclude access the enzalutamide for patients who have previously received abiraterone will mean he will have no further treatment choices apart for chemo. I urge NICE to lift this unnecessary restriction. I worked as a Cancer Network Director for the last 12 years of my working life and now am managing to live with cancer on a personal and daily basis. I want to longest possible time with my husband and this drug could give him that."

"I was given abiraterone, which, after 9 months started to damage my liver and I had to came off it. At the time, enzalutamide hadn't got a UK licence and the manufacturer was giving it away, free of charge to patients for whom abiraterone had failed. That was 14 months ago and I am now fit and healthy, living an active and useful life. My PSA is between 0.5 and 0.9. I was given enzalutamide under circumstances which no longer exist and with out it I would now be dead. Well done NICE. They have passed enzalutamide, but made it unusable."

"I have advanced prostate cancer I have had 8 months of abiraterone and now I have been taken of as it has stopped working I have received two large blasts of radiotherapy to remove the cancer

from my spine which has worked and now there are plans to give me chemotherapy which has you know will kill whatever immune system I have left there is no clinical or medical reason or monetary reason why I should not be allowed to receive the life saving treatment enzalutamide why is it the rest of the world is wrong and NICE is right even in Scotland allow Enzalutamide without restrictions by the way they are still British citizens paying taxes and NHS I am begging you please allow me a decent life I do not want to die suffering."
"Abiraterone caused liver problems for me and was stopped after 2 months. Currently having chemotherapy. Please do not deny me the chance to extend my life."

"I have been taking Abiraterone for the past few months but it no longer works - PSA shooting up. Oncologist says enzalutamide is the only alternative but he is not allowed to prescribe it. If I can find £2,700 every month I can buy it it privately. I am a pensioner - where can I find that money? Enzalutamide would keep me alive but NICE do not give a toss!"

"I have advanced prostate cancer with widespread bone metastases. Presently I am pain free and live a normal life. I receive zoladex (Goserelin) three monthly injections and my next planned treatment is to receive Abiraterone. When this treatment starts to fail, I would like the option of enzalutamide to hopefully give me more time with my friends and family. Perhaps with the promise of curative vaccines on the horizon, enzalutamide could prolong my life sufficiently to avail myself of those breakthroughs."

"My Dad, aged 56 years, has stage 4 prostate cancer. He was diagnosed on 13 April 2012 and has been, as part of a trial, on abiraterone since. The abiraterone is starting to fail and his PSA is rising. He is likely to start chemotherapy this spring. I would hate for him to be penalised and not able to benefit from enzalutamide, simply because he was willing to participate in a trial." "…the psychological impact of thinking that an avenue of possible treatment has been closed to him cannot be underestimated, on both him and on us; it is very significant. It is also possible that he would be hesitant to enter future trials, or recommend to others that they should, for fear that he/they would be penalised and, as a consequence of volunteering, be excluded from other possible treatments. I think such penalisation is intrinsically unfair."

"My husband has metastatic prostate cancer. He is 56 years old. He has 3 children one of whom is autistic. He has been taking abiraterone for 14 months and this is now ceasing to work. He will start chemotherapy to hold back further spread of the disease in the spring. We were told that his next step would be enzalutamide and that this was producing good results. It is absolutely devastating that this will be denied to a relatively young man, particularly when it is available in Scotland and I urge you strongly to reconsider."

Conclusion

Prostate Cancer UK believes that NICE's draft recommendation on enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with docetaxel-containing regimen is unacceptable which will deny those men access to it who have previously received abiraterone. We therefore call on the Committee to remove this unfair, illogical restriction on the use of enzalutamide and allow men to access to every option when they are approaching the end of their lives.

Yours sincerely,

[redacted]

[redacted]

[i] [i]Increased survival with enzalutamide in prostate cancer after chemotherapy. Scher, H et.al. The New England Journal of Medicine. September 2012.

Annex A

Prostate Cancer UK's petition calling for NICE to remove restriction on enzalutamide

""I call on NICE to remove its unfair restriction on enzalutamide, which would only make the drug available for those men who haven't had the drug abiraterone. The restriction will mean that men and their doctors will have to make an agonising decision about which treatment to try at an already very difficult time. Men with advanced prostate cancer should have all options open to them, especially when they are limited to very few towards the end of their lives."

Prostate Cancer UK sent a list of the 3,494 people that have signed the petition to NICE.