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23rd February 2012

Dear Jeremy,

Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen

Thank you for inviting The Prostate Cancer Charity to respond to the Appraisal Consultation Document (ACD) on abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen.

About us

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.[1]

Response to the ACD on abiraterone

The Prostate Cancer Charity is extremely disappointed by the preliminary decision made by the National Institute for Health and Clinical Excellence (NICE) not to recommend abiraterone for the treatment of men with castration-resistant metastatic prostate cancer who have been previously treated with a docetaxel-containing regimen.

Abiraterone is a breakthrough in the treatment of advanced prostate cancer and we strongly believe that men across England and Wales should have equal access to it. In this response we outline the reasons why we disagree with the recommendation made in the ACD. Specifically, we do not think the decision to exclude abiraterone from the end of life drug criteria is transparent or clear.

THE PROSTATE CANCER CHARITY

Abiraterone and the end of life drug criteria

The Prostate Cancer Charity believes a significant factor for abiraterone not to be recommended in the draft decision was the committee's conclusion that the patient population size for which abiraterone is indicated is too large for it to be considered as an end of life drug. We are unclear what robust evidence this decision was based on.

According to the information provided in the ACD by the drug manufacturer, the size of the population that is likely to be eligible for abiraterone is 3,300.[2] We understand that this is only an estimate as exact numbers of patients at different stages of prostate cancer do not exist. This estimate falls well below the figure of 7,000 outlined by NICE as the normal maximum patient population size for consideration within the end of life drug criteria.[3]

The Charity would therefore like NICE to explain why it considers the patient population size indicated for abiraterone to be too large for it to be considered within the end of life criteria. Specifically, we would like further clarity about the source of the evidence offered by a commissioning expert during the STA committee meeting (see 4.19 of the ACD, page 34) that the manufacturer estimates of number of people eligible were underestimates of the number of patients who would receive abiraterone in clinical practice". The evidence that underpins the statement made by this expert has not been referenced and it is not clear, therefore, how robust it is.

The Charity notes that sunitinib, which is used to treat advanced kidney cancer, was approved by NICE in 2009 as an end of life drug and appears to be indicated for similar a size of patient population as abiraterone.[4] It is also provides a similar average extension to life. We believe that the sunitinib FAD highlights significant inconsistencies in the recommendations of different NICE committees for different drugs, under the end of life criteria. We would like the committee to clarify why sunitinib was considered to be an end of life drug and abiraterone in this indication has not been, even though the size of the patient populations are comparable.

Furthermore, we have noted that the All Wales Medicines Strategy Group (AWMSG) recently reviewed abiraterone and did consider it to be an end of life drug.[5] We therefore cannot understand why the NICE committee have not reached the same conclusion. We believe that there is no reason why abiraterone should not be considered an end of life drug and that the current decision in the ACD is unclear, inconsistent and the evidence for it is not well defined.

Improving treatment options for advanced prostate cancer

Currently, the only treatment options routinely available from the NHS for men with metastatic castration-resistant prostate cancer who have had chemotherapy are palliative. For a significant number of men, abiraterone offers the chance of more time to spend with family and friends and a better quality of life for a longer period of time at the end of their lives. The Prostate Cancer Charity considers abiraterone to be one of the biggest breakthroughs in prostate cancer treatment in recent years.

Abiraterone blocks testosterone synthesis at a stage when no other hormone therapy is effective, it provides an extension of life with few side effects and it can be taken at home.

This 'breakthrough' appears to have been recognised by the committee in point 4.20 (page 34) of the ACD, which states that abiraterone "may offer a step change in treatment because it is life-extending rather than simply palliative". It is therefore a bitter blow that the draft decision is for abiraterone not to be recommended.

If NICE fail to recommend abiraterone for men in England and Wales, many men will not have fair access to this important drug. The Charity very much welcomes the recent decision by the AWMSG to recommend abiraterone[6], as part of the approved Wales Patient Scheme, particularly as they considered it to be an end of life treatment. However, we are greatly concerned that after 2013 the Cancer Drugs Fund will cease to exist in England, and it is unclear what provision will be put in place to enable men in England to access abiraterone through the NHS if it not recommended.. The NICE final decision will also over-rule the AWMSG decision, which would leave men in Wales at risk of inequities in accessing abiraterone from the very near future.

Despite the significant disadvantage that men with advanced prostate cancer face, this preliminary decision not to recommend abiraterone, coupled with the previous decision not to recommend cabazitaxel[7], send a clear signal to men that improving the treatment of men with advanced prostate cancer is not a priority.

Abiraterone: 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 abiraterone.

As we stated in our response to the consultation in September 2011[8], the Charity conducted a paper and online survey of people affected by prostate cancer to find out their opinions on abiraterone for the treatment of metastatic, castration-resistant prostate cancer. 101 people replied to the survey. Of these respondents, 7 were men with prostate cancer who were currently being treated with abiraterone.[9] (Please note that the survey was conducted just before abiraterone was licensed for use in the UK).

Of the respondents, about 9 out of 10 said that it is 'very important' for abiraterone to become available to all patients for whom it is clinically appropriate. Many respondents believed that increased survival and a better quality of life were of great importance when very limited treatment options are available.

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

"My cousin has suffered from prostate cancer for some while now, and the availability of abiraterone treatment has provided him with marked improvement, both in terms of medical results and of quality of life."

"Whilst I recognise that economic constraints influence much - if not all - of life at present, I think it entirely regrettable that NICE should make such pronouncements with apparent lack of regard for those who currently benefit from such treatment. The mark of a civilized society must be that it cares for all its members, and particularly for those in the greatest need. This decision, though only draft at present, certainly seems to be based upon financial considerations only, with no regard to those whose lives are directly - and indirectly - affected."

"My husband is 59, still running his own company, ten and a half years after diagnosis. Not exactly fighting fit, our life is restricted, however the only 'benefit' he has ever claimed is his blue badge, because of difficulties in walking, this is only used when he is struggling. If he was not given [abiraterone], we would both be on benefit, I would expect within [a] few months. It is highly likely the company would close, putting 8 people out of work. The drug is overpriced, however in his case the cost is easily covered by the saving."

"During January 2012 I commenced treatment with abiraterone having been prescribed the drug by my oncologist. I have been able to access this treatment through the Cancer Drug Fund. Firstly I wish to formally put on record my own experience with the drug which even at this early stage has been very little short of remarkable. I am experiencing dramatically less pain and enjoying substantially greater mobility than had been normal for many months prior to the commencement of the treatment. In my case the drug is proving highly effective and these quality of life benefits are both profound and tangible."

The comments above clearly express the benefit abiraterone has given to those individuals at this particular stage of prostate cancer.

Cost of abiraterone

The Charity notes that the Committee was unable to provide a QALY for abiraterone, but the Committee did believe the manufacturer's calculation of £63,200 per QALY was too low. In addition to the points we have made above, we would like to urge the manufacturer to further reduce its cost price of abiraterone for the NHS - if this will allow men with prostate cancer to be able to access this vital drug,

Conclusion

The Prostate Cancer Charity believes that NICE's preliminary recommendation on abiraterone is unacceptable, given the evidence about the clinical effectiveness of this medicine, which has been acknowledged by the Appraisal Committee. Furthermore, the decision not to include abiraterone in the end of life criteria is unclear, inconsistent and not apparently based on good evidence. We strongly recommend that NICE reconsiders its draft decision, and does not run the risk of causing an inequity in access to this breakthrough drug for men with advanced

prostate cancer in England and Wales. However, we also recognise that the cost of the drug could be further reduced for the NHS and urge the drug manufacturer to take this course of action.

Yours sincerely,

[redacted]

[1] 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

[2] Prostate cancer (metastatic, castration resistant) - abiraterone (following cytoxic therapy): appraisal consultation (February 2012)**:** http://guidance.nice.org.uk/TA/Wave26/4/Consultation/DraftGuidance

[3] http://www.nice.org.uk/newsroom/features/endoflifemedicinesconsultation.jsp

[4] Sunitinib for the first-line treatment of advanced and/or metastatic renal cell carcinoma. Nice technology appraisal guidance 169. March 2009

[5] [5] All Wales Medicines Strategy Group Final Appraisal Recommendation – 0612: Abiraterone **(**Zytiga®☐) February 2012

[6] Ibid

[7] Final Appraisal Determination (FAD) on cabazitaxel for the second line treatment of hormone refractory, metastatic prostate cancer. NICE January 2012

[8] The Prostate Cancer Charity response to NICE Single Technology Appraisal on Abiraterone for the treatment of metastatic castration resistant prostate cancer following previous cytotoxic therapy. September 2011

[9] 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. 7 people said they were currently being treated with abiraterone.