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tackle
prostate cancer
Action for patients

Jeremy Powell
NICE
Level 1
Piccadily Plaza
Manchester M1 4TB

2nd March 2014

Dear Mr Powell

NICE - ACD - prostate cancer - enzalutamide [ID600] (non-comp consultees)

On behalf of The Prostate Cancer Support Federation (please note our new working name, "**Tackle prostate cancer**") I am writing to give the response to the above ACD

Tackle,, whilst pleased that enzalutamide has been passed for use, is dismayed that a caveat has been introduce which precludes its use after Abiraterone. We believe that the insertion of this caveat is unfair, is in contravention of the very sound procedures NICE created to avoid such situations and also is not based on any sound evidence.

Has all of the relevant evidence been taken into account?

No

It would appear that introduction of the caveat is based on a very small study involving only 35 men (see http://www.ncbi.nlm.nih.gov/pubmed/23849416). Even in this, it is stated that "a small but significant number of patients showed significant benefit from sequential treatment".

NICE legitimately pride themselves on only considering level 1 phase 3 randomised trial evidence but on this occasion a decision is being made on a few anecdotal retrospective studies. This is grossly inconsistent; we need to wait for randomised sequencing studies before making any judgement on the order of therapies. Clinical experience, of just as good quality, shows that enzalutamide can work after abiraterone and this ruling will restrict a significant number of men from effective therapy. It has been estimated from the CDF that around 3000 will be treated with pre chemotherapy abiraterone and this has major implications on further therapy for them.

In my own case, in December 2012, I was given enzalutamide after it was found I could not tolerate the liver damage abiraterone was causing. Thirteen months later, I now live a totally normal and productive life, with a PSA of around 0.5. I help to run the Tackle support line and I have had men (and women) in tears on the phone to me about the death sentence that NICE have given them.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

NO

In October 2013, an ACD was circulated which approved the use of enzalutamide for hormone relapsed disease with a two caveats, namely that the patient should have undergone exactly one course of chemotherapy (docetaxel) and the manufacturer offered a discount. This was based on a reasonable interpretation of the evidence presented to the committee and discussed in public, and on the strength of it, a significant number of men who were failing with abiraterone and therefore facing imminent death were informed by their oncologists that relief was at hand and that enzalutamide would be available for them in the New Year. The subsequent insertion of the caveat regarding abiraterone dashed these men's hopes.

We understand that the process of assessing a treatment is long, and that drafts of the results are subject to change, but change is only justified if new evidence comes to light, which is not the case here. It may be that the committee felt that there was something that they had overlooked and it was this that prompted them to introduce this caveat. In issuing the first ACD NICE placed itself on record as having no reservations about the effectiveness of enzalutamide after abiraterone had failed. We think it not right to go back on that position without new evidence. To do so would be against the principles that NICE has set itself

When Abiraterone has been given, the cost to the NHS has been budgeted. As Enzalutamide is much the same price as Abiraterone, the cost to the NHS would not be any more than has already been allowed for in the budget. If the patient does not respond to Enzalutamide, it will be apparent very quickly and treatment will be stopped. Therefore, the cost to the NHS will not be great.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?.'

No

We are concerned that well established procedures have not been followed in two significant ways, and this makes the recommendation unsound and unsuitable.

First, a major caveat was introduced without discussion, and secondly, there is nothing in the STA process that allows consideration of these other factors. On the first point there is little more to be said; the caveat was not discussed at the consultation meeting and no sub groups were initially considered.

The second point is more recondite. In adding the caveat, the Commitee were acting outside their scope, which was to consider the role of enzalutamide in the post chemotherapy setting. The use of previous therapies is outside their remit and should not be included. Thus an arbitrary decision has been made without any data. (To illustrate this it is worth considering a patient's previous treatment history; it may be that response to enzalutamide differs depending on the primary treatment and subsequent androgen deprivation regime adopted, but there is no evidence what this might be. In making its decision regarding previous use of abiraterone the committee is

behaving in the same way as it would have been if it decided that enzalutamide should only be used for zoladex treated men, and not those who had prostap.

The caveat takes away all clinical freedom for clinicians who aim to maximise therapy for individual patients. Any exclusions should be considered at local level on an individual patient basis. Such a caveat has never been applied for other drugs where they have been considered on the merit of their licence and not as part of the overall prescribing pathway.

We would like to find with NICE a resolution that is agreeable to both parties. It would be very sad if we had to escalate the issue and formally appeal against the Final Assessment Document if this caveat is not removed. We would, as is our right as the voice of patients, appeal against the recommendation on 3 grounds:

1. it is unfair on men who were, last October, led to the reasonable belief that enzalutamide would soon be available;

2. the process by which the caveat has been introduced is not in accordance with NICE's procedures;

3. the evidence on which they seem to base the caveat is well below the standards normally expected by NICE;

Yours sincerely

Hugh Gunn
Hon Treasurer

Prostate Cancer Support Federation