

NICE Appraisal re Abiraterone

Use in newly diagnosed high-risk hormone sensitive metastatic prostate cancer

After a lengthy period of two years, NICE have finally given their decision on the use of abiraterone in newly diagnosed high-risk hormone sensitive metastatic prostate cancer (ndhrhsmPCa) in England and Wales. **Their decision was to reject the application** for use in this clinical scenario:

“Abiraterone with prednisolone or prednisolone plus androgen deprivation therapy (ADT) is not recommended, within its marketing authorisation, for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in adults.”

“Abiraterone is not a cost-effective use of NHS resources for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer”

In their Final Appraisal Document (FAD) the NICE Committee do not deny that hormone therapy (ADT) with the addition of abiraterone improves progression free survival and length of survival compared with ADT alone. The effectiveness of this combination therapy is, arguably, comparable with the current standard of combined treatment – i.e. ADT with chemotherapy (docetaxel)

Cost effectiveness would appear to have played a large part in reaching this negative decision:

“Abiraterone is not a cost-effective use of NHS resources for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer”

Within the FAD there is considerable discussion concerning the normal process by which drugs can be made available to the NHS at discounted prices. The Committee states that no such arrangement was agreed between NHS England and the pharmaceutical company concerned for abiraterone to be used in this proposed new clinical scenario, although a similar arrangement had been agreed previously for the drug to be used later in the treatment of advanced prostate cancer.

The Committee recognised three groups of patients within the clinical scenario:

- a) Those who were able to have docetaxel (and able to tolerate any side effects)
- b) Those patients not fit enough to have docetaxel
- c) Those patients who might choose *not* to have docetaxel even if they were potentially eligible to have it

There is a great unmet need for patients who are unable to have docetaxel for clinical reasons. Abiraterone used in this context would have been an acceptable alternative to docetaxel. This decision effectively reinforces and prolongs that unmet need.

The discussion in the text of the FAD basically states that there are no clear-cut clinical criteria to determine the group of chemotherapy-ineligible people. It is stated that no evidence of efficacy for the drug in this very specific group of patients had been presented. Thus all patients – i.e. all three groups of patients above – would be treated as one homogenous group.

“It concluded that it could not consider separately the clinical and cost effectiveness of abiraterone in people who cannot or chose not to have docetaxel,,,,”

The Committee stated that there were consequences that must be considered if abiraterone were to be used earlier in the treatment pathway:

“The committee concluded that the first-choice treatment for hormone-sensitive metastatic prostate cancer affects the follow-on treatments a person may have. It also concluded that having abiraterone in combination at this position in the pathway limits the options for follow-on treatments for people who develop hormone-relapsed disease compared with people who have had ADT alone or docetaxel in combination.”

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Basically, drugs such as abiraterone (and enzalutamide) can only be used once on the treatment pathway. This would then limit the availability of treatment later on when the cancer may have progressed further. Effectively the current NHS funding agreement for either drug only permits the use of one or other of these drugs and only once in the total treatment pathway.

Considerable discussion is given to the statistics and trial data submitted and to the economic modelling used. It is particularly difficult to be definitive about overall total patient survival times as these need to be projected from current data of patients who are still surviving. Comments on such details must be left to those with specific knowledge and experience.

There is a standard appeals process which can be invoked by stakeholders involved in this appraisal. Through our Patient Representative, Steve Allen, Tackle have already commenced the process of formulating an appeal in collaboration with Prostate Cancer UK. We feel that it is important to speak with one clear unified voice. One of the major discussion issues will be that of identifying chemotherapy ineligible patients. Recent data obtained by Prostate Cancer UK indicates that considerably fewer older men in the 'chemo-eligible' group receive docetaxel than younger men. Currently there would appear to be a significant bias towards younger men being able to have the accepted best standard of care – i.e. hormone treatment with additional therapy (docetaxel). There is no alternative available that can be used in place of docetaxel. The appeals process has strict regulations on factors that can be addressed. It is important that any such appeal presented is properly constructed. Tackle, by working in collaboration with Prostate Cancer UK, can achieve this.

However, as a patient-centred organisation, we should also reflect the thoughts and feelings of our members. Many of these thoughts may not be discussions that the appeal process will recognise as relevant. To that end Tackle will write a separate communication to NICE which will not form part of the 'official' appeal. I believe those patient voices should be heard. Such comments are detailed in a separate document.

Steve Allen
Patient Representative
Tackle Prostate Cancer

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