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

Appraisal consultation document

Response from The Institute of Cancer Research, London

The Institute of Cancer Research (ICR) welcomes the opportunity to comment on the Appraisal Consultation Document (ACD) for abiraterone in the treatment of metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy.

We are one of the world's most influential cancer research institutes, and work in close partnership with The Royal Marsden NHS Foundation Trust as the largest comprehensive cancer centre in Europe.

Abiraterone was discovered by the ICR in its laboratories, in what is now the Cancer Research UK Cancer Therapeutics Unit, and the ICR and The Royal Marsden carried out initial clinical development on the drug, as well as leading the UK arms of later-stage international clinical trials.

Abiraterone is now used as standard treatment after chemotherapy and has extended the lives of thousands of men in the UK with advanced prostate cancer. We are very disappointed that NICE, in the ACD's draft recommendations, did not feel able to recommend use of abiraterone for men with prostate cancer who are yet to receive chemotherapy.

We understand that NICE must take into account both the clinical and cost-effectiveness of a drug when conducting its appraisals. We have a number of comments on the ACD and we deal with these below.

Clinical effectiveness

We believe the evidence is clear that abiraterone is effective when given before chemotherapy and can give men many extra months free of disease. We felt it was important to respond to questions raised by the committee about the endpoint used in the phase III clinical trial, and about the effect of unblinding the trial early on estimates of abiraterone's effects.

Some 1,088 patients with prostate cancer that no longer responded to standard hormone-suppressing drugs but who had not received chemotherapy took part in the trial. Patients taking abiraterone went an average of 16.5 months before tumour growth was detected by a CT or MRI scan – twice as long as the 8.3 months among men taking a placebo.

The trial had two primary measures, radiographic progression free survival and overall survival. The trial was stopped on the recommendation of the Independent Data Monitoring Committee when radiographic free survival reached significance, since the results were so impressive that the committee felt all men in the study should have the option to receive

abiraterone. The trial was therefore stopped before the data on overall survival reached significance.

Cost effectiveness

NICE appears to have made its decision on the basis of cost, and we recognise that it does have a responsibility to achieve cost-effectiveness for the NHS. It is disappointing that abiraterone was considered too expensive to be recommended before chemotherapy. We believe that it is crucial that the NHS, NICE and the manufacturer reach an accommodation acceptable to all parties to ensure that this drug is made available and that more patients can gain the benefit of abiraterone.

The manufacturer's base-case incremental cost-effectiveness ratio (ICER) is estimated to be £46,700 per QALY, which would be inside NICE's cost limit when the end of life criteria are applied. NICE did not apply its end of life criteria in this appraisal, as men who have not yet received chemotherapy now live for longer than two years. Abiraterone has therefore in part been a victim of the success of prostate cancer medicine.

Additional value not taken into account in the economic modelling

Abiraterone is now used as standard treatment after chemotherapy and has extended the lives of thousands of men in the UK with advanced prostate cancer. It has much milder side-effects than conventional chemotherapy, and the added benefit that it can be taken by men in their own homes.

We are very disappointed that abiraterone was not recommended in the ACD for men with prostate cancer who are yet to receive chemotherapy. This decision would deny many thousands of men the opportunity to access this drug earlier in their course of treatment.

In addition to strongly supporting the availability of abiraterone for all hormone relapse prostate cancer patients before chemotherapy, we would like to highlight that there is a particular group of patients affected by this decision. Many men with prostate cancer are elderly and are not in the position to receive chemotherapy as they might not be fit enough or might be too old. These patients could still benefit from abiraterone but by restricting its use to those who have already received chemotherapy, a significant number of men could now miss out on abiraterone too.

Options for treatment are limited in this population, and they may even qualify for consideration under 'end of life' criteria as expected survival without treatment with chemotherapy or abiraterone will be considerably less than that of those who go on to receive further treatment.

As the committee points out in the consultation document, the additional benefit of delaying chemotherapy or providing treatment options for those who are unable to have chemotherapy was not captured in the economic models, and we feel that greater weight needs to be given to this in the committee's decision.