NHS
Hertfordshire

PRIVATE AND CONFIDENTIAL

20th May 2012

Public Health Department
Charter House
Parkway
Welwyn Garden City
Hertfordshire
AL8 6JL

Jeremy Powell
Project Lead
National Institute of Clinical Excellence

Direct line:
Email address:
Rasila.shah@hertfordshire.nhs.uk

www.hertfordshire.nhs.uk

Dear Jeremy,

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

On behalf of NHS Hertfordshire, I would like to submit our comments on the appraisal consultation document for abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen.

- **The appraisal committee has provisionally concluded that abiraterone is not a cost effective use of NHS resources.**

We are in agreement with the recommendations in the ACD to not to recommend abiraterone for this indication. On the basis of the evidence considered, the cost/QALY, and the potential likely numbers of patients, this treatment is unlikely to be cost effective in real life clinical practice, which is less controlled than clinical trials. We are also concerned that some of the data submitted by the manufacturer to the ERG committee, was not available to us for review.

- **The manufacturer's estimate may underestimate the true cost of abiraterone.** The appraisal committee concluded that the manufacturers ICER estimate of £63,200 per QALY was likely to underestimate the true cost because the economic model used to produce it included inappropriate values. The ICER figure of £63,200 includes an agreed patient access scheme involving a single confidential discount to the list price of abiraterone.

NHS Hertfordshire does have concerns about the value-for-money of an ICER of £63,200 and if this is underestimated because the model did not include appropriate values, this would make this treatment even less cost-effective.

- **The appraisal committee concluded abiraterone was not licensed for a small population, and therefore, did not meet the full criteria for an end of life treatment.** The manufacturer estimated the eligible population to be 3,690 in 2012 increasing to 4,214 in 2016 for the indication currently under consideration but the committee heard this may be

an underestimate. The committee also concluded that even if abiraterone did fulfill the end of life criteria the ICER per QALY would probably still be too high to justify use of limited NHS resources.

Feedback received from clinicians advising NHS Hertfordshire indicates that whilst initially the number of patients qualifying for treatment may be about 40 in a million population per year (based on current uptake of docetaxel), eventually many more patients in this stage of the disease will be willing to try docetaxel with the hope of accessing abiraterone.

NHS Hertfordshire agrees that the ICER per QALY and the potentially higher numbers of patients likely to go on this treatment would not justify the use of limited NHS resources.

NHS Hertfordshire estimates that about £1m would need to be invested for this treatment to treat about 40 patients for an overall survival benefit of 4 months. This would be a lower priority compared to other services that need development.

- **Using data supplied by the manufacturer, between six and seven (6.59) per 100,000 people are eligible for treatment with abiraterone annually for this indication at a cost of about £164,911.** These figures include the drug cost of abiraterone at £2,930/month (list price) with treatment lasting an average of 8 months and a one off monitoring cost of £1,587.72 per patient. The annual cost per patient for the drug and monitoring is £25,028. In 2013-16 the manufacturer predicts a small rise in the number of eligible patients to between 7 and 8 (7.32) per 100,000 people annually, giving a higher cost of approximately £183,200. These figures do not include the patient access scheme discount (redacted in the evaluation report) or the net budget impact of introducing abiraterone on existing treatments (estimated in the manufacturer's submission).

From the manufacturer's estimate, the numbers likely to need treatment are almost double those estimated by NHS Hertfordshire based on current use of docetaxel. However, as we have stated previously, our local specialists have indicated that any current estimate is much lower than what we are likely to see in the future. Based on this, it is NHS Hertfordshire's view that this technology does not meet the end of life criteria.

- **Evidence for clinical effectiveness is based on a single high-quality phase III RCT (COU-AA-301).** The primary outcome of this study was overall survival, the committee concluded this trial provided persuasive evidence that abiraterone offers a survival advantage to patients.
- **Abiraterone is clinically effective at extending overall survival, and survival free of disease progression, compared to a placebo.** Median overall survival was 15.8 months on abiraterone compared with 11.2 months on placebo; absolute difference 4.6 months; HR 0.74, 95%CI 0.64 to 0.86; median follow-up 20.2 months. Time to treatment discontinuation, a proxy measure of survival free of disease progression, was 8 months in those taking abiraterone compared with 4 months on placebo, an absolute difference of 4 months.
- **No robust evidence was available to compare the clinical effectiveness of abiraterone with its main clinical comparators mitoxantrone (rarely used in UK clinical practice) or best supportive care.**
- **The technology is considered safe and potential adverse reactions are generally manageable and reversible.** These include hypertension, hypokalaemia and fluid retention.
- **Abiraterone may offer a step change in treatment for patients because it is life-extending rather than simply palliative.**
- **The committee concluded the appraisal should refer to people rather than men because people, who have proposed, started or completed male to female gender**

reassignment can develop prostate cancer. This is especially important to note as the cost per 100,000 figures above refer to people and not just men.

NHS Hertfordshire would ask the NICE appraisal committee to note the following:

- There is no growth in NHS funding for the next 5 years. The inflation in NHS means that the NHS has to reduce its spend by £5bn a year.
- Whilst the NICE does not have the remit to consider affordability, commissioners have this responsibility.
- Without any growth in NHS resources, the only way commissioners can afford a NICE approved treatment is by disinvesting from other services / treatments. As the cost/QALYs of all such services / treatments are not available, we are not able compare existing treatments/ services with NICE recommended treatments. it is very likely that prioritising a NICE recommended treatment may result in disinvesting from a service / procedure/ treatment that is of better value to the NHS.
- Whist patient access schemes may appear to make a treatment more cost-effective for the NHS, the management of these schemes has resulted in a lot of work for commissioners and providers. In reality, commissioners (and therefore the NHS) has not always been able to recover the money spent.
- We believe that pressure should be put on the manufacturer to provide this product at a much more reasonable price without a patient access scheme.

In summary, in the current NHS climate, the NICE end-of-life criteria need reviewing to ensure that the NHS does not lose services that ultimately offer better value overall.

[redacted]

Yours sincerely

[redacted]

Dr Jane Halpin
Chief Executive

Stuart Bloom
Chair