NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Abiraterone acetate for the treatment of metastatic castration-resistant prostate cancer not previously treated with chemotherapy [ID503]

About you

Your name: [redacted]

Name of your organisation: **British Uro-oncology Group**
Are you (tick all that apply):

- √a specialist in the treatment of people with the condition for which NICE is considering this technology?

- √a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?

- √an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?
  Chair and Trustee of the British Uro-oncology Group

- other? (please specify)

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What is the expected place of the technology in current practice?

Men with metastatic castration-resistant prostate cancer (mCRPC) whose disease is asymptomatic or mildly symptomatic, for whom chemotherapy may not be immediately appropriate or necessary, could have limited treatment options. The British Uro-oncology Group welcomes abiraterone acetate as a significant additional therapy that has the potential to prolong survival, symptom control and quality of life for a large number of such men.

Abiraterone acetate improves radiographic progression-free survival, shows a trend toward improved overall survival, and can significantly delay clinical decline and initiation of chemotherapy in patients with mCRPC. [N Engl J Med 2013 Jan 10;368(2):138-48.]

The development of this treatment has changed our understanding of the pathogenesis of this disease and management strategies. It truly is a 'step-change' in the care of men with mCRPC.

As a tablet form abiraterone acetate can be dispensed immediately and will have relativley little impact on service delivery in the clinical setting. It would also be accessible for men without the need to travel to a cancer centre.

The advantages and disadvantages of the technology

Most UK oncologists consider patients with advanced, symptomatic prostate cancer as eligible for chemotherapy, although a poor performance status, significant co-morbid factors, advancing age, and the presence of asymptomatic disease with slowly rising prostate-specific antigen (PSA) levels would prevent chemotherapy use. [BJU Int2012 Sep;110(5):658-67]

In the COU-AA-302 trial published this year in the NEJM, the median radiographic progression-free survival is shown to be 16.5 months with abiraterone-prednisone and 8.3 months with prednisone alone (hazard ratio for abiraterone-prednisone vs. prednisone alone, 0.53; 95% confidence interval [CI], 0.45 to 0.62; P<0.001). Over a median follow-up period of 22.2 months, overall survival was improved with abiraterone-prednisone (median not reached, vs. 27.2 months for prednisone alone; hazard ratio, 0.75; 95% CI, 0.61 to 0.93; P=0.01) but did not cross the efficacy boundary at the time of analysis. Abiraterone-prednisone showed superiority over prednisone alone regarding time to initiation of cytotoxic chemotherapy, opiate use for cancer-related pain, PSA progression, and decline in performance status. Grade 3 or 4 mineralocorticoid-related adverse events and abnormalities on liver-function testing were more common with abiraterone-prednisone. [N Engl J Med 2013 Jan 10;368(2):138-48.]

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The incidence of these Grade 3 or 4 toxicities in the COU-302 study were seen in a minority of patients, hypertension 3.9 %(abiraterone-prednisone) vs 3.0 % (prednisone) ; hypokalemia 2.4 % (abiraterone-prednisone) vs 1.9 % (prednisone); ALT↑ 5.4 % (abiraterone-prednisone) vs 0.7 % (prednisone) ; AST↑ 3.0 vs 0.9 % (prednisolone).

Implementation issues

As a tablet form abiraterone acetate can be dispensed immediately and will have relativley little impact on service delivery in the clinical setting. It would also be accessible for men without the need to travel to a cancer centre.

In the UK, responsibility for initiating treatment and managing patients will most likely lie with the oncologist and their team. [BJU Int 2012 Sep;110(5):658-67] Service systems are continuously evolving, particularly in the rapidly changing field of prostate cancer, to accommodate the introduction of new treatments to improve patient outcomes.

Equality

There should not be any issues relating to equality of patients as they would be under the care of the clinical oncologist.