

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Enzalutamide for the treatment of metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of enzalutamide within its licensed indication for the treatment of metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen.

Background

Prostate cancer is a disease in which tumours develop in the prostate, a gland in the male reproductive system. Its cause is thought to be multi-factorial, involving both environmental and genetic factors. The incidence of prostate cancer increases with age and is higher in men of African-Caribbean family origin. In England and Wales, there were around 37,000 people diagnosed with prostate cancer in 2009, and over 9600 deaths from prostate cancer in 2010.

Around 55–65% of people with prostate cancer develop metastatic disease (that is, the cancer spreads to other parts of the body). Over 90% of people with metastatic prostate cancer initially respond to hormonal therapy but eventually become resistant to it. This clinical condition is described as hormone relapsed prostate cancer (but the terms 'castration-resistant prostate cancer', 'androgen-independent prostate cancer' and 'hormone-refractory prostate cancer' are also used).

For metastatic hormone relapsed prostate cancer, NICE clinical guideline 58 'Prostate cancer: Diagnosis and treatment' and NICE technology appraisal guidance 101 recommends docetaxel as a treatment option for men with metastatic hormone-refractory disease who have a Karnofsky performance-status score of 60% or more. In clinical practice, after progression during or after a docetaxel-based treatment, patients may receive a further chemotherapy treatment or a combination of palliative treatments. Management options include mitoxantrone with or without steroids such as prednisolone. NICE technology appraisal 259 recommends abiraterone in combination with prednisone or prednisolone as an option for the treatment of hormone relapsed metastatic prostate cancer which has progressed on or after one docetaxel-containing chemotherapy. Cabazitaxel is not recommended for hormone relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen (NICE technology appraisal guidance 255).

National Institute for Health and Care Excellence
Draft scope for the proposed appraisal of enzalutamide for the treatment of metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen

The technology

Enzalutamide (Xtandi, Astellas Pharma) is an androgen receptor antagonist which is thought to inhibit a number of steps in the androgen receptor signalling pathway. This biologic activity may reduce the proliferation of prostate cancer cells and lower the serum prostate-specific antigen (PSA) level, whereby stopping the growth of tumours. Enzalutamide is administered orally.

Enzalutamide does not currently have a UK marketing authorisation for the treatment of prostate cancer. It has been studied in clinical trials compared with placebo in men with metastatic hormone relapsed prostate cancer which has been treated with one or two prior chemotherapy regimens, with at least one regimen containing docetaxel.

Intervention	Enzalutamide
Population	Adults with metastatic hormone relapsed prostate cancer which has been previously treated with a docetaxel-containing chemotherapy regimen
Comparators	<ul style="list-style-type: none"> • Abiraterone in combination with prednisone or prednisolone • Mitoxantrone alone or in combination with prednisolone • Best supportive care (this may include radiotherapy, radiopharmaceuticals, analgesics, bisphosphonates, further hormonal therapies, and corticosteroids).
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • progression-free survival • response rate • prostate-specific antigen (PSA) response • adverse effects of treatment • health-related quality of life.

<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.</p>
<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation.</p>

<p>Related NICE recommendations</p>	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No. 259, June 2012, 'Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen'. Review proposal date April 2015.</p> <p>Technology Appraisal No. 255, May 2012, 'Cabazitaxel for the second-line treatment of hormone refractory, metastatic prostate cancer'. Review proposal date February 2015.</p> <p>Technology Appraisal No. 101, June 2006, 'Docetaxel for the treatment of hormone-refractory prostate cancer'. Moved to static guidance list.</p> <p>Technology Appraisal in preparation, 'Abiraterone in combination with prednisolone for the treatment of metastatic, castration-resistant prostate cancer in people who have not been previously treated with chemotherapy'. Earliest anticipated date of publication November 2013.</p> <p>Proposed Technology Appraisal, 'Sipuleucel-T for the first line treatment of metastatic castration resistant prostate cancer'.</p> <p>Related Guidelines:</p> <p>Cancer Service Guidance Urological Cancer, September 2002, Improving outcomes in urogenital cancers'.</p> <p>Clinical Guideline No. 58, February 2008, 'Prostate cancer: diagnosis and treatment'. Currently under review. Earliest anticipated date of publication November 2013.</p> <p>NICE pathway for prostate cancer. Available at http://pathways.nice.org.uk/pathways/prostate-cancer</p>
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