

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Single Technology Appraisal

Abiraterone for treating newly diagnosed high risk metastatic hormone-naive prostate cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of abiraterone within its marketing authorisation for treating newly diagnosed high risk metastatic hormone-naive prostate cancer.

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.^{1,2}

The incidence of prostate cancer increases with age and is higher in men of black African-Caribbean family origin and people with a family history of the disease¹. In England, there were over 40,000 people newly diagnosed with prostate cancer and over 9500 deaths from prostate cancer in 2014.³ Prostate cancer often leads to bone metastases, typically in the spine, pelvis and rib cage. In 2015, 21% of patients diagnosed in England with prostate cancer had metastatic disease.⁴ Hormone-naïve refers to people that are about to start (or who have started within the last 12 weeks) treatment with androgen deprivation therapy for the treatment of metastatic prostate cancer.

For metastatic prostate cancer, NICE clinical guideline 175 recommends androgen deprivation therapy, specifically, bilateral orchidectomy (removal of the testicles) or continuous luteinising hormone-releasing hormone agonist therapy. For people who are willing to accept the adverse impact on overall survival and gynaecomastia (breast swelling) in the hope of retaining sexual function, the guideline recommends offering anti-androgen monotherapy with bicalutamide. NHS England commissions docetaxel chemotherapy for treating metastatic prostate cancer in people who are about to start, or who recently started, androgen deprivation therapy.

The technology

Abiraterone (Zytiga, Janssen) is a selective androgen biosynthesis inhibitor. Abiraterone blocks cytochrome P17 (an enzyme thought to play a role in the production of testosterone), thereby stopping the testes and other tissues in the body from making testosterone. It is administered orally.

Abiraterone has a UK marketing authorisation for treating newly diagnosed high risk metastatic hormone sensitive prostate cancer in adult men in

combination with androgen deprivation therapy. In the clinical trial, high-risk prognosis was defined as having at least 2 of the following 3 risk factors: a Gleason score of ≥ 8 ; the presence of 3 or more lesions on bone scan; or presence of measurable visceral (excluding lymph node disease) metastasis.

Intervention(s)	Abiraterone in combination with prednisone or prednisolone and androgen deprivation therapy
Population(s)	Adults with newly diagnosed high risk metastatic hormone-naive prostate cancer
Comparators	<ul style="list-style-type: none"> • Androgen deprivation therapy alone (including orchidectomy, luteinising hormone-releasing hormone agonist therapy or monotherapy with bicalutamide) • Docetaxel in combination with androgen deprivation therapy
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • Overall survival • Progression-free survival • Prostate specific antigen (PSA) response • Adverse effects of treatment • Health-related quality of life.
Economic analysis	<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 commercial access agreement for the intervention and treatments included in the economic analyses will be taken into account.</p>

<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>‘Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated’ (2016) NICE technology appraisal guidance TA387. Review date April 2019</p> <p>‘Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen’ (2012). NICE technology appraisal guidance TA259. Review date to be confirmed.</p> <p>‘Docetaxel for the treatment of hormone-refractory metastatic prostate cancer’ (2006) NICE technology appraisal guidance TA101. Guidance on the static list.</p> <p>Related Guidelines:</p> <p>‘Prostate cancer: diagnosis and management’ (2014) NICE Clinical Guideline No. 175</p> <p>Related Quality Standards:</p> <p>Prostate cancer (2015) NICE quality standard QS91 https://www.nice.org.uk/guidance/QS91</p> <p>Related NICE Pathways:</p> <p>Prostate cancer (2014) NICE Pathway http://pathways.nice.org.uk/pathways/prostate-cancer</p>
<p>Related National Policy</p>	<p>NHS England B14/S/a 2013/14 NHS standard contract for cancer: specialised kidney, bladder and prostate cancer services (adult): https://www.england.nhs.uk/wp-content/uploads/2013/06/b14-cancr-kidney-blad-pros.pdf</p> <p>NHS England Manual for prescribed specialised services 2017/2018. Specialist cancer services (adults) [section 105, page 234–237]: https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services-201718</p> <p>Department of Health, NHS Outcomes Framework 2016–2017, April 2016. Domains 1-2: https://www.gov.uk/government/uploads/system/uploads</p>

	<p>/attachment_data/file/513157/NHSOF_at_a_glance.pdf</p> <p>NHS England Commissioning Policy Statement: Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer https://www.england.nhs.uk/wp-content/uploads/2016/01/b15psa-docetaxel-policy-statement.pdf</p>
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References

1. Cancer Research UK. About cancer. Prostate cancer risks and causes. Accessed November 2017. <http://www.cancerresearchuk.org/about-cancer/type/prostate-cancer/about/prostate-cancer-risks-and-causes>
2. Macmillan Cancer Support. Cancer information. Risk factors and causes of prostate cancer. Accessed November 2017. <http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Prostate/Aboutprostatecancer/Causes.aspx>
3. Cancer Research UK. Cancer stats. Prostate cancer mortality statistics. Accessed November 2014.. <http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/mortality/>
4. National Prostate Cancer Audit. Annual report 2015. Accessed October 2016. <http://www.npca.org.uk/annual-report-2015/>