

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Proposed Health Technology Appraisal

**Cabazitaxel for hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen (review of TA255)****Final scope****Remit/appraisal objective**

To appraise the clinical and cost effectiveness of cabazitaxel within its marketing authorisation for treating hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen.<sup>1</sup>

**Background**

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system. Its cause is thought to be multifactorial, involving both environmental and genetic factors. The incidence of prostate cancer increases with age and is higher in people of black African or black Caribbean family origin. In England, approximately 35,600 people were diagnosed with prostate cancer in 2011, and over 9000 people died from prostate cancer in 2012 (Cancer Research UK, 2014).

Around 55–65% of people with prostate cancer develop metastatic disease (in which 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 known 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 175 ‘Prostate cancer: Diagnosis and treatment’ and NICE technology appraisal guidance 101 recommend docetaxel as a treatment option for men with metastatic hormone-refractory disease who have a Karnofsky performance-status score of 60% or more. NICE technology appraisals 259 and 316 recommend abiraterone and enzalutamide, respectively, as options for treating metastatic hormone-relapsed prostate cancer that has progressed during or after docetaxel-containing chemotherapy. Abiraterone and enzalutamide also have marketing authorisations to be used before chemotherapy, and are available through the Cancer Drugs Fund. NICE guidance for abiraterone and enzalutamide in the pre-chemotherapy setting

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<sup>1</sup> The remit for this appraisal was formally referred to NICE in 2010 and described the condition as hormone refractory, metastatic prostate cancer. In January 2013, NICE and the Department of Health agreed that, following feedback received from stakeholders during scoping and appraisal consultations, the condition should be referred to as ‘hormone-relapsed prostate cancer’ (HRPC). The remit has therefore been reworded with the consent of the Department of Health.

are under development. Radium-223 dichloride has a marketing authorisation for the treatment of adults with hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases, and is funded by the Cancer Drug Fund whilst NICE guidance is in development .

NICE technology appraisal 255 did not recommend cabazitaxel for hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen. NICE recommendations for abiraterone and enzalutamide have since resulted in a change in clinical practice. In addition, more evidence on the effect of cabazitaxel on survival, progression free survival and health-related quality of life is now available which may address some of the key uncertainties identified during NICE technology appraisal 255. Therefore, the clinical and cost effectiveness of cabazitaxel will be reviewed and compared with the relevant technologies.

**The technology**

Cabazitaxel (Jevtana, Sanofi) belongs to a class of anticancer drugs known as taxanes. It works by disrupting the microtubular network and causes inhibition of cell division and cell death. It is administered by intravenous infusion.

Cabazitaxel has a UK marketing authorisation 'in combination with prednisone or prednisolone for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen'.

<b>Intervention(s)</b>	Cabazitaxel in combination with prednisone or prednisolone
<b>Population(s)</b>	People with hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen

<b>Comparators</b>	<ul style="list-style-type: none"> <li>• Abiraterone in combination with prednisone or prednisolone</li> <li>• Enzalutamide</li> <li>• Mitoxantrone in combination with prednisolone (not licensed in the UK for this indication)</li> <li>• Best supportive care (this may include radiotherapy, radiopharmaceuticals [apart from radium-223 dichloride], analgesics, bisphosphonates, and corticosteroids)</li> </ul> <p>For people with bone metastasis only (no visceral metastasis)</p> <ul style="list-style-type: none"> <li>• Radium-223 dichloride (NICE guidance is in development, funded by the CDF in the interim)</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• overall survival</li> <li>• progression-free survival</li> <li>• response rate</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	<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><b>Other considerations</b></p>	<p>If the evidence allows the following subgroups will be considered.</p> <ul style="list-style-type: none"> <li>• People who have received abiraterone or enzalutamide</li> <li>• People with bone metastasis only (no visceral metastasis)</li> </ul> <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><b>Related NICE recommendations and NICE Pathways</b></p>	<p>Related Technology Appraisals:</p> <p>‘Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen’ (July 2014) NICE Technology Appraisal 316 Review date TBC</p> <p>‘Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen’ (June 2012) NICE Technology Appraisal 259 Review date TBC</p> <p>‘Cabazitaxel for hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen’ (May 2012) NICE Technology Appraisal 255</p> <p>Docetaxel for the treatment of hormone-refractory metastatic prostate cancer’ (June 2006) NICE Technology Appraisal 101 Guidance on static list.</p> <p>Appraisals in development</p> <p>‘Radium-223 dichloride for treating metastatic hormone-relapsed prostate cancer with bone metastases’ NICE technology appraisals guidance [ID576] Publication expected January 2016</p> <p>‘Abiraterone for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy’ NICE technology appraisals guidance [ID503] Publication expected TBC</p> <p>‘Enzalutamide for metastatic hormone-relapsed prostate cancer when chemotherapy is not yet clinically indicated’ NICE technology appraisals guidance [ID683] Publication expected TBC</p> <p>Related Guidelines:</p>

	<p>'Prostate cancer: diagnosis and treatment' (January 2014) NICE guideline 175 Review date March 2016</p> <p>Related Quality Standards:</p> <p>'Prostate cancer' (June 2015) NICE Quality standard 91]</p> <p>Related NICE Pathways:</p> <p>'Prostate Cancer' (2015) NICE pathway</p> <p><a href="http://pathways.nice.org.uk/pathways/prostate-cancer">http://pathways.nice.org.uk/pathways/prostate-cancer</a></p>
<p><b>Related National Policy</b></p>	<p>NHS England, January 2014, '<a href="#">Manual for prescribed specialised services 2013/14</a>', Chapter 105: Specialist cancer services (adults).</p> <p>National Service Frameworks, <a href="#">Cancer</a></p> <p>Department of Health, 2013, '<a href="#">NHS Outcomes Framework 2014-2015</a>'.</p> <p>Department of Health, 2011, '<a href="#">Improving outcomes: a strategy for cancer</a>'.</p> <p>Department of Health, 2009, '<a href="#">Cancer commissioning guidance</a>'.</p> <p>Department of Health, 2007, '<a href="#">Cancer reform strategy</a>'.</p> <p>Department of Health, 2011, The national cancer strategy: stakeholder engagement report – <a href="#">Annex H: Prostate Cancer</a>.</p> <p>Department of Health, NHS Outcomes Framework 2014-2015, Nov 2013. Domains 1 and 2.</p> <p><a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf</a></p>

## References

Cancer Research UK (2014) [Prostate cancer statistics](#). Accessed May 2015