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)

Draft scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of cabazitaxel within its licensed indication for the second line treatment of hormone refractory, metastatic prostate cancer that has progressed following or during docetaxel based treatment.[1]

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 men of African-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. 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

[1] The remit for this appraisal was formally referred to NICE in 2010. 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). This was implemented for all prospective appraisals from January 2013 onwards.

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. During the development of that guidance, cabazitaxel was compared with mitoxantrone which does not have a marketing authorisation for this specific indication. NICE recommendations for abiraterone and enzalutamide resulted in a change in the clinical practice and mitoxantrone is no longer considered the most relevant comparator for cabazitaxel. 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 the appraisal. Therefore, the clinical and cost effectiveness of cabazitaxel needs to 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'.

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

Comparators	• Abiraterone in combination with prednisone or prednisolone • Enzalutamide • Best supportive care (this may include radiotherapy, radiopharmaceuticals [apart from radium-223 dichloride], analgesics, bisphosphonates, and corticosteroids) For people with bone metastasis only (no visceral metastasis) • Radium-223 dichloride (NICE guidance is in development, funded by the CDF in the interim) For people for whom abiraterone or enzalutamide are not suitable • Mitoxantrone in combination with prednisolone (not licensed in the UK for this indication)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any patient access schemes for the intervention or comparator technologies should be taken into account. Where comparator technologies are available through the Cancer Drug Fund, the cost incurred by the Cancer Drug Fund should be used in any economic analyses, rather than the list price.

Other considerations	If evidence allows the subgroups indicated in the 'comparators' section will be considered. People for whom abiraterone or enzalutamide are not suitable include people in whom; • abiraterone or enzalutamide are not expected to be effective • the disease has progressed after abiraterone or enzalutamide 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.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: 'Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen' (July 2014) NICE Technology Appraisal 316 Review date TBC 'Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen' (June 2012) NICE Technology Appraisal 259 Review date TBC 'Cabazitaxel for hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen' (May 2012) NICE Technology Appraisal 255 Docetaxel for the treatment of hormone-refractory metastatic prostate cancer' (June 2006) NICE Technology Appraisal 101 Guidance on static list. Appraisals in development 'Radium-223 dichloride for treating metastatic hormone-relapsed prostate cancer with bone metastases' NICE technology appraisals guidance. [ID576] Publication expected July 2015 Related Guidelines: 'Prostate cancer: diagnosis and treatment' (January 2014) NICE guideline 175 Review date March 2016 Related Quality Standards:

	Quality Standard in Preparation, 'Prostate cancer'. Earliest anticipated date of publication June 2015 Related NICE Pathways: 'Prostate Cancer' (2015) NICE pathway http://pathways.nice.org.uk/pathways/prostate-cancer
Related National Policy	NHS England, January 2014, 'Manual for prescribed specialised services 2013/14', Chapter 105: Specialist cancer services (adults). National Service Frameworks, Cancer Department of Health, 2013, 'NHS Outcomes Framework 2014-2015'. Department of Health, 2011, 'Improving outcomes: a strategy for cancer'. Department of Health, 2009, 'Cancer commissioning guidance'. Department of Health, 2007, 'Cancer reform strategy'. Department of Health, 2011, The national cancer strategy: stakeholder engagement report – Annex H: Prostate Cancer. Department of Health, NHS Outcomes Framework 2014-2015, Nov 2013. Domains 1 and 2. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf

Questions for consultation

Have all relevant comparators for cabazitaxel been included in the scope?

- Which treatments are considered to be established clinical practice in the NHS for hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen?
- How should best supportive care be defined?
- Is mitoxantrone in combination with prednisolone still used in clinical practice for treating hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen?

Are the subgroups suggested in 'other considerations' appropriate?

- Are people in whom advanced hormonal therapy (with abiraterone or enzalutamide) is not expected to be effective, identified in the clinical practice?
- Are there any other subgroups of people in whom cabazitaxel is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider cabazitaxel will fit into the existing NICE pathway, Prostate Cancer?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which cabazitaxel is licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider cabazitaxel to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of cabazitaxel can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction)

References

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