NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Padeliporfin for treating localised prostate cancer

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of padeliporfin within its marketing authorisation for treating localised prostate cancer.

Background

Prostate cancer is a disease in which tumours develop in the prostate, a gland in the male reproductive system. It is caused by several factors, including genes and the environment[1,2].

Localised prostate cancer refers to early stage cancer of the prostate gland where the cancer has not spread into the surrounding tissues or to other parts of the body[3]. The symptoms of localised prostate cancer are: difficulty in passing urine, passing urine more frequently than usual (especially at night), pain when passing urine and blood in the urine[4,5].

The incidence of prostate cancer increases with age and is higher in people of African-Caribbean family origin[1]. In England, about 35,500 people were newly diagnosed with prostate cancer in 2011[6] and about 9100 people died from prostate cancer in 2012[7]. The 5-year survival rate for prostate cancer is approximately 85%[8].

NICE clinical guideline 175 classifies disease as low, intermediate or high risk based on prostate-specific antigen concentration, Gleason score (based on a biopsy) and clinical stage. Treatment options may include active surveillance, prostatectomy (surgical removal of the prostate), radiotherapy or brachytherapy (radiation delivered inside the prostate gland). 'Radical' means treatment that aims to cure the disease. NICE clinical guideline 175 recommends:

- For low-risk localised prostate cancer, offer active surveillance as an option.
- For intermediate-risk localised prostate cancer, offer radical prostatectomy, or radical radiotherapy in combination with androgen deprivation therapy. Also consider the following options: active surveillance, or high-dose rate brachytherapy in combination with external beam radiotherapy.
- For high-risk localised prostate cancer, offer radical prostatectomy, or radical radiotherapy in combination with androgen deprivation therapy,

or high-dose rate brachytherapy in combination with external beam radiotherapy.

The technology

Padeliporfin (Tookad, Steba Biotech) is a photosensitising soluble agent used for vascular targeted photodynamic therapy that destroys the tumour tissue when activated by light of a specific wavelength. It is administered intravenously.

Padeliporfin does not currently have a marketing authorisation in the UK for treating localised prostate cancer. It has been studied in a clinical trial compared with active surveillance in adults with untreated low-risk localised prostate cancer.

Intervention(s)	Padeliporfin for use in photodynamic therapy
Population(s)	Adults with untreated low-risk localised prostate cancer
Comparators	• Active surveillance For people who choose radical treatment: • Radical surgery • Radical radiotherapy
Outcomes	The outcome measures to be considered include: • disease-free survival • progression to radical treatment • mortality • adverse effects of treatment (for example, erectile dysfunction or incontinence) • 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.

Other considerations	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 Guidelines: 'Prostate cancer: diagnosis and management' (2014). NICE clinical guideline 175. Review date March 2016. Related Interventional Procedures: 'Focal therapy using high-intensity focused ultrasound for localised prostate cancer' (2012). NICE interventional procedure guidance 424. 'Focal therapy using cryoablation for localised stage prostate cancer' (2012). NICE interventional procedure guidance 423. 'Laparoscopic radical prostatectomy' (2006). NICE interventional procedure guidance 193. 'High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer' (2006). NICE interventional procedure guidance 174. 'Cryotherapy as a primary treatment for prostate cancer' (2005). NICE interventional procedure guidance 145. 'Low dose rate brachytherapy for localised prostate cancer' (2005). NICE interventional procedure guidance 132. 'Cryotherapy for recurrent prostate cancer' (2005). NICE interventional procedure guidance 119. 'High-intensity focused ultrasound for prostate cancer' (2005). NICE interventional procedure guidance 118. Related NICE Pathways: Prostate cancer (2015). NICE pathway, available at: http://pathways.nice.org.uk/pathways/prostate-cancer

Related National Policy	NHS England Manual for prescribed specialised services 2013/2014. Specialist cancer services (adults) [section 105, page 234–7]: http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf Department of Health, NHS Outcomes Framework 2014-2015, Nov 2013. Domains 1-2. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf

Questions for consultation

In clinical practice, is it likely that padeliporfin will only be used for treating low-risk localised prostate cancer? Or is use in people with intermediate- and high-risk localised prostate cancer anticipated?

- Have all relevant comparators for padeliporfin been included in the scope? Which treatments are considered to be established clinical practice in the NHS for localised prostate cancer? Which treatments would be expected to be displaced by photodynamic therapy?
- Are androgen deprivation therapies relevant comparators for padeliporfin?
- How should 'active surveillance' be defined?

Have all relevant outcomes been included in the scope?

Are there any subgroups of people in whom padeliporfin is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider padeliporfin 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 padeliporfin will be 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 padeliporfin 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 padeliporfin 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

1. Cancer Research UK. About cancer. Prostate cancer risks and causes. Accessed 29 April 2015. 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 29 April 2015. http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Prostate/Aboutprostatecancer/Causes.aspx

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4. Macmillan Cancer Support. Cancer information. Symptoms of prostate cancer. Accessed 29 April 2015. http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Prostate/Symptomsdiagnosis/Symptoms.aspx

5. Cancer Research UK. About cancer. Prostate cancer symptoms. Accessed 29 April 2015. http://www.cancerresearchuk.org/about-cancer/type/prostate-cancer/about/prostate-cancer-symptoms

6. Cancer Research UK. Cancer stats. Prostate cancer key statistics. Accessed 29 April 2015. http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/incidence/

7. Cancer Research UK. Cancer stats. Prostate cancer mortality statistics. Accessed 29 April 2015. http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/mortality/

8. Cancer Research UK. Cancer stats. Prostate cancer survival statistics. Accessed 29 April 2015. http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/survival/