

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Single Technology Appraisal**

**Padeliporfin for treating localised prostate cancer**

**Final scope**

**Remit/appraisal objective**

To appraise the clinical and cost effectiveness of padeliporfin within its marketing authorisation for treating unilateral, low-risk 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<sup>1,2</sup>.

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<sup>3</sup>. Localised prostate cancer often does not cause any symptoms. If symptoms do arise, they may include difficulty in passing urine, passing urine more frequently than usual (especially at night), pain when passing urine and blood in the urine<sup>4,5</sup>.

The incidence of prostate cancer increases with age and is higher in people of African or African-Caribbean family origin and people with a family history of the disease<sup>1</sup>. In England, about 40,400 people were diagnosed with prostate cancer in 2015<sup>6</sup> and about 9500 people died from prostate cancer in 2014<sup>7</sup>.

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 active surveillance as an option for people with low-risk localised prostate cancer (prostate-specific antigen, PSA <10 ng/ml and a Gleason score ≤6 and clinical stage T1-2a). In clinical practice, radical surgery or radiotherapy may also be considered for some people with low-risk localised prostate cancer.

**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 delivered by interstitial optical fibres from a laser device. It is administered intravenously.

Padeliporfin has a marketing authorisation for treating adult patients with previously untreated, unilateral low-risk, adenocarcinoma of the prostate with a life expectancy  $\geq 10$  years and:

- Clinical stage T1c or T2a
- Gleason score  $\leq 6$  based on high-resolution biopsy strategies,
- PSA  $\leq 10$  ng/mL
- 3 positive cancer cores with a maximum cancer core length of 5 mm in any one core or 1-2 positive cancer cores with  $\geq 50\%$  cancer involvement in any core or a PSA density  $\geq 0.15$ /mL/cm<sup>3</sup>.

The marketing authorisation stipulates that padeliporfin be used in hospitals only and that it should only be used by personnel trained in the vascular-targeted photodynamic therapy procedure.

<b>Intervention(s)</b>	Padeliporfin for use in vascular-targeted photodynamic therapy
<b>Population(s)</b>	Adults with unilateral, low-risk localised prostate cancer
<b>Comparators</b>	<ul style="list-style-type: none"> <li>• Active surveillance</li> </ul> <p>For people who choose radical treatment:</p> <ul style="list-style-type: none"> <li>• Radical surgery</li> <li>• Radical radiotherapy</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• disease-free survival</li> <li>• progression of disease</li> <li>• need for radical treatment</li> <li>• mortality</li> <li>• adverse effects of treatment (for example, erectile dysfunction or incontinence)</li> <li>• health-related quality of life.</li> </ul>

<p><b>Economic analysis</b></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>The cost of the laser equipment needed to deliver this technology needs to be included in the cost effectiveness analysis.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<p><b>Other considerations</b></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><b>Related NICE recommendations and NICE Pathways</b></p>	<p>Related Guidelines:</p> <p>'Prostate cancer: diagnosis and management' (2014). NICE clinical guideline 175. Review date to be confirmed.</p> <p>Related Interventional Procedures:</p> <p>'Laparoscopic radical prostatectomy' (2006). NICE interventional procedure guidance 193.</p> <p>'High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer' (2006). NICE interventional procedure guidance 174.</p> <p>'Cryotherapy as a primary treatment for prostate cancer' (2005). NICE interventional procedure guidance 145.</p> <p>'Low dose rate brachytherapy for localised prostate cancer' (2005). NICE interventional procedure guidance 132.</p> <p>'Cryotherapy for recurrent prostate cancer' (2005). NICE interventional procedure guidance 119.</p> <p>'High-intensity focused ultrasound for prostate cancer' (2005). NICE interventional procedure guidance 118.</p> <p>Related NICE Pathways:</p> <p>Prostate cancer (2015). NICE pathway, available at: <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 (2017) <a href="#">Manual for Prescribed Specialised Services 2017/18</a>. Specialist cancer services (adults) [section 105, pages 234-7</p> <p>Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1-2. <a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p>

## References

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