

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**Appraisal consultation document**

**Padeliporfin for untreated localised prostate  
cancer**

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using padeliporfin in the NHS in England. The appraisal committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts and patient experts.

**This document has been prepared for consultation with the consultees.**

It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the [committee papers](#)).

The appraisal committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

**Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.**

After consultation:

- The appraisal committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal document.
- Subject to any appeal by consultees, the final appraisal document may be used as the basis for NICE's guidance on using padeliporfin in the NHS in England.

For further details, see NICE's [guide to the processes of technology appraisal](#).

**The key dates for this appraisal are:**

Closing date for comments: 23 July 2018

Second appraisal committee meeting: 2 August 2018

Details of membership of the appraisal committee are given in section 5.

## 1 Recommendations

- 1.1 Padeliporfin is not recommended, within its marketing authorisation, for untreated unilateral, low-risk prostate cancer in adults.
- 1.2 This recommendation is not intended to affect treatment with padeliporfin that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

### Why the committee made these recommendations

Current treatments for low-risk prostate cancer include active surveillance and for people whose disease has progressed, radical therapies such as surgery and radiotherapy. Focal therapies such as cryotherapy and high-intensity focused ultrasound can also be used, but these are not routinely available. Padeliporfin would be used as an alternative to radical or (where available) focal therapies in the NHS.

The only clinical trial evidence compared padeliporfin with active surveillance. This shows that at 2 years, padeliporfin is effective at slowing the disease. But its long-term effectiveness is unclear. There is no direct clinical evidence on how effective padeliporfin is at slowing the disease compared with radical therapies.

The most plausible cost-effectiveness estimates for padeliporfin compared with active surveillance or radical therapies are higher than what NICE normally considers an acceptable use of NHS resources. Several issues were identified with the economic model which are likely to further increase the cost-effectiveness estimates. Therefore, padeliporfin cannot be recommended for untreated low-risk prostate cancer.

## 2 Information about padeliporfin

<b>Marketing authorisation indication</b>	Padeliporfin (Tookad, Steba Biotech) is indicated as monotherapy for 'adults with previously untreated, unilateral, low-risk, adenocarcinoma of the prostate with a life expectancy of at least 10 years and: <ul style="list-style-type: none"> <li>• clinical stage T1c or T2a</li> <li>• Gleason score no more than 6, based on high-resolution biopsy strategies</li> <li>• prostate-specific antigen (PSA) no more than 10 ng/ml</li> <li>• 3 positive cancer cores with a maximum cancer core length of 5 mm in any one core or 1 to 2 positive cancer cores with at least 50% cancer involvement in any 1 core or a PSA density of at least 0.15 ng/ml/cm<sup>3</sup>'</li> </ul>
<b>Dosage in the marketing authorisation</b>	The recommended dose, given intravenously is a single dose of 3.66 mg/kg of padeliporfin, given using a vascular-targeted photodynamic therapy procedure
<b>Price</b>	The list price of padeliporfin is £3,761 per 183 mg vial (excluding VAT; company submission). The average cost of a course of treatment is £12,111 per patient (excluding consumables, leasing the laser and VAT; company submission)

## 3 Committee discussion

The appraisal committee (section 5) considered evidence submitted by Steba Biotech and a review of this submission by the evidence review group (ERG). See the [committee papers](#) for full details of the evidence.

### *Diagnosing prostate cancer and risk stratification*

#### **Diagnostic and risk stratification techniques for prostate cancer are changing**

3.1 The clinical experts explained that the techniques used to diagnose prostate cancer in the NHS are changing, for example, transrectal ultrasound (TRUS) guided biopsy is being replaced by multiparametric magnetic resonance imaging (MRI). MRI techniques are more accurate at differentiating low-risk disease that does not need treatment, from disease that is likely to progress. The clinical experts explained that the risk categories for prostate cancer are also changing and that there is uncertainty in how to define 'low' and 'intermediate' risk of disease

progression. NICE's clinical guideline on [prostate cancer](#) considers 'low-risk' disease to have a serum prostate-specific antigen (PSA) no more than 10 ng/ml, a Gleason score<sup>1</sup> no more than 6, and a clinical stage of T1 to T2a. They highlighted that the NICE prostate cancer guideline is currently updating the diagnostic criteria. The committee agreed that there is uncertainty around how to define low-risk prostate cancer.

### ***Treatment pathway for localised prostate cancer***

#### **Low-risk disease is usually managed with active surveillance but people may choose to have radical therapies**

3.2 The clinical experts explained that in practice, active surveillance (that is, monitoring for disease progression without an active treatment) is usually offered to people with low-risk disease in line with recommendations in NICE's clinical guideline on [prostate cancer](#). If the disease progresses, clinicians may offer patients radical therapies including prostatectomy, external beam radiotherapy and brachytherapy. The clinical experts explained that clinicians are more likely to monitor disease with a Gleason score of 6 than treat with radical therapies to avoid over-treatment. One expert explained that there are 4 ways to move from active surveillance to radical therapies: patients no longer wish to stay on active surveillance (surveillance 'fatigue'), increasing PSA levels ('biochemical progression'), increase in risk of disease progression, or increase in clinical stage (such as from T2a to T2b). If patients have radical therapy, surveillance continues with less intensive monitoring specific to the type of radical therapy.

#### **There is variation in access to current focal therapies in the NHS**

3.3 The clinical experts explained that padeliporfin is a type of 'focal' therapy that targets the main lesion, rather than the whole prostate. The

---

<sup>1</sup>Gleason Score is a grading system that rates the aggressiveness of the 2 largest area of prostate cancer cells in a tumour. Each area is scored on how healthy it looks (healthy tissue scores 1 or 2 and abnormal tissue scores 3, 4 or 5). For example, Gleason 3 + 4 means that most of the tumour is grade 3 and the next largest section is grade 4. A total score is given ranging from 2 to 10. For example, Gleason 3 + 4 and Gleason 4 + 3 both have a total score of Gleason 7.

committee was aware that NICE's interventional procedures guidance recommend [cryotherapy](#) and [high-intensity focused ultrasound](#) for localised prostate cancer only under special arrangements. NICE's clinical guideline on [prostate cancer](#) recommends these options only in a clinical trial setting. The committee was aware that NICE made these recommendations in 2012 and 2008, and that the evidence for these focal therapies may have progressed. The clinical experts explained that focal therapy is used as an alternative to radical therapy for clinically significant disease or for patients with low-risk disease who choose not to have active surveillance. It is not used when there are no clinical indications suggesting disease progression. The committee concluded that focal therapies are not routinely available in the NHS so there is variation in practice.

### ***Positioning of padeliporfin in the treatment pathway***

#### **Padeliporfin is not an option for people for whom active surveillance is appropriate**

3.4 The company suggested padeliporfin might be an option for people with low-risk disease who 'choose' not to have active surveillance ('surveillance fatigue'), but before radical therapies. The company stated that surveillance would continue after treatment with padeliporfin, and that the key trial included ongoing surveillance in people having padeliporfin. The committee therefore agreed that padeliporfin would not be appropriate for people with 'surveillance fatigue' because surveillance continues after padeliporfin. The company further explained that padeliporfin is not an alternative to active surveillance for 'clinically insignificant' disease, that is, disease that has little to no chance of progression in a person's expected lifetime and is unlikely to benefit from active treatments (see sections 3.1 and 3.2). The clinical experts explained that in practice, clinicians would not offer active treatment (for example, focal or radical therapy) to people with low-risk disease without disease progression. Therefore, the committee concluded that

padeliporfin is not an option for people for whom active surveillance remains appropriate.

## ***Comparators***

### **Relevant comparators are radical therapies**

3.5 The company considered the most appropriate comparators to be radical therapies (including prostatectomy, external beam radiotherapy and brachytherapy). The committee noted that other focal therapies are not routinely available in the NHS (see section 3.3). Also, a submission from a professional organisation stated that focal therapies are normally used to manage intermediate-risk disease in the NHS. Therefore, the committee agreed that focal therapies could not be considered relevant comparators. It concluded that the relevant comparators are radical therapies.

## ***Clinical evidence***

### **The key clinical evidence comes from a subgroup of 1 trial comparing padeliporfin plus active surveillance with active surveillance alone**

3.6 The evidence for padeliporfin came from a subgroup of the PCM301 trial, a phase 3, multi-centred, randomised, open-label, parallel group study. It compared padeliporfin plus active surveillance with active surveillance alone in 413 adults with untreated, low-risk prostate cancer. The subgroup had 158 patients with unilateral, low-risk but not very-low-risk prostate cancer. The co-primary outcomes at 24 months were absence of definitive cancer and treatment failure, defined as histological cancer progression from low- to intermediate or high-risk or prostate cancer-related death.

### **The patients in the PCM301 subgroup are likely to be different to those seen in the NHS**

3.7 The committee noted that patients in the PCM301 subgroup had an average age of 63 years and body mass index of 26 kg/m<sup>2</sup> which were both lower than those of NHS patients. One clinical expert explained that because of the changing thresholds for the risk of disease progression

(see section 3.1), patients in PCM301 with a Gleason score of 6 would now likely be considered to have a Gleason score of 7. The committee agreed that the patients in the PCM301 subgroup may not reflect patients with low-risk disease likely to be seen in the NHS, and therefore there was some uncertainty in how generalisable the trial results are to NHS patients.

### **Active surveillance in PCM301 does not reflect NHS clinical practice**

3.8 All patients in PCM301 had TRUS-guided biopsy. The committee recalled that these diagnostic techniques are less accurate at identifying the risk of the disease progressing and are being replaced by multiparametric MRI (see section 3.1). The committee understood that patients on active surveillance alone in PCM301 did not have multiparametric MRI. One clinical expert explained that MRI techniques are routinely used in patients starting on active surveillance. The committee concluded that the comparator arm (that is, active surveillance) did not reflect NHS clinical practice.

### **Padeliporfin plus active surveillance is likely to be clinically effective compared with active surveillance alone at 24 months**

3.9 The committee noted that, in patients randomised to padeliporfin plus active surveillance, there were higher rates of 'absence of definitive cancer' and 'absence of disease progression' compared with active surveillance alone (see table 1). The ERG noted that the disease progression was higher in the active surveillance group in PCM301 (58%) compared with other trials. For example, [Protect](#), a UK-based, randomised controlled trial on prostatectomy and external beam radiotherapy reported that 30% of patients in the active surveillance group had disease progression. The company explained that patients in PCM301 had re-biopsies at 12 and 24 months, while Protect did not have any planned re-biopsies. It suggested that these planned biopsies in PCM301 led to earlier detection of disease progression. The committee concluded that although padeliporfin plus active surveillance is likely to be



clinically effective compared with active surveillance alone, the size of the benefit is uncertain (see section 3.8).

**Table 1. Co-primary end points for PCM301 subgroup at 24 months**

Outcomes	Padeliporfin plus active surveillance (n=80, unless otherwise stated)	Active surveillance alone (n=78, unless otherwise stated)	Risk ratio (95% confidence intervals)
<b>Absence of definitive cancer at 24 months</b>			
<b>Lobe diagnosed at baseline</b>	71%	15%	4.6 (2.7 to 7.9)
<b>Whole gland</b>	45%	10%	4.4 (2.2 to 8.3)
<b>Absence of disease progression<sup>a</sup> at 27 months</b>			
<b>Lobe diagnosed at baseline</b>	90% of 71 patients	42% of 67 patients	2.2 (1.6 to 2.9) <sup>^</sup>
<b>Whole gland</b>	64% of 76 patients	25% of 71 patients	not available
<sup>^</sup> calculated by ERG; <sup>a</sup> no prostate cancer-related deaths in study			

**The company did not provide any clinical evidence comparing padeliporfin with radical therapies**

3.10 The company explained in its submission that it could not indirectly compare padeliporfin and radical therapies. This was because of the different outcomes reported in the trials and those used in its economic model, such as, time to radical therapy. The ERG agreed with the company that a network meta-analysis was not possible given the available evidence. The committee noted that the company had not presented any evidence compared with focal therapies (see section 3.5), that might have allowed an indirect comparison with radical therapies. The committee agreed that it had not seen any evidence of the effectiveness of padeliporfin compared with radical therapies, and therefore it could not conclude whether padeliporfin offered any clinical benefit compared with radical therapies.

## ***Adverse events***

### **Adverse events such as sexual and bowel dysfunction may be lower with padeliporfin than with radical therapies**

3.11 The committee noted that the rates of sexual and bowel dysfunction were much higher in the padeliporfin plus active surveillance group than in patients having active surveillance alone. The clinical experts explained that radical therapies are associated with higher rates of bowel, urinary and sexual dysfunction than those seen in patients having padeliporfin in PCM301. The committee concluded that a likely clinical benefit of padeliporfin is a lower risk of having these adverse events than with radical therapies, but agreed that it had not seen any supporting evidence (see section 3.10).

## ***Company's economic model***

### **The company used a partitioned survival model**

3.12 The company assessed cost effectiveness using 3 survival curves ('time to radical therapy', 'time to metastasis' and 'overall survival') to split people into 4 health states ('pre-radical therapy', 'post-radical therapy', 'metastasis' and 'death') in a partitioned survival model. Patients on padeliporfin (plus active surveillance) and active surveillance alone started in the 'pre-radical therapy' state. Patients in the 'post-radical therapy' state included patients on padeliporfin or active surveillance whose disease had progressed or patients who had radical therapy immediately.

## ***Outcomes in the model***

### **'Time to radical therapy' is more appropriate for a comparison of padeliporfin and active surveillance**

3.13 The company used 'time to radical therapy' and 3 adverse events (bowel, urinary and sexual dysfunction) as the main outcomes in its economic model. The committee agreed that 'time to radical therapy' may be an appropriate outcome for a comparison of padeliporfin with active

surveillance that considers how long treatment with radical therapies is delayed, but not for radical therapies because patients are already on treatment. For a comparison of padeliporfin with radical therapies, the committee considered oncological outcomes such as absence of definitive cancer or absence of disease progression more relevant.

### **Adverse events rates from ProtecT are preferred to Ramsay's estimates**

3.14 For padeliporfin and active surveillance, the company sourced the 3 key adverse events rates of bowel, urinary and sexual dysfunction from PCM301. For radical therapies, the data came from the literature, specifically from [Ramsay \(2015\)'s study of ablative therapies](#) on people with localised prostate cancer which in turn sourced adverse events rates from randomised controlled trials, non-randomised comparative studies and case series with at least 10 people. Adverse events were divided into short term (first 6 months) or long term (after 6 months). The ERG explained that Ramsay's estimates are not based on a meta-analysis and there is uncertainty on the comparability of adverse events rates applied for radical therapies. It highlighted that the rates from ProtecT, for prostatectomy and external beam radiotherapy were different to the estimates from Ramsay. One clinical expert explained that ProtecT may not give a reliable estimate of adverse events because only about 25% of patients had had their randomised treatment. However, another clinical expert confirmed that the ERG's estimates for urinary dysfunction are similar to those seen in clinical practice. The committee agreed that there is considerable uncertainty on the most appropriate adverse events rates to use in the model. However, given the similarities in rates in urinary dysfunction between ProtecT and clinical practice, the committee agreed that the ERG estimates from ProtecT are preferred for decision making.

### ***Assumptions in the model***

#### **The company assume that all options have the same ‘time to metastasis’ and ‘overall survival’**

3.15 The company assumed that all options (padeliporfin, active surveillance and radical therapies) have the same ‘time to metastasis’ and ‘overall survival’. The clinical experts noted that although clinical studies may not have been large enough or done for long enough to find any differences in death rates between options, the assumption is plausible for low-risk disease. The committee understood that this meant that any difference in modelling outcomes between treatments are related to the costs and quality of life associated with adverse events (see section 3.14).

#### **‘Time to metastasis’, ‘overall survival’ and ‘time to radical therapy’ curves should be adjusted for general population mortality**

3.16 The company adjusted the ‘overall survival’ and ‘time to metastasis’ curves for general population mortality but not the ‘time to radical therapy’ curve. The ERG explained that not adjusting for general population mortality in ‘time to radical therapy’ overestimates the number of people in the ‘pre-radical therapy’ health state. The committee agreed that ‘time to radical therapy’ curve should be adjusted for general population mortality.

#### **The most plausible ‘time to radical therapy’ extrapolation curves for active surveillance and padeliporfin are uncertain**

3.17 The company preferred a log-normal parametric curve to extrapolate the ‘time to radical therapy’ beyond the trial follow-up period for both padeliporfin and active surveillance. It based this choice of curve on better fit statistics, visual inspection and more clinically plausible extrapolation. At 10 years, the log-normal curve predicted that most patients on active surveillance would have radical therapy. However, ProtecT reported that only 55% would have radical therapy at this point. The clinical experts explained that it was unlikely that such a high proportion of patients would have radical therapy within 10 years. The committee agreed that the log-

normal curve for active surveillance was unrealistic. It noted that there was little difference between fit statistics (such as the Akaike information criterion and the Bayesian information criterion) of the different curves in padeliporfin, but that the mean and median time to radical therapy varied greatly depending on the choice of curve (for example, the mean ranged from 5 for the Gompertz and gamma curves to 15 for the exponential curve). The committee concluded that the log-normal curves used for padeliporfin and active surveillance 'time to radical therapy' were not clinically plausible, and that it would consider a range of curves in its decision making.

### ***Utility values in the economic model***

#### **The committee preferred the utility decrement for bowel dysfunction from the ERG**

3.18 Based on [Ramsay](#), the company applied decrements for bowel, urinary and sexual dysfunction of 0.16, 0.05 and 0.04 respectively. The ERG checked the source of these values and highlighted that the company did not apply a multiplier to the bowel dysfunction decrement, resulting in an overestimate of the original value. Also, the ERG explained that the company had applied the utility decrements for all 3 adverse events additively rather than multiplicatively. The committee was aware that NICE Decision Support Unit's [technical support document 12](#) suggests using age-adjusted multipliers. However, the ERG explained that the company's model would need substantial restructuring to allow for cycle-specific utility estimates. The committee agreed that the ERG's utility decrement for bowel dysfunction should be used, and would have liked to have seen age-adjusted multipliers used in the model.

### ***Costs in the economic model***

#### **Multiparametric MRI, day-case procedure for padeliporfin, adjuvant and salvage therapies and once-only bowel dysfunctions costs are preferred**

3.19 The company included the following costs in its base case:

- No multiparametric MRI costs for padeliporfin and active surveillance (£343). The committee recalled that patients starting on active surveillance would routinely have multiparametric MRI in the NHS (see sections 3.1 and 3.8). The committee agreed that these costs should apply to both padeliporfin and active surveillance.
- Day-case costs for the padeliporfin procedure, rather than an overnight stay. The clinical experts explained that padeliporfin is likely to be a day-case procedure.
- Adjuvant and salvage therapies. The clinical experts explained that adjuvant and salvage therapies are given in practice. The committee agreed that these costs should be included.
- Adverse events related to bowel dysfunction on an annual basis. One clinical expert explained that bowel dysfunction is chronic and tends to worsen over time. The ERG reviewed the original source of these costs that used mean cost per patient and explained that it would be more appropriate to apply the costs once only. The committee understood that although these costs were applied once only, they reflected the total costs over the patient's lifetime.
- Prostatectomy. The committee noted that the company did not include the cost of using robotic devices for prostatectomy, and agreed that these should be considered.
- Padeliporfin. The committee noted that the company did not consider wastage of padeliporfin in its model and that it should be included.

### ***Cost-effectiveness estimate***

#### **There are no analyses that include the committee's preferred assumptions**

3.20 The committee recalled its concerns about the company's base-case analyses, which were that:

- the only clinical trial evidence compared padeliporfin with active surveillance, which is not relevant comparator in NHS practice (see sections 3.4 and 3.10)

- the outcomes may not be appropriate for comparing padeliporfin with radical therapies (see section 0)
- the ‘time to radical therapy’ curves were not adjusted for general population mortality (see section 3.16)
- there was substantial uncertainty on the most appropriate distributions to use for the ‘time to radical therapy’ extrapolation curves for padeliporfin and active surveillance (see section 3.17)
- the adverse events rates for radical therapies were uncertain (see section 3.14)
- there was uncertainty on the costs of prostatectomy and padeliporfin (see section 3.19).

The committee noted that the ERG’s exploratory analyses had not addressed all of its concerns.

### **Full incremental analyses are preferred**

3.21 The company presented fully incremental analyses with and without active surveillance as a comparator and pairwise comparisons with padeliporfin. It also presented a pairwise comparison based on market share of a ‘blended comparator’ (without padeliporfin) and ‘blended intervention’ (with padeliporfin). In line with [NICE’s guide to the methods of technology appraisal](#), the committee did not accept the analysis including the blended intervention and comparator. Although the committee acknowledged that active surveillance was not a relevant comparator for NHS practice in patients with low-risk prostate cancer without disease progression (see sections 3.4 and 3.5), it agreed to review the results from the economic analysis. Also, the committee did not see any clinical effectiveness evidence comparing padeliporfin with radical therapies (see section 3.10), and it acknowledged that no oncological outcomes were included (see section 0) for this comparison. However, it agreed to review the results from the economic analysis separately.

**An acceptable ICER would lie towards the lower part of the £20,000 to 30,000 per QALY gained range specified in the methods guide**

3.22 The committee acknowledged that there was substantial uncertainty in the evidence base (see section 3.20). Therefore, it agreed that an acceptable incremental cost-effectiveness ratio (ICER) would lie, at the lower end of the £20,000 to 30,000 per quality-adjusted life year (QALY) gained range specified in the NICE methods guide for technology appraisals. The committee discussed whether any other factors, such as the health-related benefits that may not have been included in the model or the innovative nature of padeliporfin (see section 3.26) could lead it to accept a higher maximum acceptable ICER. It agreed there were none.

**Cost-effectiveness estimates for padeliporfin plus active surveillance compared with active surveillance alone are higher than what NICE considers an acceptable use of NHS resources**

3.23 The committee noted that the ICER for padeliporfin plus active surveillance compared with active surveillance alone in the company's base case was estimated to be £49,415 per QALY gained. The ICERs in the relevant ERG's exploratory analyses ranged from £49,424 to £58,047 per QALY gained. The committee agreed that combining the different scenarios in the ERG's exploratory analyses would be likely to further increase the ICER. It noted that the ICERs were sensitive to the distributions of 'time to radical therapy' extrapolation curves for padeliporfin and active surveillance, and adverse events rates and agreed that this increased the uncertainty about the most plausible ICER. Taking into account its concerns about economic modelling (see section 3.20), the committee agreed that the most plausible ICER for padeliporfin plus active surveillance compared with active surveillance alone would be much higher.



### **Padeliporfin plus active surveillance compared with radical therapies is not a cost-effective use of NHS resources**

3.24 In the fully incremental analysis without active surveillance, the committee noted that in the company's base case, prostatectomy was dominated (that is, prostatectomy was less effective and cost more than other treatment options) and brachytherapy was extendedly dominated (that is, the ICER is higher than that of the next more effective option) by external beam radiotherapy. The ICER for padeliporfin plus active surveillance compared with external beam radiotherapy in the company's base case was estimated to be £26,728 per QALY gained. The ICERs in the relevant ERG's exploratory analyses ranged from £26,942 to £37,727 per QALY gained. After taking into account its concerns with the analyses (see section 3.20), the committee concluded that padeliporfin plus active surveillance compared with radical therapies is not a cost-effective use of NHS resources.

### ***Other factors***

#### **Guidance is not restricted by gender**

3.25 The committee noted that, as in previous appraisals for technologies for treating prostate cancer, its recommendations should apply to people with prostate cancer because men and transgender women have a prostate.

#### **Padeliporfin is a new method of applying focal therapy**

3.26 The committee heard differing views about whether padeliporfin was innovative in its potential to have a substantial effect on health-related benefits in low-risk disease. One clinical expert explained that adverse events resulting in sexual dysfunction do not capture important toxicities associated with prostatectomy such as loss of penile function and incontinence during sexual intercourse. The committee agreed that padeliporfin used a new method of applying focal therapy. However, it did not hear that there were any additional gains in health-related quality of life over those already included in the QALY calculations.

## 4 Proposed date for review of guidance

- 4.1 NICE proposes that the guidance on this technology is considered for review by the guidance executive 3 years after publication of the guidance. NICE welcomes comment on this proposed date. The guidance executive will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Amanda Adler  
Chair, Appraisal Committee  
June 2018

## 5 Appraisal committee members and NICE project team

### ***Appraisal committee members***

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by [committee B](#).

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The [minutes](#) of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### ***NICE project team***

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

### **Sharlene Ting**

Technical Lead

**Jasdeep Hayre**

Technical Adviser

**Jeremy Powell**

Project Manager

ISBN: [to be added at publication]