NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Appraisal consultation document

Abiraterone for untreated high-risk hormone-sensitive metastatic 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 abiraterone 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 abiraterone 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: 27 June 2018

Second appraisal committee meeting: 10 July 2018

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

1.1 Abiraterone plus androgen deprivation therapy (ADT) is not recommended, within its marketing authorisation, for untreated high-risk hormone-sensitive metastatic prostate cancer in adults.

1.2 This recommendation is not intended to affect treatment with abiraterone plus ADT 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 treatment for untreated high-risk hormone-sensitive metastatic prostate cancer includes ADT alone and docetaxel plus ADT. The clinical trial results show that, compared with ADT alone, abiraterone plus ADT increases the time until the disease progresses and the overall length of time people live. They also show that, compared with docetaxel plus ADT, abiraterone plus ADT increases the time until the disease progresses but not the overall length of time people live. This could be because people having abiraterone plus ADT benefit from treatment early on, but have fewer available follow-on treatments after prostate cancer has progressed compared with people having docetaxel plus ADT.

The company’s economic model does not reflect the number of treatments available to people with high-risk hormone-sensitive metastatic prostate cancer in NHS clinical practice, and does not give plausible estimates for modelled survival. Also, clinical effectiveness and quality of life with abiraterone plus ADT compared with docetaxel plus ADT have not been fully explored using all available data relevant for this population. This means that no plausible cost-effectiveness estimate for abiraterone plus ADT compared with docetaxel plus ADT can be established. So,
there is no basis on which to recommend abiraterone plus ADT for untreated high-risk hormone-sensitive metastatic prostate cancer in adults.

2 Information about abiraterone

<table>
<thead>
<tr>
<th>Marketing authorisation</th>
<th>Abiraterone (Zytiga; Janssen) has a UK marketing authorisation for treating ‘newly diagnosed high risk metastatic hormone-sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)’. In the LATITUDE clinical trial, high-risk prognosis was defined as having at least 2 of the following 3 risk factors: a Gleason score of 8 or more; 3 or more lesions on bone scan; and measurable visceral metastasis (excluding lymph node disease).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage in the marketing authorisation</td>
<td>1,000 mg as a single daily dose. It is administered orally.</td>
</tr>
<tr>
<td>Price</td>
<td>The company has a commercial arrangement (commercial access agreement) for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated (technology appraisal guidance 387) and castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen (technology appraisal guidance 259). The details of the commercial arrangements are confidential.</td>
</tr>
</tbody>
</table>

3 Committee discussion

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

Clinical management

Androgen deprivation therapy (ADT) with and without docetaxel are the first-line treatment options for metastatic hormone-sensitive prostate cancer

3.1 The clinical experts explained that people with newly diagnosed hormone-sensitive (that is, hormone-naive) metastatic prostate cancer have ADT or docetaxel plus ADT in clinical practice. NICE’s guideline for prostate cancer recommends ADT, specifically continuous luteinising hormone-
releasing hormone agonists, bilateral orchidectomy (removal of the testicles), or bicalutamide monotherapy. The clinical experts explained that orchidectomy and bicalutamide monotherapy are rarely used in this way in the NHS. The committee agreed that ADT alone or with docetaxel or abiraterone would include luteinising hormone-releasing hormone agonists. It understood that, although docetaxel is not licensed for use with ADT for hormone-sensitive metastatic prostate cancer, NHS England commissions 6 cycles of docetaxel with ADT based on evidence from 3 trials assessing docetaxel plus ADT (CHAARTED, GETUG-AFU 15 and STAMPEDE). The committee concluded that ADT and docetaxel plus ADT were appropriate comparators.

There are no clear-cut clinical criteria to define people who can have abiraterone but not docetaxel

3.2 A patient expert explained that there is an unmet need for an alternative treatment option for people who cannot have docetaxel plus ADT. The committee heard that general fitness would determine whether a person could have docetaxel or not. It noted that the NHS England’s commissioning policy states that the decision to start docetaxel plus ADT should be based on whether someone is fit enough to tolerate 6 cycles of docetaxel. The Cancer Drugs Fund’s clinical lead noted that around 50% of people presenting with hormone-sensitive metastatic prostate cancer are not fit enough for docetaxel and have ADT alone. The committee was aware that most of the population included in the key clinical trial of abiraterone plus ADT (LATITUDE, see section 3.4) would be considered fit enough to have docetaxel (more than 95% of people in the trial had an Eastern Co-operative Oncology Group performance status of 0 or 1). The clinical experts explained that there are no clear clinical criteria to differentiate between people eligible for abiraterone plus ADT and those eligible for docetaxel plus ADT. The committee heard that some people prefer having abiraterone first, rather than docetaxel, because it has fewer adverse effects and is better tolerated. However, it also heard that some people choose to have docetaxel first because of its shorter treatment
duration. In addition, it understood that a person’s choice of treatment may depend on the availability of follow-on treatments (see section 3.3). The committee concluded that although there are reasons for a person’s treatment preference at this point in the treatment pathway, there are no clear-cut clinical criteria to define who could have abiraterone but not docetaxel. Therefore, it did not consider separately the clinical and cost effectiveness of abiraterone in people who cannot have docetaxel.

**The choice of first treatment for metastatic hormone-sensitive prostate cancer affects the follow-on treatments a person might have**

3.3 The clinical experts explained that people who have previously had docetaxel as first-line treatment can be given docetaxel again (for up to 10 cycles) because the benefit of docetaxel is not exhausted when used with ADT for only 6 cycles. The Cancer Drugs Fund clinical lead explained that abiraterone and enzalutamide are commissioned by NHS England only once in the treatment pathway because there is as yet no evidence of clinical benefit for enzalutamide after abiraterone and vice versa. The committee understood that people who have abiraterone plus ADT for hormone-sensitive prostate cancer have fewer active follow-on treatment options available because they will not have abiraterone (or enzalutamide) later in the treatment pathway. It noted that the sequence of follow-on treatments may vary from person to person and possible follow-on treatments include:

- After ADT alone:
  - abiraterone or enzalutamide (before or after docetaxel)
  - docetaxel
  - other active treatments such as cabazitaxel or radium-223.

- After docetaxel plus ADT:
  - abiraterone or enzalutamide (before or after docetaxel)
  - docetaxel again
  - other active treatments such as cabazitaxel or radium-223.

- After abiraterone plus ADT:
docetaxel
other active treatments such as cabazitaxel or radium-223.

The committee concluded that the first-choice treatment option for hormone-sensitive metastatic prostate cancer affects the follow-on treatments a person may have, and that having abiraterone plus ADT results in fewer follow-on treatment options than having ADT alone or docetaxel plus ADT.

Clinical evidence

LATITUDE and STAMPEDE are both relevant for assessing the clinical effectiveness of abiraterone plus ADT

3.4 Two randomised controlled trials have investigated the clinical effectiveness of abiraterone plus ADT–LATITUDE and STAMPEDE:

LATITUDE was a double-blind trial including 1,199 patients with newly diagnosed high-risk hormone-sensitive metastatic prostate cancer. Patients were randomised to either abiraterone plus ADT or ADT alone.

STAMPEDE was a multi-arm multi-stage non-blinded adaptive trial of patients with newly diagnosed high-risk metastatic, node-positive or localised disease that was previously treated with radical surgery or radiotherapy and was now relapsing with high-risk features. Randomised trial arms included abiraterone plus ADT, ADT alone and docetaxel plus ADT. The abiraterone plus ADT compared with ADT alone comparison was pre-specified in the trial protocol and compared patients in these arms recruited at the same time. Data were available for 502 patients with metastatic prostate cancer in the ADT alone arm, 500 in the abiraterone plus ADT arm and 115 in the docetaxel plus ADT arm.

The company considered LATITUDE to be the most relevant trial for appraising the clinical effectiveness of abiraterone plus ADT. It considered STAMPEDE to be less relevant because it included both patients with
locally advanced and patients with metastatic prostate cancer, which was broader than the licensed population for abiraterone. The results from STAMPEDE for docetaxel plus ADT compared with abiraterone plus ADT in hormone-sensitive metastatic prostate cancer have been published. However, the clinical experts explained that results for the licensed population (that is, the subgroup of patients with high-risk disease) had been collected, but not yet published. Two clinical experts, who were also investigators in STAMPEDE, explained that there was no reason to believe that there was any subgroup of people for whom abiraterone was more or less effective; abiraterone appeared similarly effective in localised, metastatic and high-risk hormone-sensitive prostate cancer. The committee agreed that, although STAMPEDE assessed treatments in a broader population than the population covered by the marketing authorisation for abiraterone, data from STAMPEDE are broadly generalisable to the population for whom abiraterone plus ADT is being appraised. However the committee would have preferred to see evidence from patients with high-risk metastatic disease from STAMPEDE when available. It concluded that LATITUDE and STAMPEDE were both relevant for assessing the clinical effectiveness of abiraterone plus ADT for high-risk metastatic hormone-sensitive prostate cancer.

**Follow-on treatments in STAMPEDE reflect clinical practice in England more than those in LATITUDE**

3.5 STAMPEDE was a trial in patients from the UK and was unblinded. This meant that follow-on treatments in STAMPEDE reflected what people would have in clinical practice in UK because the choice of next treatment depends on the first treatment had, unlike in the blinded LATITUDE trial. The company had noted that a limitation of LATITUDE was that the follow-on treatments did not reflect those used in the UK. As such, the committee concluded that the estimates of survival from STAMPEDE after a patient needed a next treatment were likely to be more relevant to clinical practice in England than those from LATITUDE.
STAMPEDE provides direct evidence when comparing abiraterone plus ADT with docetaxel plus ADT

3.6 STAMPEDE provided a direct comparison of abiraterone plus ADT with docetaxel plus ADT. However, the company did a network meta-analysis to compare abiraterone plus ADT with docetaxel plus ADT because of its concerns about the generalisability of the STAMPEDE population to people with high-risk hormone-sensitive metastatic prostate cancer (see section 3.4). The clinical experts explained that the trials of docetaxel plus ADT compared with ADT alone in the company’s network meta-analysis (that is, CHAARTED and GETUG-AFU 15) included a different population from LATITUDE. This was because they included both patients who were or were not newly diagnosed, and only a subgroup of patients with high-volume disease (which is similar to high-risk disease). The committee was aware that STAMPEDE was not statistically powered to detect a difference in survival between abiraterone plus ADT and docetaxel plus ADT in the metastatic subgroup because it was a post-hoc analysis in STAMPEDE. The committee considered the results from STAMPEDE to be more robust than those from the network meta-analysis because it collected direct, randomised data that were generalisable to the UK population. Therefore, it preferred direct evidence from patients with high-risk metastatic disease from STAMPEDE for the comparison between abiraterone plus ADT with docetaxel plus ADT to indirect evidence from the company’s network meta-analysis, which did not include STAMPEDE. However, the committee concluded that the direct evidence could be further supported by a network meta-analysis including evidence from patients with high-risk metastatic disease from STAMPEDE, CHAARTED, GETUG-AFU 15 and LATITUDE. This would combine evidence from a larger number of people and potentially decrease the uncertainty about the relative effectiveness of abiraterone.
Abiraterone plus ADT extends survival compared with ADT alone

3.7 Abiraterone plus ADT statistically significantly improved both progression-free and overall survival compared with ADT alone in LATITUDE and in patients with metastatic disease in STAMPEDE, and the size of improvement was similar in the 2 trials. In LATITUDE, median progression-free survival was 14.8 months with ADT alone and 33.0 months with abiraterone plus ADT (hazard ratio [HR] 0.47, 95% confidence interval [CI] 0.39 to 0.55), and median overall survival with ADT alone was 34.7 months and was not reached with abiraterone plus ADT (HR 0.62, 95% CI 0.51 to 0.76). In STAMPEDE, the hazard ratio for progression-free survival was 0.43 (95% CI 0.36 to 0.52), and for overall survival was 0.61 (95% CI 0.49 to 0.75). The committee concluded that abiraterone plus ADT improved both progression-free and overall survival compared with ADT alone.

Compared with docetaxel plus ADT, the effects of abiraterone plus ADT on disease progression and overall survival vary

3.8 In patients with metastatic disease in STAMPEDE, abiraterone plus ADT improved progression-free survival compared with docetaxel plus ADT (HR 0.69, 95% CI 0.50 to 0.95), but overall survival was similar (HR 1.13, 95% CI 0.77 to 1.66). In the company’s network meta-analysis (including data from LATITUDE, CHAARTED and GETUG-AFU 15), no differences were found between abiraterone plus ADT compared with docetaxel plus ADT in progression-free survival (HR 0.76, 95% Credible Interval [CrI] 0.53 to 1.10) or in overall survival (HR 0.92, 95% CrI 0.69 to 1.23). Taking into account the uncertainty around the data from STAMPEDE (see sections 3.4 and 3.6), the committee concluded that although data from STAMPEDE suggested abiraterone plus ADT improves progression-free survival, there was currently no evidence that abiraterone plus ADT improves overall survival compared with docetaxel plus ADT.
The company has not fully explored the effect on overall survival of fewer treatment options after abiraterone plus ADT

3.9 Two of the clinical experts explained that the reason for a progression-free survival benefit but lack of overall survival benefit with abiraterone plus ADT compared with docetaxel plus ADT in STAMPEDE (see section 3.8) was that patients may have had fewer treatment options after abiraterone plus ADT than after ADT alone or docetaxel plus ADT. The clinical experts involved in STAMPEDE explained that that post-progression survival was reduced after abiraterone plus ADT compared with after ADT alone in this trial. The committee was aware that LATITUDE was blinded, so patients may not have had the most clinically effective follow-on treatments, and that the follow-on treatments in LATITUDE did not reflect clinical practice in England (see section 3.5). It agreed that the effect of follow-on treatments in LATITUDE made the magnitude of the overall survival estimates uncertain. The committee would have preferred to have seen analyses on the effect of different sequences and numbers of follow-on treatments to understand the relationship between progression-free survival and overall survival in high-risk metastatic hormone-sensitive prostate cancer.

The company’s economic model

The company's model does not include relevant data from STAMPEDE

3.10 The company assessed cost effectiveness using a multi-state Markov model. The probability of progressing and dying while on abiraterone plus ADT and ADT was modelled using data from LATITUDE, and data from the network meta-analysis (excluding STAMPEDE) for docetaxel plus ADT. The committee stated it would have preferred data from patients with high-risk metastatic disease from STAMPEDE to have been included in the modelling (see sections 3.4 and 3.6).
The company’s model does not reflect the treatment pathway and does not give plausible survival results

3.11 In the company’s model, after progression to hormone-refractory prostate cancer each person could have up to 3 follow-on treatments in each of the modelled treatment arms. The committee disagreed with the company’s assumptions on follow-on treatments because: it did not model a second treatment course with docetaxel after docetaxel plus ADT; and it did not reflect that people having abiraterone plus ADT for hormone-sensitive prostate cancer have fewer treatment options available for hormone-refractory prostate cancer. The company presented 2 approaches to modelling survival in the 3 hormone-refractory health states (that is, being on the first, second or third treatment for hormone-refractory prostate cancer). In its base case, it used survival estimates for a sequence of treatments used in a different economic model (in NICE’s technology appraisal guidance on abiraterone for treating hormone-relapsed prostate cancer before chemotherapy is indicated), calibrating it to align with extrapolated overall survival data from LATITUDE. The company’s alternative approach was to use unadjusted data from LATITUDE to model survival in the hormone-relapsed health states. The committee noted that the problem with both of these modelling approaches was that the length of time a person lived after progressing on treatments for hormone-sensitive prostate cancer was kept similar regardless of treatment. This also meant that the modelled overall survival was longer with abiraterone plus ADT than the comparator treatments because the modelled progression-free survival was longer with abiraterone plus ADT. Based on the data from STAMPEDE and the clinical experts’ statements, the committee concluded that post-progression survival would not be the same across treatment arms (see sections 3.4 and 3.9). It also concluded that the company’s model does not reflect the treatment pathway and does not give plausible survival estimates.
Utility values in the model

The utility estimates for being on abiraterone plus ADT, docetaxel plus ADT and ADT alone should be based on the same measure of quality of life.

3.12 The company took into account separately the effects on quality of life of adverse effects and of being on treatment. The sources of these data are in Table 1.

Table 1 Data sources for the utility value estimates in the model

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Quality of life relating to treatment</th>
<th>Quality of life relating to adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADT alone</td>
<td>Based on EQ-5D data from LATITUDE.</td>
<td>Published utility values for adverse effects and skeletal-related events.</td>
</tr>
<tr>
<td>Abiraterone plus ADT</td>
<td>Based on EQ-5D data from LATITUDE. There was a utility increase for being on abiraterone compared with ADT alone.</td>
<td></td>
</tr>
<tr>
<td>Docetaxel plus ADT</td>
<td>Based on a company survey. There was a utility decrement both when treated with docetaxel and when treated with ADT after stopping docetaxel compared with ADT alone.</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: ADT, androgen deprivation therapy.

The committee was aware that the company used different approaches to estimate the effect on quality of life of having abiraterone plus ADT or ADT than to estimate the effect with docetaxel plus ADT. The utility values for being on abiraterone plus ADT were based on EQ-5D results from LATITUDE, and for being on docetaxel plus ADT were based on a separate survey of the general public carried out by the company. The committee was aware that the NICE methods guide states that EQ-5D is the preferred measure of health-related quality of life. The committee further noted that the company could have used trial-based EQ-5D results for docetaxel plus ADT in its model because STAMPEDE collected these...
for the trial arms assessing abiraterone plus ADT, docetaxel plus ADT and ADT alone. The committee stated that although it considered the metastatic subgroup from STAMPEDE to be generalisable to the population under appraisal (see section 3.4), it was plausible that a person’s quality of life may be affected by their prognostic risk. It concluded that it was preferable to use EQ-5D data from the subgroup of people from STAMPEDE with metastatic and high-risk hormone-sensitive prostate cancer to assess quality of life because comparable data were available for abiraterone plus ADT, docetaxel plus ADT and ADT alone.

A worse quality of life while on docetaxel, and after docetaxel, is not plausible

3.13 The company assumed a decrease in quality of life (a utility decrement), both for having docetaxel plus ADT, and for having ADT after docetaxel plus ADT. The clinical experts explained that they did not consider it plausible that quality of life would be worse while having docetaxel plus ADT because any treatment that improves prostate cancer symptoms would improve quality of life. One clinical expert noted that, in CHAARTED (a trial of docetaxel plus ADT compared with ADT), quality of life slightly declined on docetaxel in the first 3 months but then returned to normal. The clinical experts involved in STAMPEDE stated that quality of life was improved on docetaxel plus ADT in that trial. The committee noted that although adverse effects were worse during treatment with docetaxel plus ADT than with abiraterone plus ADT or ADT alone, the effect of adverse effects on quality of life had been accounted for separately in the company model (see section 3.14) thereby potentially double counting the utility loss from adverse events. It concluded that it was appropriate to include utility decrements for adverse effects. It further concluded that EQ-5D data for patients with high-risk metastatic disease from STAMPEDE could give a more reliable comparison of a person’s quality of life while taking docetaxel plus ADT compared with abiraterone plus ADT or ADT alone.
Utility decrements for adverse events or skeletal-related events are expected to be larger than the company’s preferred estimates

3.14 The company model applied utility decrements for adverse events and skeletal-related events. The committee noted that the larger decrements estimated from the company’s regression analysis of EQ-5D data from the LATITUDE trial were more plausible than the values obtained from the literature, which the company had used in its base case. The committee concluded that the company had underestimated utility decrements for adverse events in its base case.

Costs used in the company’s model

Few people will stop treatment with abiraterone plus ADT before progression

3.15 The ERG was concerned about how the company had adjusted the costs of abiraterone in the progression-free hormone-sensitive health states for people who had stopped having abiraterone before disease progression. The company modelled time on treatment in the health state using the time people continued to take abiraterone relative to the time to disease progression in LATITUDE. The ERG estimated this based on the proportion of tablets taken in the safety population of LATITUDE, which was larger than the company’s estimate of the proportion of people who would continue having abiraterone before disease progression. The clinical experts explained that they expected few people would stop having abiraterone plus ADT before disease progression because it is generally well tolerated. The committee concluded that it was appropriate to consider time on treatment data when modelling the cost of abiraterone plus ADT.

Cost-effectiveness results

It is not possible to determine a plausible cost-effectiveness estimate

3.16 The committee stated that, because the company’s model structure did not reflect the treatment pathway for metastatic hormone-sensitive
prostate and gave implausible survival estimates (see section 3.11), it was unable to determine a plausible incremental cost-effectiveness ratio (ICER) for abiraterone plus ADT compared with ADT alone or with docetaxel plus ADT. It noted that none of the sensitivity analyses provided by the company or the ERG allowed it to assess different numbers of follow-on treatments in each modelled treatment arm or the effect of different numbers of follow-on treatments on post-progression survival. The committee expected that, if the model reflected the treatment pathway, the benefits of abiraterone plus ADT in delaying progression might be balanced by the potential benefits of the availability of more treatment options after a person’s prostate cancer has become hormone-relapsed after ADT alone or docetaxel plus ADT. It concluded that it was not possible to determine a plausible ICER for abiraterone plus ADT compared with ADT or with docetaxel plus ADT, and that without a plausible ICER it could not recommend abiraterone as a cost-effective use of NHS resources.

The committee would like to see cost-effectiveness estimates from analyses that include its preferences

3.17 The committee agreed that it’s preferred approach to modelling would include:

- allowing for a different number of follow-on treatments across modelled treatment arms (see sections 3.3 and 3.11)
- reflecting plausible post-progression and overall survival across modelled treatment arms, and allow for sensitivity analyses around the assumptions on post-progression and overall survival (see sections 3.8 and 3.11)
- including clinical-effectiveness data from patients with high-risk metastatic disease from STAMPEDE in the company’s primary assessment of clinical effectiveness (see sections 3.4 and 3.6)
• including data from STAMPEDE in the company’s assessment of quality of life while having treatments for high-risk hormone-sensitive metastatic prostate cancer (see section 3.12).

**Equality issues**

The recommendations are not restricted by gender

3.18 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. No other equality issues were raised during the scoping process or in the submissions for this appraisal.

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
May 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.

**Mary Hughes**

Technical Lead

**Jasdeep Hayre**

Technical Adviser

**Jeremy Powell**

Project Manager

ISBN: [to be added at publication]