NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final appraisal document

Abiraterone for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer

1 Recommendations

1.1 Abiraterone with prednisone or prednisolone plus androgen deprivation therapy (ADT) is not recommended, within its marketing authorisation, for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in adults.

1.2 This recommendation is not intended to affect treatment with abiraterone with prednisone or prednisolone 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 newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in the NHS in England is ADT alone or docetaxel plus ADT.

Clinical trial results show that abiraterone with prednisone or prednisolone plus ADT increases the time until the disease progresses and how long people live compared with ADT alone. They also show that it increases the time until the disease progresses compared with docetaxel plus ADT, but has a similar effect on how long people live.

There are concerns that the trials may overestimate the effectiveness of abiraterone. This is because the treatments offered in the trials after the disease progresses do

not reflect those offered in the NHS, where more people on standard care have effective treatments after their disease progresses than in the trials.

The company proposes a commercial arrangement which would make abiraterone available to the NHS at a discount. However, this was not agreed with NHS England. Even accounting for the offered price for abiraterone, the cost-effectiveness estimates of abiraterone with prednisone or prednisolone plus ADT compared with both ADT alone and docetaxel plus ADT are higher than the range normally considered a cost-effective use of NHS resources. So, abiraterone is not recommended for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

The cost-effectiveness estimates without a commercial arrangement are higher than the range normally considered a cost-effective use of NHS resources. Commercial discussions continued between the company and NHS England and NHS Improvement to identify an arrangement that would support the use of abiraterone as a cost-effective use of NHS resources, but concluded without an agreed arrangement that could be considered by the committee. Therefore, abiraterone is not recommended for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

2 Information about abiraterone

Marketing authorisation

2.1 Abiraterone (Zytiga; Janssen) with prednisone or prednisolone 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).

Dosage in the marketing authorisation

2.2 The licensed dose of abiraterone is 1,000 mg as a single daily dose. It is administered orally. It is used with 5 mg of prednisone or prednisolone daily.

Price

2.3 The cost of abiraterone is £2,735 for a pack of 56 500 mg tablets (excluding VAT; BNF online, accessed April 2020). The company has commercial arrangements making abiraterone available to the NHS with a discount when it is used for treating hormone-relapsed metastatic prostate cancer before chemotherapy is indicated and for hormone-relapsed metastatic prostate cancer previously treated with a docetaxel-containing regimen. The company and NHS England discussed but did not agree a commercial arrangement for abiraterone for the indication in this appraisal, that is, newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

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 hormone-sensitive metastatic prostate cancer

3.1 The clinical experts explained that, in clinical practice, people with newly diagnosed hormone-sensitive metastatic prostate cancer have ADT alone or docetaxel plus ADT plus the oral corticosteroid prednisolone (from now on, 'docetaxel in combination'). NICE's guideline for prostate cancer recommends ADT in the form of continuous luteinising hormone-releasing hormone agonists, bilateral orchidectomy (removal of the testicles) or

bicalutamide with ADT. It also recommends docetaxel. Docetaxel is not licensed for hormone-sensitive metastatic prostate cancer, but NHS England commissions it for up to 6 cycles. Docetaxel is taken with prednisolone 5 mg twice daily for 3 weeks. The clinical experts explained that orchidectomy and bicalutamide are rarely used in the NHS. The committee agreed that ADT would include luteinising hormone-releasing hormone agonists. It concluded that ADT alone and docetaxel in combination were appropriate comparators to abiraterone plus ADT plus 5 mg of the oral corticosteroid prednisone (from now on, 'abiraterone in combination').

It is not appropriate to consider separately the clinical and cost effectiveness of abiraterone in combination in people who currently have ADT alone

3.2 The company proposed abiraterone in combination as an alternative for patients who would currently have ADT alone, rather than those who would have docetaxel in combination. The Cancer Drugs Fund's clinical lead noted that around two-thirds of people presenting with hormone-sensitive metastatic prostate cancer in England have ADT alone. Of these people, some are not fit enough for docetaxel, and many choose not to have it because of the adverse events associated with chemotherapy. The committee recognised that there are 2 distinct populations who do not have docetaxel in combination and considered each in turn:

- **People who are not fit enough for docetaxel:** A patient expert explained that there is an unmet need for an alternative treatment option for people who cannot have docetaxel in combination. NHS England's commissioning policy indicates that someone may not be fit enough for docetaxel if they have a poor overall performance status (World Health Organization [WHO] performance 3 to 4), pre-existing peripheral neuropathy, poor bone marrow function or a life-limiting illness. The policy also states that docetaxel should be used with caution in people with a WHO performance status of 2 and that there are few absolute contraindications for docetaxel therapy. The

committee was aware that LATITUDE and STAMPEDE, the key clinical trials of abiraterone in this indication (see section 3.4), included only people with adequate haematological function, an Eastern Cooperative Oncology Group (ECOG) status or WHO performance status of 0, 1 or 2 (meaning they were reasonably fit). They also did not have any condition that would interfere with them taking part in the trial. The Cancer Drug's Fund clinical lead explained that many factors besides a person's performance status may affect whether they could have docetaxel. The committee was not presented with evidence of abiraterone's effectiveness in people who cannot take docetaxel. Without this evidence, it could not say whether abiraterone would be safe or effective in this group.

- **People who choose not to have docetaxel:** The committee recognised that most people who currently choose to have ADT alone rather than docetaxel in combination do so mainly because they wish to avoid the adverse events associated with docetaxel.

In summary, the committee agreed that there are no clear-cut clinical criteria to define who can have abiraterone in combination, but not docetaxel in combination. It also agreed that there is no supporting evidence of the safety or effectiveness of abiraterone in combination for people who cannot have docetaxel in combination. The committee recognised the importance of patient choice when all treatment options are clinically and cost effective. However, it considered that it would be inappropriate to consider abiraterone only for those who currently choose to have ADT alone, and not those who currently chose to have docetaxel. It concluded that it could not consider separately the clinical and cost effectiveness of abiraterone in people who cannot or chose not to have docetaxel, or to consider only ADT alone as a comparator.

The first treatment for hormone-sensitive metastatic prostate cancer affects the type and number of follow-on treatments during hormone-relapsed disease

3.3 The clinical experts explained that people who have previously had docetaxel as first-line treatment in the hormone-sensitive setting can have docetaxel again (for up to an additional 10 cycles). This is because the benefit of docetaxel is not exhausted when used 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 substantial clinical benefit for enzalutamide after abiraterone and vice versa. The committee understood that people who have abiraterone in combination for hormone-sensitive prostate cancer have fewer options for active follow-on treatments than people who start with something other than abiraterone in combination. This is because they cannot have abiraterone or enzalutamide later in the treatment pathway. The committee noted that the sequence of follow-on treatments may vary from person to person, and that 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 in combination:
  - abiraterone or enzalutamide (before or after docetaxel)
  - docetaxel again
  - other active treatments such as cabazitaxel or radium-223
- after abiraterone in combination:
  - docetaxel
  - other active treatments such as cabazitaxel or radium-223.

The committee concluded that the first-choice treatment for hormone-sensitive metastatic prostate cancer affects the follow-on

treatments a person may have. It also concluded that having abiraterone in combination at this position in the pathway limits the options for follow-on treatments for people who develop hormone-relapsed disease compared with people who have had ADT alone or docetaxel in combination.

Clinical evidence

LATITUDE and STAMPEDE are both relevant for assessing the clinical effectiveness of abiraterone in combination

3.4 Two randomised controlled trials have investigated the clinical effectiveness of abiraterone in combination in hormone-sensitive metastatic disease:

- LATITUDE was a double-blind trial including 1,199 patients with newly diagnosed high-risk hormone-sensitive metastatic prostate cancer. High risk was defined as at least 2 of a Gleason score of 8 or more (that is, cancer which is aggressive or likely to spread); 3 or more lesions on a bone scan; or visceral metastasis (excluding lymph nodes). Patients were randomised to either abiraterone plus ADT plus a corticosteroid (5 mg prednisone once daily) or ADT alone. The coprimary endpoint of the trial was progression-free and overall survival.
- STAMPEDE was a multi-arm non-blinded adaptive trial that included some patients with newly diagnosed hormone-sensitive metastatic, node-positive or high-risk localised disease (with at least 2 of: a tumour stage of 3 or 4; a Gleason score of 8 to 10, and prostate-specific antigen levels of 40 ng/ml or more); or prostate cancer previously treated with radical surgery or radiotherapy and now relapsing with high-risk features. Randomised trial arms included, but were not limited to, abiraterone plus ADT plus a corticosteroid (5 mg prednisolone once daily), ADT alone and docetaxel plus ADT plus a corticosteroid (10 mg prednisolone once daily). The primary endpoint was overall survival.

Data were available for 502 patients with metastatic prostate cancer in the ADT alone arm, 500 in the abiraterone in combination arm and 115 in the docetaxel in combination arm. A comparison between abiraterone in combination and ADT alone was pre-specified in the trial protocol and a comparison between abiraterone and docetaxel was done post-hoc.

The company considered LATITUDE to be the most relevant trial for appraising the clinical effectiveness of abiraterone in combination. It considered STAMPEDE to be less relevant because it included patients with locally advanced and patients with metastatic prostate cancer, which was broader than the licensed population for abiraterone. During the course of the appraisal, the STAMPEDE investigators published 2 analyses aligned to the licensed population (that is, the subgroup of patients with high-risk metastatic disease). These were for abiraterone in combination compared with ADT alone (Hoyle et al. 2018) and docetaxel in combination compared with ADT alone (Clarke et al. 2019). No analyses comparing abiraterone in combination with docetaxel in combination in the licensed population have been published.

The estimate least likely to be biased is from randomised direct comparisons of abiraterone with docetaxel from STAMPEDE

3.5 For the comparison of abiraterone in combination with docetaxel in combination, the company was concerned that results from the STAMPEDE subgroup of people with metastatic disease were not generalisable to the licensed population for abiraterone (see section 3.4). It further stated that STAMPEDE was not statistically powered to detect a difference in survival in this post-hoc analysis. The company instead developed a network meta-analysis which, as well as including the direct data from STAMPEDE, included several other trials. The company argued that, given the uncertainties in the direct analysis, these additional trials contributed important information to the estimated treatment effect of

abiraterone compared with docetaxel. The trials included in the network were:

- abiraterone in combination compared with docetaxel in combination: data from the STAMPEDE broad metastatic subgroup
- abiraterone in combination compared with ADT alone: data from LATITUDE (licensed population) and STAMPEDE (subgroup matching the licensed population)
- docetaxel in combination compared with ADT alone: data from STAMPEDE (subgroup matching the licensed population) CHAARTED and GETUG-AFU 15 (subgroups with 'high-volume' disease, which the company considered similar to the licensed population).

The committee noted that the company had not requested data from STAMPEDE directly comparing abiraterone in combination with docetaxel in combination for the subgroup matching the licensed population. The clinical experts stated that the effect of abiraterone is unlikely to be modified by disease volume. However, the committee considered that the trials in the network may have differed in other ways that could have influenced the effect estimate. The committee acknowledged that both direct and indirect evidence contributes to the total body of evidence. However, given the difference in results between the direct and indirect comparisons (see section 3.7), it concluded that the results from the direct comparison, being randomised, were less likely to be biased.

Abiraterone in combination extends survival compared with ADT alone

3.6 Abiraterone in combination improved both progression-free and overall survival compared with ADT alone in LATITUDE and in patients with high-risk metastatic disease in STAMPEDE. 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 in combination (hazard ratio [HR] 0.47, 95% confidence interval [CI]

0.39 to 0.55). Based on the planned final analysis of overall survival, the median overall survival with ADT alone was 36.5 months and was 53.3 months with abiraterone in combination (HR 0.66, 95% CI 0.56 to 0.78). In STAMPEDE, the hazard ratio for progression-free survival in the high-risk metastatic subgroup was 0.46 (95% CI 0.36 to 0.59), and for overall survival was 0.54 (95% CI 0.41 to 0.70). The committee concluded that abiraterone in combination improved both progression-free and overall survival compared with ADT alone. However, it noted that there was uncertainty about the magnitude of the long-term survival gain with abiraterone in combination because of potential differences in the proportion of people who had life-extending treatments after disease progression on ADT in LATITUDE and STAMPEDE compared with clinical practice (see section 3.9).

Compared with docetaxel in combination, abiraterone may improve progression-free survival but not overall survival

3.7 In patients with metastatic disease in STAMPEDE, abiraterone in combination improved progression-free survival compared with docetaxel in combination (HR 0.69, 95% CI 0.50 to 0.95). However, the hazard ratio for overall survival was similar (HR 1.13, 95% CI 0.77 to 1.66), with the point estimate favouring docetaxel. In the company's updated base case, rather than use the results reflecting a direct comparison from STAMPEDE, it used the results of the indirect network meta-analysis that included data from LATITUDE, CHAARTED, GETUG-AFU 15 and STAMPEDE. This showed similar results to the direct comparison for progression-free survival. However, the point estimate for overall survival favoured abiraterone, but the credible interval included 1, that is, the possibility of no difference in benefit of 1 treatment over the other. The results of the network meta-analysis are considered confidential by the company and cannot be reported here. Two of the clinical experts explained that a possible reason for a benefit in progression-free survival but lack of benefit in overall survival with abiraterone in combination compared with docetaxel in combination in STAMPEDE related to the

treatments that people have later in the treatment pathway. People who had docetaxel in combination or ADT alone could still go on to have abiraterone and docetaxel, whereas people who had already had abiraterone could only go on to have docetaxel. The clinical experts involved in STAMPEDE confirmed that post-progression survival was shorter after abiraterone in combination than after ADT alone in this trial. Considering the direct and indirect comparisons, the committee concluded that abiraterone in combination improves progression-free survival, but not overall survival compared with docetaxel in combination.

Neither STAMPEDE nor LATITUDE likely capture all the benefit on overall survival of follow-on treatments used in NHS clinical practice

3.8 The committee recognised that life-extending treatments offered when the disease is no longer hormone sensitive (that is, is hormone relapsed) affects life-expectancy. The committee was aware that follow-on treatments in the unblinded UK STAMPEDE trial were expected to reflect what people would have in NHS clinical practice. This was because the choice of next treatment depends on knowing the first treatment. In STAMPEDE, people were aware of their treatment, but in the blinded LATITUDE trial, people were not aware of their treatment. The committee noted that the trials differed from UK clinical practice in 2 ways:

- In LATITUDE, after abiraterone, 10% of the intention-to-treat (ITT) population had enzalutamide, and 5% had abiraterone again. In STAMPEDE 3% of the ITT population had enzalutamide after abiraterone, and 1% had abiraterone again.
- After ADT alone, fewer people in both STAMPEDE and in LATITUDE had follow-on treatment for hormone-relapsed disease with abiraterone or enzalutamide than would occur in NHS clinical practice. Of patients who had treatments for hormone-relapsed disease, 40% had enzalutamide or abiraterone in LATITUDE, and 55% had enzalutamide or abiraterone in STAMPEDE. This was lower than the 80% modelled by the company, which was based on an estimate of UK market shares

for these treatments (see section 3.13).

The committee recognised that the trials may have overestimated the clinical effectiveness of abiraterone if fewer people in the trials had had, and had benefitted from, follow-on treatments taken for hormone-relapsed prostate cancer than do in NHS clinical practice. The committee concluded that the estimates of survival from STAMPEDE after a patient needed a next treatment were likely more relevant to clinical practice in the NHS than those from LATITUDE.

Company's economic model

The company's Markov model does not give plausible estimates of post-progression and overall survival

3.9 The company provided 2 models. In its original submission, it provided a multistate Markov model. The committee deemed that this did not provide plausible estimates of post-progression or overall survival and did not generate valid estimates of cost effectiveness. In its submission for the third committee meeting, the company provided a partitioned survival model. Both models were split into 2 phases:

- A **hormone-sensitive** phase, in which the company used LATITUDE to model probabilities of progressing and dying while on abiraterone in combination or ADT alone: For abiraterone in combination compared with docetaxel in combination, the company applied hazard ratios from its revised network meta-analysis (including STAMPEDE) to data from LATITUDE.

A **hormone-relapsed** phase: In the Markov model, the company based time spent in the hormone-relapsed phase on the survival curves from NICE's technology appraisal guidance on abiraterone for treating metastatic hormone-relapsed prostate cancer before docetaxel is indicated. However, this approach did not produce valid estimates of overall survival for docetaxel. For example, modelled overall survival was

much longer with abiraterone in combination than with docetaxel in combination, even when using the hazard ratio for overall survival that suggested a survival benefit for docetaxel (1.13 from the STAMPEDE direct comparison). The partitioned survival model extrapolated progression-free and overall survival from LATITUDE, with the time spent in the hormone-relapsed phase being the difference between these 2 survival curves.

The committee concluded that, because the company's Markov model did not give plausible estimates of post-progression and overall survival, it would consider the company's partitioned survival model.

The Weibull distribution is more plausible than the log-logistic distribution for extrapolating progression-free and overall survival

3.10 The committee agreed with the company that the hazards of progression and death for abiraterone in combination compared with ADT alone from LATITUDE were not proportional, so it was appropriate to fit curves to each arm separately. The company presented results using the log-logistic distribution for each modelled treatment arm (which the company considered plausible but optimistic) and the Weibull distribution (which it considered plausible but pessimistic). The committee considered that the Weibull curves were plausible for progression-free survival. The ERG explained that data from Clarke et al. (2019), which presented results for docetaxel in combination compared with ADT alone in a subgroup of STAMPEDE aligned with the marketing authorisation for abiraterone, suggested that 10% of people who take ADT are alive at 9 years. This was a higher proportion than predicted by the Weibull extrapolation of the LATITUDE trial data, which suggested that 3% of people would be alive in the ADT arm at 10 years. The committee noted that extrapolating overall survival using the generalised gamma distribution may have given an estimate close to the results from STAMPEDE for long-term survival following ADT. The ERG highlighted that a consequence of the model was that the company assumed that the treatment effect is maintained over

the long term when, in clinical practice, it may wane. The committee shared the ERG's concerns. It considered that the ERG's scenario in which the hazards were equalised after 8 years was useful. The committee noted that there was uncertainty about at which time point it is appropriate to equalise the hazards. The committee concluded that the progression-free and overall survival curves extrapolated using the Weibull distribution were broadly appropriate, but may have underestimated overall survival for ADT alone. It further concluded that the generalised gamma distribution could have provided plausible estimates when extrapolating overall survival beyond the period of the trial.

Utility values in the model

The utility estimates should be based on the same measure of quality of life and from the same source as the data on effectiveness

3.11 The company considered 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 Company's sources of data for modelled utility values

Treatment	Quality of life relating to treatment	Quality of life relating to adverse events
Androgen deprivation therapy alone	Based on EQ-5D data from LATITUDE	Published utility values for adverse effects and skeletal-related events
Abiraterone in combination	Based on EQ-5D data from LATITUDE. The company modelled a further utility increase for being on abiraterone compared with androgen deprivation therapy alone.	Published utility values for adverse effects and skeletal-related events
Docetaxel in combination	Based on a survey commissioned by the company. The company modelled a further utility decrement for being on docetaxel	Published utility values for adverse effects and skeletal-related events

The company used different approaches to estimate the effect on quality of life of having abiraterone in combination or ADT alone than to estimate the effect with docetaxel in combination. It sourced utility values for being on abiraterone in combination from EQ-5D results from LATITUDE, and for being on docetaxel in combination from a separate survey of the general public that it had carried out. The NICE methods guide states that EQ-5D is the preferred measure of health-related quality of life. The committee noted that STAMPEDE collected EQ-5D data for a UK population randomised to abiraterone in combination, to docetaxel in combination and to ADT alone. In response to consultation and in the third committee meeting, the company confirmed that it did not request or have access to these data. The ERG carried out a scenario using the disutility estimate for docetaxel from the economic evaluation of docetaxel in combination in NICE's guideline for prostate cancer. The ERG derived the disutility value from EQ-5D data collected in STAMPEDE (whole population and metastatic subgroup). The company stated that the ERG's scenario was consistent with the results from the company's survey. The committee considered that the effectiveness data from the metastatic

subgroup from STAMPEDE was generalisable to the higher-risk population under appraisal (see section 3.4). However, it thought that it was plausible that the level of risk affects quality of life. It concluded that it was preferable to use EQ-5D data from the subgroup of people from STAMPEDE with high-risk hormone-sensitive metastatic prostate cancer to assess quality of life. It further noted that comparable data were available for abiraterone in combination, docetaxel in combination and ADT alone. In the absence of these data, the committee concluded the ERG's estimate was likely to be broadly appropriate.

Costs used in the company's model

The company's model includes the costs of follow-on treatments in the NHS, but not the full benefits of these treatments

3.12 In response to the committee's second meeting, the company revised the treatment pathways in the hormone-relapsed state to reflect NHS market shares of treatments for hormone-relapsed disease. It based its estimates of market shares on the opinion of 4 clinicians, which the committee concluded may not reflect the actual market shares in UK clinical practice. The company assumed that:

- About 80% of people had abiraterone or enzalutamide after ADT alone or docetaxel in combination.
- People who had docetaxel in combination could have docetaxel again.
- People in each modelled treatment arm could have 3 treatments once their prostate cancer was hormone relapsed. Fewer people in the abiraterone arm had an active treatment as their third treatment for hormone-relapsed prostate cancer than in the comparator arms.

The committee noted that there was a mismatch between the modelling of treatments for hormone-relapsed prostate cancer and the proportions of people who had these treatments in LATITUDE and STAMPEDE (see also section 3.9). The committee recognised that the

company's model therefore accounted for the high costs of some of these treatments, but potentially not all of the life-extending benefits. This was because these benefits may not have been fully captured in the trials. The committee concluded that it had not been presented with a validated estimate of treatments offered in the NHS. It further concluded that accounting for the costs, but not the benefits, of life-extending treatment could have biased the cost-effectiveness results. This would mean that the incremental cost-effectiveness ratio (ICER) for abiraterone in combination compared with its comparators may be higher than that estimated by the model.

Cost-effectiveness results

The company's base case does not reflect the committee's preferred assumptions

3.13 The committee agreed that its preferred approach to modelling would reflect the company's base case with the following assumptions:

- incremental probabilistic, rather than pairwise deterministic, analyses comparing abiraterone in combination with the relevant comparators (that is, ADT alone and docetaxel in combination)
- progression-free survival extrapolated using the Weibull distribution and overall survival extrapolated using both the Weibull and generalised gamma distributions
- the same rates of overall survival for abiraterone in combination and docetaxel in combination (that is, assume an overall survival hazard ratio of 1.00).

The committee also considered the following scenarios useful:

- using the hazard ratio of 1.13 for overall survival for abiraterone in combination compared with docetaxel in combination from the metastatic subgroup direct comparison from STAMPEDE

- assuming equal hazards of progression and overall survival at 8 or 10 years.

Given the uncertainties relating to follow-on treatments, the committee concluded that abiraterone would need to have an ICER of less than £20,000 per quality-adjusted life year gained in the fully incremental analysis to be considered a cost-effective use of NHS resources.

Abiraterone is not a cost-effective use of NHS resources for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer

3.14 The company initially presented analyses including a commercial proposal. However, this had not been approved by NHS England and NHS Improvement for consideration in this appraisal and therefore could not be used to inform the committee's decision-making. The cost-effectiveness estimates without a commercial arrangement were considerably higher than the range normally considered a cost-effective use of NHS resources. Commercial discussions continued between the company and NHS E/I to identify an arrangement that would support the use of abiraterone as a cost-effective use of NHS resources. The discussions concluded without an agreed arrangement that could be considered by the committee. Therefore, the committee concluded that it could not recommend abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

Equality issues

The recommendations apply to all people with prostate cancer

3.15 The committee noted that, as in previous NICE technology appraisals prostate cancer treatments, its recommendations should apply to all people with prostate cancer, including transgender women. No other equality issues were raised during the scoping process or in the submissions for this appraisal.

4 Review of guidance

4.1 The guidance on this technology will be considered for review 3 years after publication. 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 2020

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.

Jessica Cronshaw and Mary Hughes

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