NICE National Institute for Health and Care Excellence

NICE guidance

Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer

Technology appraisal guidance
Published: 20 December 2017

www.nice.org.uk/guidance/ta495

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Palbociclib, with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Palbociclib is recommended only if the company provides it with the discount agreed in the patient access scheme.

2 The technology

Description of the technology	Palbociclib (Ibrance, Pfizer) is a selective, small-molecule inhibitor of cyclin-dependent kinases 4 and 6, which prevents DNA synthesis by stopping cell cycle progression from the G1 to S phase.
Marketing authorisation	Palbociclib is indicated for treating 'hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer: • in combination with an aromatase inhibitor • in combination with fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone agonist'. This appraisal only considers the use of palbociclib in combination with an aromatase inhibitor.
Adverse reactions	The most common (20% or more) adverse reactions of any grade reported in patients having palbociclib in randomised clinical studies were neutropenia, infections, leukopenia, fatigue, nausea, stomatitis, anaemia, alopecia and diarrhoea. The most common (2% or more) adverse reactions of grade 3 or over to palbociclib were neutropenia, leukopenia, anaemia, fatigue and infections. For full details of adverse reactions and contraindications, see the summary of product characteristics.
Recommended dose and schedule	The recommended dose is 125 mg of palbociclib, taken orally, once daily for 21 consecutive days followed by 7 days off treatment (schedule 3/1) to make up a complete cycle of 28 days. Treatment with palbociclib should be continued as long as the patient is having a clinical benefit from therapy or until unacceptable toxicity occurs. Some adverse reactions may need to be managed by temporary dose interruptions or delays, dose reductions, or permanently stopping the treatment. For full details of dose reduction schedules, see the summary of product characteristics.

Price	£2,950 for a 21-capsule pack of 125-mg capsules (excluding VAT; MIMS online, accessed January 2017). The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of palbociclib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.

3 Evidence

The appraisal committee (section 6) considered evidence submitted by Pfizer and a review of this submission by the evidence review group (ERG). See the committee papers for full details of the evidence.

4 Committee discussion

The appraisal committee reviewed the data available on the clinical and cost effectiveness of palbociclib, having considered evidence on the nature of hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and the value placed on the benefits of palbociclib by people with the condition, those who represent them, and clinical experts. It also took into account the effective use of NHS resources.

Clinical management

4.1 The committee was aware that metastatic breast cancer is an incurable condition. NICE recommends endocrine therapy (such as aromatase inhibitors) as first-line treatment for people with metastatic hormone receptor-positive and HER2-negative breast cancer. But if symptoms are severe or the disease is rapidly progressive, people may need chemotherapy. The committee discussed the company submission and the evidence from the clinical trials, which investigated palbociclib in combination with letrozole (an aromatase inhibitor) compared with letrozole alone. The clinical experts explained that in clinical practice the available aromatase inhibitors are all considered to be equivalent, because they have similar clinical effectiveness and acquisition costs. The committee also heard that palbociclib in combination with an aromatase inhibitor would be used for people who have not had previous treatment for metastatic breast cancer, and who would otherwise be offered an aromatase inhibitor alone. The clinical experts explained that after disease progression most people would have several lines of further therapy, including chemotherapy. In response to consultation the company estimated that, based on market research and clinical feedback, 30% of the population eligible for palbociclib with an aromatase inhibitor would have chemotherapy first-line for metastatic disease. However the clinical expert explained that NICE guidance and other clinical guidelines recommend aromatase inhibitors for this population, with first-line chemotherapy being reserved for patients whose disease is imminently life-threatening or requires early relief of symptoms. The expert and the Cancer Drugs Fund (CDF) clinical lead highlighted that in most specialist centres an aromatase inhibitor would

be the treatment of choice when palbociclib in combination with an aromatase inhibitor is indicated. However, the expert also stated that real-world experience shows that some of these patients have chemotherapy. The clinical experts explained that in their opinion, the proportion of the eligible population having chemotherapy would be much less than the company's estimate of 30%. The committee concluded that the company submission had appropriately placed palbociclib in the treatment pathway, and that aromatase inhibitors are the comparator.

Patient experience

4.2 The committee heard from the patient and clinical experts that quality of life is much lower for people whose disease is treated with chemotherapy than with endocrine therapy, because of the side effects of chemotherapy. Endocrine therapies are therefore preferred when possible. Palbociclib, by increasing the effect of aromatase inhibitors, has the potential to reduce the number of people who need first-line chemotherapy, and delay such treatment in others. The committee heard from the patient expert that staying in a progression-free state for as long as possible and being able to continue with normal activities, including working, is very highly valued by patients and their families, and this benefit should not be underestimated. The committee noted that during consultation, 8 UK clinicians in an advisory board, held by the company, advised that the quality-of-life difference between the progression-free and progressed states should be valued as highly as the difference between the progressed-disease state and death. The committee also took into account the consultation comments received emphasising how patients value delaying both disease progression and the need for chemotherapy. The committee agreed that people value delaying progression of the disease and an important consideration is delaying the time to chemotherapy.

Clinical effectiveness

Clinical trial evidence

4.3 The committee noted that the clinical-effectiveness evidence for palbociclib plus letrozole compared with letrozole alone came from 2 studies: PALOMA-1 and PALOMA-2. PALOMA-2 was a larger (666 patients) placebo-controlled, double-blind trial, and PALOMA-1 was a smaller (165 patients) open-label study. The committee discussed the generalisability of the PALOMA trials to UK clinical practice. It noted that PALOMA-1 contained no UK patients, but 7 of the PALOMA-2 sites were in the UK. The committee heard from the clinical experts that both trials had a greater proportion of people with metastatic disease when first diagnosed than is seen in UK practice (37% in PALOMA-2 compared with about 5% to 10% in UK clinical practice). The committee noted that there was no significant difference in treatment response for people with metastatic disease at first diagnosis and were reassured by the clinical experts that a difference would not be expected. The committee agreed that the populations in both PALOMA trials were similar to the population seen in clinical practice in England. But the committee considered that, because PALOMA-2 was a blinded larger trial, its results are likely to be more reliable for decision-making. The committee raised concerns that the higher incidence of haematological adverse events in the palbociclib arms of the trials would have resulted in some patients and investigators becoming unblinded to patient allocation during PALOMA-2. The committee heard that to mitigate this, both investigator-assessed and blinded independent central review (BICR) of progression-free survival was carried out. The committee concluded that the BICR results would be more appropriate for decision-making.

PALOMA-1 progression-free and overall survival data

4.4 The committee noted that in the overall intention-to-treat population, the BICR median progression-free survival reported in PALOMA-1 was 25.7 months for palbociclib plus letrozole, and 14.8 months for letrozole alone. This was reported as statistically significant when using a 1-sided p value (p=0.0286), but not if a 2-sided p value had been used. The

median overall survival from an interim analysis, which was available at the time of the first committee meeting, was 37.5 months for palbociclib plus letrozole compared with 33.3 months for letrozole alone. This was not a statistically significant difference. In response to consultation the company submitted the final analysis for overall survival from PALOMA-1, which showed a median overall survival of 37.5 months for palbociclib plus letrozole compared with 34.5 months for letrozole alone. The committee noted a slightly smaller difference in median overall survival gain of 3 months for palbociclib plus letrozole compared with letrozole alone than at the interim analysis (4.2 months), but again there was no statistically significant difference between the treatment arms. The committee concluded that in PALOMA-1 palbociclib improved progression-free survival, but no significant improvement in overall survival had been shown.

PALOMA-2 progression-free and overall survival data

4.5 The committee noted that in the BICR intention-to-treat population, the median progression-free survival was 30.5 months for palbociclib plus letrozole compared with 19.3 months for letrozole alone (hazard ratio 0.653; confidence interval 0.505 to 0.844). The committee heard from the company that overall survival results from this trial are not available because the required number of events has not been reached, and the company remains blinded to the results. The committee concluded that in PALOMA-2 palbociclib statistically significantly improved progression-free survival, but no data on overall survival are available.

Relationship between progression-free and overall survival

4.6 The committee noted that progression-free survival gains were seen in both trials. But an overall survival gain was seen only in PALOMA-1 and it was not statistically significant. The committee noted the ERG's comment that final overall survival data from PALOMA-1 should be considered the best available evidence on overall survival. It also noted the small number of patients in PALOMA-1, and considered that the results are associated with a wide confidence interval. The clinical experts indicated that they would expect an improved progression-free survival with metastatic breast cancer to result in some benefit in overall

survival. However, they judged that the situation is complex and difficult to predict because of the number of further lines of treatment that the person would have, and because the precise relationship between progression-free and overall survival is unclear. The committee agreed that data from PALOMA-2, when available, will reduce the uncertainty around overall survival gain attributable to palbociclib plus letrozole. However the best available evidence at present is from PALOMA-1, which showed a non-statistically significant survival gain of less than the progression-free survival gain. The committee concluded that palbociclib has a clear and important benefit in improving progression-free survival, and that it is likely that this would result in some improvement in overall survival. However, it reiterated that the size of this benefit remains uncertain.

Adverse effects of palbociclib

4.7 The committee noted that the trial evidence suggested a high incidence of haematological adverse events. It was aware that the marketing authorisation states that full blood counts must be done during treatment, so extra visits may be needed for monitoring. However, it heard from the clinical and patient experts that the adverse events are reversible and manageable. The clinical expert highlighted that many incidences of neutropenia observed in the trials were laboratory findings only and did not result in clinical infections. They expect that in clinical practice, many of these people will continue having palbociclib. In the trials people developing neutropenia may have discontinued treatment, because of protocol restrictions. The committee concluded that, although the incidence of neutropenia in particular was high, the adverse events were manageable and in clinical practice treatment discontinuation because of adverse events will be lower than in the trials.

Cost effectiveness

4.8 The committee discussed the cost-effectiveness evidence presented by the company and its critique by the ERG. It accepted the structure of the economic model developed by the company and considered it appropriate for decision-making.

Data sources in the model

4.9 The committee noted that the company's original model used overall survival from PALOMA-1, because this is the only source available, but it used progression-free survival data from PALOMA-2. The ERG stated that it considers the mixing of the 2 data sets to be methodologically flawed, because it assumes that progression-free survival and overall survival were independent of one another. Therefore, the ERG preferred to use the PALOMA-1 time-to-event data throughout. The committee noted that in the revised analyses submitted during consultation, the company used progression-free survival data from PALOMA-1 and also the updated final overall survival data from PALOMA-1 (see section 4.4). The committee noted that in the revised analyses the company had accepted all amendments suggested in the ERG's exploratory base case, except the modelling of overall survival.

Modelling overall survival

4.10 In its revised analyses the company used 2 different approaches for modelling overall survival. The company's 'lower bound' survival was based on a parametric curve (exponential) fitted to the individual patient data from the final analysis of PALOMA-1. This method closely resembled the ERG's preferred approach. The company also calculated its 'upper bound' survival, by increasing the overall survival gain in PALOMA-1 to match the modelled progression-free survival gain (that is, 11.2 months). The committee recalled that the relationship between progression-free and overall survival is complex and difficult to predict, but that palbociclib would be expected to improve overall survival. It noted the company's comments that the lack of a statistically significant overall survival gain in PALOMA-1 could be because overall survival data are confounded by randomness of response to post-progression treatments. The committee concluded that although it is possible that the overall survival gain might be better than that in PALOMA-1, there is no evidence to support an assumption of overall survival gain equal to the progression-free survival gain without further overall survival data from PALOMA-2.

Costs for post-progression states

4.11 In its original submission the company did not include any treatment-related costs beyond first-line therapy. It included only disease-related costs, estimated using package 2 care from NICE's clinical guideline on advanced breast cancer. After seeking advice from clinical nurse specialists, and making adjustments to reflect current NHS practice and variations in lines of treatment, the company incorporated an average disease-related cost of £573.86 per cycle (28 days) in the post-progression state. The ERG did not agree that treatment-related cost such as drug acquisition costs for second-line therapy and beyond could be ignored. It recommended more precise costing. The company presented revised analyses with higher estimated costs for post-progression states (£2,000; £1,395; and £1,140 per cycle). The ERG estimated an average post-progression cost of £1,200 per cycle for active treatment states, and £975 per cycle for best supportive care. These estimates were based on a retrospective review of medical records for patients with hormone receptor-positive, HER2-negative metastatic breast cancer in the UK (Kurosky et al. 2015), together with clinical advice. They also took into account the company's original estimates of disease-related costs. The CDF clinical lead also submitted average costs for second-, third- and fourth-line treatments, estimated in consultation with experts in the Chemotherapy Clinical Reference Group of NHS England. These estimates were presented as commercial in confidence because they included confidential pricing agreements and are therefore not presented here. The committee noted the different estimates and could not be sure which estimate could be considered the most plausible. However, the committee was reassured by the fact that, despite having used different sources, the estimates from the ERG and the CDF clinical lead are reasonably close. It therefore agreed that the ERG's estimates for post-progression costs are plausible.

Utility value for progression-free state

4.12 In its original base case, the company used different utility values for people in the progression-free state having palbociclib plus letrozole (0.74) or letrozole alone (0.71). These values were derived from the corresponding treatment arms of PALOMA-2. Taking into account that

the difference in the EQ-5D values between the 2 arms of PALOMA-2 was not statistically significant, the ERG estimated an average utility value (0.72) by pooling EQ-5D values for European patients from the first 21 cycles in PALOMA-2. The committee noted the company's comments that the ERG's preferred estimate undervalues progression-free survival, because people with progression-free disease can have a near-normal life. The company referred to NICE's technology appraisal guidance on everolimus with exemestane for treating advanced breast cancer after endocrine therapy. This used a utility value of 0.771 for people with hormone receptor-positive, HER2-negative disease that recurred or progressed after treatment with an aromatase inhibitor, who were having second-line treatment with everolimus plus exemestane. It argued that people on first-line treatment (as in this appraisal) should be assumed to have at least the same quality of life as accepted for those having second-line treatment after progression. The company also presented a scenario using a utility value of 0.75 for progression-free survival, a midpoint between 0.72 and 0.77.

4.13 The committee discussed the most appropriate source of utility values for use in economic modelling, particularly those gathered directly in the relevant trials compared with those sourced from elsewhere. It noted that there is a strong preference for people wanting to delay starting chemotherapy (see section 4.2). It also noted that because EQ-5D measures the health state of people at points in time, it may not fully capture a person's preference to avoid future events. The committee was aware that EQ-5D data from trials is recommended for use in the NICE reference case. It was, however, aware that there has been inconsistency in the utility values used for similar disease stages across different NICE appraisals for metastatic breast cancer. The committee concluded that it is difficult to precisely predict the quality of life of someone with progression-free disease who is taking endocrine therapy. It agreed to explore a range of utility values for progression-free disease (0.72 to 0.77) for its deliberation on the cost effectiveness of palbociclib.

Incremental cost-effectiveness ratios

4.14 The committee discussed the company's revised base case incorporating a confidential patient access scheme. It noted that the

company had presented a range of incremental cost-effectiveness ratios (ICERs) using 2 approaches to modelling overall survival, 3 utility values for progression-free state (0.72, 0.75 and 0.77) and 3 estimates for post-progression costs (£1,140; £1,395; and £2,000 per cycle). These ICERs were presented as commercial in confidence to maintain confidentiality around the patient access scheme. The committee agreed that after applying a discount to the list price as agreed in the patient access scheme, and using a more realistic estimation of the subsequent treatment costs, the ICERs would be within the range that can be considered cost effective.

Innovation

4.15 The committee discussed the innovative nature of palbociclib. It noted that the Medicines and Healthcare products Regulatory Agency recognises palbociclib as a promising innovative medicine. The committee agreed that there is a clinical need for better treatments for this patient group, and that it prolongs progression-free survival in this population. It recognised that this is important to patients and that no weight had been given in the cost-effectiveness analysis to the specific benefit of delaying chemotherapy with its attendant side effects, which patients consider important. The overall survival gain also remains an area of significant uncertainty, and could be greater than that shown in PALOMA-1.

Conclusion

4.16 The committee noted that there are uncertainties in the calculation for the most plausible ICERs, including:

- overall survival modelling; the relationship between the overall survival and progression-free survival
  - using overall survival data from PALOMA-1, which implied that overall survival gain is 27.5% of progression-free survival gain or
  - assuming that overall survival gain is equal to the gain in progression-free survival

- the utility value for progression-free disease
- the cost of subsequent treatments.

However the committee agreed that using a more realistic cost for progressive disease (closer to the ERG's estimate), and applying the discount agreed in the patient access scheme, results in ICERs that fall within the range considered a cost-effective use of NHS resources. Therefore, the committee recommended palbociclib in combination with an aromatase inhibitor as a cost-effective use of NHS resources for treating hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer in adults.

Pharmaceutical Price Regulation Scheme (PPRS) 2014

4.17 The committee was aware of NICE's position statement on the Pharmaceutical Price Regulation Scheme (PPRS) 2014, and in particular the PPRS payment mechanism. It accepted the conclusion 'that the 2014 PPRS payment mechanism should not, as a matter of course, be regarded as a relevant consideration in its assessment of the cost effectiveness of branded medicines'. The committee heard nothing to suggest that there is any basis for taking a different view about the relevance of the PPRS to this appraisal. It therefore concluded that the PPRS payment mechanism was not relevant in considering the cost effectiveness of the technology in this appraisal.

Summary of appraisal committee's key conclusions

TA495	**Appraisal title: Palbociclib with an aromatase inhibitor for previously untreated hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer**	**Section**
Key conclusion		

Palbociclib, with an aromatase inhibitor, is recommended within its marketing authorisation, as an option for treating previously untreated hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer as initial endocrine-based therapy in adults. Palbociclib is recommended only if the company provides it with the discount agreed in the patient access scheme. The committee concluded that palbociclib improves progression-free survival, but no significant improvement in overall survival has been shown. The committee agreed that with the discount agreed in the patient access scheme, palbociclib is a cost-effective use of NHS resources and it can be recommended.		1.1, 4.4, 4.5, 4.16
Current practice		
Clinical need of patients, including the availability of alternative treatments	NICE recommends endocrine therapy as first-line treatment for metastatic hormone receptor-positive and HER2-negative breast cancer but, if the symptoms are severe or the disease is rapidly progressing, people may need chemotherapy. People having treatment value delaying progression of the disease and an important consideration is delaying the time to chemotherapy.	4.1, 4.2
The technology		
Proposed benefits of the technology How innovative is the technology in its potential to make a significant and substantial impact on health-related benefits?	Palbociclib, by increasing the effect of aromatase inhibitors, may reduce the number of people who need first-line chemotherapy and delay such treatment in others. Palbociclib is recognised by the Medicines and Healthcare products Regulatory Agency as a promisingly innovative medicine. The committee agreed that there is a clinical need for better treatments for this patient group, and that it prolongs progression-free-survival.	4.2, 4.15

What is the position of the treatment in the pathway of care for the condition?	Palbociclib, in combination with an aromatase inhibitor, would be used for people who have not had previous treatment for metastatic breast cancer, and who would otherwise be offered an aromatase inhibitor alone.	4.1
Adverse reactions	Although the incidence of haematological adverse events in the palbociclib trials was high, they were reversible and manageable.	4.7
Evidence for clinical effectiveness		
Availability, nature and quality of evidence	Clinical-effectiveness evidence for palbociclib plus letrozole compared with letrozole alone came from 2 studies, PALOMA-1 and PALOMA-2. Because the PALOMA-2 trial was a blinded larger trial, the committee considered that its results are likely to be more reliable for decision-making. Final analysis for overall survival from PALOMA-1 was submitted in response to consultation. However, overall survival results from PALOMA-2 are not available because the required number of events has not been reached. Data on progression-free survival were available from both trials.	4.3 to 4.5
Relevance to general clinical practice in the NHS	The relevance to general clinical practice was not raised during this appraisal.	–
Uncertainties generated by the evidence	Data from the trials showed that palbociclib improved progression-free survival, but no significant improvement in overall survival had been shown. An improved progression-free survival with metastatic breast cancer would be expected to have some benefit on overall survival. However, the size of benefit is uncertain.	4.4 to 4.6

Are there any clinically relevant subgroups for which there is evidence of differential effectiveness?	No specific groups of people were presented for whom the technology is particularly clinically effective.	–
Estimate of the size of the clinical effectiveness including strength of supporting evidence	The committee concluded that palbociclib has a clear and important benefit for improving progression-free survival, and that it is likely that this would result in some improvement in overall survival. However, the size of benefit is uncertain.	4.6
Evidence for cost effectiveness		
Availability and nature of evidence	The committee accepted the structure of the economic model developed by the company and considered it appropriate for decision-making.	4.8
Uncertainties around and plausibility of assumptions and inputs in the economic model	The committee concluded that it is possible that the overall survival gain may be better than that in PALOMA-1 but, without further overall survival data from PALOMA-2, an assumption of overall survival gain equal to the progression-free survival gain is not supported by any evidence.	4.10

Incorporation of health-related quality-of-life benefits and utility values Have any potential significant and substantial health-related benefits been identified that were not included in the economic model, and how have they been considered?	In its original base case, the company used different utility values for people in the progression-free state having palbociclib plus letrozole (0.74) or letrozole alone (0.71). These values were derived from the corresponding treatment arms of PALOMA-2. The ERG estimated an average utility value (0.72) by pooling EQ-5D values for European patients from the first 21 cycles in PALOMA-2. The committee noted that because EQ-5D measures the health state of people at points in time, it may not fully capture a person's preference to avoid future events. It was, however, aware that there has been inconsistency in the utility values used for similar disease stages across different NICE appraisals for metastatic breast cancer.	4.12
Are there specific groups of people for whom the technology is particularly cost effective?	No specific groups of people were presented for whom the technology is particularly cost effective.	–
What are the key drivers of cost effectiveness?	The approaches to modelling overall survival, the utility values for progression-free state and cost for post-progression disease states were the key drivers of the cost-effectiveness results.	4.10 to 4.13

Most likely cost-effectiveness estimate (given as an ICER)	The committee agreed that using a more realistic cost for progressive disease, and applying the discount agreed in the patient access scheme on the list price of the palbociclib, produced ICERs within the range considered a cost-effective use of NHS resources. (These ICERs incorporated a confidential patient access scheme, and were presented as commercial in confidence.)	4.16
Additional factors taken into account		
Patient access schemes (PPRS)	The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of palbociclib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.	2
End-of-life considerations	No end-of-life considerations were raised during the appraisal.	–
Equalities considerations and social value judgements	No equality issues were raised during the appraisal.	–

5 Implementation

5.1 Section 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

5.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal determination.

5.3 The Department of Health and Pfizer have agreed that palbociclib will be available to the NHS with a patient access scheme, which makes it available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the company to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to pfizerNICEaccount@pfizer.com.

6 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 A.

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.

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