

Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer

Technology appraisal guidance

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www.nice.org.uk/guidance/ta476

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	4
2 The technology.....	6
3 Committee discussion	7
Clinical need and patient perspective.....	7
Current practice and comparators	8
Nab-paclitaxel compared with gemcitabine.....	10
Nab-paclitaxel compared with gemcitabine plus capecitabine and FOLFIRINOX	11
Adverse events.....	12
Cost-effectiveness evidence	13
Model assumptions	13
Cost-effectiveness estimates	14
End of life	15
Other factors	17
Conclusion	17
4 Implementation.....	19
5 Appraisal committee members and NICE project team	20
Appraisal committee members	20
NICE project team	20

This guidance replaces TA360.

This guidance should be read in conjunction with NG85.

1 Recommendations

- 1.1 Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine is recommended as an option for untreated metastatic adenocarcinoma of the pancreas in adults, only if:
- other combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy and
 - the company provides nab-paclitaxel with the discount agreed in the patient access scheme.
- 1.2 This recommendation is not intended to affect treatment with nab-paclitaxel 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

NICE reviewed its technology appraisal guidance on paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) in combination with gemcitabine for previously untreated metastatic pancreatic cancer (TA360) because the company submitted more evidence and proposed a patient access scheme that would make nab-paclitaxel available with a confidential price discount.

Nab-paclitaxel plus gemcitabine would normally be considered for people with metastatic adenocarcinoma of the pancreas who would otherwise have gemcitabine.

Evidence shows that nab-paclitaxel plus gemcitabine is more effective in increasing survival than gemcitabine monotherapy, but is less effective than FOLFIRINOX (a combination of fluorouracil, leucovorin, irinotecan and oxaliplatin) and similarly effective to gemcitabine plus capecitabine (although the results were uncertain).

Nab-paclitaxel plus gemcitabine met NICE's end-of-life criteria when compared with gemcitabine monotherapy, but not when compared with gemcitabine plus capecitabine or FOLFIRINOX because it did not improve survival.

The most likely estimate of cost effectiveness compared with gemcitabine monotherapy is £41,000 to £46,000 per quality-adjusted life year (QALY) gained. Nab-paclitaxel plus gemcitabine is not cost effective compared with gemcitabine plus capecitabine or FOLFIRINOX.

Nab-paclitaxel plus gemcitabine can therefore be recommended for people with metastatic pancreatic cancer only if other combination chemotherapies are not suitable, and they would otherwise have gemcitabine monotherapy.

2 The technology

Table 1 Summary of paclitaxel as albumin-bound nanoparticles

Marketing authorisation	Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel; Abraxane, Celgene) with gemcitabine is indicated 'for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas'.
Recommended dose and schedule	<p>Dosage:</p> <p>Nab-paclitaxel: 125 mg/m² intravenous infusion on days 1, 8 and 15 of a 28-day cycle.</p> <p>Gemcitabine: 1,000 mg/m² intravenous infusion immediately after each nab-paclitaxel administration.</p> <p>Average length of a course of treatment:</p> <p>Treatment should be continued until disease progression or unacceptable toxicity (median time in pivotal trial 15 weeks).</p>
Price	<p>The UK list price is £246.00 per 100-mg vial.</p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of nab-paclitaxel, 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.</p>

3 Committee discussion

The [appraisal committee](#) considered evidence submitted by Celgene and a review of this submission by the evidence review group (ERG). It took into account the evidence and committee considerations in NICE's technology appraisal guidance on paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) in combination with gemcitabine for previously untreated metastatic pancreatic cancer (TA360) and the new evidence submitted as part of this review of that guidance. See the [committee papers](#) for full details of the evidence.

Clinical need and patient perspective

Clinicians and patients would value additional options for pancreatic cancer

- 3.1 The committee understood that untreated metastatic adenocarcinoma of the pancreas is associated with a poor prognosis because many people are not diagnosed until the cancer is very advanced, and survival may be only 2 to 6 months. The patient expert explained that a diagnosis of pancreatic cancer can have a devastating effect on patients and their families. The committee recognised that extension to life is therefore very important to people with this condition and their families. The committee understood that current treatment options for pancreatic cancer have a number of limitations. In particular, FOLFIRINOX (a combination of fluorouracil, leucovorin, irinotecan and oxaliplatin) can be associated with serious adverse effects. Some people are unable to take FOLFIRINOX or choose not to do so, whereas gemcitabine monotherapy is better tolerated but less effective. The patient expert explained that many patients would be willing to accept some additional side effects if it resulted in longer life expectancy. The committee acknowledged that the prognosis for people with untreated metastatic pancreatic cancer is poor and that current treatments are limited in efficacy or associated with significant adverse events. It therefore recognised the value of additional treatment options in this area.

Current practice and comparators

FOLFIRINOX, gemcitabine plus capecitabine and gemcitabine monotherapy are potentially relevant comparators for nab-paclitaxel

- 3.2 The clinical experts explained that FOLFIRINOX is the preferred choice in clinical practice for untreated pancreatic cancer, because it has the most favourable survival compared with the other available treatments. The committee heard that patients for whom FOLFIRINOX is unsuitable would normally be offered gemcitabine monotherapy, which, although more tolerable, is associated with poorer overall survival than FOLFIRINOX. The clinical experts explained that there is a group of patients in clinical practice for whom FOLFIRINOX is unsuitable but who would be fit enough to tolerate a doublet therapy such as nab-paclitaxel plus gemcitabine. The committee understood that the suitability of FOLFIRINOX could not be defined by specific criteria, and would depend on a number of factors, including age, performance status, comorbidities and patient choice. It understood that some patients for whom FOLFIRINOX is otherwise suitable would choose not to have this treatment because of its considerable toxicity. The clinical experts explained that gemcitabine plus capecitabine is rarely used in practice, but the committee was aware of evidence that showed there is some use of gemcitabine doublet chemotherapy for pancreatic cancer in the NHS in England. The committee was also aware that the NICE scope and company decision problem listed FOLFIRINOX, gemcitabine plus capecitabine and gemcitabine monotherapy as comparators, and considered that all 3 were options in the NHS for the population covered by this appraisal. The committee took into account its decision in TA360. It concluded that FOLFIRINOX, gemcitabine plus capecitabine and gemcitabine monotherapy were all potentially relevant comparators for nab-paclitaxel plus gemcitabine.

Gemcitabine monotherapy is the most appropriate comparator if other combination chemotherapies are unsuitable

- 3.3 The committee acknowledged that the company considered gemcitabine monotherapy to be the most relevant comparator, because nab-paclitaxel plus

gemcitabine would not displace FOLFIRINOX or gemcitabine plus capecitabine in clinical practice.

- The company stated that FOLFIRINOX is an intensive and toxic therapy that is only suitable for a clinically defined group of patients, for whom nab-paclitaxel would not be considered and who would continue to have this regimen despite the availability of nab-paclitaxel. However, the committee recalled that the suitability of FOLFIRINOX could not be defined by specific criteria, and would depend on a number of factors including patient choice (see [section 3.2](#)). It therefore considered that there may be some people for whom nab-paclitaxel plus gemcitabine is an option who would otherwise have had FOLFIRINOX.
- The company also stated that gemcitabine plus capecitabine has not shown a significant survival benefit over gemcitabine monotherapy and is only used in a few UK centres. The committee heard that the clinical experts did not consider gemcitabine plus capecitabine to be an alternative to nab-paclitaxel plus gemcitabine. However, the committee did not hear how patients who would be offered gemcitabine plus capecitabine or nab-paclitaxel were distinct.

The committee heard from the clinical experts that nab-paclitaxel plus gemcitabine would be considered for people for whom other combination chemotherapies are unsuitable (and hence would otherwise have gemcitabine monotherapy) but who would be fit enough to tolerate nab-paclitaxel plus gemcitabine. It recalled that such patients could be identified in clinical practice (see [section 3.2](#)). The committee concluded that although all 3 currently used treatments are potentially relevant comparators, gemcitabine monotherapy is the most appropriate comparator in people for whom other combination chemotherapies are unsuitable.

Nab-paclitaxel compared with gemcitabine

Nab-paclitaxel plus gemcitabine is more effective than gemcitabine monotherapy

- 3.4 The committee noted that study CA046 showed that nab-paclitaxel plus gemcitabine had statistically significantly longer overall survival and progression-free survival, and higher response rates, than gemcitabine monotherapy. In the most recent data cut (May 2013), median overall survival increased by 2.1 months (the mean increase was 2.4 months) with nab-paclitaxel plus gemcitabine compared with gemcitabine monotherapy (median overall survival: 8.7 months compared with 6.6 months; hazard ratio [HR] 0.72; 95% confidence interval [CI] 0.62 to 0.83, $p < 0.0001$). Data from the September 2012 data cut showed that progression-free survival increased by 1.8 months with nab-paclitaxel plus gemcitabine compared with gemcitabine monotherapy (median progression-free survival: 5.5 months compared with 3.7 months; HR 0.69; 95% CI 0.58 to 0.82, $p < 0.001$). The committee noted that the ERG expressed concerns about the generalisability of CA046 to UK clinical practice, because older patients were under-represented. The committee was aware that the summary of product characteristics states that for patients aged 75 years and older, no benefit for nab-paclitaxel plus gemcitabine compared with gemcitabine monotherapy has been shown, but there were more serious adverse reactions and adverse reactions that led to stopping treatment. However, the committee understood that this was based on a small subgroup. The committee understood that clinicians would be cautious about using nab-paclitaxel plus gemcitabine in older patients, and considered that the evidence from CA046 was suitable for decision-making. The committee concluded that nab-paclitaxel plus gemcitabine was more clinically effective than gemcitabine monotherapy.

Nab-paclitaxel compared with gemcitabine plus capecitabine and FOLFIRINOX

The indirect comparison is uncertain but suitable for decision-making

- 3.5 The company presented a mixed treatment comparison using a fixed-effects model to compare nab-paclitaxel plus gemcitabine with FOLFIRINOX and with gemcitabine plus capecitabine. The committee noted that this model was updated from that used in TA360, including 2 more trials and focusing only on the population with metastatic pancreatic cancer (consistent with the committee's preference in TA360). It also noted that the updated results were very similar to the results of the mixed treatment comparison in TA360. It noted the ERG's comments that the validity of the results relied on the overall survival and progression-free survival hazards being proportional for all the trials included in the mixed treatment comparison, and that the ERG stated this was not true for CA046. The ERG also noted that the base-case mixed treatment comparison included a number of additional comparators, and stated that restricting the comparators to those in the decision problem would be more appropriate. The committee agreed that, taking into account the uncertainty from the proportional hazards assumption not being met, the mixed treatment comparison was preferable to having no data on which to make a decision. The committee, although recognising the uncertainty, concluded that the mixed treatment comparison could be used to compare nab-paclitaxel plus gemcitabine with gemcitabine plus capecitabine and with FOLFIRINOX.

Nab-paclitaxel plus gemcitabine is less effective than FOLFIRINOX and similarly effective to gemcitabine plus capecitabine

- 3.6 The committee noted that the results of the mixed treatment comparison showed that FOLFIRINOX improved overall survival compared with nab-paclitaxel plus gemcitabine, although this result was not statistically significant (company base case: HR 0.77; 95% credible interval [CrI] 0.58 to 1.01). It also noted that the

results of the mixed treatment comparison showed there was no evidence to suggest a difference in overall survival between nab-paclitaxel plus gemcitabine and gemcitabine plus capecitabine (company base case: HR 0.97; 95% CrI: 0.64 to 1.47). The committee concluded that nab-paclitaxel plus gemcitabine was likely to be less clinically effective than FOLFIRINOX, and similarly effective to gemcitabine plus capecitabine.

Adverse events

Nab-paclitaxel plus gemcitabine may cause more adverse events than gemcitabine monotherapy or gemcitabine plus capecitabine

- 3.7 The company presented adverse event data from CA046 and the SIEGE trial. The committee understood that combining therapies was likely to increase the rate of adverse events, and noted that nab-paclitaxel plus gemcitabine was associated with more adverse events than gemcitabine monotherapy, including higher rates of peripheral neuropathy, neutropenia and fatigue. It noted that the company had presented adverse event data from the mixed treatment comparison analysis in TA360, which showed that the rates of neutropenia, febrile neutropenia, fatigue, peripheral neuropathy and leukopenia were higher for people who had nab-paclitaxel plus gemcitabine than for people who had gemcitabine plus capecitabine. It recognised that it was difficult from the data available to draw firm conclusions about the rates of adverse events between nab-paclitaxel plus gemcitabine and gemcitabine plus capecitabine. The committee recalled its consideration in TA360 that, based on the adverse event profiles in the pivotal studies, both nab-paclitaxel plus gemcitabine and FOLFIRINOX were associated with considerable toxicity, and that a difference in their adverse event profiles could not be reliably determined from the data available. The committee recognised that in clinical practice the dosage and administration schedules of combination therapies are modified to maintain efficacy but minimise adverse events. The clinical expert explained that the adverse effects associated with nab-paclitaxel, although serious, were mainly manageable. The committee concluded that nab-paclitaxel plus gemcitabine may be associated with more adverse events than gemcitabine or gemcitabine plus capecitabine.

Cost-effectiveness evidence

The model structure is appropriate for decision-making

- 3.8 The committee considered the company's model, the associated assumptions and the ERG's critique. It noted that the company had updated the model in TA360. It also noted its conclusions in TA360 that the model structure was largely appropriate. The committee therefore agreed that the structure of the company's model appropriately captured the aspects of untreated metastatic pancreatic cancer and was appropriate to use for decision-making.

Model assumptions

The assumptions in the economic model are generally reasonable, and the committee accepts the ERG's amendments

- 3.9 The committee discussed the company's assumptions for survival estimates, utilities and costs. It noted that the revised model incorporated the confidential discount for nab-paclitaxel proposed in the company's patient access scheme. The committee heard from the company that it had aimed to keep its base case as close as possible to NICE's preferred base case from TA360. The committee noted that the company had modelled overall survival, progression-free survival and time on treatment using parametric distributions, but the ERG proposed to use the Kaplan–Meier data where available and extrapolate the 'tails' of the curves only. The committee recalled its consideration in TA360 that neither method could be considered more appropriate, but recognised that the choice of method made very little difference to the cost-effectiveness estimates.
- 3.10 The committee noted that the company had used utility estimates from the Romanus study (with UK adjustment) in its base-case analysis, and the company and ERG had used estimates based on EQ-5D-5L from SIEGE in scenario analyses. The committee also noted that the ERG had disputed some of the company's costing assumptions, in particular that drug costs were based on a single average body surface area for all patients (rather than a different body

surface area estimate for men and women) and that not all available vial and pack sizes were included. The committee noted that the ERG amended these assumptions in its exploratory analysis, and considered this amendment reasonable. The ERG also explored the costs associated with adverse events (diarrhoea, dehydration and vomiting of grade 3 or higher) in a scenario analysis. The ERG noted that the company base-case analysis includes adverse event disutilities (decreases in utility values because of adverse events) alongside health-state utility values from a clinical trial. The ERG considered this to be double counting and therefore proposed removing the disutilities; the committee accepted this approach. The committee concluded that the assumptions in the economic model were generally reasonable, and accepted the ERG's amendments to the company's assumptions.

Cost-effectiveness estimates

The most plausible ICER for nab-paclitaxel plus gemcitabine compared with gemcitabine is between £41,000 and £46,000 per QALY gained

3.11 The committee noted that in the company's base case, the incremental cost-effectiveness ratio (ICER) for nab-paclitaxel plus gemcitabine compared with gemcitabine was £46,657 per quality-adjusted life year (QALY) gained. It noted that in the ERG's preferred exploratory analysis the ICER was £41,250 per QALY gained. This analysis included the ERG's proposed changes:

- to the modelling of overall survival, progression-free survival and time on treatment
- to the costs, to use all available vial and pack sizes
- to use different body surface areas for men and women and
- to remove adverse event disutilities (see [section 3.9](#)).

The committee also noted that the results of the ERG scenario analyses, which adjusted the costs of adverse events and used alternative utility

values, increased the ICER to £45,571 per QALY gained. The committee was aware that the ICER remained below £50,000 per QALY gained in all of the ERG's scenarios, and almost all of the company's scenarios. Recalling that it accepted the ERG's amendments to the company's assumptions (see section 3.9), the committee it concluded that the most plausible ICER compared with gemcitabine was in the range of £41,000 to £46,000 per QALY gained.

Nab-paclitaxel plus gemcitabine is not cost effective compared with FOLFIRINOX or gemcitabine plus capecitabine

3.12 The committee noted that the company's base case showed that nab-paclitaxel plus gemcitabine was dominated by FOLFIRINOX (that is, nab-paclitaxel plus gemcitabine was less effective and more costly). Nab-paclitaxel plus gemcitabine remained dominated by FOLFIRINOX in the ERG's exploratory analysis and scenario analyses. The company's base case also showed that nab-paclitaxel plus gemcitabine was dominated by gemcitabine plus capecitabine. The committee noted that the ERG's preferred exploratory analysis (in which the model was amended as outlined in [sections 3.9 and 3.10](#)) for nab-paclitaxel plus gemcitabine compared with gemcitabine plus capecitabine had an ICER of £99,837 per QALY gained. This increased to £107,898 per QALY gained in the scenario analyses that adjusted the costs of adverse events and used alternative utility values. The committee recognised the uncertainty associated with these ICERs, particularly given that they were based on the results of the mixed treatment comparison. The committee concluded that although the analyses comparing nab-paclitaxel plus gemcitabine with gemcitabine plus capecitabine and with FOLFIRINOX were subject to uncertainty, it was confident that nab-paclitaxel plus gemcitabine would not be considered a cost-effective use of NHS resources compared with these treatments.

End of life

3.13 The committee considered the advice about life-extending treatments for people with a short life expectancy in [NICE's Cancer Drugs Fund technology appraisal](#)

process and methods.

Nab-paclitaxel plus gemcitabine meets the end-of-life criteria compared with gemcitabine monotherapy

- 3.14 The committee noted that the average life expectancy of people with pancreatic cancer was up to 6 months and therefore concluded that the short life expectancy criterion was met. It also noted that, compared with gemcitabine monotherapy, nab-paclitaxel plus gemcitabine had been shown to increase overall survival by a mean of 2.4 months in CA046. The committee noted that the survival data were mature and therefore considered that the survival gain estimate was robust. It recognised that this survival gain should be considered in the context of the very poor prognosis for metastatic pancreatic cancer. The committee noted that the survival gain was below what is normally considered appropriate for the extension-to-life criterion to be met (that is, it was less than 3 months). However, it agreed that the survival gain was particularly important relative to the average survival of people with this condition, and therefore this criterion could be accepted as met in this circumstance. The committee concluded that, for the comparison with gemcitabine monotherapy, nab-paclitaxel plus gemcitabine met the criteria to be considered a life-extending end-of-life treatment.

Nab-paclitaxel plus gemcitabine does not meet the end-of-life criteria compared with FOLFIRINOX or gemcitabine plus capecitabine

- 3.15 The committee understood that both end-of-life criteria had to be met for the advice to be applied. The committee recalled that the mixed treatment comparison showed that FOLFIRINOX had a greater survival benefit than nab-paclitaxel plus gemcitabine and there was no difference in survival between nab-paclitaxel plus gemcitabine and gemcitabine plus capecitabine (see [section 3.6](#)). It concluded that the extension-to-life criterion had not been met for the comparison of nab-paclitaxel plus gemcitabine with FOLFIRINOX or gemcitabine plus capecitabine, because there was no survival benefit with

nab-paclitaxel compared with these comparators. It further concluded that nab-paclitaxel plus gemcitabine did not meet the criteria to be considered a life-extending end-of-life treatment compared with gemcitabine plus capecitabine or with FOLFIRINOX.

Other factors

3.16 No equalities issues were identified.

3.17 The Pharmaceutical Price Regulation Scheme (2014) payment mechanism was not relevant in considering the cost effectiveness of nab-paclitaxel.

3.18 The committee discussed how innovative nab-paclitaxel plus gemcitabine is in its potential to have a significant and substantial effect on health-related benefits. It understood that nab-paclitaxel is a novel formulation of paclitaxel and there is a high level of unmet need in terms of clinically effective treatment options for metastatic pancreatic cancer. The committee concluded that all health-related benefits had been adequately captured by the QALYs in the model.

Conclusion

Nab-paclitaxel is recommended when other combination chemotherapies are unsuitable

3.19 The committee recognised that, although gemcitabine and combination chemotherapies were appropriate comparators, clinicians could identify patients for whom combination chemotherapies were unsuitable (and who would otherwise have gemcitabine) but for whom nab-paclitaxel plus gemcitabine could be considered. It is this population who would have treatment with nab-paclitaxel plus gemcitabine in clinical practice. The committee noted that nab-paclitaxel plus gemcitabine was more effective than gemcitabine monotherapy. Taking into account the patient access scheme, the most plausible ICER was between £41,000 and £46,000 per QALY gained. The committee considered that the end-of-life criteria were met, because the survival gain of 2.4 months was particularly

important relative to the average survival of people with this condition. Therefore, nab-paclitaxel plus gemcitabine could be considered a cost-effective use of NHS resources. Compared with combination chemotherapies (FOLFIRINOX and gemcitabine plus capecitabine), nab-paclitaxel plus gemcitabine did not provide a survival benefit, and could not be considered cost effective. The committee therefore concluded that nab-paclitaxel plus gemcitabine was recommended for people with adenocarcinoma of the pancreas for whom other combination chemotherapies were unsuitable and who would otherwise have gemcitabine monotherapy.

4 Implementation

- 4.1 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.
- 4.2 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.
- 4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has pancreatic cancer and the doctor responsible for their care thinks that nab-paclitaxel is the right treatment, it should be available for use, in line with NICE's recommendations.

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 D](#).

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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