NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Appraisal consultation document

Pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement

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

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

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

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

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

After consultation:

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

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 26 May 2021

Second appraisal committee meeting: 16 June 2021

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

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1 Recommendations

1.1 Pemigatinib is not recommended, within its anticipated marketing authorisation, for treating locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that has progressed after systemic therapy in adults.

1.2 This recommendation is not intended to affect treatment with pemigatinib 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 advanced cholangiocarcinoma with an FGFR2 fusion or rearrangement that has progressed after systemic therapy is symptom control, with or without modified folinic acid, 5-fluorouracil and oxaliplatin (mFOLFOX) chemotherapy.

Clinical evidence suggests that pemigatinib may be more effective than current treatments, but this is highly uncertain because the trial did not directly compare pemigatinib with symptom control or mFOLFOX. The results of an indirect comparison are very uncertain.

Pemigatinib meets NICE's criteria for a life-extending treatment at the end of life. But the most likely cost-effectiveness estimates are higher than what NICE considers a cost-effective use of NHS resources. Pemigatinib does not meet the criteria for inclusion in the Cancer Drugs Fund. So pemigatinib is not recommended.

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2 Information about pemigatinib

Anticipated marketing authorisation indication

2.1 On 28 January 2021 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for pemigatinib (Pemaryze, Incyte Corporation) for treating 'adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy'.

Dosage in the marketing authorisation

2.2 The dosage schedule will be available in the summary of product characteristics.

Price

2.3 The list price of pemigatinib is £7,159.04 for a 14-pack of 13.5 mg tablets (company submission), which equates to an annual cost of £124,430. The company has a commercial arrangement, which would have applied if the technology had been recommended.

3 Committee discussion

The appraisal committee considered evidence submitted by Incyte Corporation, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the committee papers for full details of the evidence.

The appraisal committee was aware that several issues were resolved during the technical engagement stage, and agreed that:

- active symptom control, with or without modified folinic acid, 5-fluorouracil and oxaliplatin chemotherapy (mFOLFOX), are the relevant comparators in this appraisal (issue 7, see ERG report page 19)

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- it is appropriate to use the Weibull curve to extrapolate pemigatinib time-on-treatment (issue 9, see ERG report page 20)
- regression model 3, with covariates for baseline utility and progression status only, is appropriate to estimate the health state utility values when mapping EORTC-QLQ-C30 data from the FIGHT-202 trial to EQ-5D-3L (issue 11, see ERG report page 20)
- drug wastage for pemigatinib should be included in the cost-effectiveness analysis (issue 12, see ERG report page 21).

It recognised that there were remaining areas of uncertainty associated with the analyses presented and took these into account in its decision making. It discussed the following issues (issues 1, 2, 3, 4, 5, 6, 8 and 12), which were outstanding after the technical engagement stage.

Treatment pathway and comparator

There is an unmet need for a disease-modifying treatment for advanced cholangiocarcinoma with an FGFR2 fusion or rearrangement after systemic therapy

3.1 Cholangiocarcinoma is a rare cancer that develops from the epithelial lining of the bile ducts. It is classified as intrahepatic or extrahepatic based on the location of the primary tumour. Fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement may lead to the tumours forming. The clinical experts advised that the aim of treatment for advanced cholangiocarcinoma with FGFR2 fusion or rearrangement that is refractory to chemotherapy is to improve symptoms, delay tumour progression and extend survival. There are no licensed, targeted or disease-modifying therapies currently available in the NHS to treat this condition. The clinical and patient experts highlighted that treatment for the condition has not improved in over a decade. Therefore, current treatment is further chemotherapy containing modified folinic acid, 5-fluorouracil and oxaliplatin, plus active symptom control

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(mFOLFOX+ASC). If further chemotherapy is not suitable, active symptom control (ASC) alone is offered. The patient and clinical experts emphasised the aggressive nature of this cancer and its poor prognosis. The patient experts described the difficulty of being diagnosed with a cancer for which there are very few treatment options and being told of the poor prognosis often while feeling well. They also highlighted difficulty accessing experts in this condition. There is a lack of effective treatment options and chemotherapy may or may not extend life at the expense of debilitating side-effects, which may have a significant effect on quality of life. The committee concluded that there is an urgent unmet need for people with advanced cholangiocarcinoma with FGFR2 fusion or rearrangement after systemic therapy, and people with this condition would welcome a disease-modifying treatment option like pemigatinib.

mFOLFOX+ASC and ASC alone are the most appropriate comparators

3.2 The company submission compared pemigatinib with mFOLFOX+ASC and ASC alone in people with advanced cholangiocarcinoma with FGFR2 fusion or rearrangement after systemic therapy. The ERG noted uncertainty in clinical guidelines and an absence of real-world prescribing data. It highlighted that some clinical advice to the company suggested that capecitabine with oxaliplatin may be preferred to mFOLFOX for some people. It advised that it is likely that other chemotherapy agents are also given in routine NHS practice. The clinical experts advised that the relevant comparators currently used in routine clinical practice include mFOLFOX+ASC and ASC alone. The committee concluded that mFOLFOX+ASC and ASC alone are the most appropriate comparators for this appraisal.

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Clinical-effectiveness evidence

The clinical evidence for pemigatinib is from a single-arm non-randomised trial

3.3 The clinical evidence for pemigatinib came from FIGHT-202. This is a phase 2, single-arm, non-randomised, open label trial in people with advanced or surgically unresectable cholangiocarcinoma that has not responded to previous therapy. Only cohort A of FIGHT-202, which included people with FGFR2 fusion or rearrangement, is relevant to this appraisal. The clinical evidence from the latest data cut is considered confidential by the company so cannot be reported here. In an earlier data cut (March 2019), the median progression-free survival was 6.9 months and the median overall survival was 21.1 months. The committee noted that because FIGHT-202 is a single-arm trial, it does not provide evidence of the relative effectiveness of pemigatinib compared with current treatment options. But it acknowledged that doing trials for advanced chemo-refractory cholangiocarcinoma is difficult because of the rarity of this cancer. In the absence of direct evidence, indirect comparisons were needed to assess the relative effectiveness of pemigatinib compared with the comparators.

The population in cohort A of FIGHT-202 is appropriate for decision making

3.4 The ERG highlighted that cohort A of FIGHT-2020 is a subset of the population in the anticipated marketing authorisation. It highlighted that 98% of cohort A had intrahepatic disease. However, the anticipated marketing authorisation and the NICE scope include people with non-intrahepatic disease. The company stated that there is no biological reason that pemigatinib would not provide benefit to people with non-intrahepatic cholangiocarcinoma with FGFR2 fusion or rearrangement. The clinical experts advised that about 40% of people with advanced cholangiocarcinoma have intrahepatic disease. However, they explained

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that in advanced cancer it is difficult to differentiate intrahepatic disease from other subtypes. They advised that FGFR2 fusion or rearrangement can be present in non-intrahepatic disease but it is uncommon. To be eligible for pemigatinib, people will be identified by the presence of an FGFR2 fusion or rearrangement and not by the disease subtype. The committee concluded that the population in cohort A of FIGHT-202 is appropriate for decision making.

Comparative evidence

The comparative evidence from ABC-06 is appropriate for decision making but has limitations

3.5 No studies directly compared pemigatinib with treatments currently used in the NHS. The main comparative evidence was from the ABC-06 trial. This is a phase 3, randomised, open label study of mFOLFOX+ASC or ASC alone for people with locally advanced or metastatic biliary tract cancers previously treated with gemcitabine plus cisplatin chemotherapy. The committee noted that ABC-06 was done in a different population to FIGHT-202 and did not report FGFR2 mutation status in either treatment group. It understood that FGFR2 mutation status appears to be an important prognostic indicator and not knowing the FGFR2 mutation status in the ABC-06 population was a significant limitation. The clinical experts explained that because of the rarity of this cancer it is difficult to do comparative studies in the relevant sub-population. The committee acknowledged that because of the rarity of the cancer, data on the comparators from ABC-06 was the best available evidence. Despite the limitations, it concluded that the comparative efficacy and safety data from ABC-06 is the most appropriate evidence for decision making.

Pemigatinib is likely to be more effective than the comparators

3.6 In the absence of direct comparative evidence, the estimate of the relative treatment effect of pemigatinib compared with mFOLFOX+ASC and ASC alone was based on an unanchored matching adjusted indirect

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comparison of patient-level data from FIGHT-202 and data from ABC-06. The weightings were derived using a propensity score logistic regression model adjusted for selected prognostic factors. The weighted hazard ratios for overall survival and progression-free survival are considered confidential by the company and exact results cannot be reported here. In general, the results were more favourable for pemigatinib. The hazard ratio for overall survival was lower for pemigatinib compared with mFOLFOX+ASC and ASC alone. The hazard ratio for progression-free survival was also lower for pemigatinib compared with mFOLFOX+ASC. Progression-free survival data was not available for the ASC-alone arm from ABC-06. So, the company assumed the progression-free survival hazard ratio for pemigatinib compared with ASC alone was the same as the progression-free survival hazard ratio for pemigatinib compared with mFOLFOX+ASC. The ERG advised that the estimate of comparative treatment effect is highly uncertain and likely to be biased, because the matching adjusted indirect comparison was done between mismatched trial populations (see section 3.5). The committee noted the lack of direct comparative evidence (see section 3.3) and the limitations of using a matching adjusted indirect comparison to compare the efficacy of pemigatinib with the comparators. However, it recognised the rarity of the cancer and limitations in the available evidence for the comparators. It concluded that the matching adjusted indirect comparison suggests pemigatinib is more effective than the comparators, but this is uncertain.

Comparative safety evidence is likely to have little effect on the cost-effectiveness estimates

3.7 The company did not do a matching adjusted indirect comparison for the safety of pemigatinib compared with the comparators. Instead, it used unadjusted adverse event rates for pemigatinib from FIGHT-202 and for mFOLFOX+ASC and ASC alone from ABC-06. The ERG advised that no conclusions can be drawn about the safety of pemigatinib, relative to mFOLFOX+ASC and ASC, in the specified population without comparative safety evidence. It noted that there is little value in

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performing a matching adjusted indirect comparison with poor quality evidence. During technical engagement, the company provided additional analyses that varied the modelled adverse events rates for the comparator to extreme values. These showed that the cost-effectiveness estimates are not sensitive to comparative safety data. The committee concluded that there is a lack of comparative safety evidence for pemigatinib and its comparators, but this is likely to have little effect on the cost-effectiveness estimates.

Economic model

The company's economic model is appropriate for decision making

3.8 The company's partitioned survival model used parametric survival models to predict outcomes including time-on-treatment, progression-free survival and overall survival. The model included people in both the progression-free and post-progression health states, either on or off treatment. It used a life-time horizon with a cycle length of 1 week. An annual discount rate of 3.5% was applied to costs and outcomes. The committee concluded the company's economic model is appropriate for decision making.

Survival analysis

The clinical plausibility of the survival extrapolations is unclear

3.9 In the company's base case, long-term survival with pemigatinib was estimated by fitting parametric survival models to unadjusted overall-survival data from cohort A of FIGHT-202. Long-term survival for the comparators was estimated by applying the inverse of the relative treatment effect from the matching adjusted indirect comparison (see section 3.6). The company's clinical expert suggested a 5% probability of overall survival at 5 years but struggled to choose the most plausible curve for the pemigatinib survival extrapolation. Literature sources identified by the company reported an estimated 5-year survival

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probability of less than 10% for people who are diagnosed late with unresectable, locally advanced, or metastatic disease. The company preferred the log-logistic curve to extrapolate survival with pemigatinib because the company's clinical experts agreed that a declining hazard function over time is plausible. The ERG advised that other models also predict a declining hazard function similar to the log-logistic model, including the generalised gamma and log normal curves. The ERG preferred the generalised gamma model for the long-term extrapolation of survival with pemigatinib. This predicted a lower proportion of people would be alive at 5-years than the company's log-logistic model. However, the committee noted that the Weibull model gave the closest estimate to the clinical opinion. The clinical experts advised that 5% survival with pemigatinib is based on historical data. They would expect to see a 5-year survival with pemigatinib of about 10%. The committee noted a lack of clinical validation for the comparator arm but acknowledged that a recent updated publication of ABC-06 may be informative. The committee concluded that the justification for the preferred parametric curve and the clinical expectations of survival were unclear, so the cost-effectiveness estimates for pemigatinib were uncertain.

Fitting independent models to each group is more appropriate

3.10 The committee considered that it was not appropriate to apply the hazard ratio to the treatment arm to generate parametric curves for comparator survival. It noted that applying the hazard ratios from the indirect comparison requires the assumption of proportional hazards. It also noted that the company's selected log-logistic parametric curve is not a proportional-hazards curve. The committee considered that it would be more appropriate to fit independent models to the treatment and comparator arms.

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Long-term survival estimates are highly uncertain in both groups and further analyses are needed

3.11 Given the uncertainty from the survival analysis and lack of clear justification for the selected parametric curves, the committee was cautious about choosing a preferred parametric curve for extrapolating long-term survival for pemigatinib. Taking a pragmatic approach and with the current evidence available, it considered both the generalised gamma curve and the Weibull curve in its decision making. However, it would have preferred to see a clear justification of the selection of independent parametric survival models for overall survival in both groups. It would like to see clinical expectations of survival in both groups at 3 and 5 years, any relevant external data to estimate expected survival for the comparator group, consideration of the empirical hazard function for overall survival over time in each treatment group and whether the selected model is consistent with the observed empirical hazard function over time and the assessment of statistical fits. It also noted that using data for 2 comparators in the indirect comparison produces 2 weighted datasets for pemigatinib. Any subsequent analyses provided by the company will need to select 1 weighted dataset, and the committee would like to see evidence that both weighted datasets are similar.

Additional costs

NHS England's genetic testing costs should be included in the cost-effectiveness analysis

3.12 The company did not include the costs of FGFR2 genetic testing in its base-case analysis. However, it did provide genetic testing costs in a scenario analysis. Based on clinical consultation the company estimated a unit cost of £550 per FGFR2 test. The company applied an 8.6% prevalence of an FGFR2 fusion or rearrangement from Hollebecque et al. (2019). This resulted in a cost of £6,395 per additional FGFR2-positive patient identified. The clinical experts advised that FGFR2 testing is not

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done as part of routine clinical practice in the UK. The committee noted that the 2020/21 National Genomic Test Directory does not include FGFR2 mutation testing for people with cholangiocarcinoma. The Cancer Drugs Fund clinical lead advised that there is already a multi-target panel test for people with cholangiocarcinoma to assess eligibility for other treatments. The prevalence of FGFR2 fusion or rearrangement is about 10% across all types of cholangiocarcinoma and adding FGFR2 as a target would incur an additional cost of £34, which would be applicable if pemigatinib was recommended for routine use in NHS practice. This gives a preferred cost of £340 per additional FGFR2-positive patient identified. The committee concluded that NHS England's genetic testing costs and the prevalence of FGFR2 fusion or rearrangement should be included in the cost-effectiveness analysis.

Costs of optical coherence tomography should be included in the cost-effectiveness analysis

3.13 Pemigatinib treatment can sometimes cause retinal pigment epithelial detachment. The Cancer Drugs Fund clinical lead advised that ophthalmological examination using optical coherence tomography would be required before and after starting treatment with pemigatinib in the NHS. The company agreed that this would be detailed in the summary of product characteristics. The committee noted that the company and the ERG did not include the costs of optical coherence tomography in the cost-effectiveness analyses. So the effect on the cost-effectiveness estimate is unknown. The committee concluded that the costs of optical coherence tomography should be included in the economic analysis.

End of life criteria

Pemigatinib is considered to be a life-extending treatment at the end of life

3.14 The committee considered the advice about life-extending treatments for people with a short life expectancy in NICE's guide to the methods of

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technology appraisal. For the short life expectancy criterion, the company's base-case model estimated a mean undiscounted life expectancy of 8.0 months and 7.3 months for mFOLFOX+ASC and ASC alone respectively. For the life-extension criterion, the company's base-case model estimated an undiscounted mean incremental life expectancy with pemigatinib of 25.6 months and 26.4 months compared with mFOLFOX+ASC and ASC alone respectively. The ERG advised that these estimates are highly uncertain given the uncertainty in the results from the matching adjusted indirect comparison and the approach used to estimate health outcomes in the company's economic model. The clinical experts confirmed that people with relapsed or refractory cholangiocarcinoma with FGFR2 fusion or rearrangement have a life expectancy of between 4.7 and 10 months with current treatment. The committee was satisfied pemigatinib meets the short life expectancy criterion with current care. It acknowledged that the extension to life criteria with pemigatinib is less certain because of limitations in the survival analysis (see section 3.9, section 3.10 and section 3.11). However, it considered that the risk of the extension to life criterion not being met is relatively small, given the estimates are substantially greater than 3 months. The committee concluded that pemigatinib could be considered a life-extending treatment at the end of life.

Cost-effectiveness estimates

The most plausible ICERs are above £50,000 per quality-adjusted life year gained

3.15 NICE's guide to the methods of technology appraisal highlights that judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the incremental cost-effectiveness ratios (ICERs). The committee will be more cautious about recommending a technology if it is less certain about the ICERs presented. The committee noted the high level of uncertainty, specifically about the:

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- matching adjusted indirect comparison (see section 3.6) and
- survival analysis (see section 3.9, section 3.10 and section 3.11).

For a life-extending treatment at the end of life, the upper limit of the range usually considered to represent a cost-effective use of NHS resources is £50,000 per quality-adjusted life year (QALY) gained. Because of the uncertainty in this appraisal, the committee agreed that the ICERs would have to be substantially below this upper limit for pemigatinib to be considered cost-effective.

The committee noted that the company's base-case ICERs for pemigatinib were £49,186 per QALY gained compared with mFOLFOX+ASC, and £51,952 per QALY gained compared with ASC alone. The committee recalled its preferred assumptions for decision making:

- using the generalised gamma and Weibull curves to extrapolate long-term overall survival with pemigatinib (see section 3.11)
- including the cost of FGFR2 testing and the prevalence of FGFR2 fusion or rearrangement, as advised by the Cancer Drugs Fund clinical lead (see section 3.12).

Using these preferred assumptions, the ICERs were £58,511 (generalised gamma) and £68,798 (Weibull) per QALY gained compared with mFOLFOX+ASC, and £61,517 (generalised gamma) and £71,766 (Weibull) per QALY gained compared with ASC alone. However, the committee noted it had not seen ICERs including the costs of optical coherence tomography, which it prefers to see in the cost-effectiveness estimates. The committee preferred ICERs are all above the range NICE considers to be an acceptable use of NHS resources for a life-extending treatment at the end of life. So pemigatinib was not recommended for routine use in the NHS.

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Cancer Drugs Fund

Pemigatinib is not recommended for use in the Cancer Drugs Fund

3.16 Having concluded that pemigatinib could not be recommended for routine use, the committee then considered if it could be recommended for treating advanced cholangiocarcinoma with an FGFR2 fusion or rearrangement that has progressed after systemic therapy within the Cancer Drugs Fund. The committee discussed the arrangements for the Cancer Drugs Fund agreed by NICE and NHS England in 2016, noting NICE's Cancer Drugs Fund methods guide (addendum). The committee noted that the company had not expressed an interest in pemigatinib being considered for use in the Cancer Drugs Fund. The committee noted that the key uncertainty was the lack of direct comparative effectiveness evidence. It was not aware of any planned future studies of pemigatinib or its comparators that might resolve this uncertainty. Also, it understood that data to inform comparative effectiveness could not be collected as part of the Cancer Drugs Fund. It concluded that pemigatinib does not meet the criteria to be considered for inclusion in the Cancer Drugs Fund.

Innovation

Pemigatinib is an innovative treatment for advanced cholangiocarcinoma with an FGFR2 fusion or rearrangement

3.17 The company considered pemigatinib to be innovative because there are currently no other licensed or targeted disease-modifying treatment options for advanced cholangiocarcinoma with an FGFR2 fusion or rearrangement. The patient and clinical experts emphasised the importance of improving debilitating symptoms and health-related quality of life, and of extending life, and the potential benefit from pemigatinib in achieving this. The committee noted the potential benefits of pemigatinib for people with advanced cholangiocarcinoma with an FGFR2 fusion or rearrangement. But it concluded that it had not been presented with

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evidence of any additional benefits that had not been captured in the QALY calculations.

Equalities considerations

There are no equalities issues relevant to the recommendation

3.18 No equalities issues were raised during scoping and technical engagement. No potential equality issues were identified in the company submission. The committee concluded that there were no equalities issues relevant to the recommendation.

4 Proposed date for review of guidance

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

Stephen O'Brien
Chair, appraisal committee
April 2021

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 C.

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.

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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.

Zain Hussain
Technical lead

Alexandra Filby and Victoria Kelly
Technical advisers

Louise Jafferally
Project manager

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