

Statement of intent on NICE's approach to ongoing evaluations ahead of proposed changes to NICE's standard cost-effectiveness thresholds: response to stakeholder consultation feedback

Introduction

NICE uses cost-effectiveness thresholds in health economic evaluations to determine whether health technologies represent value for money for use in the NHS in England.

The Department of Health and Social Care (DHSC) has signalled its intent to increase the standard cost-effectiveness threshold that NICE uses in technology appraisals (TAs) from £20,000 to £30,000, to £25,000 to £35,000. NICE cannot implement this change until it receives a direction from the Secretary of State for Health and Social Care, and underpinning changes to the NICE regulations have been proposed by the DHSC to enable this. Subject to parliamentary approval, DHSC processes and associated timelines, we anticipate that the DHSC will direct NICE to implement the increased threshold from April 2026.

NICE's standard approach for implementing updates to its manuals is to only apply changes to new evaluations that are started after the manual has been updated. However, the increase to NICE's cost-effectiveness thresholds will be made following a direction by DHSC ministers and therefore is not a typical methods change.

Because following the usual approach for manual updates is likely to result in significant delays in and terminations of ongoing evaluations of new medicines, NICE considers that an alternative transitional approach to implementing the increase to its cost-effectiveness threshold is required. This approach will allow NICE's committees to use the new standard cost-effectiveness threshold in all committee meetings from the point of direction.

The statement of intent outlines our transitional approach for managing ongoing evaluations.

This paper summarises the themes arising from the public consultation on the statement of intent and NICE's response to them.

Consultation overview

Between 16 January and 30 January 2026, a public consultation was held on the proposed approach for managing ongoing evaluations.

The consultation asked for views on NICE's proposed implementation approach to managing ongoing evaluations.

Respondents were asked to answer 5 questions on the statement of intent. Twelve organisations responded to the consultation (see table 1).

1. Is the proposed implementation approach for new and ongoing evaluations clear and understandable?
2. If this is not clear, what could we do to make it clearer? (optional, maximum 300 words)
3. It is for the Department of Health and Social Care (DHSC) to decide which guidance programmes a threshold change will apply to. It has not yet been signalled that HealthTech and guidelines are in scope of a proposed threshold change. If later confirmed, do you agree that we should take a similar approach to HealthTech and guidelines as the approach set out above for technology appraisals?
4. If no, are there any characteristics of the HealthTech and guidelines programmes that need consideration in implementation? What adaptations would you propose to NICE implementation for these programmes as a result? (optional, maximum 300 words)

5. Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of

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people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? (optional, maximum 300 words)

6 Additional comments: If there are any further comments you would like to make in relation to the proposed approach set out in this consultation, please include them here. (optional, maximum 300 words)

Table 1 Consultation responses by organisation type

Respondent	Number of organisations or individuals	Percentage of respondents
Industry	7	58%
Voluntary and community sector organisations	5	42%

Overall, there was support from respondents for NICE's proposed implementation approach to managing ongoing evaluations ahead of the proposed changes to NICE's standard cost-effectiveness threshold. There was also support for a similar approach in the HealthTech and guidelines programmes, should the DHSC decide these programmes are in scope. Respondents highlighted the importance of clear communication with stakeholders throughout the process and consideration of how pauses in timelines may affect particular patient groups.

Findings from the consultation

Questions 1 and 2: Clarity of the proposed approach

Summary of comments

Most respondents agreed that the proposed implementation approach for new and ongoing evaluations was clear and understandable. No respondents disagreed.

One respondent requested more information about whether NICE will be reconsidering previous evaluations in which medicines were not recommended. They stated that timeliness would be important for such reconsiderations and suggested that a process of re-evaluation could begin before the formal direction comes from the DHSC.

Another respondent said that more clarity is needed for non-specialist stakeholders, including patients. Patients would benefit from a worked example to show how ongoing evaluations would be affected. They also requested clarity on:

- how NICE will assess claims that applying the new threshold could lead to a positive recommendation
- what would happen to any evaluations paused if the direction to NICE from the DHSC was delayed
- how patients will be kept informed about paused evaluations.

Our response and any changes to the statement of intent

The approach outlined in the statement of intent clarifies how NICE will implement the changes for ongoing topics in NICE's work programme. These changes only apply to topics currently going through the process or future topics.

Under the proposed implementation approach, if an ongoing topic is not found cost effective using our current thresholds but, where applying the new thresholds or commercial discussion, or both, could result in a positive recommendation, the submitting company can request that NICE pause the evaluation. Publication of final draft guidance will then be paused until commercial discussions are complete or NICE can apply the new thresholds.

As described in the statement of intent, if NICE does not receive a direction from the DHSC in a timely manner, the standard cost-effectiveness threshold will stay at its current level of £20,000 to £30,000 and the statement of intent will be retired. Any topics that were paused under this approach to wait for the

new threshold will be restarted and guidance published using the current threshold. NICE will engage closely with the DHSC and our stakeholders throughout, to anticipate and mitigate potential disruption and delays in such a scenario.

NICE has communicated about the proposed changes with stakeholders for individual ongoing evaluations for which a committee meeting has already been held and a pause has been requested. This information will be stated on the NICE website for transparency to the wider public. The statement of intent has been amended to reflect this.

Upon receipt of the ministerial direction from the DHSC, we will contact stakeholders for all topics ongoing in the work programme. For evaluations that are paused, we will communicate with stakeholders for the individual topics, outlining that the topic will continue and that the committees and NHS England will now use the new thresholds for the evaluation and any commercial negotiations.

Technologies with published NICE guidance are outside the scope of the statement of intent. NICE does not routinely re-evaluate negative recommendations and NICE will not apply the new threshold retrospectively. As per the standard NICE processes, companies can request a new evaluation when there is a good reason to do so, for instance, if significant new evidence is available that is likely to have a material effect on the recommendations. Importantly, NICE makes its recommendations based on a number of factors, not just cost. The evidence on how well a treatment works is equally important.

NICE's standard approach to rapid reviews will apply as usual. In line with our existing processes, [section 5.9.41 of NICE's technology appraisal and highly specialised technologies guidance manual](#) notes that within 16 weeks of publication of final guidance, companies can request a rapid review to consider new patient access scheme or commercial access agreement proposals.

Questions 3 and 4: Implementation in HealthTech and Guidelines

Summary of comments

There was broad agreement from respondents that NICE should take a similar approach to HealthTech and guidelines as the approach set out for technology appraisals (TAs), should the DHSC signal that HealthTech and guidelines are in scope of a proposed threshold change. No respondents disagreed.

One respondent stated that the uncertainty around whether the threshold changes would be applied to HealthTech and guidelines may cause delays in submissions or withdrawal from evaluation pathways while stakeholders await clarity, which may particularly affect topics for rare conditions. They stated that programme-specific principles should be set out in advance. Some stakeholders stated that it was less clear how a change in threshold would apply to the guidelines programme.

Our response and any changes to the statement of intent

The DHSC has only confirmed that the proposed changes will apply to NICE's TA guidance. NICE has proposed that the increase in threshold should be applied across all NICE guidance and we await a government decision on application to the HealthTech and guideline programmes.

Should it be agreed that the new thresholds will apply to HealthTech and guidelines, NICE would follow a similar, pragmatic implementation approach to that set out for TA, considering appropriate adjustments to reflect the different characteristics of the programmes. Importantly, in alignment with TA, the new threshold would apply to ongoing evaluations and guidelines from the point of a change to the respective manuals.

In this situation, NICE would inform stakeholders as early as possible to provide clarity on our approach.

Question 5: Equality impact assessment

Summary of comments

One respondent stated that applying the updated thresholds to all programmes at the same time would reduce the possibility of discrimination. Another respondent highlighted concerns that patients with conditions characterised by rapid progression, high unmet need or small patient populations may be disproportionately affected by delays to evaluations. They suggested that NICE could set out safeguards to minimise delays to these evaluations and ensure clear communication with patient groups when these evaluations are paused.

Our response and any changes to the statement of intent

These comments have been noted and, once the DHSC direction is given, we will continue paused topics as soon as possible, based on readiness and completion of commercial discussions with NHS England. Currently, it is not considered that a prioritisation would be required as there are only a small number of paused topics. Details about exact timings for individual evaluations will be communicated with stakeholders for all paused topics, including patient groups.

Question 6: Additional comments

Summary of comments

There was broad support for NICE's approach to implementing a change in the threshold, and for applying the same approach to guidance for HealthTech and guidelines. One respondent said that there should also be an increase in the threshold for highly specialised technologies.

Stakeholders said that it should be made clear that the date the threshold will be changed is 1 April and that updates to manuals will be completed before then.

More information was requested around how the changes will be communicated to committees to ensure consistency in decision making, and how the implementation will be monitored.

Respondents suggested that in addition to updating principle 7 with the revised threshold values, the accompanying text could be adapted to reflect NICE's role in supporting wider government objectives.

One respondent highlighted the importance of maintaining clear communication with stakeholders and minimising delays where possible. Another respondent said that more clarity is needed on which topics will be paused, and on whether recently published topics could be reviewed rapidly, for which applying the new threshold could change the outcome.

Our response and any changes to the statement of intent

It is for the DHSC to decide which NICE guidance programmes a threshold change will apply to. The DHSC has indicated that the threshold used for highly specialised technologies will remain unchanged.

Subject to parliamentary approval, DHSC processes and associated timelines, we anticipate that the DHSC will direct NICE to implement the increased threshold from April 2026. The exact date that NICE will implement the increased threshold and publish updated manuals is dependent on when we receive the direction. We will draft updated manuals in advance so that they can be published as soon as the direction is received. NICE will continue to engage closely with the DHSC, NICE users and wider stakeholders to anticipate and mitigate disruption should expected timelines change significantly. The statement of intent has been amended to make this clearer.

NICE's advisory committees are independent and unbiased. They have been fully briefed on the potential upcoming changes to the threshold and are aware that this is a government directive. Timelines for the changes to the threshold will be clearly communicated with committee members to ensure that the updated thresholds can be applied from the point of DHSC direction.

The NICE team present at all committee meetings will monitor the implementation and ensure the change is applied consistently and fairly.

While the thresholds described in principle 7 will be updated, we will not be amending the text associated with the principle. Committees will still be asked to consider the opportunity cost of recommending a treatment, albeit at a higher value, because any recommendation will result in the displacement of funds that could be used to provide care or treatment elsewhere in the health service. This has been clarified in the statement of intent.

NICE will not be publishing a list of topics that are being paused because the decision to pause topics may be taken at different times. Instead, stakeholders for individual evaluations will be informed throughout the process of any changes to timelines, and information will be available on the NICE website on each in-development topic webpage. Paused topics will be resumed as soon as possible and this will be clearly communicated with stakeholders.

NICE's standard approach to rapid reviews will apply as usual. In line with our existing processes, [section 5.9.41 of NICE's technology appraisal and highly specialised technologies guidance manual](#) notes that within 16 weeks of publication of final guidance, companies can request a rapid review to consider new patient access scheme or commercial access agreement proposals.