NICE National Institute for Health and Care Excellence

NICE HealthTech programme manual

NICE process and methods

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This corporate replaces PMG33 and PMG34.

Introduction

This guide describes the methods and processes that NICE follows when evaluating HealthTech products and interventional procedures for HealthTech or interventional procedures guidance. The methods and processes are designed to produce robust guidance for the NHS in an open, transparent and timely way, with appropriate contribution from stakeholders. Organisations invited to contribute to health technology evaluation should read this guide in conjunction with the NICE-wide topic prioritisation process. This sets out the process for identifying, prioritising and routing new guidance topics and updates to existing NICE guidance.

The NICE HealthTech programme combines the former NICE Diagnostics Assessment programme, Interventional Procedures programme and Medical Technologies Evaluation programme.

Where HealthTech is considered for technology appraisal or highly specialised technologies guidance, NICE technology appraisal and highly specialised technologies guidance: the manual describes the methods and processes that NICE follows.

To avoid duplication, this guide refers to the NICE technology appraisal and highly specialised technologies guidance: the manual for methods and processes that are the same. This guide sets out the new approaches in the HealthTech programme, including further detail for clarity. Section 1 covers process. Section 2 covers methods (except for interventional procedures guidance, which can currently be found in NICE's interventional procedures programme manual).

HealthTech products and interventional procedures can offer significant benefits to patients, such as a quicker diagnosis, faster recovery, and reduced risk. They also have the potential to improve efficiency and reduce costs, such as by streamlining patient flow, tailoring treatments to an individual, and reducing hospital admissions.

The HealthTech programme provides 2 types of guidance: HealthTech guidance and interventional procedures guidance.

HealthTech guidance

HealthTech is often used interchangeably with 'medtech'. For NICE guidance, HealthTech includes non-medicine technologies. This means diagnostics, medical devices and digital technologies including artificial intelligence. Examples include technologies, techniques, strategies and pathways that help diagnose, monitor, prognose, predict or symptomatically screen for health conditions, and technologies that treat, manage or prevent a health condition.

Recommendations are made based on assessment of clinical and cost effectiveness of HealthTech products.

When multiple technologies that can be used for the use case, or use cases, being assessed in a guidance topic are available to the NHS, they will be assessed in 1 piece of guidance. When only 1 technology is available, guidance will be produced for a single technology. It is expected that most HealthTech assessments will be for multiple technologies.

Interventional procedures guidance

Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy.

Recommendations are made based on assessment of the efficacy and safety of new, significantly modified or established procedures. Although some interventional procedures can involve implanting or using a health technology, the guidance and recommendations are about the procedure.

NICE's interventional procedures programme manual has more information on interventional procedures guidance, including the remit of NICE's work.

Lifecycle approach

The approaches taken to develop guidance, and the types of recommendation made, reflect what stage a technology or procedure is at in the lifecycle.

For early use

This approach considers HealthTech products that could address a national NHS unmet need. It rapidly assesses products early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

For interventional procedures guidance, new or significantly modified procedures can be conditionally recommended for use while more evidence is generated to check if they are safe and efficacious.

For routine use

This approach considers HealthTech products that address a national NHS unmet need and may be suitable for routine widespread use in the NHS. Recommendations are based on assessment of clinical and cost effectiveness, or cost comparison.

For interventional procedures guidance, a recommendation that the procedure can be used is made if there is enough evidence on the safety and efficacy of the procedure for healthcare professionals to consider it as an option.

For existing use

This approach considers HealthTech products that are already in established use within the NHS, to inform commissioning and procurement decisions.

1 Processes for developing guidance in the HealthTech programme

This section covers the process for developing guidance in the HealthTech programme for HealthTech or interventional procedures guidance. Links are made to sections in NICE technology appraisal and highly specialised technologies guidance: the manual as appropriate.

The process set out here will be used for developing interventional procedures guidance, superseding any process described in the interventional procedures programme manual.

1.1 General information

1.1.1 NICE sends correspondence for an evaluation to key contacts identified by each stakeholder organisation. Stakeholders must notify NICE of any change in contact details, or in organisation or company name, during the evaluation. This and any other correspondence should be to the email address provided by NICE.

1.1.2 Companies with a technology being assessed must inform NICE as soon as possible of any significant new information relevant to the assessment that occurs during guidance development.

1.1.3 Technologies will not be withdrawn from a scope or guidance purely because of a company request.

Information handling

1.1.4 Details on information handling, including confidential information, are described in sections 5.3 and 5.4 of NICE technology appraisal and highly specialised technologies guidance: the manual. Further detail is available from NICE.

Technology costs

1.1.5 The price of a technology is important for economic evaluations. Companies can provide costs relevant to using their technology in their response to a request for information or an evidence request (see section 1.3.4) and updated costs at consultation on draft guidance (see section 1.5.5). Outside of these times it may not be possible to consider new or updated prices. If companies believe there are extenuating circumstances for why the technology cost cannot be disclosed in public documents, further information on these circumstances must be provided for NICE to consider whether this is acceptable. In circumstances when NICE agrees to accept a price marked as confidential, a further price that can be publicly disclosed should also be provided.

1.1.6 Guidance can include recommendations on a technology for which no price has been provided. But if the price is needed for an economic evaluation and cannot otherwise be determined, it will impact on recommendations made about the technology. This is because it leads to uncertainty about the cost effectiveness and budget impact.

1.2 Guidance development process overview

1.2.1 The guidance development process starts after a topic has been selected and scheduled for NICE guidance development. It consists of 3 phases: scoping, assessment and developing recommendations. Subsequent process for finalising and publishing the guidance are described in section 7 of NICE technology appraisal and highly specialised technologies guidance: the manual.

1.2.2 It is not possible to set absolute timelines for the phases of the process. The length of time needed for each phase can vary depending on the nature of the evaluation. Illustrative lengths are shown in table 1. A shorter process can typically be used for technologies assessed for early use and interventional procedures because typically the assessment phase can be shorter.

1.2.3 Stakeholders are encouraged to input at several stages. These are described in the process details in sections 1.3 to 1.5, and a summary is provided in table 1.

Table 1 Overview of the 3 phases of HealthTech programme guidance development

Phase	Overview	Opportunities for stakeholder input
Scoping	Developing and finalising the assessment scope. This phase typically takes about 10 weeks.	• Providing responses to any requests for information or other questions from NICE. • Providing comments on the draft scope during consultation (if held) or a scoping workshop (if held).
Assessment	Producing an assessment report. Comment period on external assessment report (if produced). This phase typically takes between 12 and 30 weeks.	• Providing responses to any requests for information, evidence requests or other questions from NICE. • Companies can submit comments on the factual accuracy of an external assessment report and any economic model produced.
Developing recommendations	Committee meeting and producing draft guidance and final draft guidance.	• Attending committee meetings. • Submitting comments during a consultation period.

1.2.4 Throughout guidance development, up-to-date information about timelines and progress is published on the NICE website.

1.2.5 NICE informs stakeholders about timeline changes during an evaluation and the reasons for these changes. When the reasons are commercially sensitive, NICE works with the company to release as much information as possible to stakeholders and on the NICE website.

Stopping guidance development

1.2.6 In exceptional circumstances, NICE may need to permanently stop guidance development. This decision is made by NICE. If guidance development is stopped, registered stakeholders are informed, and the NICE website is updated. Guidance production can be stopped for several reasons. This includes if it is no longer possible to produce recommendations, for example, if there have been changes to the regulatory status of technology.

1.3 Scoping

1.3.1 Sections 2.3 and 2.4 of NICE technology appraisal and highly specialised technologies guidance: the manual describe the initial steps in developing the draft scope, including identifying stakeholders.

1.3.2 During the scoping phase, NICE will speak to individuals and organisations to gather information needed to develop the draft scope. This can include healthcare professionals, committee members, patients and carers, companies with technologies that may be relevant to the assessment, voluntary and community sector organisations, and other organisations as necessary. A key activity is identifying technologies that may be relevant to the assessment, which includes asking for suggestions and input during any scoping workshop or scope consultations (see section 1.3.18).

1.3.3 Requests for information may be sent to companies during scoping if they have technologies that could be included in the assessment or otherwise be relevant to it (for example, for interventional procedures guidance, requests can be sent to companies producing devices that may be used to do the procedure). A request for information does not mean that a technology will be included in the scope for the assessment. Information provided is often used to determine if a technology is suitable to include in the scope.

Requests for information and evidence

1.3.4 Company evidence submissions are not made for HealthTech programme

assessments. Instead, companies can be asked to provide responses to requests for information and evidence requests. Requests for information may be made as needed throughout the guidance development process but are typically made during the scoping phase. Evidence requests are made after the scope publishes.

1.3.5 Unpublished evidence can be provided with a returned request for information or evidence request. See section 1.1.4 for information on how to provide confidential information to NICE.

1.3.6 A completed checklist of confidential information must be provided with a returned request for information or evidence request.

1.3.7 Economic models can be submitted as part of the response to an evidence request. But economic models may not be considered in the assessment period if they are not fully executable and using standard software, that is, Excel, DATA/ Treeage, R or WinBUGs. When the company submits a fully executable electronic copy of the model, it must give NICE full access to the programming code and provide instructions on how to run the model.

1.3.8 A technology or procedure will not be withdrawn from a scope or guidance because a response to a request for information or evidence request has not been received. But not providing information needed by NICE may affect the assessment of a technology or procedure and consequently the recommendation.

Information provided by non-company stakeholders or other organisations

1.3.9 NICE can also invite non-company stakeholders or other organisations to provide evidence to inform scoping and the assessment. This can include qualitative, real-world and experiential evidence from voluntary and community sector organisations. This is to reflect the experience of patients, healthcare professionals and commissioners of current care in the NHS. It can also help understand the potential impact of using the new technology. Information on implementation issues, such as staffing and training needs, could also be provided.

Experts

1.3.10 The following experts can provide evidence, and their views and experience throughout the evaluation:

- health and social care professionals
- non-health and social care professionals (such as scientists, software specialists, data analysts, engineers or people with procurement or other technical experience, as needed)
- people with a condition and their carers, who can provide information about the impact of both the condition and the technology being assessed
- commissioning experts.

  Experts will typically be selected during the scoping period but can also be selected later in the process if needed, for example, if gaps are identified in the knowledge and expertise needed by a committee.

Identifying experts

1.3.11 Experts are selected from those nominated by consultee organisations or by NICE, taking into account NICE's policy on declaring and managing interests for NICE advisory committees. When necessary NICE may ask for expressions of interest to identify potential experts, particularly for patient experts.

1.3.12 Relevant NHS commissioners of the technology can be invited to nominate NHS commissioning experts if commissioning expertise is specifically needed or if the population is covered by an NHS England specialised commissioning group.

Expert eligibility and selection

1.3.13 Sections 1.3.14 and 1.3.15 of NICE technology appraisal and highly specialised technologies guidance: the manual describe the process of selecting experts and requirements that must be met.

1.3.14 The number of experts appointed will vary between guidance topics and will be informed by the knowledge and expertise needed by the committee. Typically, this would be up to 10 experts.

Expert participation

1.3.15 Experts help clarify issues that NICE has identified throughout guidance development (including during scoping) and can also provide further input as needed. Experts can attend committee meetings, and they may submit written evidence such as completed questionnaires.

1.3.16 In committee meetings experts are expected to interact fully in the discussions with the committee, including responding to questions. Section 1.3.19 of NICE technology appraisal and highly specialised technologies guidance: the manual further explains the role of experts in committee meetings.

1.3.17 Experts are asked to leave the meeting before the committee makes its decision and finalises the guidance recommendations in the private session (part 2) of the committee meeting, which is closed to the public. The chair may ask experts to remain for part of the private session (part 2A) to respond to any questions from the committee about information that cannot be discussed in the public session (part 1).

Draft scope: scoping workshops and scope consultations

1.3.18 After a draft scope is produced, NICE may hold a scoping workshop, have a consultation on the draft scope, or both.

1.3.19 A scoping workshop or draft scope consultation will not be held if NICE judges that there are no substantive uncertainties related to the scope to resolve.

1.3.20 Section 2.5 of NICE technology appraisal and highly specialised technologies guidance: the manual describes the process for consultation on the draft scope. The consultation will be 5 to 10 working days, but can be extended to 20 working days if there is a higher level of uncertainty about elements of the draft scope.

Scoping for guidance updates

1.3.21 For updates of existing guidance, NICE will update the original scope. This is to make sure that the guidance update considers the care pathway and use of the technology at the time the guidance update starts. NICE can review any element in the scope, including whether to expand the scope of the guidance update to include additional technologies.

1.3.22 When changes to the original scope are made, NICE may consult on a draft scope or hold a scoping workshop.

1.3.23 Guidance updates include any procedures or technologies conditionally recommended for use while more evidence is generated that are re-evaluated once this evidence is generated. This will be done according to the NICE HealthTech programme process and methods, and in the context of the healthcare system at the time of the guidance update, rather than at the time the original recommendation was made.

Final scope

1.3.24 After any scoping workshop or consultation held has completed, NICE agrees the final scope. Section 2.9 of NICE technology appraisal and highly specialised technologies guidance: the manual describes the process for finalising and issuing a scope.

1.3.25 If the scope for an evaluation is too large for the available resources, NICE may revise it in collaboration with experts and members of the committee. Input from stakeholders, including information provided by companies, will be considered in this decision. Input from an external assessment group (EAG), if appointed, will also be important to understand the work that can be done with the resource available.

1.3.26 NICE will publish the final scope on its website.

1.3.27 A decision will be made by NICE at the end of the scoping process about what guidance will be developed in terms of the lifecycle approach to be used (for

early-, routine- or existing-use guidance; see section 2.1.28 for detail). This decision will be communicated in the final scope.

Assessment protocol

1.3.28 For topics with an EAG appointed (see section 1.4.5), this group develops an assessment protocol, derived from the final scope of the evaluation. The protocol will not be consulted on.

Amending the final scope after publication on the NICE website

1.3.29 There can be circumstances when the final scope may need amending after it has been published on the NICE website. NICE decides whether to amend the scope.

1.3.30 If a final scope is amended after publication, registered stakeholders are informed. The revised scope and revised assessment protocol, if needed, are published on the NICE website. Further consultation on the scope would not usually be done.

1.4 Assessment period

1.4.1 The assessment may need to be paused. This may be because of external factors such as ongoing studies that will generate relevant evidence that will be available within or soon after the proposed guidance timeframe. NICE decides whether to pause the assessment period. Registered stakeholders are informed if the assessment period is paused.

1.4.2 An assessment report is generated to support guidance development. This report can be produced by either NICE or an EAG (see section 1.4.5). When produced by an EAG, this is an external assessment report, and the EAG is responsible for the content and quality of the report.

1.4.3 The length of the assessment period will be based on the expected amount or complexity of evidence and the extent of any economic evaluation needed. If this is more extensive than expected, the assessment period may need to be extended, and the scope may be updated (see sections 1.3.29 and 1.3.30).

1.4.4 Information provided during the assessment period that is not in response to a request for information or evidence request from NICE or agreed in advance with NICE, may not be able to be considered in the assessment report.

EAGs

1.4.5 EAGs can be commissioned to produce an external assessment report to support guidance production (see section 1.3.24 of NICE technology appraisal and highly specialised technologies guidance: the manual for further description of EAGs). They can be used when there is a larger volume or complexity of evidence, or if more complex statistical analysis or an economic evaluation is needed.

1.4.6 Experts selected by NICE may also support the EAG during the evaluation. But they cannot be appointed as advisers to the EAG (that is, contribute to the EAG's work to the extent that they are authors on the assessment report). This is so they can maintain sufficient independence from the evidence and contribute to a committee's discussions on the quality of the external assessment report.

Factual accuracy checks for an external assessment report

1.4.7 NICE will share a copy of the external assessment report with companies that have a named technology in the assessment (that is, the technology name is specified in the assessment scope as an intervention or comparator) for comment in advance of committee meetings. Comments should be submitted on issues of factual accuracy in the assessment report, and model if produced. Factual accuracy would include issues such as inaccuracies in reports or models. When produced the results from a user preference assessment will also be sent to companies with a named technology in the assessment at this time.

1.4.8 If an economic model is produced as part of the assessment, NICE offers to send

the economic model (in its executable form) to the same companies that receive the external assessment report (as specified in section 1.4.7). If the model contains confidential material that the data owner is unwilling to share, despite the assurances provided through the signed confidentiality agreements, NICE will ask the group who have generated the model to replace this with dummy data or redact it if this can be done without severely limiting the model's function. A request for a copy of the model must be made in writing. NICE provides the model on the basis that the recipient agrees, in writing, to the conditions of use set out in section 5.5.16 of NICE technology appraisal and highly specialised technologies guidance: the manual.

1.4.9 In exceptional circumstances it may not be possible to provide the economic model. For example, if it is not possible to do so without revealing confidential information.

1.4.10 Comments must be submitted in a 10 working day period.

1.4.11 If comments need an EAG response, NICE sends them to the EAG. Its responses will be presented at the next committee discussion.

1.5 Developing recommendations

1.5.1 The developing recommendations phase of the process has 4 possible stages:

- consideration of the evidence at a committee meeting to discuss the content of the draft guidance
- development of, and consultation on, the draft guidance
- review of the draft guidance after comments from consultation
- development of the final draft guidance.

Committee meetings

Preparing for the committee meeting

1.5.2 The committee is described in sections 1.2.1 to 1.2.4 of NICE technology appraisal and highly specialised technologies guidance: the manual.

Committee meetings

1.5.3 Details on committee meetings are in sections 5.8.4 to 5.8.20 of NICE technology appraisal and highly specialised technologies guidance: the manual. However, final draft guidance is subject to resolution (as described in section 1.5.17) not appeal. Committee papers are usually shared with committee members 1 week before the meeting. For HealthTech programme guidance, experts may make a presentation to the committee.

1.5.4 Details on the participation of company representatives at the committee meeting are in sections 1.3.5 and 1.3.6 of NICE technology appraisal and highly specialised technologies guidance: the manual.

Consultation on the draft guidance

1.5.5 The draft guidance and committee papers are sent to stakeholders for consultation. These documents are confidential until NICE publishes them on its website. Information designated as confidential will be redacted from the documents.

1.5.6 The committee papers and the draft guidance document are made available during consultation on draft guidance. Section 5.8.45 of NICE technology appraisal and highly specialised technologies guidance: the manual describes draft guidance, and section 5.8.48 describes the purpose of consultation.

1.5.7 Stakeholders have 15 working days from the date of sending to submit comments on the draft guidance.

1.5.8 NICE publishes the draft guidance and any additional committee papers not already shared on its website with an electronic comment facility within 5 working days of sending to stakeholders. The deadline for comments on the draft guidance from non-stakeholders is the same as for stakeholders.

1.5.9 After the draft guidance has been developed, new evidence provided to NICE will not be accepted. This is unless it is specifically requested by the committee, or if a stakeholder requests that NICE considers additional evidence and NICE specifically confirms it will accept it in writing. Responses to requests for information or evidence requests (see section 1.3.4) should be used to provide evidence to NICE.

1.5.10 The committee may be unable to develop recommendations without further scrutiny or further analyses. If this is the case, the evaluation can be paused. NICE may request that a company or EAG submits specific information, further analyses or an updated economic model.

After draft guidance consultation

1.5.11 The committee chair will review the consultation comments received. When the comments will not change the recommendations, the chair can decide that another committee meeting is not needed. This decision will be made in consultation with NICE. Factual changes and corrections to the guidance are made and final draft guidance and recommendations are agreed by the committee electronically.

1.5.12 The chair's decision will be shared with stakeholders. This will be a brief statement of the decision.

1.5.13 If needed the committee can meet again to consider the preliminary recommendations in the draft guidance with comments received. Before the meeting, NICE sends the committee members the full text of the comments from stakeholders. Sections 5.8.56 and 5.8.58 of NICE technology appraisal and highly specialised technologies guidance: the manual describe the process of a further committee meeting.

1.5.14 When consultation comments are received that lead to a substantial revision of the committee's previous decision, involving a significant change in the recommendations, discussions or the evidence base, NICE and the committee chair will decide whether it is necessary to have a further draft guidance consultation. The decision to hold another consultation will extend the timelines for the evaluation. NICE will distribute any further committee papers with the second draft guidance, together with initial consultation comments. The process of a further consultation is the same as for the initial consultation.

Developing final draft guidance

1.5.15 Sections 5.8.64 to 5.8.66 of NICE technology appraisal and highly specialised technologies guidance: the manual describe the process of developing final draft guidance. However, NICE issues the final draft guidance for resolution (as described in section 1.5.17), not appeal.

1.5.16 For comments received on the draft guidance, NICE reserves the right to summarise and edit comments received during consultations. In exceptional circumstances, it can also decide to not publish them at all when, in the reasonable opinion of NICE, publication would be unlawful or otherwise inappropriate.

Resolution

1.5.17 For interventional procedures and HealthTech guidance, stakeholders can use the resolution process on the final draft guidance and the process followed. Definitions for 'stakeholders' and 'consultees', as mentioned in this section, can be found in sections 1.2.16 and 1.2.17 of NICE technology appraisal and highly specialised technologies guidance: the manual.

1.5.18 The resolution process is a final quality-assurance step to ensure that NICE acts fairly, follows its own processes, and produces clear, accurate guidance. It happens after NICE has approved the final draft guidance for publication and before it is published. After approval, NICE sends all stakeholders the final draft guidance. Resolution does not apply to decisions about selecting technologies for

evaluation. It also does not apply to the external assessment report or other documents produced during guidance development, unless the resolution request on these documents is important for an issue in the guidance itself.

1.5.19 After receiving the final draft guidance, any stakeholder can ask for factual errors to be corrected. Only consultees can raise a resolution request based on a breach of the published process.

1.5.20 If NICE either does not receive a resolution request, or receives a request that can be resolved quickly, the guidance is published as soon as possible after the resolution period ends. If NICE receives a resolution request that needs further investigation, it suspends publishing the guidance while it investigates the request and informs stakeholders of the delay to publication.

Grounds for resolution

1.5.21 NICE only considers resolution requests that clearly meet one or both of the following grounds:

- Ground 1: Breach of NICE's published process for the development of guidance.
- Ground 2: Factual errors in the guidance.

1.5.22 A factual error is an objective error of material fact in the final draft guidance. Conflicting scientific or clinical interpretations or judgements are not considered to be factual errors. For example, if a resolution request states that a statistic quoted in the guidance is incorrect, NICE establishes whether the final guidance misquoted the statistic, or if one statistic was preferred out of several because the committee considered it to be more reliable. The former is a factual error; the latter is a difference of scientific or clinical judgement.

Making a resolution request

1.5.23 NICE sends the final draft guidance and, when a draft guidance consultation has taken place, any consultation comments and NICE's response to those

comments, to all stakeholders.

1.5.24 Eligible stakeholders must make a resolution request on one or both of the grounds within 21 days. Requests should specify the resolution they seek. NICE can then fully understand the nature of their concern and take appropriate action.

Initial scrutiny

1.5.25 All eligible resolution requests are subject to an initial scrutiny process. NICE investigates the matters raised and decides whether the request is in the scope of the resolution process. Initial scrutiny continues for 21 days after the resolution request period ends. If multiple resolution requests are made, either from the same or different sources, each request is treated separately.

Ground 1: breach of process

1.5.26 If the programme director considers that the resolution request does not meet ground 1 (breach of process), or does not have a reasonable prospect of success, NICE informs the consultee that made the request and publishes the guidance.

1.5.27 If the programme director considers that ground 1 appears to have been met, a resolution panel is convened.

Ground 2: factual errors

1.5.28 If the associate director considers that the resolution request does not meet ground 2 (factual errors), or does not have a reasonable prospect of success, the person or organisation that made the request is informed and NICE publishes the guidance.

1.5.29 If the associate director considers that the guidance contains a factual error or a point that needs clarification, but this does not affect the committee's recommendations, the guidance is amended and signed off internally without being referred to a resolution panel. NICE then publishes the final guidance.

1.5.30 If the associate director considers that there may be a major factual error that may affect the committee's recommendations, the programme director will convene a resolution panel.

1.5.31 If there are multiple resolution requests, not all requests may qualify to be referred to a resolution panel. To avoid pre-empting the outcome of resolution, NICE informs everyone who has submitted a resolution request that the panel will be convened, and that NICE will tell them the outcome of their request after the panel's decision is made.

Table 2 Initial scrutiny of resolution requests

Outcome of initial scrutiny	NICE action
Ground 1 not met	Guidance is published
Ground 1 met	Resolution panel is convened
Ground 2 not met	Guidance is published
Ground 2 met, minor factual error	Guidance is amended and published
Ground 2 met, major factual error	Resolution panel is convened

The resolution panel

1.5.32 The panel consists of 2 NICE board members: 1 non-executive director and 1 executive director not previously involved in developing guidance on the technology. The panel is to decide whether there has been a breach of process or factual error and, if so, what action is appropriate.

1.5.33 The resolution panel meeting is held within 35 days after the initial scrutiny process. The meeting is usually held virtually. The NICE team prepares a briefing, which the panel uses when considering resolution requests. For ground 1, this means establishing what process was followed when developing the guidance and what events or omissions are alleged in the resolution request. In the case of ground 2, this involves setting out what evidence is behind the alleged errors.

1.5.34 The briefing is shared with the consultee making the resolution request. They have 10 days to comment on the briefing, then their comments are provided to

the panel.

1.5.35 The resolution panel may hold a meeting where the panel members meet (without other parties) to consider the written evidence and make a decision. The panel may decide to hold an oral meeting where both the NICE team and the consultee attend to answer the panel questions and provide clarification. Committee members may also attend. These attendees are not members of the panel and do not contribute to the outcome of the resolution. Consultees cannot bring legal representation to the panel meeting.

Resolution outcome

Ground 1: breach of process

1.5.36 If the resolution panel decides that there has been no breach of process, NICE can publish the final guidance. If the panel decides that there has been a breach of process, it decides what action is appropriate. This may involve repeating part of the evaluation process and, if necessary, referring the guidance back to the committee or doing another consultation, or both.

Ground 2: major factual errors

1.5.37 If the resolution panel decides that there are no factual errors, NICE can publish the final guidance. If the panel decides that there are factual errors or elements to be clarified, NICE produces an amended version of the guidance. The panel decides whether the error can be corrected and the amended version of the guidance approved by NICE before publication, or whether the committee should review the wording of the amended guidance because of the error.

1.5.38 NICE considers whether to publish the amended guidance or whether there is a need for further consultation. Further consultation normally happens if:

- NICE makes a substantive change to the wording of the recommendations, or
- changes to the guidance not involving the recommendations are significant

or likely to be of interest to the people who made the resolution request.

Table 3 Outcome of resolution panel

Outcome of resolution panel meeting	NICE action
Ground 1 not met	Guidance is published
Ground 1 met	Appropriate action as decided by resolution panel
Ground 2 not met	Guidance is published
Ground 2 met	Appropriate action as decided by resolution panel

1.5.39 NICE implements the panel's decision and informs everyone who made resolution requests of the resolution outcome. This normally happens within 7 days of the panel reaching its final decision. This timescale does not apply if the committee needs to reconsider the recommendations. The resolution panel's decision is final and there are no further opportunities for redress within NICE.

Publishing the guidance

1.5.40 Once the resolution process is complete and any changes to guidance following those processes are complete, final guidance is published on the NICE website and all stakeholders are informed. NICE also publishes a lay version for patients and carers, known as 'information for the public'.

1.5.41 The following documents are available on the NICE website when guidance is published (all confidential information will be removed from the documents before publication):

- guidance
- external assessment report, any additional analysis and clarification questions and responses
- any evidence submissions
- consultation comments (anonymised) and NICE's responses

- further analysis or correction, if any, done by NICE or the external assessment group after the external assessment report (in an addendum)
- implementation support tools (usually at the same time as the guidance, and within 3 months of publication at the latest) when the technology is recommended (as an option)
- equality impact assessment
- a lay explanation of the recommendations.

1.5.42 If NICE is advised of any potential errors in the guidance or the supporting documents after publication, these are dealt with according to NICE's standard procedures.

Tools and resources

1.5.43 Tools and resources can be produced to support guidance. This includes resource impact tools or statements. NICE's assessing resource impact process manual has further details.

1.5.44 During guidance development for interventional procedures (and other HealthTech guidance when useful and applicable), appropriate clinical classification codes for the procedure are identified and reviewed by the committee. These codes are published with guidance on the NICE website. NICE liaises with relevant partners to identify when a new code is needed for a procedure because no appropriate codes currently exist. New codes are published on the NICE website when they become available.

1.5.45 For interventional procedures guidance, an audit tool template for procedures is available on the NICE interventional procedures guidance webpage.

Evidence generation plans

1.5.46 For technologies conditionally recommended for use while further evidence is generated in early-use HealthTech guidance, an evidence generation plan will be

produced (see section 1.7).

1.6 Guidance surveillance

1.6.1 The process of guidance surveillance is described in processes and methods for NICE-wide guidance surveillance, and section 8 of NICE technology appraisal and highly specialised technologies guidance: the manual. This includes monitoring activities related to the safety of recommendations and any changes to regulatory status.

1.7 Evidence generation process for early-use HealthTech guidance

Overview

1.7.1 The evidence generation process is designed to help companies work with NHS sites, data custodians and analytical partners to generate evidence needed to support future NICE guidance. This process will start from the point of the decision to take a topic through early-use assessment and will support the development of guidance.

1.7.2 The evidence generation process will aim to deliver proportionate and pragmatic approaches to evidence generation. The evidence generated during the period of use in the NHS should provide the information needed for NICE to make a recommendation about routine use in the future.

Stakeholder roles for the evidence generation process

1.7.3 NICE:

- identifies uncertainties that are essential to resolve for future decision making and that should be prioritised for further evidence generation

- assesses the feasibility of evidence generation while the technologies are used in the NHS
- engages with stakeholders about ongoing or planned studies and considers if and how they could address the uncertainties
- highlights NHS real-world data sources that could support or contribute to evidence generation
- suggests an approach to evidence generation that could address the uncertainties
- highlights potential sources of funding when NICE is aware of these
- highlights potential partners that could support evidence generation, such as research groups, clinical networks or implementation specialists when NICE is aware of these
- monitors progress of evidence generation.

1.7.4 Companies:

- are responsible for addressing identified gaps in the evidence
- are responsible for organising funding to support evidence generation
- engage with and support the NICE evaluation and monitoring process
- engage with partners to support evidence generation, by:
  - choosing appropriate NHS sites to generate the evidence
  - using robust approaches to evidence generation, considering aspects such as data quality, study design, analysis, and reporting and partnering with experts in research and analysis when necessary to ensure key uncertainties are addressed
  - ensuring new evidence is generated in accordance with all applicable data protection legislation
- ensure that safety is monitored, and signals of concern are discussed with clinical leads and reported to the Medicines and Healthcare products

Regulatory Agency and NICE as appropriate

- minimise burden of data collection whenever possible, for example, by using real-world data collections that build on existing clinical information flows
- consider advice laid out in NICE's technology appraisal and highly specialised technologies guidance: the manual, real-world evidence framework and evidence standards framework for digital health technologies to inform evidence generation
- make the evidence generated available to NICE in a form that can be used for decision making. For example, structuring and presenting findings as for a research publication, and ideally being able and ready to provide individual patient data if possible.

The evidence generation process

Feasibility assessment

1.7.5 The feasibility assessment considers barriers and facilitators to addressing the likely uncertainties during a standard evidence generation period. It will be finalised shortly before the first committee meeting and will use information from the EAG report as well as information already gathered from topic selection and scoping stages.

1.7.6 The feasibility assessment considers the following aspects:

- if key uncertainties could be resolved in a fixed period of 3 years from the point of guidance publication (longer periods than this will only be allowed in exceptional circumstances)
- the likely number and complexity of new studies needed
- facilitators that increase the likelihood that evidence generation will be successful (based on knowledge of relevant data sources, previously completed research, or known funding opportunities).

1.7.7 The feasibility assessment will be informed by:

- uncertainties highlighted in the EAG report
- consideration of the evidence landscape, including:
  - ongoing or planned studies
  - real-world data sources
- consideration of methodological approaches to address the evidence gaps, for example, those outlined in NICE's real-world evidence framework
- knowledge of existing funding sources
- knowledge of potentially suitable implementation partners.

1.7.8 Key conclusions from the feasibility assessment can be presented to the committee.

Evidence generation plan

1.7.9 The committee will identify the uncertainties that need to be addressed to support future NICE guidance on a technology. An evidence generation plan will be developed that describes the uncertainties and what evidence should be generated for a NICE re-evaluation of the technologies again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. The evidence generation plan will sit alongside the guidance.

Evidence generation monitoring

1.7.10 Once early-use guidance is published, NICE will monitor the company's evidence generation activities. The monitoring process is designed to support companies to deliver the evidence that NICE needs and to support NICE planning for a future evaluation.

1.7.11 NICE has the right to withdraw or change individual technology recommendations at any stage. Information collected through the monitoring process will inform decision making about withdrawal. Reasons a recommendation to use a technology while further evidence is generated may be withdrawn include:

- the technology is not available to the NHS
- NICE is unable to contact the company
- the company volunteers to withdraw
- there are significant regulatory or safety concerns about the technology
- the company is not engaging in evidence generation
- evidence generation will not address the essential uncertainties.

1.7.12 The monitoring period will begin at the date of publication of the guidance and evidence generation plan. The monitoring process includes several touchpoints, which can vary in frequency as needed, but broadly will occur:

- 6 months after guidance publication: NICE will contact companies to confirm they are engaging with NICE processes and have begun evidence generation.
- 12 months after guidance publication: NICE can ask for a summary of overall progress with evidence generation and the status of data collection. Ideally, companies will share their study protocol and, when relevant, evidence of engagement with implementation partners.
- Annually from 12 months: companies will be expected to report on their data collection. At this point they can also be asked if they consider that the evidence generated is sufficient to address the essential uncertainties.

1.7.13 In addition to routine monitoring, companies should inform NICE as soon as possible of anything that may significantly affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- any safety concerns

- the technology significantly changing in a way that affects the evidence generation process.

1.7.14 If data collection is expected to end later than planned, the company should contact NICE.

1.8 Re-evaluation of technologies recommended for use while further evidence is generated (HealthTech guidance)

1.8.1 Technologies recommended for use while further evidence is generated that complete the evidence generation process will be re-evaluated by NICE. This is to decide whether the technology can be recommended for routine use, considering the further evidence generated. Details on the process of scoping in this scenario are described in section 1.3.23. Re-evaluation follows the process for guidance production described in section 1. Re-evaluations can be done as technology appraisal guidance, rather than HealthTech guidance. In such cases, detail on process to be followed can be found in NICE technology appraisal and highly specialised technologies guidance: the manual.

1.8.2 As part of monitoring done during the evidence generation process, companies can submit evidence at the touchpoints if they consider the evidence generated is sufficient to address the essential uncertainties identified in the guidance and evidence generation plan (see section 1.7.12). NICE may consider evidence provided before the end of the evidence generation period. This will follow the surveillance review process set out in sections 8.1 and 8.2 of the NICE technology appraisal and highly specialised technologies guidance: the manual. It will consider if re-evaluation of some or all of the technologies in the guidance should start before the end of the evidence generation period. When doing the surveillance review, NICE will consider the status of evidence generation for other technologies recommended for use with evidence generation in the same guidance and how close the end of the evidence generation period is. This may lead to the surveillance review being deferred to a later date to consider evidence generated by other companies, or not being done if it is likely

completion would be close to or after the end of the evidence generation period. It is expected that most re-evaluations will take place after the full evidence generation period.

2 Methods for guidance produced in the NICE HealthTech programme

Interventional procedures guidance

Detail on methods for developing interventional procedures guidance (based on an assessment of efficacy and safety) can be found in NICE's interventional procedures programme manual.

HealthTech guidance

Methods for developing HealthTech guidance are set out in the following sections. These methods apply to all HealthTech guidance. Section 3 sets out additional detail for early-use HealthTech guidance assessments (previously called early value assessment [EVA]) and section 4 sets out additional detail for existing-use HealthTech assessments (previously called late-stage assessment [LSA]).

2.1 Scoping

General

2.1.1 The scoping process aims to define what questions the evaluation will answer. The scope provides the framework for the evaluation and describes a decision problem. It defines the issues for consideration and sets the boundaries for the work to be done.

2.1.2 Key overarching points to define in scoping are:

- what use or uses of the technology will be assessed (use cases; see section 2.1.3)
- what potential impacts using the technology for this use case, or use cases, may have (value proposition; see section 2.1.4).

It is important to understand how using the technology for the specified use cases is expected to achieve the proposed benefits, or value proposition. This can help to identify how the technology is expected to be used and any changes to care, practice or infrastructure that are needed for the technology to achieve its proposed impact (see sections 2.1.8 and 2.1.9).

2.1.3 The priorities of the health and care system are a key consideration in deciding aspects of the scope. These are identified and considered during topic prioritisation (see the chapter on identifying priorities for the health and care system in NICE-wide topic prioritisation: the manual). Health technologies can often be used in multiple different ways or for various purposes (use cases). For example, in different populations or at different points in a care pathway. The scope will define what uses of the technology to include in the assessment, using input from healthcare professionals, patients and other stakeholders. Considerations include what uses of the technology are most likely to maximise benefit to the NHS, the population of England and areas of unmet need.

2.1.4 Scoping will establish the potential impacts of a technology, compared with current practice (its value proposition). This can involve direct impacts on people's health and aiding earlier diagnosis. It can also involve improving access to health services, changing how care is delivered and improving efficiency of service delivery. For example, to address current system infrastructure or workforce capacity constraints or burden.

Components of the scope

Interventions

2.1.5 HealthTech guidance can include multiple health technologies or defined groups or classes of health technology (see section 2.1.7). This is if there is likely benefit to the NHS of evaluating multiple technologies for the use cases being assessed, and they are alternative options for 1 or more of the use cases being assessed. These are specified in the scope.

2.1.6 The scope can set out the criteria that technologies need to meet to be included in the assessment. These will typically be based on advice from healthcare professionals and patients. Criteria will include features or functions that are considered essential for the technology to be used in the way being assessed (use case) or to have the proposed impact (value proposition).

2.1.7 Interventions may be defined as a group or class of technologies that have shared features or functions. For example, laboratory tests for a particular genetic marker or analyte. This may be considered when what the technologies do or how they function are very similar or the same.

2.1.8 The scope can specify further detail on a technology if needed to understand its proposed use, particularly if this is integral to its value proposition. For example:

- who would use the technology and the setting for use
- how it should be used, including in relation to other technologies (for example, in a sequence of tests)
- components or features of the technology
- for technologies producing information, such as for diagnosis or prognosis or for monitoring and response assessment, how this information is intended to be used and any specific test thresholds.

  In some instances, assessments may evaluate different ways technologies could be used (for example, tests used in different sequences), which can be defined in the scope.

2.1.9 The scope should describe any changes to infrastructure, care pathways or care delivery that are expected to be needed for the technology to be used in practice and achieve its proposed impact. For example, any additional equipment, resource or changes to service arrangements.

2.1.10 NICE will not develop HealthTech guidance on a technology outside of its indication or intended purpose for use, as defined by any regulatory approval for use in the UK.

2.1.11 Technologies not yet available in England or without appropriate regulatory

approval may be included within a scope. The appropriate regulatory approval is usually a UK Conformity Assessed (UKCA) or CE mark (as a medical device). The Medicines and Healthcare products Regulatory Agency (MHRA) may apply different regulation procedures to certain products, such as in-house tests.

2.1.12 For technologies assessed as a group or class (see section 2.1.7), at least 1 available technology must have appropriate regulatory approval.

The population

2.1.13 The scope defines the population for whom the technology is being evaluated as precisely as possible. It may highlight potential subgroups for which the technology's clinical effectiveness or value for money might differ from the overall population, or groups that need special consideration.

2.1.14 Identifying groups for whom the clinical or cost effectiveness may differ from the overall population is particularly important if differences relate to a potential equality issue that will need to be considered in guidance (see section 2.1.29).

Comparators

2.1.15 The scope identifies relevant comparators that are established practice in the NHS or are recommended in existing guidance from NICE or other bodies. This can include 'no activity' if nothing is done in current practice. Comparators may include technologies that do not have regulatory approval for the population defined in the scope if they are considered established clinical practice in the NHS. The comparator will typically not include use of the intervention being assessed, even if it is currently in use in practice to some degree. Exceptions include when the assessment is focused on assessing different ways that current care can be delivered (for example, using a different threshold for established tests or using an established technology in a different setting).

2.1.16 The comparators should be defined as precisely as possible. It is important this accurately represents current care. It is also important that any challenges with current care which may form part of the value proposition for the intervention are

accurately represented (for example, access to care, variation in practice or delays to having treatment or appointments).

Outcomes and costs

2.1.17 Relevant outcomes and costs are those resulting directly or indirectly from the technologies being evaluated. The perspective taken in NICE's reference case (see section 4.2 of NICE technology appraisal and highly specialised technologies guidance: the manual) should be considered when deciding relevant outcomes and costs to include in the scope.

2.1.18 Consideration of potentially relevant outcomes and costs should reflect the value proposition for the technology (see section 2.1.4) and any potential positive or negative impacts that using the technology, compared with the comparators, could have for patients and the healthcare system.

2.1.19 If available, a high-quality 'core outcome set', developed with people with the condition, may help with outcome selection. One source is the Core Outcome Measures in Effectiveness Trials (COMET) database. The Core Outcome Set Standards for Development (core outcome sets-STAD) and Core Outcome Set Standards for Reporting (core outcome sets-STAR) should be used to assess the suitability of identified core outcome sets.

2.1.20 Included outcomes should reflect what is important to address for the decision problem set out in the scope, rather than outcomes for which evidence is known to exist.

2.1.21 In addition to clinical outcomes, the scope can specify any outcomes related to the NHS and personal social services (PSS) that may be impacted by use of the technology. These can include outcomes related to resource use and system efficiency (for example, related to waiting times, or time to diagnosis or treatment).

2.1.22 Further outcomes can be considered when relevant, including those related to technology functions, such as measures of ability to perform a specific task or function, and those related to people's behaviour or activity. The extent to which

such outcomes can be used in estimates of cost effectiveness is likely to depend on the extent to which they are predictive of impact on clinical or resource-use outcomes.

2.1.23 Quantitative outcomes are needed to evaluate the cost effectiveness of a technology. Consideration should be given to how potential impacts could be captured quantitively when identifying relevant outcomes. For example, for technologies that are proposed to be easier to use, relevant outcomes may be related to procedure times, incidences of successful procedures or need to repeat procedures.

2.1.24 Outcomes related to the needs and preferences of patients and healthcare professionals for different technologies (quantitative or qualitative; see section 2.1.25), or particular functions or features of technologies, may be useful for decision making and can be specified in the scope. This may particularly be the case when there are multiple technologies defined as interventions in the scope, and evidence that compares clinical and system outcomes between these technologies is likely to be absent or weak.

2.1.25 To supplement quantitative outcome measures, or when these are not possible or unlikely to be collected, qualitative outcomes can be specified in the scope. This can include informational outcomes of value to the patient for the relief, or infliction, of anxiety or for personal planning. Qualitative research can explore areas such as values, preferences, acceptability, feasibility and equity implications.

Prioritisation of outcomes

2.1.26 The scope may prioritise key outcomes that are most relevant to addressing the decision problem. Input should be sought from stakeholders and experts during the scoping process. The views of people with the condition and users of the technology will be particularly important when prioritising outcomes. This will ensure that specified outcomes reflect the preferences of patients and, when relevant, their carers, and healthcare professionals or other staff who would use the technology. The GRADE working group provides guidance on approaches that can help determine which outcomes should be prioritised for decision making.

Assessment and guidance details

2.1.27 The scope will include, when relevant, details of the type of evaluation that will be done during the assessment phase, for example a cost–utility or cost-comparison approach (see section 2.3.2). This will be informed by considerations of which type of evaluation is most appropriate for the technology and value proposition being considered. For example, a cost-comparison approach to economic evaluation may be specified for technologies considered likely to provide similar health benefits at similar or lower cost than comparators. This can be the case for technologies that are likely to have only a healthcare system benefit.

2.1.28 The scope will also specify what guidance will be developed in terms of the lifecycle approach to be used (for early, routine or existing-use guidance). This decision is made by NICE. It considers, when relevant, feedback received during the scoping process, for example at a scoping workshop, and what value NICE will add to the health and care system by producing each type of guidance. The decision is made in the context of the use case and value proposition being considered. General principles for this decision are described in table 4. The HealthTech programme makes an initial decision about whether guidance is developed for a technology or topic in line with NICE-wide topic prioritisation: the manual.

Table 4 General principles used to determine which lifecycle approach to take for producing guidance

Lifecycle approach	General principles for selecting which lifecycle approach to take
Early use	• Limited or no current use in the NHS • Limited evidence available for all technologies • Technologies have the potential to address a high unmet need in the NHS • Usually recent, ongoing or upcoming appropriate regulatory approval for use in the UK

Lifecycle approach	General principles for selecting which lifecycle approach to take
Routine use	• Greater level of evidence available, which means that some technologies may be suitable for routine widespread use in the NHS • Any technologies that have been previously assessed in early-use guidance and have gone through the evidence generation period • The assessed technologies (interventions) are not considered established practice in the NHS, so a comparator separate from the intervention(s) can be defined (more detail on how established practice is determined is in section 2.1.15) • Technologies that are potential transformative or disruptive innovations, as defined by the Department of Health and Social Care's medical technology innovation classification framework
Existing use	• The assessed group of technologies (interventions) comprise similar technologies, at least some of which would be considered established practice in the NHS (more detail on how established practice is determined is in section 2.1.15) • Technologies that are potential incremental innovations, continuous improvements or copycat devices, as defined by the Department of Health and Social Care's medical technology innovation classification framework • There is likely to be variation in price between alternative technologies in the assessed group of technologies

Equality considerations

2.1.29 The scope will include, when relevant, details of:

- issues relating to advancing equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics and society as a whole
- potential issues relating to health inequalities, including whether the

technology could address inequality or unfairness in the distribution of health across society.

Existing NICE guidance

2.1.30 Identifying relevant NICE guidance (both published and in development) is a key element of scoping. This helps to see where and how the potential recommendations are likely to relate to existing recommendations in other guidance. The scope can include, when relevant, details of related NICE guidance, such as other evaluations and clinical guidelines, and related policy developments.

2.2 Evidence

2.2.1 Evidence is identified during the assessment phase and presented in the assessment report. This is based on the scope for the assessment and the decision problem described therein.

2.2.2 Sections 3.1 and 3.2 in NICE technology appraisal and highly specialised technologies guidance: the manual describe approaches to assessing the evidence and guiding principles for evidence. The Decision Support Unit produces a series of technical support documents that provide further information on technical aspects of health technology evaluations.

Types of evidence

2.2.3 All types of evidence can be considered for evaluations (although not all types will be included in the assessment report; see section 2.2.11). This includes evidence from published and unpublished data, data from non-UK sources and economic evaluations of technologies. The assessment report will comment on the quality of evidence sources, and the type and quality of evidence will be considered by the committee in its decision making (see section 2.4.6).

2.2.4 The NICE real-world evidence framework describes best practices for planning, doing and reporting real-world evidence studies (this includes the conduct of qualitative research studies, described in appendix 4). NICE's evidence standards framework for digital health technologies outlines critical considerations for evidence generation for digital health interventions.

2.2.5 Evidence exploring the views and experiences of people with the condition and healthcare professionals who will use the technology may be presented to committee. This evidence may come from published sources or from evaluations done specifically for the assessment.

Synthesis of evidence

Evidence review

2.2.6 Section 3.4 of NICE technology appraisal and highly specialised technologies guidance: the manual details approaches for assessing evidence for an evaluation. Literature searches are done as an integral part of evidence identification during the assessment phase.

2.2.7 In addition to literature searches, evidence provided or identified by companies or other stakeholders is considered, if provided at appropriate points in response to a request from NICE (see section 1.3.4). Any unpublished evidence provided should be accompanied by sufficient details to enable a judgement as to whether it meets the same standards as published evidence and to determine potential sources of bias. Ideally it should be structured and presented in the form of a research publication. Detail should be provided in line with relevant reporting guidelines (for example, those endorsed by the EQUATOR network) to allow critical appraisal of unpublished evidence.

2.2.8 Evidence on predecessor versions of a technology may be considered, particularly if there is limited evidence on the currently available model or version. But the extent to which it is appropriate to use such evidence should be considered and commented on in the assessment report, for the committee to consider in its decision making.

2.2.9 Existing systematic reviews and meta-analyses may be used or updated, if possible and in line with the decision problem outlined in the scope. As part of the assessment a judgement will be made on which elements of the previous systematic review can be reused, and which need to be redone or updated.

2.2.10 The evidence review should flag when no appropriate data for outcomes specified in the scope has been identified. When possible, the assessment report should describe any identified ongoing studies or real-world data sources that may be able to address these evidence gaps.

Study selection

2.2.11 There can be many available studies, or study types, that report on a particular outcome. This may require decisions to be made about which studies are prioritised in an assessment report for consideration by committees. NICE's Decision Support Unit technical support document 27 provides guidance on potential approaches.

Critical appraisal

2.2.12 The quality of a study's overall design, its execution and the validity of its results determine its relevance to the decision problem. Studies should be appraised using a checklist appropriate for the study design, where available. An assessment of the generalisability of data from studies to the decision problem is also an important consideration, particularly for non-UK studies. When there is a large number of studies, critical appraisal may be prioritised for studies considered key for decision making, particularly those providing data used for economic models.

2.2.13 Whenever possible, checklists for assessing published studies should be used to assess the validity of unpublished studies.

Further considerations and evidence synthesis challenges

2.2.14 Section 3.4 of NICE technology appraisal and highly specialised technologies guidance: the manual includes detail related to evidence synthesis, including factors that can affect effectiveness estimates and the use of pairwise meta-analysis, indirect comparisons and network meta-analyses.

2.2.15 Meta-analysis of test accuracy data can be complicated because of the correlation between sensitivity and specificity. In addition, there are likely to be many sources of heterogeneity across test results, arising from differences in setting, patient population, reference standard, equipment, procedures and skill levels of test operators. The cut-off point at which test accuracy data is reported may also differ between studies. Several methods for meta-analysis of test accuracy data exist. They vary in complexity and in the assumptions that need to be made. The appropriate choice of method depends on the data available and should be justified. NICE's Decision Support Unit technical support document 25 provides guidance on methods for meta-analysis of test accuracy data.

2.3 Economic evaluation

2.3.1 Chapter 4 of NICE technology appraisal and highly specialised technologies guidance: the manual provides detail of the methods that should be used to assemble and synthesise evidence on a technology in an economic evaluation. This is needed to estimate the technology's relative clinical effectiveness and value for money compared with current practice in the NHS. It includes a reference case, which specifies the methods NICE considers to be most appropriate for analysis when developing guidance. This does not prevent additional analyses being done in which 1 or more aspects of the methods differ from the reference case. However, these must be justified and clearly distinguished from the reference case. The Decision Support Unit produces a series of technical support documents that provide further information on technical aspects of health technology evaluations.

Economic evaluation

2.3.2 The methods NICE considers to be most appropriate for estimating value for money are cost–utility analysis and cost-comparison analysis.

2.3.3 These analyses show the impacts of using a technology, relative to a comparator or other health technologies specified as interventions, in terms of changes in costs, or changes in both costs and quality-adjusted life years (QALYs). These changes can be based on both the short- and long-term impacts, potentially occurring across a patient's lifetime. Sections 4.2.22 to 4.2.25 of NICE technology appraisal and highly specialised technologies guidance: the manual explain the time horizon used in economic evaluations.

2.3.4 Sections 4.3 and 4.4 of NICE technology appraisal and highly specialised technologies guidance: the manual provide detail on measuring and valuing health effects in cost–utility analyses and the use of evidence on resource use and costs.

2.3.5 Distributional cost-effectiveness analysis (DCEA) will not be done in economic evaluations produced by external assessment groups (EAGs) on behalf of NICE for HealthTech guidance. DCEA evidence can be provided by companies as part of the information requested on the evidence base and their technology. For more information on these analyses, see section 4.12 of NICE technology appraisal and highly specialised technologies guidance: the manual.

2.3.6 When any impacts of a technology are not captured, or not fully captured, in terms of incremental costs or QALY outputs from modelling and therefore cost-effectiveness estimates:

- The economic evaluation should clearly highlight that such impacts are not captured in the cost-effectiveness estimates.
- The assessment report should present, when possible, any incremental differences in non-cost or non-QALY outcomes generated from the model, or available from identified studies, that help quantify the impact of the technology that has not been captured in cost-effectiveness results (see section 2.3.26).

- If linking effects to a QALY gain is not possible for all health-related impacts of a technology, links to a clinically relevant or a related outcome should be considered to help illustrate and quantify the impact of a health technology, compared with current practice (see above bullet point).
- The assessment report should narratively discuss how the uncaptured impacts may impact on health and resource use.

2.3.7 Understanding the magnitude of any uncaptured impact, and how this could affect cost-effectiveness estimates, is important for decision making. Any analyses that could inform this consideration would be beneficial.

Existing economic evaluations

2.3.8 Existing economic evaluations can be used as an alternative or supplement to de novo modelling, if they are adequate, appropriate and relevant to the decision problem. Other considerations include whether the model code is available and the extent to which it can be shared. Such evaluations include those identified in a literature review, done to support existing guidance from NICE or other bodies, and any identified in responses from companies to evidence requests (see section 1.3.4). Applicable economic models produced for existing NICE guidance should be used whenever possible.

Modelling approach

2.3.9 Sections 4.5 to 4.7 of NICE technology appraisal and highly specialised technologies guidance: the manual describe NICE's preferred approaches to discounting, modelling methods to generate estimates of clinical and cost effectiveness and cost comparison, and exploring uncertainty. Providing an all-encompassing definition of what constitutes a high-quality model is not possible. Economic evaluations for HealthTech guidance are made available for review (see sections 1.4.7 and 1.4.8).

2.3.10 Models produced for HealthTech assessments may require strong assumptions to be made. Provided that such assumptions are clearly highlighted, the committee

can consider them in its decision making and decide on their appropriateness (see section 2.4.6). Assumptions included in models should, when appropriate, be validated by relevant experts. The impact of strong assumptions in models should be explored using sensitivity or scenario analyses, when possible.

2.3.11 Using expert elicitation or expert opinion should be considered to provide evidence to support economic evaluation work. When the elicited data is to be quantitative, preference should be given to formal elicitation techniques (see sections 3.3.21 to 3.3.23 of NICE technology appraisal and highly specialised technologies guidance: the manual).

2.3.12 Details about services that would be impacted by using the technologies and how they would be impacted (in terms of greater or reduced use) should be discussed. This should include direct impacts of using the technologies, and any impacts that are likely to occur upstream or downstream of use (ideally model outputs will help to estimate the size of impact; see section 2.3.25). Details of any changes to service organisation and any other activities needed to implement the technologies should also be described.

Surrogate and intermediate outcomes

2.3.13 Guidance on the use of surrogate outcomes is provided in sections 4.6.6 to 4.6.11 of NICE technology appraisal and highly specialised technologies guidance: the manual. Lower levels of evidence to support validation of a surrogate end point (biological plausibility of relationship between surrogate end point and final outcomes, as defined in Ciani et al. 2017; see section 4.6.6 of NICE technology appraisal and highly specialised technologies guidance: the manual) are acceptable to justify use in modelling; the acceptability of this and associated uncertainty can be considered in decision making for guidance recommendations (see section 2.3.10). Stronger evidence that the relative effect of a technology on the surrogate end point is predictive of its relative effect on the final outcome will increase confidence in generated cost-effectiveness results. When possible, the uncertainty associated with the relationship between the surrogate end points and the final outcomes should be quantified and captured in the model's probabilistic analysis.

2.3.14 For evaluations of diagnostic technologies (including prognostic and predictive tests and models), there may be some direct benefits from the knowledge gained and some direct harm from the testing. But most of the outcomes typically come after testing because of treatment or preventive measures being started, modified or stopped. Tests can sometimes be evaluated using clinical trials, but this is unusual. If direct data on the impact of a diagnostic technology on final outcomes is not available, it may be necessary to combine evidence from different sources. A linked evidence modelling approach should be used, which links data from different studies together to estimate impact. The links used, such as between test results, decisions about care or treatment based on this result and final outcomes should be specified and justified, for example with relevant data or justification of assumptions.

2.3.15 When only surrogate or intermediate outcomes (such as test accuracy) are available to support a value proposition, it is beneficial that companies provide any supporting information in response to evidence requests that support the use of such outcomes. For example, evidence that the relative effect of a technology on the surrogate end point is predictive of its relative effect on the final outcome.

Impacts on system efficiencies and capacity

2.3.16 Value propositions for technologies can include a proposed impact on system efficiencies, which can potentially increase capacity to deliver healthcare. Relevant outcomes in such cases will be specified in the scope (see section 2.1.21).

2.3.17 Evidence should quantify the effect of the technology on resource use in terms of physical units (for example, days in hospital or visits to a GP). These effects should be valued in monetary terms using appropriate prices and unit costs, such as unit costs found in the Personal Social Services Research Unit (PSSRU) report on unit costs of health and social care.

2.3.18 Any health or other benefits that may arise from system efficiencies, such as ruling out the need for unnecessary procedures or reducing waiting times, should be considered in estimates of cost effectiveness (for example, for reducing waiting times, through impacting progression to more advanced disease states)

or noted as uncaptured benefits if this is not possible (see section 2.3.6).

Technology costs

2.3.19 Reference-case analyses should be based on prices that reflect as closely as possible the prices that are paid in the NHS. This could be the public list price. When there are nationally available price reductions, the reduced price can be used in the reference-case analysis to best reflect the price relevant to the NHS. Analyses based on price reductions for the NHS will be considered only when the reduced prices are transparent and consistently available across the NHS, and when the reduced price is available for a guaranteed period. In the absence of a published list price and a price agreed by a national institution, an alternative price may be considered, provided it is nationally and publicly available. If no other information is available on costs, local costs may be used.

2.3.20 When a group of related technologies is being evaluated as part of a group or class (see section 2.1.7), an analysis using the individual costs for each technology should be presented in the reference case. Exceptionally, if there is a very wide range of technologies and costs to be considered, then analyses should use the weighted mean cost and the highest and lowest cost estimates.

2.3.21 For technologies that have multiple uses in the NHS beyond the uses under evaluation, for example diagnostic tests that could identify multiple markers or technologies that can be used across multiple populations, the average cost should initially be identified. This should be based on the expected use or throughput of the device for only the uses being evaluated. In some cases, an analysis using marginal costs may be provided in addition to the analysis based on average costs. This is if a technology is already recommended for another purpose and there is enough spare capacity to allow the use for the condition in the current evaluation.

2.3.22 Analyses using adjusted or apportioned technology costs can also be provided as non-reference-case analyses, for example if the technology has multiple uses beyond the indication under evaluation and introducing the new technology will lead to identifiable benefits that are not captured in health technology evaluations (see section 4.4.15 of NICE technology appraisal and highly

specialised technologies guidance: the manual for further detail).

2.3.23 When the cost of introducing the technology is likely to be high, for example disruptive technologies requiring new ways of working or changes to care pathways, sensitivity or threshold analyses investigating the impact of higher upfront costs associated with adopting the new technology may be beneficial to assess the robustness of cost-effectiveness estimates.

Subgroups

2.3.24 For many technologies, the level of benefit will differ for patients with differing characteristics. This can be explored by providing clinical and cost-effectiveness estimates separately for each relevant subgroup. Section 4.9 of NICE technology appraisal and highly specialised technologies guidance: the manual provides further guidance and considerations. When possible, potentially relevant subgroups will be identified at the scoping stage (see section 2.1.14). However, this does not prevent the identification of subgroups later in the process, for example during the assessment period or committee discussions.

Outputs

2.3.25 Guidance for presenting model results is described in section 4.10 of NICE technology appraisal and highly specialised technologies guidance: the manual. In addition to costs and QALYs, outputs from the model should be provided that are useful to help understand the estimated impact of the technologies and what has been captured in cost-effectiveness estimates. For example, values that would be meaningful for healthcare professionals and those that show the impact of technology use on services, such as staff time and resource use.

2.3.26 Any outputs from models should be presented that help quantify impacts that are not captured or not fully captured in incremental cost and QALY outputs (see section 2.3.6), or composite measures of these (for example, net health benefit).

2.3.27 For technologies that are likely to have rapid iteration and multiple new versions after guidance is published, threshold analyses can be beneficial for parameters

related to technology performance or impact that drive cost-effectiveness results, to identify a parameter 'switching value'. A switching value is the value of an input variable that would change a decision on whether the technology represents a good use of NHS resources for a given threshold (for example, £20,000 and £30,000 per QALY gained).

Priorities for further research

2.3.28 Key drivers of decision uncertainty should be identified in the economic evaluation to inform any recommendations for further research (see sections 2.4.20 and 2.4.21). Because the extent of further research activities that are feasible may be limited, uncertainties should be highlighted that are essential to resolve for future guidance development.

Impact on the NHS

2.3.29 Resource impact assessment for HealthTech guidance can be done by NICE alongside, or after, guidance production (see the webpage on assessing the resource impact of NICE guidance). The assessment can:

- support decisions about uses of the technologies under evaluation
- complement any other economic evaluation done
- help assess the expected changes in expenditure and capacity requirements as a result of implementing the guidance.

2.3.30 The committee may consider resource impact assessments when considering the level of uncertainty about the value for money associated with a technology (see section 2.4.9).

2.4 Committee recommendations

Decision making

2.4.1 The committee bases its recommendations on the evidence presented, including:

- information provided by non-company stakeholders or other organisations (see section 1.3.9)
- the assessment report, which includes consideration of information provided by companies in response to requests for information or evidence requests (see section 1.3.4)
- comments received on the assessment report or economic model (see sections 1.4.7 and 1.4.8)
- views expressed by experts, including clinical experts, particularly their experience of the condition, current care and technology use in clinical practice, and the experience of people with lived experience of the condition.

2.4.2 The committee uses estimates of cost effectiveness based on cost–utility or cost-comparison analyses as the primary consideration when making decisions about the acceptability of technologies as a cost-effective use of NHS resources. Analyses will typically contain an estimate from a base-case analysis, generated using the EAG's preferred model assumptions and input parameters. Analyses will also include scenario and sensitivity analyses that can show uncertainty in, and explore the impact of alternative parameter values and model assumptions on, generated cost-effectiveness estimates. The committee considers all analyses in its decision making and can decide whether the EAG's base case is its preferred analysis, or how much weight to apply to this in decision making.

2.4.3 The committee should also consider the extent that any impacts of a technology are not captured, or not fully captured, in cost-effectiveness estimates, the potential magnitude of this, and how it would affect cost-effectiveness estimates (see sections 2.3.6 and 2.3.7).

2.4.4 Interventions with an incremental cost-effectiveness ratio (ICER) below £20,000 per QALY gained are generally considered cost effective. Above this, decisions

about the acceptability of the technology as an effective use of NHS resources will specifically consider the following factors:

- the degree of certainty about cost-effectiveness estimates
- aspects that relate to uncaptured benefits and non-health factors. Specifically, the committee will consider:
  - if its decisions have a bearing on broader social considerations and the extent that these are covered by principles on social value judgements in our principles on the NICE website
  - if there are strong reasons to suggest that the health benefits of the technology have been inadequately captured, or otherwise considered, and therefore may misrepresent the health utility gained
- aspects that relate to health inequalities.

As the ICER for a technology increases between £20,000 and £30,000 per QALY gained, and particularly over £30,000 per QALY gained, the committee will need to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, considering the factors listed in the bullets above.

2.4.5 The committee will consider the severity of the condition, defined as the future health lost by people living with the condition with standard care in the NHS (including use of other available treatments, diagnostics or best supportive care). The extent of unmet health need is reflected within the severity definition. Initially, the severity modifier will not be applied to HealthTech guidance. The severity of the condition should be captured within the QALY benefits and then deliberatively within decision making. NICE is exploring how the severity modifier could be applied for HealthTech guidance.

2.4.6 Decisions about the acceptability of a technology as an effective use of NHS resources will specifically take into account the degree of certainty around the value for money. Considerations include uncertainty expressed in cost-effectiveness estimates, and factors that may not be captured, or fully captured, in these analyses, including:

- the assumptions necessary in the economic modelling

- the source of parameters used to estimate cost effectiveness, typically model parameters that differ between intervention and comparator (or between different interventions). The committee should consider the reliability and generalisability of the evidence presented when considering cost-effectiveness estimates. This includes study type and assessment of study quality.

2.4.7 The committee may be more cautious about recommending a technology if it is less certain about its cost effectiveness. But it should be proportionate and take into account factors related to the technology and condition (for example, if the condition is rare), and how feasible or realistic it is to generate further evidence to reduce uncertainty about cost effectiveness.

2.4.8 The degree of certainty about a technology's value for money can be expressed qualitatively if needed. To ensure that language is used consistently, terms set out in an available common probability yardstick (available on GOV.UK's webpage on communicating probability) may be used.

2.4.9 The degree of certainty of the cost effectiveness of a technology should be proportionate to the impact of technology adoption on NHS resources and the risk to patients. The committee may need more robust evidence to support estimates of cost effectiveness of technologies that are expected to have a large impact on NHS resources.

Technologies that provide less health benefit at a lower cost

2.4.10 Technologies that provide less health benefit at a lower cost relative to the relevant comparators (that is, that fall in the south-west quadrant of a cost-effectiveness plane) should be considered using the usual cost-effectiveness range of £20,000 to £30,000 per QALY. Any relevant additional factors should be taken into account, as described above.

Subgroups

2.4.11 The committee can make specific recommendations for subgroups of the overall population. Section 6.2.28 of NICE technology appraisal and highly specialised technologies guidance: the manual contains further details and consideration for this.

Economic evaluations based on cost-comparison analyses

2.4.12 When a cost-comparison analysis is done, key considerations include whether:

- there is enough certainty that the technology has at least equivalent clinical benefits to the comparator
- the technology is likely to reduce costs or resource use (for example, staff or facilities) compared with the comparator.

2.4.13 Interventions that are cost neutral or cost saving are generally considered cost effective. For technologies that are cost incurring, decisions about the acceptability of the technology as an effective use of NHS resources will specifically consider the following factors:

- the degree of certainty about the cost impact estimates
- aspects that relate to uncaptured benefits and non-health factors. Specifically, the committee will consider:
  - if its decisions have a bearing on broader social considerations and the extent that these are covered by principles on social value judgements in our principles on the NICE website
  - if there are strong reasons to suggest that the health benefits of the technology have been inadequately captured, or otherwise considered
- aspects that relate to health inequalities.

  As the incremental cost increases, the committee will need to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, considering the factors listed in the bullets above.

Recommendations

2.4.14 Recommendations are made only for use of technologies in the terms of the assessed use case or use cases as set out in the scope.

2.4.15 When interventions in a scope are defined as a group or class of health technologies (see section 2.1.7), recommendations will be issued for the whole group or class. If named technologies are specified in identified studies, this may be included in the assessment report and within the guidance document, but recommendations will not be issued for individual technologies.

Types of recommendation

2.4.16 The committee produces recommendations based on the extent to which the potential patient and system benefits are supported by evidence. The rationale for recommendations made is described in the guidance document. The recommendations in table 5 are relevant for routine-use HealthTech guidance. Detail on recommendations for early-use and existing-use guidance can be found in section 3 and section 4.

Table 5 Overview of recommendations in routine-use HealthTech guidance

Recommendation type	What this means in practice
Can be used	There is enough evidence that the technology provides benefits and value for money, so it should be routinely available across the NHS, and paid for using core NHS funding.
Can be used during the evidence generation period	The technology can be used as an option in the NHS during the evidence generation period and paid for using core NHS funding. During this time, more evidence will be collected to address uncertainties. Companies are responsible for organising funding for evidence-generation activities. After this, NICE will review this guidance, and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

Recommendation type	What this means in practice
More research is needed	There is not enough evidence to support funding the technology in the NHS. Access to technology should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.
Should not be used	The technology does not offer benefit or value for money and should not be used in the NHS.

Recommending a technology (can be used)

2.4.17 The committee will recommend that a technology can be used (as an option) when it considers that there is enough evidence that it provides appropriate benefits and value for money, so should be made available in the NHS.

2.4.18 The committee may recommend that the technology can be used only under specific circumstances. For example, the recommendation can be optimised or restricted to people who meet specific clinical eligibility criteria, to a specific subgroup of people (see section 2.4.11), or to provision by staff with certain training or in a particular care setting. Recommendations for using a diagnostic test may also be limited to specific circumstances, such as:

- the patient's characteristics
- the condition's aetiology
- the training and skills of those providing the test
- availability of equipment
- availability of other portions of the care pathway.

Recommendation for use during the evidence-generation period

2.4.19 In exceptional circumstances, when no technologies are recommended for use in routine-use guidance, 1 or more of the technologies may be recommended for use with evidence generation, following the approach used for early-use guidance (see section 3). Considerations and rationale for decision making

should follow the approach set out in section 3.4.

Recommendation for more research

2.4.20 When the evidence of clinical or cost effectiveness or impact of a technology on other health outcomes is either absent, weak or too uncertain, the committee may recommend that more research is needed.

2.4.21 This type of recommendation needs to be accompanied by defined uncertainties that the committee considers it worthwhile and feasible to collect further evidence to address (see section 2.4.28).

Not recommended (should not be used)

2.4.22 If the benefits and value for money of a technology are not supported by the evidence and are not likely to be realised in practice, even if further evidence was generated, the technology is not recommended.

Multiple intervention considerations

2.4.23 Evidence generated using a technology should typically not be used to show performance of others in the assessment. This is unless the committee can provide strong reasoning why it considers this appropriate, or the technology is being assessed as part of a group or class of technologies (see section 2.1.7).

2.4.24 Different recommendations can be made for different technologies included in the guidance.

2.4.25 Health technologies specified as interventions (see section 2.1.5) will be compared with each other, when possible, as well as with the comparator. If there is strong evidence that an intervention dominates the alternatives, it should normally be recommended. However, if 1 intervention is more effective but also more costly than another, then the comparative cost-effectiveness estimate should be considered. When multiple technologies are being compared, cost-

effectiveness rankings may be used to present the results of probabilistic model analyses (see section 6.3.3 of NICE technology appraisal and highly specialised technologies guidance: the manual for more detail).

2.4.26 The extent of evidence comparing an intervention with alternative interventions should be considered when deciding if, when multiple interventions are considered cost effective compared with the comparator, 1 or a subset of them should be recommended in preference to others.

2.4.27 When recommending multiple technologies that cannot be distinguished from each other based on cost effectiveness (see sections 2.4.25 and 2.4.26), committees may specify what should be considered when choosing between them, if it considers this appropriate. Considerations can be related to:

- the price of the technologies and any additional costs associated with use, including a recommendation to use the least expensive option
- environmental sustainability
- factors related to technologies that are important for patients or healthcare professionals
- health inequalities
- accommodating people with specific clinical presentations.

Areas for more research

2.4.28 For technologies with a recommendation for more research (see section 2.4.20) or for use with evidence generation (see section 2.4.19), the uncertainties that the committee needs more data on to support future decision making should be listed. While the guidance can describe broader evidence that would be beneficial, the recommendations should focus on uncertainties that are essential to future decision making and are considered feasible to address.

Additional considerations

Phased rollout

2.4.29 If technologies are recommended for use in a large population, or if there are any other reasons why guidance may take longer to be implemented, the guidance may identify subgroups of the population to whom the technology could be offered initially as part of a phased rollout. This can be based on subgroups of the population for which the technology is recommended for use, for whom the clinical effectiveness or value for money of the technology is higher than for the overall population. When considering subgroups, the committee pays particular attention to its legal obligations with respect to legislation on human rights, discrimination and equality.

Rationale for recommendation for use

2.4.30 When 1 or more technologies are recommended for use, the guidance will set out the rationale for this, such as a description of the evidence and demonstrated performance that underpins the positive recommendation.

Updated versions of technologies

2.4.31 For technologies that are recommended for use that may undergo rapid iteration and multiple new versions after guidance is issued, guidance may indicate ranges or values for performance of technologies or impact on outcomes that need to be maintained for it to remain cost effective (see section 2.3.27).

3 Early-use HealthTech guidance assessments

Detail set out in this section supersedes NICE's early value assessment interim statement and covers early-use HealthTech guidance (previously called early value assessment [EVA]).

3.1 Background

3.1.1 Early-use assessments are an evidence-based approach designed to improve the care of people and effective use of NHS resources through quicker access to promising health technologies that address high unmet need for patients or the NHS. It champions stronger partnership working between regulatory, healthcare and research organisations to benefit people and better support innovators while ensuring value for money for the NHS.

3.1.2 There are 4 key aims of the early-use assessment approach:

- To focus on promising innovations that meet the needs and priorities of people, and the health and social care system.
- To enable earlier access to useful innovations through faster assessments and timely guidance production, while additional data is collected.
- To better support use of technologies and evidence generation by embedding early-use assessments in cross-partnership working.
- To realise the benefits of promising innovations and ensure value for money for the health and social care systems.

3.1.3 The aims will be achieved for selected technologies by:

- identifying available evidence
- exploring if the technologies have the potential to address the identified unmet need and offer value for money

- helping inform further evidence generation for future evaluations
- determining if any clinical, economic and system risk posed by early use can be managed and, consequently, if the technologies should be used while further evidence is generated.

3.2 Evidence

3.2.1 Section 2.2 describes the approaches for using evidence for HealthTech guidance assessments. Early-use assessments happen earlier in the lifecycle of a technology, so the evidence assessment has been adapted to reflect this.

Evidence identification

3.2.2 The aim of the evidence review is to identify the most relevant evidence relating to the decision problem defined in the scope. It is expected that the available evidence will vary substantially between topics and technologies. If no evidence is identified that is directly relevant to the decision problem, a broader evidence base should be considered. For example, evidence from the technology's use in a different population or setting.

3.2.3 Data on final outcomes may be limited so surrogate and intermediate outcomes should be considered. Supplemental searching and grey literature searching may also be helpful for technologies with limited published evidence. Broad evidence-mapping searches may need to be done to identify evidence on the technologies because articles may be published in less well-known journals, and studies may not be well indexed or may only be presented as conference abstracts. Companies and other stakeholders will be given the opportunity to provide evidence to NICE in response to an evidence request (see section 1.3.4). Published and unpublished studies provided by companies and other stakeholders should be considered.

3.2.4 Searches should also identify existing economic evaluations and resource and cost-impact analysis that addresses similar or related decision problems that may provide relevant information for the economic evaluation.

3.2.5 Searches for ongoing studies should also be done.

Evidence reviews

3.2.6 Pragmatic or rapid-review methodology and principles can be used in the literature review, with specific components of the systematic review process being either restricted or omitted. For example, the Cochrane Rapid Reviews Methods Group provides guidance on doing rapid reviews of the effectiveness of health interventions. Justification and rationale for this should be described in the assessment protocol, along with clear explanation of the components of the review process that have been restricted or omitted.

3.2.7 A full critical appraisal of all studies and outcomes is not expected. But the review should discuss the potential biases in key studies, how the risk of bias could affect key outcomes, and the generalisability of the results to clinical practice in the NHS.

3.2.8 The review should describe evidence gaps and suggest outcomes to focus on in future evidence generation, including those relating to patient safety. The report should describe any identified ongoing studies that may address the evidence gaps. It would also be beneficial to describe any data collections or real-world data sources that may address evidence gaps identified during the evidence review.

3.3 Economic evaluation

3.3.1 The economic evaluation that will be most beneficial for committee decision making is likely to vary by topic.

3.3.2 The key objectives of the economic evaluation are to:

- assess how well the technologies are likely to resolve the specified unmet need
- assess how likely the technologies are to offer value for money

- identify uncertainties that are likely to be key drivers of decision uncertainty.

3.3.3 The economic evaluation should ideally generate estimates of clinical and cost effectiveness, or cost comparison, from an economic model. The model should follow, as closely as possible, the modelling methods and exploration of uncertainty as described in sections 4.6 and 4.7 in NICE technology appraisal and highly specialised technologies guidance: the manual. Advice on approaches to follow can be found in the NICE Decision Support Unit's report on economic evaluation in NICE early value assessments. For example, making greater use of existing models or model outputs, or if these are not available then producing simplified models or reporting intermediate outcomes with threshold analyses.

3.3.4 There is likely to be less evidence and limited time to develop full new models for early-use assessments. So, it should be pragmatically decided how to provide analyses that inform considerations of how likely the technologies are to offer value for money. Analyses can be provided that may be considered more exploratory or based on larger assumptions than would usually be considered to support guidance for routine use of technologies. The economic evaluation should clearly describe the limitations of these analyses and the assumptions made for them. The committee can then decide to what extent it uses such analyses in its decision making.

3.3.5 Using expert elicitation or expert opinion should be considered to provide evidence to support economic evaluation work (see sections 3.3.21 to 3.3.23 of NICE technology appraisal and highly specialised technologies guidance: the manual).

3.3.6 The reference case is the same as described in section 4.2 of NICE technology appraisal and highly specialised technologies guidance: the manual. Additional analyses can be presented when 1 or more aspects of methods differ from the reference case. But these must be justified and clearly distinguished from the reference case. Intention to provide such analyses, for example, a non-reference case type of economic evaluation, should be discussed with NICE as early as possible.

3.3.7 The economic evaluation should highlight any potential impacts of technology use that are not captured in model results. This could, for example, relate to

impacts on the health and social care workforce or system efficiencies.

3.3.8 The economic evaluation should present any model outputs that show how well the technologies are likely to resolve the specified unmet need.

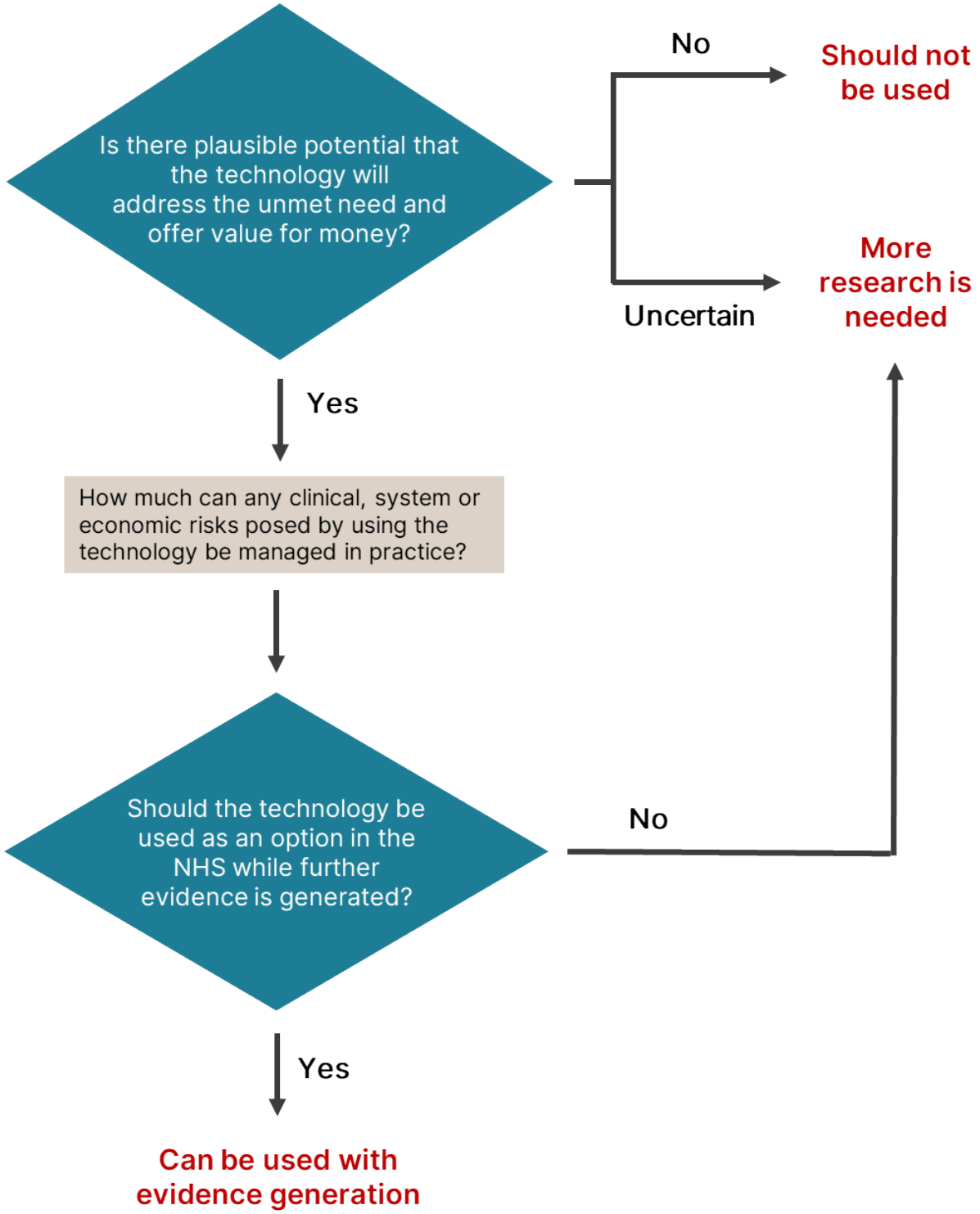
3.4 Decision making

3.4.1 Key goals for decision making in early-use assessments are to decide if technologies should be used as an option in the NHS while further evidence is generated and to prioritise uncertainties that need to be reduced by collection of further data to support future decision making. This evidence is for future NICE guidance to decide whether to recommend a technology for routine use.

3.4.2 Recommendations will only be for the use, or uses, of the technologies as specified in the scope.

3.4.3 When making decisions the committee will consider if a technology has plausible potential to address the specified unmet need and offer value for money. It will also consider how much any clinical, system or economic risks of using the technology could be managed in practice (further description is provided in sections 2.1.24 to 2.1.26). The flow chart in figure 1 describes how these considerations link to available recommendations.

Figure 1 Overview of decision making for early-use guidance



3.4.4 **Is there plausible potential that the technology will address the specified unmet need?** Considerations include the extent that this is supported by available evidence and other relevant information (including the views and experiences of people who will use the technology).

3.4.5 **Is there plausible potential that the technology offers value for money?** This consideration is based on assessing if the technology is expected to be cost effective, including providing similar or greater health benefits at similar or lower cost than the relevant comparator. Technologies considered unlikely to offer value for money typically would not meet this criteria. Considerations include:

- The likely size of any impacts of technology use (positive, including addressing the unmet need, and negative) on patients, and, when relevant, carers, the NHS and personal social services (including impacts on system efficiencies), and the extent that available evidence or other information supports this.
- Analyses done as part of the economic evaluation work to assess how likely the technology is to offer value for money.

3.4.6 **How much can any clinical, system or economic risks posed by using the technology be mitigated or managed in practice?** For example, by specifying how the technology should be used or whether provision could be made for special safety monitoring measures. Or, if there could be reductions in technology cost or alternative ways in which the technology is charged for, particularly if there are large irreversible costs associated with using it.

3.4.7 **Should the technology be used in the NHS as an option while further evidence is generated?** Important considerations include:

- the potential of the technology to address the specified unmet need and offer value for money
- the extent that any risks of using the technology in practice can be managed.

  If there are greater risks associated with early use (for example, substantial irreversible costs that cannot be recovered if a recommendation for use is later changed), there should be greater confidence that the technology is expected to offer value for money. The extent to which the identified uncertainties (see section 2.4.28) will be resolved by ongoing evidence generation activities (that is, that are occurring or will occur regardless of a NICE recommendation), the timescale for this and any possible impact of a recommendation on these activities should also be considered.

3.4.8 When multiple technologies are considered, each should be assessed independently, unless the committee believes it is appropriate for available data that has been generated using a technology to be used for others. The committee may need to consider any difference between technologies in terms of whether they may solve the specified unmet need and any differences in further evidence needs. Different recommendations can be made for different technologies included in the guidance.

Types of recommendations

3.4.9 **Use while further evidence is generated**

If there is plausible potential that the technology will address the unmet need and offer value for money, and that any economic, system or clinical risks posed by uncertainty in evidence can be managed, then the technology can be used in the NHS while further evidence is generated (during the evidence generation period) and be paid for using core NHS funding. Any identified measures for mitigating risks of using the technology are presented with the recommendation.

This recommendation needs to be accompanied by defined uncertainties that the committee considers are worthwhile and feasible to address by collecting further evidence during the evidence generation period (see section 2.4.28).

Technologies should only be used in the NHS during the evidence generation period if the evidence outlined in the evidence generation plan is being generated.

3.4.10 **More research is needed**

More research is needed before the technology can be used routinely or funded by the NHS. Access to the technology (for the use or uses assessed in the guidance) should only be through company, research or non-core NHS funding. This can be because it is too uncertain that the technology will address the unmet need or offer value for money.

3.4.11 **Should not be used**

If the technology will not address the unmet need or offer value for money. For example, because of how it functions, potential safety issues or based on available evidence on performance, particularly if it has a high cost.

3.4.12 For recommendations for use while further evidence is generated during the evidence generation period the uncertainties that the committee needs further data on to support future decision making should be listed and include a focus on those that:

- are essential to future decision making, and
- can be resolved in 3 years from the point of guidance publication (longer periods than this will only be allowed in exceptional circumstances).

3.4.13 Technologies recommended for use while further evidence is generated and that complete the evidence generation process (see section 1.7) can be re-evaluated by NICE (see section 1.8).

4 Existing-use HealthTech guidance assessments

Detail set out in this section supersedes NICE's late-stage assessment interim statement and covers existing-use HealthTech guidance (previously called late-stage assessment [LSA]).

4.1 Background

4.1.1 Existing-use assessments are designed to support procurement and commissioning decisions, promote effective use of NHS resources and improve care, through assessing a group of similar technologies that are already in established use in the NHS. Section 2.1.28 and table 2 describe general principles for existing-use guidance topics.

4.1.2 There may be uncertainty about whether price variation between similar technologies is justified. For example, whether differences between technologies resulting from continuous improvements or incremental innovations have produced real differences in patient or system outcomes. Existing-use assessments can help to determine whether these differences can justify any price variation. The assessments can also help identify factors that can inform decisions about which technology to purchase. This will help healthcare professionals, procurement services and commissioners to work together to make well-informed decisions. This will also ensure that effective technologies that are value for money are available for use while maintaining an appropriate level of choice in the system. This is in line with the 3 main objectives of the Department of Health and Social Care's medical technology strategy for the NHS to have the right product, at the right price, in the right place.

4.2 Scoping

4.2.1 The scope for existing-use assessments will follow the methods described in section 2.1, except that:

- Value propositions should focus on how the interventions within a group of technologies differ from each other and the potential impacts of these differences, such as on patient outcomes or healthcare resource use.
- Scoping may investigate the development history of product lines to determine the types of innovation that have occurred and the applicability of evidence from predecessor technologies (see section 2.2.8).
- Specific characteristics of the technologies being assessed can be identified, including any additional functions or features that may not be essential for use but are proposed to be beneficial. These can relate to clinical or system impacts and outcomes, but also potential impacts on the usability of a technology and patient experience.
- Technologies included in the scope of an assessment may be grouped according to shared features, functions or other characteristics. This may particularly be the case when what the technologies do or how they function are very similar or the same.
- The scope may not define a comparator because the assessed group of technologies (the interventions) is considered established practice. Comparisons are made between interventions.
- Outcomes related to the needs and preferences of patients and healthcare professionals for different technologies, or particular functions or features of technologies, may be useful for decision making for existing-use guidance and can be specified in the scope (see section 2.1.24).
- The scope may include relevant information on how technologies are currently provided to the NHS, for example procurement frameworks.

4.2.2 Scoping will identify the relevant user groups for user preference assessment and may outline potential methods for user preference assessment (see section 4.5).

4.2.3 Technologies in existing use are more likely to be present in registries or post-marketing surveillance datasets than newly available technologies. Scoping may identify real-world data sources that could support the evaluation.

4.3 Evidence

4.3.1 Section 2.2 describes the approaches for using evidence for HealthTech guidance assessments.

Evidence identification

4.3.2 The aim of the evidence review is to identify the most relevant evidence relating to the decision problem defined in the scope. It is expected that the available evidence will vary significantly between topics and technologies. If no evidence is identified that is directly relevant to the decision problem, a broader evidence base may be considered. For example, evidence from the technology's use in a different population or setting.

4.3.3 Post-market surveillance data and non-clinical technical assessments may be used, if appropriate, when topics have little or no evidence, or to complement published clinical evidence.

Evidence reviews

4.3.4 The approach to the evidence review is described in sections 2.2.6 to 2.2.15.

4.3.5 If agreed with NICE, pragmatic or rapid-review methodology and principles can be used in the literature review for existing-use guidance, with specific components of the systematic review process being either restricted or omitted. For example, the Cochrane Rapid Reviews Methods Group provides guidance on doing rapid reviews of the effectiveness of health interventions. Justification and rationale for this should be described in the assessment protocol, along with clear explanation of the components of the review process that have been restricted or omitted.

4.4 Economic evaluation

4.4.1 The economic evaluation that will be most beneficial for committee decision making is likely to vary by topic. See section 2.3 for full detail on economic evaluation.

4.4.2 The key objectives of the economic evaluation are to:

- estimate the relative cost effectiveness of available technologies, or groups of technologies with certain features, functions or other characteristics
- identify key uncertainties.

4.4.3 Exploratory analyses may be used to investigate the feasibility of justifications for price differences or to help identify areas for future evidence generation. For example, threshold or sensitivity analysis to investigate how changes in the effectiveness of technologies affect whether they represent good value for money at a given threshold (for example, £20,000 per QALY gained). The results of any such analyses should be clearly presented as exploratory, with appropriate reference to any uncertainty associated with the results. The committee can consider exploratory analyses in its decision making and decide on their appropriateness.

4.5 User preference assessment

4.5.1 Existing-use assessments evaluate technologies that are in widespread or established use. People are likely to have experience of using the technologies, so can provide insights into which factors are important to them when choosing which technology to use. This experience can be useful for committee considerations, especially when there is less evidence available to evaluate clinical and cost effectiveness. User preference assessment increases and enhances expert input into guidance production (see section 1.3.15).

4.5.2 Users are people whose experience with the technologies would allow them to make informed choices between different options. Ideally, they have experience of direct involvement in deciding to choose 1 technology over another. This could

include people who:

- have the condition that the technology is intended for (for example, people with a stoma choosing a colostomy bag)
- prescribe the technology (for example, a nurse choosing an appropriate wound dressing)
- use the technology frequently (for example, sonographers choosing an ultrasound machine).

The most relevant user group or groups for determining user preference will be identified during scoping. NICE aims for the sample of users to be as balanced and as representative as possible. Users are selected taking into account the NICE policy on declaring and managing interests for NICE advisory committees. Users are also selected based on their relevant experience, including experience of the assessed technologies, and can include experts selected to advise on other parts of the assessment.

4.5.3 Alongside the clinical and economic evaluation, additional information may be collected about factors that are important to users when selecting a technology. This information can be used to assess how well these factors are captured by the clinical and economic evaluation. A user preference assessment will involve user preference exercises and workshops. The objectives are to:

- identify users who are key decision makers when choosing a technology
- identify the key criteria that are important to users of the technology when deciding which technology to choose
- understand the importance of these criteria to users
- understand how users apply these criteria when choosing a technology
- identify how well the clinical and cost effectiveness evidence presented in the assessment report captures criteria that are important to users.

This assessment may be done by NICE or an external assessment group.

4.5.4 A user preference report will report the results from the user preference

assessment. The user preference report is subject to factual accuracy checking (see section 1.4.7). But the experts' opinions on what is important to them about the technologies cannot be considered factually inaccurate.

4.5.5 In addition to the user preference exercises and workshops described in section 4.5.3, other activities may be done to further explore factors that influence technology choice. These may include, but are not limited to:

- surveys of users or other groups of healthcare professionals or people with relevant experience
- reviews of literature which discuss relevant experience.

4.6 Decision making

4.6.1 The committee will apply the same considerations for decision making as described in section 2.4.

4.6.2 The committee can consider:

- if there are differences in clinical or cost effectiveness that can justify price variations between technologies
- factors not captured in the clinical evidence or economic modelling that could affect value, such as preferences identified through user preference assessments (see section 4.5)
- if more information is needed to help choose the most appropriate technology.

4.6.3 Recommendations will only be for the use, or uses, of the technologies as specified in the scope.

4.6.4 Recommendations may refer to individual technologies, or groups of technologies defined by having certain features or functions, depending on the approach defined during scoping (see section 4.2.1).

Types of recommendations

Table 6 Overview of recommendations in existing-use guidance

Recommendation type	What this means in practice
Should be used over other similar technologies in existing use in the NHS	There is enough evidence of clinical or cost effectiveness to recommend a technology over other similar options in existing use in the NHS. This may be only under specific circumstances, potentially related to a price that can be justified compared with other specified options.
What to consider when choosing between similar technologies in existing use in the NHS	There is not enough evidence of clinical or cost effectiveness to determine if any technologies can be recommended over other similar options or to determine whether or not price variations between these options are justified. There may be additional factors that could be considered when choosing a technology, which are specified in the recommendations.

4.6.5 **Should be used over other similar technologies in existing use in the NHS**
The committee will recommend that a technology should be used over other similar options available when it considers that there is enough evidence of clinical or cost effectiveness compared with these other options in existing use in the NHS. The committee may recommend that the technology should be used over other similar technologies only under specific circumstances, potentially related to costs that can be justified compared with other available options.

4.6.6 **Not enough evidence of clinical or cost effectiveness to recommend use over other options**
When the evidence of clinical or cost effectiveness is absent, weak or too uncertain, no technology will be recommended over other available options. It is not possible to determine from this evidence whether price variations are justified between different technologies. Committees will specify what should be considered when choosing between the available technologies, if it considers this appropriate. Considerations can be related to:

- price of the technologies and any additional costs associated with use, including a recommendation to use the least expensive option

- environmental sustainability
- factors related to technologies that are important for patients or healthcare professionals, including factors highlighted in the user preference report
- impact on health inequalities
- accommodating people with specific clinical presentations.

4.6.7 In exceptional circumstances, a should not be used recommendation may be made for technologies in existing-use guidance (see section 2.4.22).

4.6.8 Existing-use guidance can make research recommendations when further evidence will be useful to support future decision making (see section 2.4.28).

4.6.9 Recommendations may include additional factors that the committee agrees are important considerations related to the technologies. These can include, but are not limited to:

- specifying an appropriate range of technologies that need to be available
- providing information and guidance for procurement and commissioning, people with the condition or healthcare professionals
- guidance on the basic requirements for a technology.

Update information

December 2025: This manual has been updated to include the resolution process, which was previously described in NICE technology appraisal and highly specialised technologies guidance: the manual.

October 2025: This manual has been updated to include approaches for developing guidance for HealthTech products already in existing use within the NHS. This replaces the late-stage assessment interim process and methods statement.

For medtech and diagnostics guidance that started development before 14 July 2025, the pre-July 2025 version of the NICE health technology evaluations manual (PMG36) applies.

For early-use guidance that started development before 14 July 2025, the NICE early value assessment interim statement applies.

For existing-use guidance that started development before 23 October 2025, the NICE LSA interim process and methods statement applies.

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