

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interim methods and process statement for late-stage assessment

1 Introduction

- 1.1 Late-stage assessment (LSA) forms part of NICE's new lifecycle approach to technology evaluation, that ensures NICE can look at any technology at any stage across the product lifecycle. This statement describes the interim methods and processes to support the approach to LSA launched in October 2023. It describes the differences to NICE's existing methods and processes and should be read alongside the relevant sections of [NICE's health technology evaluations manual](#).
- 1.2 Learnings from the initial assessments will inform the final design of LSA, which will then be published in a final manual after consultation.

Rationale

- 1.3 Both patients and healthcare professionals can benefit from having a range of technologies to choose from. The Medicines and Healthcare Regulatory Agency (MHRA) has over 3 million different technologies registered for use in the UK, with around 500,000 regularly used in the NHS. The [Department of Health and Social Care's \(DHSC\) MedTech Strategy](#) outlines in detail the benefits and challenges with product choice in the NHS. The main challenge for the UK health and care system is intelligently exercising choice across such a diverse range of products and innovations in a way that maximises value for money, where patient outcomes are a fundamental component of that value.

- 1.4 LSA aims to assess technologies that are in widespread or established use in the NHS to support procurement and commissioning decisions. Products within a category may have undergone continuous improvement or incremental innovation, leading to price variation. The [DHSC medical technology innovation classification framework](#) defines different forms of innovation. LSA will assess if the value added by incremental innovation justifies the price variation. This will involve capturing the product features most relevant to users and NHS healthcare providers, and evaluating how they impact outcomes and user preferences. These product features can include basic product specifications and features that add value. This will help procurement services and commissioners to make well-informed decisions and ensure that effective technologies are available for use while maintaining choice in the system.
- 1.5 Existing procurement and commissioning decisions and frameworks will contribute to the scoping and decision-making process.
- 1.6 LSA will consider affordability to the NHS. This will take into account factors affecting the NHS such as the predicted net budget impact, policy and procurement strategies.

2 Stakeholder involvement and responsibilities

Involvement and participation

- 2.1 Many groups and individuals take part in developing guidance within NICE and externally. The groups and their roles are summarised in [section 1 of NICE's health technology evaluation manual](#).

- 2.2 Participants will have roles and responsibilities as described in [section 1 of NICE's health technology evaluations manual](#), except for the differences described in sections 2.3 to 2.5.
- 2.3 Companies will be asked to provide summary information on their technologies and related evidence in a request for information document. This is to inform scoping and to be used by the external assessment group (EAG) in developing the external assessment report. Companies may also be asked to supply information to support the assessment of their technology against user preference (see sections 4.26 to 4.34).
- 2.4 Companies will also be invited to take part in the scoping process. This can include being invited to a scoping workshop, to provide feedback during scope consultation and providing clarity on information the company provides to the NICE team.
- 2.5 Topic-specific patient experts, clinical experts and specialist committee members will be selected alongside standing committee members for each LSA topic. They typically include clinicians or researchers using the technology or practising in the care pathway, as well as people with lived experience with a perspective on the condition and experience of using the technology being considered, such as patients, carers or patient and carer organisations. Experts and specialist committee members may also be asked to provide information about user preference as described in section 4. NICE aims to select a range of experts and specialist committee members with experience covering a wide range of technologies in the assessment. Both experts and specialist committee members are selected, taking into account the NICE policy on declaring and managing interests for NICE advisory committees.
- Specialist committee members have the same decision-making role as standing members of the committee. Any reference to

the committee includes the specialist committee members.

Specialist committee members are recruited in accordance with the appointments to advisory bodies policy and procedure.

- For LSA, additional expertise may be needed and selected, for example, procurement, commissioning and technical experts. These experts are not involved in the committee decision making.
- NHS Supply Chain will be asked for topic-related information about the technologies and their use, including the respective procurement frameworks and processes when appropriate.
- NICE can invite commissioning and procurement experts from NHS England, NHS Supply Chain, integrated care boards (ICBs) or other relevant national and local commissioning and procurement organisations to help clarify issues about the scope and submitted evidence. They may be asked to provide advice before, during and after committee meetings on different aspects including:
 - their views and experiences of the technology
 - the condition and care pathway
 - considerations about how the technology could be delivered in the NHS
 - when treatment eligibility criteria may be used in the NHS for high-cost treatments
 - aligning with procurement and commissioning decisions in the NHS.

3 Late-stage assessment timelines

- 3.1 The LSA timelines are expected to range between 6 and 9 months. The length of time needed for each stage can vary depending on the nature of the topic and the assessment. Timelines may be amended during the LSA.

- 3.2 Throughout the LSA, up-to-date information about timelines will be published on the NICE website. Registered stakeholders will be informed about timeline changes.

4 Interim methods and process

Topic choice

- 4.1 The topics will be selected in collaboration with the Department of Health and Social Care (DHSC). The technologies considered for LSA are expected to have:

- high annual cost to the NHS (based on the technologies being procured at high cost, or low cost and high volume)
- existing procurement framework for the category in the NHS
- price variation between technologies in the market
- incremental innovation and performance claims that may have led to incremental price increases.

Scoping

- 4.2 Technologies selected for LSA will be scoped in line with sections on medical technologies and diagnostic technologies in [section 2 of NICE's health technology evaluation manual](#). Changes to the scoping process for LSA include:

- Consultation on the scope will take 7 days and will be followed by a scoping workshop. The scoping workshop gives stakeholders the opportunity to provide detailed input about the decision problem such as the care pathway, the clinical and economic evidence base.
- The scope can include details of the innovative aspects of the technologies and their evaluation (see section 4.19). It can also present information on patient and carer views, current commissioning and procurement in the NHS and related issues.

- The scope can include the technology features, regulatory approvals and outcomes that could be used to determine comparability in terms of clinical effectiveness in the economic evaluation (see section 4.22).
- The scope can state user preferences.
- Determining user preferences may form part of the discussion at the scoping workshop (see section 4.26).
- When technologies have multiple uses or indications, the most relevant use will be defined in scoping.
- The quality and quantity of evidence is expected to vary by LSA topic. To investigate the evidence NICE will do scoping searches to support scope development. These complement the literature searches done during the formal EAG review (see sections 4.5 to 4.13).

4.3 The scoping searches and company information will be used to determine whether there are existing economic models that can inform, or be an appropriate base for, the economic evaluation, such as models developed for the NHS using data from a UK setting. The searches will also scope the available clinical evidence. This will guide further methodological considerations, including those for the economic evaluation, as detailed in the protocol and the assessment (see sections 4.7 and 4.19).

4.4 The scoping searches, along with stakeholder advice, can also identify relevant UK-based registries that may be able to provide data to inform the assessment.

Evidence

4.5 NICE considers all types of evidence in its evaluations as outlined in [section 3 of NICE's health technology evaluation manual](#). This includes evidence from published and unpublished data, data from non-UK sources, databases of ongoing clinical trials, end-to-end

studies, conference proceedings, and data from registries, real-world evidence and other observational sources. The aim of the evidence review is to identify the most relevant data and evidence relating to the decision problem. Evidence identified will be used to adapt and populate an existing economic model or develop a new model as discussed in section 4.14 to 4.25.

- 4.6 In addition to the evidence types described above, technical evidence, post-market surveillance data and technical assessments may be used when topics have little or no evidence, or to complement published clinical evidence.
- 4.7 The EAG will develop an assessment protocol from the final scope of the evaluation. The assessment protocol outlines what the EAG will do during the evaluation and the information it will provide in the external assessment report. Examples of information in the protocol include:
- the approach to the evidence review, including the review of company-provided information
 - search strategies and data requests
 - inclusion and exclusion criteria
 - quality assessment and critical appraisal strategies
 - methods of analysis or synthesis
 - the approach to the economic modelling.
- 4.8 The evidence reviews may be done using pragmatic approaches when appropriate. Rapid review methods could include, but are not limited to:
- single screening and data extraction
 - searching a limited selection of databases
 - umbrella reviews, that collate evidence from other existing reviews.

- 4.9 When there is a large amount of relevant evidence to present during the assessment stage, the EAG can prioritise the studies or data it considers most valid and relevant to the decision problem presented in the scope. Specific details of the prioritisation approach will be adapted to the needs of the topic and the evidence available. Along with relevance to the decision problem, the relevance of evidence related to earlier versions of the technologies should be considered.
- 4.10 Updating existing systematic reviews and meta-analyses may be done if appropriate. 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. This will be based on the level of similarity between the original and new scope, protocols and methods. Examples of elements that can be considered for reuse include:
- literature searches and literature search results
 - evidence tables for included studies
 - critical appraisal of included studies
 - data extraction and meta-analysis
 - previously identified information on equalities and health inequalities.
- 4.11 A quantitative meta-analysis (including network meta-analysis) may be done if relevant and appropriate. Published meta-analyses may be described and used if available and appropriate. More detail on meta-analyses can be found in [section 3 of NICE's health technology evaluation manual](#).
- 4.12 Critical appraisal of key studies will be done in accordance with [section 3 of NICE's health technology evaluations manual](#). Real-world evidence should be critically appraised as described in [NICE's real-world evidence framework](#). The critical appraisal will

focus on studies that report key outcomes relevant to the decision problem. Quality assessment using validated checklists will be done for pivotal clinical studies, systematic review or meta-analysis, and key economic studies. The quality and reliability of the studies in the evidence base will be summarised and reported. For example, the potential main sources of bias and comments on the generalisability (external validity) of the results to clinical practice in the NHS.

4.13 The evidence assessment processes will include:

- an EAG producing an assessment report for the LSA projects
- stakeholder and specialist committee members being invited to comment on the assessment report, with a focus on factual accuracy, before the committee discussion
- stakeholders being informed of the dates of any comment period before documents are released.

Economic evaluation

4.14 LSA will aim to include an economic evaluation to assess the economic case for the technologies. The approach to economic evaluation will be tailored to the topic to account for the specifics of the clinical area, available data and previous technology evaluations. Proposed analyses will be discussed and agreed between the NICE team and the EAG after the scope has been finalised to inform development of the protocol for the assessment (see section 4.7). More detail on approaches can be found in [section 4 of NICE's health technology evaluation manual](#).

4.15 The objectives of the economic evaluation are to:

- when feasible and appropriate, develop an economic evaluation that represents current practice, based on national guidance and policy, real-world experience and recent data

- assess the potential benefits of individual technologies or relevant features, to determine whether the differences in outcomes and costs between technologies represent value for money to the NHS
- identify the key cost drivers and uncertainties of the economic evaluation.

- 4.16 The reference case will be the same as described in section 4.2 of NICE's health technology evaluation manual. In some circumstances deviation from the reference case will be considered, to better inform decision making in the NHS. Deviations will be specified and justified, and the likely implications quantified. The committee will discuss the weight it attaches to results of non-reference-case analyses.
- 4.17 The willingness-to-pay threshold will remain the NICE reference case of £20,000 per QALY gained in the base case. Further analysis to inform decisions on affordability may be done when necessary.
- 4.18 The comparator for the economic evaluation will depend on the specifics of the topic area, and will be chosen by the EAG.
- 4.19 Models are needed for most economic evaluations. If a relevant economic model is identified at scoping (see section 4.3), the EAG will independently verify its suitability. The EAG can make structural and parameter changes to optimise an existing model. If a pre-existing model is not identified, the EAG will develop a de novo economic model in line with [section 4.6 of NICE's health technology evaluation manual](#).
- 4.20 The EAG can refer to economic models submitted by stakeholders. An economic model submitted by a company cannot be used directly for the economic evaluation but may be used to inform the EAG's model.

- 4.21 Feedback on the economic model can be given when the external assessment report is consulted on. An executable version of the economic model can be made available on request to stakeholders who have signed a confidentiality agreement (see [section 5.4 of NICE's health technology evaluation manual](#)).
- 4.22 When it can be reasonably assumed that technologies are comparable in terms of clinical effectiveness, a cost-comparison approach may be used. For example, if expert experience suggests that their usability is comparable, or evidence from the EAG's clinical review indicates high likelihood of similar clinical effectiveness. Limitations and assumptions should be clearly stated. Cost-comparison analysis is more likely to be appropriate when technologies with few or no distinct features (as determined during scoping) are assessed. Further information on cost-comparison analyses can be found in sections 4.2.18 to 4.2.21 of NICE's health technology evaluation manual.
- 4.23 When the clinical data for decision making is particularly limited, a summary of all relevant costs, that can include maintenance, training, implementation and disinvestment, can be produced. Expert opinion or expert elicitation on the clinical effectiveness and resource impact of technology features or a technical assessment can be reported. Where the elicited data is to be quantitative, preference should be given to formal elicitation techniques (see section 3.3.21 to 3.3.23 of NICE's health technology evaluation manual). A conceptual model may be developed to identify key drivers for showing additional value. A full economic evaluation may not be possible.
- 4.24 When evidence for some technologies is limited, a summary of the available evidence may be used to inform assumptions made in economic modelling.

- 4.25 Guidance for presenting data and results of models is described in section 4.10 of NICE's health technology evaluation manual. Outputs of models should be presented to easily allow users to validate model results. The extent of work done to validate model outcomes should be described.

User preferences

- 4.26 Alongside the assessment of a technology's value based on costs and effectiveness, the committee will consider user preferences that influence decision making when selecting which technology to use.
- 4.27 LSA evaluates technologies later in the life-cycle, in the post-market surveillance stage. This means that they are embedded in practice, there may be more copycat technologies, more users of the technologies and more collective experience among the users in making decisions about which technology to select among the available alternatives. So, users of these technologies can comment on the importance of characteristics or features of these technologies that may not be captured elsewhere in the evidence base.
- 4.28 The aim of capturing user preferences is to transparently collect and present information to the committee on the criteria that users consider important when deciding which technology to choose. Users are defined as those who will use the technology and are directly involved in the decision to choose one technology over another.
- 4.29 Capturing user preferences aims:
- to identify the key criteria that are important to users of the technology to make a decision on which technology to choose,

to understand the importance of these criteria to the users, and how performance against these criteria would be measured

- to provide information to the committee on how the technologies in the assessment meet the criteria and provide transparent documentation of this process, highlighting areas of uncertainty to inform committee decision making.

4.30 Capturing user preferences will not replace or supersede the outcome from the health economic evaluation, when applicable it will complement it. The output will be used as described in sections 6.2.7 and 6.2.8 in NICE's health technology evaluation manual.

4.31 The process has been designed with MCDA principles ([ISPOR Task Force Report, 2016](#)). When appropriate, the process will include:

- identifying users who are key decision makers when choosing a technology
- identifying and defining criteria
- criteria ranking and weighting
- development of the performance matrix
- technologies, or features of technologies, assessed against the performance matrix
- reporting.

4.32 Companies will be asked to supply information to support the assessment of their technologies against the performance matrix, if applicable. The performance of the technologies against the performance matrix will be reported. This will give an indication of how the technologies, or features of technologies, perform in each of the criteria, and how important these criteria are to the users.

4.33 The following will be included in the report to indicate the level of uncertainty:

- participation with each stage in the process
- heterogeneity in users' responses to the ranking and weighting exercises (if applicable)
- heterogeneity between and within different user groups (if applicable)
- any conflicts of interests of users, which will be handled in the same manner as interests for all experts, taking into account the NICE policy on declaring and managing interests for NICE advisory committees.

4.34 The user preference report will be published alongside the assessment report to allow companies to collect evidence on how their technologies address user preferences. The output is not a substitute for standard criteria that are already used in the existing procurement framework for the category. Instead, it may be used to complement these criteria.

Committee recommendations

4.35 The recommendations and rationale may include:

- whether the technologies can be considered clinically comparable
- whether price variations are justified by differences in clinical effectiveness
- key economic and clinical outcomes that could justify price variation
- key user preferences and technical requirements not captured in economic modelling that could justify price variation.

4.36 The recommendations and rationale may:

- state the level of clinical effectiveness or cost at which a technology would become cost effective

- describe affordability considerations, based on factors affecting the NHS such as the predicted net budget impact, policy and procurement strategies
- describe procurement and commissioning considerations
- highlight uncertainties in the evidence that could justify price variation, and be addressed by further data collection to improve future decision making.

Committee decision making

4.37 The committee considerations include:

- assessing clinical, user preferences and technical requirements pricing and NHS budget impact
- other potential impacts on the healthcare system
- patient and carer views on the condition and experience of using the technology
- equality issues
- the uncertainty and quality of the evidence.

4.38 The committee can consider budget impact analyses when exploring the level of decision-making uncertainty associated with the technologies being assessed.

4.39 Further detail on how committee should reach its decisions can be found in [section 6 of NICE's health technology evaluation manual](#).

Developing and finalising the guidance

4.40 NICE will consult on draft guidance as outlined in [sections 5.8.44 to 5.8.63 of NICE's health technology evaluation manual](#).

Stakeholders will have 14 days from the date of sending to submit comments on the draft guidance.

4.41 Based on the consultation comments received, the chair can decide whether another committee meeting is needed.

- 4.42 The guidance will then be finalised as outlined in sections 5.8.64 to 5.8.69 and 7.2 of [NICE's health technology evaluation manual](#), including the resolution process.

Updates to this interim methods and process statement

- 4.43 After completing the LSA topics, the final methods and processes will be consulted on, and then included in NICE's methods and processes manuals.