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NICE National Institute for Health and Care Excellence

NICE health technology evaluations: the manual

NICE process and methods

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This corporate replaces PMG40.

Introduction to health technology evaluation

This guide describes the methods and processes, including expected timescales, that NICE follows when carrying out health technology evaluations. 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 development should read this manual in conjunction with the NICE-wide topic prioritisation process. All documents are available on the NICE website.

Health technology evaluations are developed by NICE's Centre for Health Technology Evaluation. This manual describes the methods and processes used for developing guidance in the:

- Diagnostics Assessment Programme
- Medical Technologies Evaluation Programme
- Highly Specialised Technologies Evaluation Programme
- Technology Appraisal Programme.

The health technology evaluation methods and processes are designed to provide recommendations, in the form of NICE guidance, on the use of new and existing medicines, products and treatments in the NHS. Health technologies include:

- medicinal products
- medical devices
- diagnostic techniques
- digital products
- surgical procedures or other therapeutic techniques

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- therapeutic technologies other than medicinal products
- systems of care
- screening tools.

Some of these technologies will also be considered by other programmes within NICE, such as NICE guidelines or the Interventional Procedures Programme, or will have medicines and prescribing support from the Medicines and Technologies Programme. This manual relates only to technologies evaluated through the health technology evaluation programmes.

To support the robustness of NICE's processes, all health technology evaluation programmes and processes comply with the principles underpinning the UK government's review of quality assurance of government models (the Macpherson recommendations). The director of the Centre for Health Technology Evaluation has overall responsibility for assuring the quality of models developed in the director's areas of responsibility. Model quality is assured through the requirements for evidence submission development and the process used to involve stakeholders in testing the reliability of models.

NICE is committed to advancing equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics and society as a whole, and to complying with its legal obligations on equality and human rights. NICE's equality scheme describes how NICE meets these commitments and obligations.

In formulating its recommendations, NICE's independent committees will have regard to the provisions and regulations of the Health and Social Care Act 2012 relating to NICE. The committees will also take into account NICE's social value judgements: principles for the development of NICE guidance. This document, developed by NICE's Board, describes the principles NICE should follow when designing the processes used to develop its guidance. In particular, it outlines the social value judgements that NICE and its advisory bodies, including evaluation committees, should apply when making decisions about the effectiveness and value for money of interventions.

Service-level agreements are in place to help disseminate NICE technology evaluation guidance in the devolved administrations in Wales and Northern Ireland.

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Diagnostics Assessment Programme

The Diagnostics Assessment Programme evaluates diagnostic technologies. It is responsible for evaluating diagnostic tests and technologies when such evaluation is complex, for example, if recommendations can only be made on the basis of clinical utility and cost-effectiveness analysis or if meaningful assessment requires the consideration of multiple technologies or indications. The Diagnostics Assessment Programme evaluates diagnostic technologies that have the potential to improve health outcomes but whose introduction is likely to be associated with an overall increase in cost to the NHS. The Diagnostics Assessment Programme also evaluates diagnostic technologies that may offer similar health outcomes at less cost, or improved health outcomes at the same cost as current NHS practice.

The programme evaluates diagnostics that are intended for use in the NHS in England and are paid for by the NHS with public funds, either in part or in whole.

The aims of the programme are to:

- promote the rapid and consistent adoption of innovative clinically and cost-effective diagnostic technologies in the NHS
- improve treatment choice or length and quality of life by evaluating diagnostic technologies that have the potential to improve key clinical decisions
- improve the efficient use of NHS resources by evaluating diagnostic technologies that have the potential to improve systems and processes for the delivery of health and social care.

Medical Technologies Evaluation Programme

The Medical Technologies Evaluation Programme evaluates new or innovative medical technologies (including devices and simple diagnostics). It aims to help the NHS adopt efficient and cost-saving medical devices and simple diagnostics more rapidly and consistently. This supports innovation and transformation and improves healthcare delivery.

The programme looks at medical technologies that:

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- deliver treatment – like those implanted during surgical procedures
- give greater independence to patients
- detect or monitor medical conditions.

The Medical Technologies Evaluation Programme uses a cost-minimisation approach to assess products. This approach considers the costs and resource consequences resulting from, or associated with, the technology under evaluation and comparator technologies. It considers clinical benefits (for example, effectiveness outcomes) alongside the cost analysis.

Technology Appraisal and Highly Specialised Technologies Programmes

The Technology Appraisal and Highly Specialised Technologies Programmes appraise technologies using clinical utility and cost-effectiveness analysis. The process normally covers new technologies (typically, new pharmaceutical products or new licensed indications) and enables NICE to produce guidance soon after the technology is introduced in the UK.

These programmes have a range of processes available:

- the single technology appraisal process (this is the most commonly used process across the programmes and is used for the first assessment of a technology and updates to existing guidance)
- the multiple technology appraisal process
- cost comparison
- rapid review
- update after loss of market exclusivity of a technology.

For the Technology Appraisal and Highly Specialised Technologies programmes, the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 indicate that NICE may make a recommendation:

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- in relation to a health technology identified in a direction by the secretary of state
- that relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients.

The Health and Social Care Act 2012 describes NICE's general duties as follows: 'In exercising its functions NICE must have regard to:

- the broad balance between the benefits and costs of the provision of health services or of social care in England
- the degree of need of persons for health services or social care in England, and
- the desirability of promoting innovation in the provision of health services or of social care in England.'

The regulations require clinical commissioning groups, NHS England and NHS Improvement, and, with respect to their public health functions, local authorities, to comply with NICE technology appraisal guidance that recommends the relevant health service body provides funding within the period specified. When NICE recommends that a treatment be funded by the NHS, the regulations require that the period within which the health service must comply will be stated in the recommendations as 3 months, except when particular barriers to implementation within that period are identified (see section 5.10 on varying the funding requirement). NICE provides advice and tools to support the local implementation of its guidance. This includes resource impact tools or statements for most technology appraisals and additional tools for some technology appraisals.

Further information and advice

Committees and stakeholders should refer to this manual throughout evaluations.

NICE also has additional resources and advice to help stakeholders and committees apply the methods and use the programme manual. Committees and stakeholders are encouraged to refer to these resources when helpful, but they are not bound by them and may depart from the information and advice if they consider it appropriate.

Similarly, the Decision Support Unit produces a series of technical support documents, which provide further information on technical aspects of health technology evaluations.

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Other resources are available on the NICE website, including:

- the following webpages, which provide more information about each programme, including submission templates:
  - Technology Appraisals Programme
  - Medical Technologies Evaluation Programme
  - Diagnostics Assessment Programme
  - Highly Specialised Technologies Programme
- the NICE real-world evidence framework
- the principles that guide the development of NICE guidance and standards
- Patient Access Scheme Liaison Unit
- Into practice guide
- Resource impact of NICE guidance
- NICE equality scheme.

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How to use this manual

This manual explains how NICE does health technology evaluations. It includes both the processes we use – that is, what steps happen, when, and who is involved – and the methods – that is, how different types of evidence are collected and considered, and the principles and considerations that go into making recommendations. The processes and methods are presented throughout the manual, to show what happens and how throughout the evaluation process.

You can use this manual to find out how health technology evaluations happen either by reading it in full, or by exploring particular sections to find out in detail what happens at a particular stage, for a particular participant or for a particular type of evidence. The following sections describe where particular information can be found.

What the manual contains

This manual has 8 chapters:

1. Involvement and participation

- Describes who is involved in health technology evaluations, at different stages, and how they participate.

2. The scope

- Describes how we develop the scope for an evaluation – that is, what question it will answer, and what will and will not be included.
- Includes the steps that happen during the scoping stage, and what the scope document contains.

3. Evidence

- Describes the principles for how different types of evidence are collected, presented and considered.

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- Includes all types of evidence (such as randomised controlled trials, non-randomised evidence, diagnostic test accuracy, qualitative research and expert evidence), as well as how evidence is combined (or 'synthesised') from multiple studies or sources.

4. Economic evaluation

- Describes the methods for evaluating the costs and benefits of health technologies in an economic evaluation, to understand its value for money.
- Includes different types of economic evaluation, including cost–utility analyses (which consider costs and health benefits measured using quality-adjusted life years) and cost-comparison analyses (which consider only the costs and effects on NHS resources).
  - Where the manual refers to multiple programmes, the term 'value for money' has been used as a generic term to describe economic evaluation approaches.
- Presents NICE's preferred methods for economic evaluation (the reference case) and alternative methods (non-reference case), including which costs and benefits are included, how and over what period, how future costs and benefits are considered, methods for modelling and exploring uncertainty, and how the results should be presented.

5. Developing the guidance

- Describes the processes for making guidance.
- Includes the steps involved in the evaluation from start to finish, how information and evidence is collected, reviewed and handled, how committee meetings work, and the steps involved in commercial and managed access discussions in evaluations.

6. Committee recommendations

- Describes the methods that committees use to reach decisions and make recommendations.
- Includes how committees assess the strengths and limitations of evidence, the factors, considerations or 'modifiers' they take into account, and how they reach a decision based on the evidence.

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7. Finalising and publishing the guidance

- Describes what happens after a recommendation is made, in order to complete the evaluation and publish the guidance.
- Includes the opportunities to challenge diagnostic and medical technologies guidance (termed 'resolution'). Appeals for guidance with a funding requirement are presented in the guide to the technology appraisal and highly specialised technologies appeal process.

8. Guidance surveillance

- Describes how NICE monitors and reviews its guidance to make sure it is up to date, valid and accurate.

Where to find information

The following table details where to find commonly used information. It is not exhaustive, and you should refer to the whole manual for full details.

Where to find information in the manual

If you want to find out about…	Look in…
How to get involved in an evaluation, how to become an expert, what experts do	Chapter 1 – involvement and participation
How the scoping process works, what it includes, how to get involved, how scoping workshops work	Chapter 2 – the scope Section 2.4 – identifying stakeholders Section 2.5 – consultation on the draft scope Section 2.7 – The scoping workshop

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If you want to find out about...	Look in...
Who can submit evidence and how, and what types of evidence are considered	Principles and types of evidence: Chapter 3 – evidence How it is considered: Chapter 6 – (particularly sections 6.2 and 6.3) – committee recommendations Who can submit: Chapter 1 – involvement and participation
Economic evaluations – what they are, what they include, how they affect recommendations	Chapter 4 – economic evaluation Chapter 6 (particularly sections 6.2 and 6.3) – committee recommendations
How committees make recommendations, how they think about comparators, clinical and cost evidence, and additional factors ('modifiers')	Chapter 6 (particularly sections 6.1 to 6.4) – committee recommendations
The steps involved in an evaluation	Chapter 2 – the scope Chapter 5 (particularly sections 5.1 to 5.10) – developing the guidance
Confidential information – what is confidential and why, and how it is handled	Sections 5.3 and 5.4 – information handling
Managed access – what it is, how decisions are made, what happens after managed access	Section 6.4 – types of recommendation Section 5.6 – evidence review Section 5.9 – patient access schemes and commercial access agreements Chapter 8 – guidance surveillance Section 2.8 – scoping after managed access
What happens after an evaluation, and how NICE decides whether guidance needs to be reviewed	Chapter 7 – finalising and publishing the guidance Chapter 8 – guidance surveillance

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1 Involvement and participation

1.1 Introduction

1.1.1 Many groups and individuals take part in developing guidance within NICE and externally. The groups and their roles are summarised in participants of the technology evaluation process. NICE also invites evidence from a number of stakeholders, which can include:

- companies
- commissioning bodies
- clinical experts, commissioning experts and patient experts
- an external assessment group (EAG)
- healthcare professional organisations
- patient and carer organisations.

The following information details which groups take part in an evaluation, including who is invited to provide written or oral evidence.

1.2 Participants in the evaluation process

Committee

1.2.1 The committee considers and discusses the evidence for a technology. It is an independent standing committee that produces recommendations. NICE recruits committee members through open, competitive advertising and appoints members initially for 3 years. Committee members are from:

- the NHS

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- lay backgrounds (with an understanding of patient and public perspectives on healthcare)
- academia
- life sciences companies
- experts in regulation.

1.2.2 Full details of how NICE recruits members are in the recruitment and selection procedure for advisory bodies. NICE is committed to the values of equality, diversity and inclusion and welcomes applications for membership of the committee from all sectors of the community.

1.2.3 The diagnostics advisory committee recruits several specialist committee members alongside the standing committee members for each individual evaluation. They are committee members for that topic only. They typically include clinicians or researchers using the diagnostic technology or practising in the care pathway, as well as lay people with a perspective on the condition being diagnosed. Specialist committee members have the same decision-making role as standing members of the committee. Any reference to committee includes the specialist committee members.

1.2.4 Members will normally remain in the same committee for the duration of their membership. Sometimes members from one committee may be needed to join another committee. This is to ensure that a meeting is quorate, and that business can be done in line with the committee standing orders and terms of reference.

1.2.5 Although the committee seeks the views of organisations representing healthcare professionals, patients, carers, companies and government, its advice is independent. Names of committee members, standing orders and terms of reference of each committee are published on the NICE website.

Lead team

1.2.6 A lead team is selected from the committee members at the start of each evaluation. They work with the NICE team to guide the evaluation and present the

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topic to the committee. The lead team normally consists of 2 or 3 committee members who focus on clinical effectiveness, value for money or patient and carer evidence (called the lay lead).

The technical team

1.2.7 The technical team consists of the chair or vice chair of the committee along with the NICE team, which normally includes the associate director, the technical adviser and the technical lead.

1.2.8 The technical team is responsible for considering the evidence submissions and the external assessment report. It identifies and explores issues, comes to preliminary scientific judgements, and advises the committee in its discussion of the evidence.

1.2.9 The technical team will seek input from the lead team, the EAG, experts and committee members when appropriate.

Company

1.2.10 The company that holds the regulatory approval (marketing authorisation, UK Conformity Assessed or CE mark, or other equivalent regulatory approval or guidance issued by the regulator) for the technology being evaluated or its agents.

Clinical experts and patient experts

1.2.11 Clinical experts and patient experts are selected from those nominated by consultee organisations or by NICE, taking into account the NICE policy on declaring and managing interests for NICE advisory committees. Experts are invited to provide written evidence, clarify issues about the evidence base and participate in committee meetings. They may be asked to provide advice before, during and after committee meetings. References to clinical and patient experts means the specialist committee members for diagnostics evaluations.

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External assessment group

1.2.12 The EAG is an independent academic group that reviews the evidence including any stakeholder submissions and the clinical and cost effectiveness, or cost comparisons of the technology or technologies being evaluated. The EAG develops an external assessment report for the committee.

NHS commissioning experts

1.2.13 NICE invites NHS commissioning experts from NHS England and NHS Improvement and clinical commissioning groups (or other relevant commissioning organisations) to help clarify issues about the submitted evidence. They may be asked to provide advice before, during and after committee meetings about:

- their views and experiences of the technology
- the condition from an NHS perspective
- 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, or for technologies recommended with managed access.

NHS England and NHS Improvement national clinical lead

1.2.14 The NHS England and NHS Improvement national clinical lead (or a nominated deputy) for the clinical area relevant to the technology being evaluated is invited to provide an evidence submission and attend committee meetings for technology appraisal and highly specialised technology evaluations.

1.2.15 In some circumstances a national clinical lead is invited to attend the private session (part 2) of the committee meeting to discuss confidential information.

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Stakeholders

1.2.16 Stakeholders are organisations that have registered to participate in a technology evaluation.

1.2.17 NICE invites the following stakeholders (when relevant) to take part in the evaluation:

- the company that holds, or is expected to hold, the regulatory approval for the technology
- relevant comparator technology companies
- national organisations representing patients and carers
- organisations representing healthcare professionals
- the Department of Health and Social Care
- relevant healthcare representatives from the devolved nations
- NHS England and NHS Improvement as the commissioner for specialised services
- relevant NHS commissioning organisations
- a provider of NHS services
- any relevant groups developing clinical and social care guidelines, or public health guidance
- other related research groups (for example, the Medical Research Council and the National Cancer Research Institute)
- other groups (such as the NHS Confederation, the NHS Commercial Medicines Directorate, the Medicines and Healthcare products Regulatory Agency and the Academic Health Science Networks).

1.2.18 The following stakeholder groups, when relevant to the evaluation, are considered consultees and are invited to submit evidence and nominate clinical, patient and commissioning experts:

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- the company that holds, or is expected to hold, the regulatory approval for the technology being evaluated
- national organisations representing patients and carers
- organisations representing healthcare professionals
- clinical, patient and NHS commissioning experts
- the Department of Health and Social Care
- the Welsh government
- NHS England and NHS Improvement as the commissioner for specialised services (for relevant evaluations)
- clinical commissioning groups (or other relevant commissioning organisations).

NICE Decision Support Unit

1.2.19 The Decision Support Unit is commissioned by NICE to provide a research and training resource to support NICE's technology guidance programmes and the methods of evaluation.

Members of the public

1.2.20 Members of the public may:

- comment on draft guidance consultations
- apply to observe committee meetings as public observers.

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NICE staff

Centre director

1.2.21 The centre director is responsible for delivering all outputs of the Centre for Health Technology Evaluation and ensures that evaluations are done in line with the published process and methods.

Programme director

1.2.22 The programme director is responsible for all aspects of managing and delivering the evaluation work programme. The programme director works with the NICE sponsor branch at the Department of Health and Social Care and other national bodies, and with healthcare industry bodies. The programme director is responsible for signing off guidance at specific stages of an individual evaluation. The programme director is also responsible for ensuring that evaluations are done in line with the published process and methods.

Associate director

1.2.23 The associate director is responsible for leading the development of individual evaluations within the programme and has delegated responsibility, from the programme director, for approving documents at specific stages of an individual evaluation.

Technical adviser

1.2.24 The technical adviser is responsible for the technical quality of the evaluation. This involves providing advice on technical issues, and if appropriate, reviewing and quality assuring the work of the technical lead. The technical adviser also ensures a consistent approach is taken across the programme.

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Technical lead

1.2.25 The technical lead is the analyst responsible for the technical aspects of the evaluation, including liaising with the EAG and the company, scoping the topic, preparing drafts of guidance and advising the committee. There may be more than 1 technical lead for an evaluation.

Project team

1.2.26 The project team is responsible for planning individual evaluation timelines, ensuring the timelines and process are communicated and followed by all participants, and liaising with stakeholders and others contributing to the evaluation.

Communications lead

1.2.27 The communications lead is responsible for circulating and communicating the guidance to appropriate groups within the NHS in England, and to patients and the public, and companies.

Guidance information services lead

1.2.28 The guidance information services lead supports the technical lead during scoping. The information services lead gathers information on the technology and its evidence base to support the development of the scope. For some topics they will also track key information throughout the evaluation.

Editorial lead

1.2.29 The editorial lead is responsible for ensuring that guidance is clear and consistent. The editorial lead prepares the final versions of the guidance and information for the public.

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Public Involvement Programme (PIP) adviser

1.2.30 PIP is the team at NICE that supports and develops public involvement across NICE's work programme. The public involvement adviser works alongside the evaluation team to support the involvement of patients, carers, people who use services, and the organisations who represent them, throughout the evaluation. A public involvement adviser is assigned to each evaluation.

Commercial and Managed Access teams

1.2.31 The Commercial and Managed Access teams work with stakeholders during NICE's evaluation processes. They inform their commercial and managed access activities and enable timely discussions between NHS England and NHS Improvement and the company. This helps ensure timely guidance and patients' access to cost-effective technologies.

Resource impact lead

1.2.32 The resource impact lead works with the technical team, committee, the company and experts to produce guidance-related resource impact assessment tools. The tools consist of a resource impact report (which may be a short summary report) and template to help organisations assess the resource impact of implementing NICE guidance. If the resource impact is not expected to be significant, a resource impact statement is produced. The tools are subject to a limited consultation and are published at the same time as the guidance. The resource impact lead may also be involved at the topic selection stage.

Adoption lead

1.2.33 The adoption and implementation team produces an adoption report at the scoping stage for medical technologies and diagnostics guidance. The report is developed with NHS clinicians and focuses on the practicalities of adopting the technology. The report is shared with the committee when it drafts recommendations and is published as part of the committee papers.

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1.2.34 If needed, the team may also develop adoption support resources. They are developed with clinical experts, commissioners, patient and carer organisations and companies. They identify adoption barriers and solutions and describe the experiences of health and social care organisations.

1.3 How participants are involved

Companies

1.3.1 Companies are invited to submit evidence on the technology or technologies being evaluated. They should identify all evidence relevant to the evaluation, including all studies known to them, including clinical trials, follow-up studies and evidence from registries. The submission may include confidential study evidence that is not in the public domain. Companies should provide a summary of information for patients written in plain English using the template provided by NICE.

1.3.2 For evaluations to develop diagnostics guidance, companies are not formally invited to make an evidence submission but provide information requested on the evidence base and their technology to enable the EAG to develop the external assessment report.

1.3.3 At the earliest opportunity, NICE will ask companies for details of the studies they intend to include in their submission. If information is unpublished, companies should include the study reports.

1.3.4 In a single technology evaluation, the company must provide a systematic review of the clinical and cost evidence and an economic evaluation. Evidence requirements are explained in detail in the evidence section of this guide.

1.3.5 If an evaluation is updating guidance on a technology that was recommended with managed access, the company must also provide the evidence described in the published data collection agreement.

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Participation of company representatives at the committee meeting

1.3.6 Two representatives from the company (usually 1 with health economics expertise and 1 with medical expertise) for the technology being evaluated can attend the public session (part 1) of the committee meeting. The chair will ask them to respond to questions from the committee and comment on any matters of factual accuracy before concluding part 1. The chair may ask the representatives to remain for part of the private session (part 2) of the committee meeting, specifically to respond to questions from the committee about confidential information in the company's submission. Each representative must:

- be an employee of the company or have been involved in the company's evidence submission, or participated in the evaluation on behalf of the company when no company submission is needed
- have relevant detailed knowledge of the technology being evaluated
- be able to comment on the clinical effectiveness or value for money of the technology
- agree to be bound by the terms and conditions of NICE's confidentiality agreement
- be willing and able to discuss the condition and the technology with members of a large committee at a meeting where members of the public and press may be observing
- be familiar with the purpose and processes of NICE.

1.3.7 Company representatives will not receive any confidential appendix that the EAG creates for an evaluation with a comparator that has a confidential commercial arrangement.

Clinical experts, patient experts and commissioning experts

1.3.8 Clinical experts, patient experts and commissioning experts provide their views and experience throughout the evaluation. They help clarify issues that the technical team has identified, give written evidence, participate in any technical

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engagement (when needed), and attend the committee meeting (if required).

1.3.9 For diagnostics guidance, specialist committee members act as clinical and patient experts (but they do not give written evidence). Specialist committee members are recruited in accordance with the appointments to advisory bodies policy and procedure.

Expert nomination

1.3.10 Stakeholder organisations are invited to nominate clinical experts, patient experts and commissioning experts, which are then selected by NICE to contribute to the evaluation. NICE may also nominate clinical experts who have been involved in evaluations in related care pathways or who have relevant knowledge of using the technology.

1.3.11 Experts involved during scoping may be invited to continue participating during the evaluation. They do not have to continue to participate and there is still the opportunity for stakeholders to nominate alternative experts. All expert nominations have the same review and selection process.

1.3.12 The public involvement adviser can provide advice and support to patient and carer organisations when nominating experts. Patient and carer organisations may nominate both patient and clinical experts.

1.3.13 Professional organisations may nominate patient, clinical and commissioning experts for the evaluation.

1.3.14 For technology appraisals and highly specialised technologies guidance, NICE asks NHS England and NHS Improvement and 2 clinical commissioning groups selected at random to nominate NHS commissioning experts.

1.3.15 For diagnostics and medical technologies guidance, relevant NHS commissioners of the technology are invited to nominate NHS commissioning experts only if commissioning expertise is specifically needed or if the population is covered by an NHS England specialised commissioning group.

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1.3.16 The nominating organisation and the experts (clinical, patient or NHS commissioning) complete a nomination form that includes information on their experience and knowledge of the condition, experience of the technology, any conflicts of interest and any previous involvement with NICE.

Expert eligibility and selection

1.3.17 NICE selects experts from the nominations received and those invited to continue participation from scoping. Clinical and patient experts are chosen based on their experience of the technology and the condition that the technology is designed for. Selection takes into account NICE's policy on declaring and managing interests for committees. Ideally, the clinical and patient experts will have complementary rather than similar backgrounds and experiences. Clinical experts, patient experts and NHS commissioning experts must be able to meet the following requirements:

- They agree to be bound by the terms and conditions of NICE's confidentiality agreement.
- They agree to their name and affiliation appearing in the guidance documents.
- They have knowledge or experience of the condition, the technology being evaluated, or the way it is used in the NHS.
- They are willing and able to discuss the condition and the technology at a committee meeting when members of the public and press are observing.
- They are familiar with the purpose and processes of NICE (the public involvement adviser can give patient experts support so they can contribute to the evaluation and discussions at committee meetings).
- They are prepared to declare any interests they have in writing and at committee meetings.

1.3.18 Clinical experts must meet the following additional requirements:

- They are in active clinical practice and have specialist expertise in the subject area of the evaluation.

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- Their principal place of work is in the NHS.
- If they have acted as a clinical expert for the company, or the EAG, they agree to declare this in any submission and at committee meetings.
- They hold no official office (that is, no paid employment, unpaid directorship or membership of a standing advisory committee) with the company or any relevant comparator technology companies. However, there is discretion to invite an expert who holds official office when the work of the committee would be seriously compromised without their testimony.
- They are not under investigation by the General Medical Council, do not have interim restrictions placed on their practice, and have not been removed from the medical register.
- They are not under investigation for professional misconduct and have not been found to be in breach of appropriate professional standards by the relevant professional body.

1.3.19 Usually, a maximum of 2 clinical experts or 2 patient experts are selected for each evaluation. NHS commissioning experts are selected for technology appraisals and highly specialised technologies guidance and for other guidance when needed.

1.3.20 For diagnostic evaluations clinical and lay specialist committee members are recruited at the beginning of the evaluation process. Additional specialist committee members may be appointed after the final scope is published if gaps are identified in the knowledge and expertise needed by the committee. They may support the EAG on behalf of the committee during the evaluation. However, they cannot be appointed as advisers to the EAG so they can maintain sufficient independence from the evidence and contribute to the committee's discussions on the quality of the external assessment report and the development of guidance recommendations.

Expert participation in the evaluation

1.3.21 NICE asks experts to submit written evidence on the technology, the way it

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should be used in the NHS in England, and current management of the condition. If the clinical and patient experts choose to support their nominating organisation's written submission, they do not need to submit a separate statement. The committee uses these submissions in its discussion, and they are published as part of the committee papers.

1.3.22 Experts are invited to participate in technical engagement (if held) before the committee meeting. They are also expected to comment during part 1 of the meeting on the evidence in the written submissions, and to interact fully in the discussions with the committee, including responding to questions.

1.3.23 The experts' views shared at the committee meeting can:

- Identify important variations in clinical practice in managing the condition and in the current use of the technology, including:
  - geographical variations
  - identification of subgroups
  - constraints on local implementation
  - specific issues for implementation that affect patients and carers directly.
- Identify what support is needed to implement guidance on the technology, including:
  - extra staff or equipment
  - education and training for NHS staff and for patients on how to use the technology
  - special requirements in the community for patients and carers (for example, travel to hospital for treatment)
  - ways in which adherence to treatment can be improved.
- Give personal perspectives on the use of the technology and any difficulties, what benefits are important to patients and carers, and the range and significance of adverse effects.

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- Inform how response to the technology should be assessed and in what circumstances its use might be stopped.
- Identify subgroups of patients for whom the benefits and risks of the technology might differ.
- Respond to queries from the NICE technical team, lead team and issues raised by the chair and other committee members, the EAG, other experts, and responses from the company to questions.

1.3.24 The experts attend the committee meeting (if held) as individuals and not as formal representatives of their nominating organisation. NICE aims to select a cross-section of people from the nominations received, taking into account any declared conflicts of interest. For example, for patient experts, NICE would select a person with direct personal experience of the condition and, if possible, the technology, and a member of a patient, carer or professional organisation. The experts are asked to leave the meeting before the committee makes its decision and finalises the recommendations in the guidance in the private session (part 2) of the meeting, which is closed to the public.

1.3.25 Experts are not routinely invited to committee meetings for cost-comparison evaluations, and single technology appraisals and highly specialised technologies evaluations that are considered appropriate for a streamlined approach. For these, the committee decision can be taken outside of a formal meeting. Experts who have been selected to take part in the appraisal may be invited to contribute on a case-by-case basis if they are needed to address specific questions.

1.3.26 NICE publishes the names and affiliations of the clinical, patient and NHS commissioning experts and the NHS England and NHS Improvement national clinical lead (or their deputy) in the minutes of committee meetings.

1.3.27 It is important that there is enough expertise at all stages of the evaluation. NICE welcomes and values the input from all experts. Experts can opt out of attending a committee meeting if they feel their views are adequately reflected in the committee papers, key areas of uncertainty have been addressed, and their attendance would not add to the committee discussion.

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External assessment groups

1.3.28 NICE commissions independent experts from one of several EAGs to review and critique the available evidence for each technology under evaluation. They produce and are responsible for an external assessment report.

1.3.29 For a single technology evaluation, the EAG prepares a report that assesses the evidence and any evidence submissions. The EAG may recommend that NICE requests additional analyses from the company, may do additional exploratory analyses itself, or both.

1.3.30 For a multiple technology evaluation (including all diagnostic evaluations), the EAG creates a report that independently synthesises the evidence from published information and any evidence submissions about the clinical effectiveness and value for money of the technologies. In addition to a systematic review of the clinical and cost evidence, the external assessment report normally includes an economic evaluation and an economic model informed by a review of the evidence. Evidence requirements are explained in section 3.

NHS England and NHS Improvement (technology appraisals and highly specialised technologies only)

1.3.31 NHS England and NHS Improvement are invited to provide a written submission. It may also develop treatment eligibility criteria based on the licensed indication for the technology, clinical trial evidence, biological plausibility and treatment pathways. Treatment eligibility criteria are developed for highly specialised technologies, cancer, and high-cost technologies. NHS commissioning experts will include information about the proposed treatment eligibility criteria as part of their submission to NICE. When treatment eligibility criteria are not defined at the point of the evidence submission, NHS commissioning experts will explain in their submission what factors are being considered in the development of treatment criteria (for example, the presence of specific biomarkers).

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Patient and carer organisations

1.3.32 NICE invites written submissions from all patient and carer organisations involved in the evaluation to provide perspectives on:

- the experience of having the condition (before or after diagnosis) or caring for someone with the condition
- the experience of receiving care for the condition in the healthcare system
- the experience of having specific treatments or tests for the condition
- treatment outcomes that are important to patients or carers (which may differ from the outcomes measured in the relevant clinical studies and the aspects of health included in generic measures of health-related quality of life)
- the acceptability of different treatments and modes of treatment
- their preferences for different treatments and modes of treatment
- their expectations about the risks and benefits of the technology.

  If the technology was previously recommended with managed access, additional patient and carer perspectives could include:

  - whether and how the experience of living with the condition has changed with access to treatment during the managed access period
  - how the treatment of the condition in the NHS has changed since the original evaluation
  - the experience of having the technology during the period of managed access.

1.3.33 The information is best received directly from people with the condition (or their family or carers) as written accounts of their experiences and points of view. NICE's PIP team has a template for collecting patient and carer perspectives.

1.3.34 The committee is interested in a range of patient and carer perspectives, especially if there are differences of opinion.

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1.3.35 In the context of the evaluation, the committee is interested in any limitations in the published research literature identified by patient organisations. In particular, the extent to which patient-reported outcome measures, or other end points reported in clinical studies, capture outcomes that are important to patients. Patients may assess research-based evidence from a different perspective to researchers and clinicians and they may judge the evidence according to different criteria. Also, it is helpful to have the perspective of patients or carers about how relevant the clinical outcomes and the standardised generic instruments for measuring health-related quality of life (as specified in the reference case) are to the disease or condition.

Healthcare professionals and commissioners of health services

1.3.36 NICE invites submissions from all professional organisations and relevant NHS organisations involved in the evaluation, including:

- the Royal Colleges of the appropriate clinical disciplines
- the specialist societies of the appropriate clinical disciplines
- other appropriate professional bodies and NHS organisations including commissioners of NHS services.

1.3.37 Healthcare professionals and commissioners of health services provide a view of the technology in relation to current clinical practice. This puts into context the evidence from studies and will help to identify any differences in outcomes from the clinical trials to that achieved in routine clinical practice.

1.3.38 The written submissions provide a professional view of the place of the technology in current clinical practice and in the care pathway. This includes evidence that relates to some or all of the following:

- Variations between groups of patients, in particular different baseline risks of the condition and the potential for different subgroups of patients to benefit.
- Identifying appropriate outcome and surrogate outcome measures.
- Significance of side effects or adverse reactions.

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- The clinical benefits.
- Circumstances in which the technology or treatment is used, including:
  - the need for concomitant treatments
  - the settings in which technology is used (for example, primary or secondary care, or in specialist clinics)
  - the need for additional professional input (for example, community care, specialist nursing or other healthcare professionals).
- Relevant potential comparators.
- Information on unpublished evidence. Such information 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.
- Evidence from registries and clinical audit.
- Published clinical guidelines produced by specialist societies.
- The effect of potential guidance on how care is delivered.
- Education and training requirements of NHS staff.
- Patients who would use the technology.

If the technology was previously recommended with managed access, then the written submissions could include:

- experience of the technology during the managed access period
- how many patients had the technology and whether anyone declined treatment, and the reasons for this
- the variation between groups of patients who had the technology and the potential for different subgroups of patients to benefit
- expected use of the technology in clinical practice

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- any points of learning arising from the managed access period.

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2 The scope

2.1 Introduction

2.1.1 The scoping process aims to define what question the evaluation will answer and what will and will not be included. The scope provides the framework for the evaluation. It defines the issues for consideration (for example, population, comparators, care pathway, and outcome measures) and sets the boundaries for the work to be done by the external assessment group, and any evidence submissions for the evaluation.

2.1.2 The areas detailed in the scope include:

- the disease or health condition and the population(s) for whom the technology is being evaluated
- the technology being evaluated (and where it will be used, for example, in a hospital inpatient or outpatient setting, or in the community)
- the care pathway
- the relevant potential comparator technologies (and where they are used, if relevant)
- the principal outcome measures appropriate for the analysis
- the costs, including when the Department of Health and Social Care asks NICE to consider costs (or savings) to the public sector outside the NHS and personal social services
- the costs of any companion diagnostic needed for a treatment, if not in routine use
- the time horizon over which health effects and costs will be evaluated
- consideration of patient subgroups for whom the technology might be particularly clinically effective or value for money

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- issues relating to advancing equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with particular protected characteristics and society as a whole
- the remit of the evaluation for any technologies referred by the Department of Health and Social Care
- other special considerations and issues that are likely to affect the evaluation, for example, existing relevant NICE guidance and the innovative nature of the technology.

2.1.3 For new technology appraisals and highly specialised technologies guidance, scoping normally takes place during (and is used in) topic selection. For new medical technologies and diagnostics guidance, scoping takes place after topic prioritisation and the evaluation follows immediately after.

2.1.4 If the scoping process gathers additional information that suggests the topic should be evaluated by a different guidance programme, NICE may pause progression of the evaluation to request that the prioritisation board reconsider the routing decision (see the NICE-wide topic prioritisation process). Routing decisions are not subject to appeal.

2.1.5 For updates of published guidance, the process starts with the scoping stage and the evaluation follows immediately after.

2.2 Components of the scope

Background information on the disease or health condition

2.2.1 The scope briefly describes the condition relevant to the technology being evaluated, with information on its prognosis, epidemiology and standard care or alternative technologies used in the NHS.

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The technologies

2.2.2 The scope includes information about the regulatory approval of the technology, and the stage of approval for technologies that have not yet received approval. The scope specifies how and in what circumstances technologies are used, particularly if this is different from that of alternative technologies or standard care for the same patient group, or when there are several other circumstances in which the technology may be used.

2.2.3 The technology may have multiple uses. For medicines, the relevant use will normally depend on the (expected) marketing authorisation or marketing authorisation extension. For other types of technology, the most relevant use (within the intended purpose or specified indications for use) is notified to NICE and included in the topic selection briefing. The scoping stage refines and clarifies the use of the technology in the clinical pathway after input from clinicians, patients and other stakeholders. The considerations include: the uses of the technology most likely to maximise benefit to the NHS and the population of England; areas of unmet need; and the degree of complexity of the assessment.

2.2.4 For diagnostic evaluations, alternative technologies that are not in common use or are newly available (or soon to be) may be included with the notified technology. The scoping process for these alternatives is similar to that for the technology. Alternative technologies are normally similar in action or intent to the notified technology. They are generally included when, for example, the technology might be used in very similar settings or circumstances and there is likely to be some benefit to the NHS in developing guidance on more than one technology.

2.2.5 A technology is only evaluated if it has or is expected to have regulatory approval (or appropriate regulatory signal) by the planned draft or final guidance publication date.

2.2.6 Unless the Department of Health and Social Care specifically indicates otherwise, NICE will not develop technology appraisal or highly specialised technology guidance on a technology for indications that have not been given regulatory approval in the UK. That is, for unlicensed or 'off-label' use outside the terms of

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the technology's regulatory approval.

2.2.7 For diagnostic technologies that are used in sequence, all technologies that make up the potential sequence should be included. The technology being evaluated needs to be precisely described because there may be many variants of a single technology that could be used (for example, different thresholds). These variants may need to be evaluated separately, or in different sequences.

2.2.8 All technologies that are to be included and evaluated as part of a technology evaluation must meet the eligibility criteria for selection in the NICE-wide topic prioritisation process.

The population

2.2.9 The scope defines the population for whom the technology is being evaluated as precisely as possible. The scope may highlight potential subgroups of the population when the clinical effectiveness or value for money of the technology might differ from the overall population, or groups who need special consideration.

2.2.10 Outcomes can vary significantly depending on the population evaluated. For example, there may be differences in: the prior probabilities for various conditions identified by the technologies; test accuracy in different populations; the effect of treatment, and side effects or complication rates. For many technologies there may be multiple populations. For medicines, the relevant population will normally be informed by the (expected) marketing authorisation or marketing authorisation extension. In other cases, to keep the evaluation to a reasonable size, some people who could use the technology may not be included in the scope. Excluding people from the scope does not mean that the technology is not appropriate for these people. Because resources for the evaluation are limited, the patient populations may need to be selected carefully to maximise the benefit of the evaluation.

2.2.11 Defining the population also includes where, why and how the technology is used in the care pathway. This is described for each defined population.

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Comparators

2.2.12 The scope identifies all potentially relevant comparators that are established practice in the NHS. It considers issues likely to be discussed by the committee when selecting the most appropriate comparator. At this stage of the evaluation, identifying comparators should be inclusive.

2.2.13 Comparator technologies may include branded and non-proprietary (generic) medicines and biosimilars. They may also include technologies that do not have regulatory approval for the population defined in the scope if they are considered to be established clinical practice for the population in the NHS.

2.2.14 Sometimes both the technology and comparator or standard care are part of a sequence in the care pathway. In these cases, the evaluation may compare alternative sequences.

2.2.15 Technologies that NICE has recommended with managed access are not considered established practice in the NHS and are not considered suitable comparators.

Care pathway

2.2.16 The care pathway is an important consideration for evaluating the technologies' effectiveness and costs. It includes the entire sequence of tests and treatments relevant to the evaluation. It may also include technologies used to help with any adverse effects. The care pathway can vary depending on the patient's conditions, characteristics or comorbidities. It includes the stages after diagnosis or treatment. The treatment pathway or range of treatment pathways must be understood for the value of the technology to be assessed.

2.2.17 If appropriate, the scope describes the care pathway. For a diagnostic technology it includes any variations according to test results or the technologies used. It defines the time frame for the treatments covered, key steps leading to final outcomes, and the outcomes relevant to treatments that will be included in the evaluation. It covers the diagnostic sequences, treatments, monitoring, retreatment, treatment for adverse effects and complications that a person may

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have. In some cases, the care pathway includes tests and interventions that are not done because of the results of the test being evaluated. For example, if a test diagnoses a condition that would not have been diagnosed by the comparator, then the benefits of not having other treatments or tests are relevant. Even if a test diagnoses an untreatable condition, the costs and harms of treatment that can now be avoided are relevant.

Clinical outcomes

2.2.18 As far as possible, the scope identifies the main measures of outcomes that are relevant to estimating clinical effectiveness. That is, they measure health benefits and adverse effects that are important to patients and their carers. For evaluations in which quality-adjusted life years (QALYs) are calculated, the clinical outcome measures may include quantification of survival or health-related quality of life that translates into QALYs to evaluate cost effectiveness.

2.2.19 Relevant outcomes include any health outcomes resulting directly or indirectly from any technologies being evaluated. They may also include informational outcomes of value to the patient for the relief, or imposition, of anxiety or for personal planning.

2.2.20 People with the condition should be consulted when selecting outcome measures in studies. A high-quality 'core outcome set', developed with people with the condition, may help with outcome selection. Core outcome sets should be used if suitable based on quality and validity; one source is the 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.

2.2.21 Patient-reported outcome measures can capture important aspects of conditions and interventions such as health-related quality of life, performance status, symptom and symptom burden, and health-related behaviours such as anxiety and depression. They can be either general or disease specific.

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Measuring costs

2.2.22 The potential effect on resource costs and savings that would be expected from introducing the technology should be considered from the perspective of the NHS and personal social services. In exceptional circumstances for medicines, when requested by the Department of Health and Social Care in the remit for the evaluation, the scope will list requirements for adopting a broader perspective on costs.

2.2.23 The scope defines the relevant cost areas for the evaluation, but it does not detail all the specific costs and other resource details to be incorporated in the evaluation.

Other issues likely to affect the evaluation

2.2.24 The scope can include, when relevant, details of:

- Related NICE guidance, such as other evaluations and clinical guidelines.
- Related policy developments.
- Service settings related to the technology being evaluated that are either of particular interest or will be excluded from consideration.
- The potential innovative nature of the technology, in particular its potential to have a substantial effect on health-related benefits that are unlikely to be included in the economic evaluation.
- The evidence available, including any evidence gaps that may cause uncertainty during the evaluation, and whether the company believes the technology is a candidate for managed access.
- Issues relating to advancing equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular 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.

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- Which type of evaluation is most appropriate for the technology.
- Issues relating to the technology that are not particular to specific clinical situations. For example, a new imaging machine may have costs or radiation exposure that cover a broad range of clinical conditions. In this case the scope defines a wide category of patients, but the subsequent care pathway for those patients may not be included in the evaluation.

2.3 Developing the draft scope

2.3.1 After identifying topics through the NICE-wide topic prioritisation process, NICE develops a draft scope for each potential evaluation and seeks the views of stakeholders.

2.3.2 The first step in the scoping process is to identify information about the technology or technologies. This is done using literature searches, checking the availability of relevant evidence, and requesting information from the company. NICE uses this information, along with the technology briefing, to prepare a draft scope.

2.4 Identifying stakeholders

2.4.1 Identifying stakeholders is an important stage of the process. NICE identifies stakeholders before it consults on the draft scope or holds a scoping workshop.

2.4.2 A patient and carer organisation or professional organisation can be a stakeholder if it works at a national level (covering the UK or England, or a UK branch of an international body) and represents patients, carers or healthcare professionals either broadly or directly related to the technology being considered. Other stakeholders include the company, NHS commissioning groups and specialist centres that manage care in conditions with small patient populations.

2.4.3 When there is no patient and carer organisation working at a national level for the

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technology being considered, as defined above, NICE may request and approve an international organisation becoming a stakeholder in the evaluation at its discretion.

2.4.4 Stakeholders also include research organisations with an interest in the technology, developers or distributors of a relevant technology, a provider of NHS services in England, organisations that cover the NHS as a whole such as the NHS Confederation, patient and professional organisations covering Northern Ireland or Scotland or Wales only, and relevant comparator and companion diagnostic test companies. Other organisations may be included as stakeholders when appropriate.

2.4.5 Any specialist committee member applicants for diagnostic evaluations are automatically registered as stakeholders.

2.4.6 During the scoping phase, NICE aims to identify the widest possible range of relevant stakeholders who have an interest in the technology or disease area being considered. This includes, but is not restricted to, national organisations representing relevant specific ethnic groups, disabled people, and people with mental health problems or a learning disability.

2.4.7 It is important that enough expertise goes into developing the scope. NICE welcomes and values all input from stakeholders at consultation and during workshops.

2.4.8 If an organisation wants to be a stakeholder, it needs to contact the project manager (see the NICE website for details). Organisations can ask to take part as a stakeholder at any point up to the issue of final draft guidance.

2.4.9 For guidance being updated, including those which are recommended with managed access, NICE will update the original stakeholder list ahead of the guidance update commencing.

2.5 Consultation on the draft scope

2.5.1 The aim of the consultation is to make sure the evaluation covers all the relevant

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areas and issues.

2.5.2 NICE sends the draft scope and stakeholder list to stakeholders for comment and asks them if there are other organisations that need to be included in the consultation. The draft scope and list of stakeholders is then published on the NICE website.

2.5.3 Consultations are either 28 days (long), 14 days (medium), or 7 days (short). Long consultations will be used if there is a reasonable degree of uncertainty about elements of the draft scope or whether the technology should be evaluated. If the draft scope contains only a small degree of uncertainty, or a scope has previously been well defined in other related NICE outputs in the last 12 months, a medium or short consultation may be used. Please see the consultation lengths table below for distinctions between the consultation lengths.

Table 2.1 Consultation lengths

Length of time	When consultation length is used
7 calendar day consultation (short)	For medical technologies – information for the scope has already been gathered during the development of the medtech innovation briefing. Technology appraisals and highly specialised technologies will not use this approach.
14 calendar day consultation (medium)	If there is a small degree of uncertainty or a scope has previously been well defined in other related NICE outputs within the last 12 months.
28 calendar day consultation (long)	If there is a reasonable degree of uncertainty about elements of the draft scope, or whether the technology should be evaluated. Diagnostics, technology appraisals and highly specialised technologies will normally use this approach.

2.5.4 NICE asks the company to confirm the expected timing and details of regulatory approval in the UK. Companies should also highlight any evidence gaps and if they intend to make a managed access proposal to generate more evidence, as part of their response to the draft scope consultation.

2.5.5 NICE publishes the draft scope and list of stakeholders on its website, for

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information, within 7 days of sending these documents to stakeholders.

2.5.6 For diagnostics evaluations, NICE normally holds a scoping workshop and does not have a consultation on the draft scope.

2.6 Consultation on the draft scope – determining cost-comparison suitability

2.6.1 At scoping consultation, questions will be asked relating to the population, treatment pathway, benefit and clinical similarity to help establish whether cost comparison is appropriate. The aim is to establish whether the intervention is clinically similar, such that it can be compared with another intervention that NICE has previously recommended in technology appraisal guidance for the same indication, using cost-comparison methods. The chosen comparator must be established in practice and have substantial use in the NHS in England for the same indication.

2.6.2 The draft scope sent out at consultation will indicate whether NICE considers a cost-comparison evaluation would be a potentially suitable process to follow. NICE welcomes early engagement from the company on cost-comparison suitability.

2.6.3 During scope consultation, NICE's medicines optimisation team will engage with medicines and prescribing associates to create a briefing report on the appropriateness of cost comparison. This report will be published alongside topic information on the NICE website.

2.6.4 The scoping consultation will enable NICE to decide on the suitability of the cost-comparison process, taking into account input from stakeholders. If it is established that cost comparison is appropriate, NICE will invite stakeholders to make a cost-comparison submission. If cost comparison is not appropriate, stakeholders will be invited to submit to a single or multiple technology appraisal. This decision will consider relevant risks associated with the appraisal and the decision to use cost comparison. Decisions on which process a topic will follow are not subject to appeal.

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2.7 The scoping workshop

2.7.1 NICE decides whether to hold a scoping workshop to discuss the draft scope with stakeholders. This may happen if the topic covers a new disease area or care pathway that NICE has not evaluated before or recently, or there are uncertainties about the evaluation that a workshop could address. The scoping workshop will usually be held virtually. NICE invites stakeholders to send representatives to this workshop.

2.7.2 The aims of the workshop are to:

- make sure the scope is appropriately defined
- discuss the issues raised by stakeholders during any previous consultation
- discuss the appropriateness of completing an evaluation and the appropriate evaluation process
- discuss any other issues relevant to the potential evaluation.

2.7.3 At the scoping workshop, the company can provide preliminary details of the evidence it will submit in the evaluation. This may include details of trials in progress, for example the inclusion and exclusion criteria used, and any evidence gaps that may cause uncertainty during the evaluation.

2.7.4 At the end of the workshop, if needed, the company can confidentially discuss commercially sensitive information and technical issues about the proposed evaluation with NICE.

2.7.5 For diagnostic technologies, after the scoping workshop, NICE meets with the assessment subgroup (committee chair, specialist committee members, committee lead and the external assessment group) to agree the final scope and protocol for the evaluation.

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2.8 Scoping a technology after a period of managed access

2.8.1 For technologies that were recommended with managed access, NICE will update the original scope. This is to make sure that the guidance update considers the care pathway and use of the technology in England at the time the guidance update starts. NICE can review any element in the scope, including changes that happened during the managed access period to the:

- eligible patient population
- treatment pathway
- relevant health outcomes measures.

2.8.2 NICE may also consider whether to expand the scope of the guidance update for technologies that had recommendations (see section 6.4) with managed access.

2.8.3 When changes to the original scope are identified after a period of managed access, NICE will consult on a draft scope as described above.

2.8.4 When no or limited changes to the original scope are identified after a period of managed access, the original scope and stakeholder list will have a consultation period of 14 days.

2.8.5 NICE may hold a scoping workshop as part of scoping activities for technologies after a period of managed access when there are issues relevant to the guidance update or uncertainties in the draft scope that a workshop could address. At the scoping workshop, the company will be asked to provide preliminary details of the evidence it will submit in the evaluation. This may include details of trials in progress, for example the inclusion and exclusion criteria used, and any evidence gaps which may cause uncertainty during the evaluation.

2.9 Final scope

2.9.1 NICE updates the scope, considering comments received during any

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consultation, and the discussions at any scoping workshop.

2.9.2 It may become clear during scoping that a topic is not suitable for evaluation and NICE may decide not to proceed. The decision is made by the centre director or prioritisation board. Stakeholders are told about the decision and the reason why.

2.9.3 If the scope for a diagnostic evaluation is too large for the available resources, NICE may revise it in collaboration with the assessment subgroup and the external assessment group.

2.9.4 If there is a significant length of time between scoping and the evaluation, NICE may need to update the scope. Depending on the extent of the update, NICE may engage further with stakeholders. NICE does not routinely hold another scoping workshop.

2.9.5 The final scope is signed off internally and published on NICE's website once NICE is ready to start the evaluation.

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3 Evidence

3.1 Assessment of the evidence

3.1.1 A comprehensive evidence base is fundamental to the evaluation process. Evidence of various types and from multiple sources may inform the evaluation. To ensure that the guidance issued by NICE is appropriate and robust, the evidence and analysis, and their interpretation, must be of the highest standard possible and transparent.

3.1.2 Evaluating effectiveness needs quantification of the effect of the technology under evaluation and of the relevant comparators on appropriate outcome measures.

3.1.3 For costs, 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.

3.1.4 In addition to evidence on the technology's effects and costs, health technology evaluation should consider a range of other relevant issues. For example:

- the impact of having a condition or disease, the experience of having specific treatments or diagnostic tests for that condition, the experience of the healthcare system for that condition
- organisational issues that affect patients, carers or healthcare providers
- NICE's legal obligations on equality and human rights
- the requirement to treat people fairly
- issues relating to health inequalities.

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3.2 Guiding principles for evidence

3.2.1 The evidence considered by the committee should be:

- Relevant to the evaluation in terms of patient groups, comparators, perspective, outcomes and resource use as defined in the scope. It should include transparent reporting of data, study design, analysis, and results.
- Clear in the rationale for the selection of outcomes, resource use and costs.
- Assembled systematically and synthesised in a transparent way that allows the analysis to be reproduced.
- Analysed in a way that is methodologically sound and, in particular, minimises any bias.

  NICE has defined a 'reference case' that specifies the methods it considers to be most appropriate for estimating clinical effectiveness and value for money. This is to ensure that the evidence base for evaluations is consistent with these principles.

3.2.2 There are always likely to be limitations in the evidence available to inform an evaluation. There may be questions about internal validity of the evidence because of data quality or methodological concerns. Or there may be questions about the external validity because of, for example, the population and settings. It is essential that limitations in the evidence are fully described and the impact on bias and uncertainty fully characterised and ideally quantified. Committees will reach judgements about the acceptability of all the evidence according to the evaluation context (including, for example, the type of technology, evaluation or population).

3.3 Types of evidence

3.3.1 NICE considers all types of evidence in its evaluations. 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.

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3.3.2 The preferred source of evidence depends on the specific use being considered. For relative treatment effects there is a strong preference for high-quality randomised controlled trials (RCTs). Non-randomised studies may complement RCTs when evidence is limited or form the primary source of evidence when there is no RCT evidence. For diagnostic technologies, there is a preference for end-to-end studies. When there is insufficient evidence from these studies, a linked evidence approach should be taken. For clinical outcomes such as natural history, treatment patterns or patient experiences, real-word evidence may be preferred.

3.3.3 The need to search beyond RCTs for treatment effects should be informed by the residual uncertainties, the likelihood of this uncertainty being resolved through non-randomised evidence, and the practicalities of the evidence search. The search could be done in an iterative, hierarchical way, searching first for more robust forms of non-randomised evidence before searching for less reliable study designs.

3.3.4 Whatever the sources of evidence available on a particular technology and patient group, a systematic review of the relevant evidence relating to a technology should be done using a pre-defined protocol. This protocol should allow evidence to be included from all sources likely to inform the decision about using the technologies by the NHS. A systematic review attempts to assemble all the available relevant evidence using explicit, valid and replicable methods in a way that minimises the risk of biased selection of studies. The data from the included studies can be synthesised, but this is not essential. All evidence should be critically appraised, and potential biases must be identified (see section 6.2).

Randomised controlled trials

3.3.5 RCTs minimise potential external influences to identify the effect of 1 or more interventions on outcomes. Randomisation ensures that any differences in baseline characteristics between people assigned to different interventions at the start of the trial are because of chance, including unmeasured characteristics. Blinding (when applied) prevents knowledge of treatment allocation from influencing behaviours, and standardised protocols ensure consistent data collection. The trial should, in principle, provide a minimally biased estimate of the

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size of any benefits or risks associated with the technology relative to those associated with the comparator. RCTs are therefore considered to be most appropriate for measures of relative treatment effect.

3.3.6 The relevance of RCT evidence to the evaluation depends on both the internal and external validity of each trial. Internal validity is assessed according to the design, analysis and conduct of a trial. It includes blinding (when appropriate; this is often not possible when trials use specific medical devices or diagnostics), the method of randomisation and concealment of allocation, and the completeness of follow up. Other important considerations are the size and power of the trial, the selection and measurement of outcomes and analysis by intention to treat. External validity is assessed according to the generalisability of the trial evidence, that is, whether the results apply to wider patient groups and to routine clinical practice.

3.3.7 When basket trials are used, they should be appropriately designed and analysed, include assessment of heterogeneity and allow borrowing between baskets. They should include relevant comparators, use a random allocation of treatments, use appropriate clinical endpoints (including a validated relationship with the overall survival and quality of life of the patients) and enrol all patient groups relevant to the indication.

3.3.8 High-quality RCTs directly comparing the technology being evaluated with relevant comparators provide the most valid evidence of relative efficacy. However, there are some key limitations of RCTs:

- For some indications or technologies, RCTs may not provide enough evidence to quantify the effect of treatment over the course of the condition.
- In some circumstances, or for particular conditions, RCTs may be unethical or not feasible.
- For some evaluations the results may not be generalisable to the population of interest, either because of the relevance of comparator or the relevance of the population, setting and treatment pathway in which it was used.
- For some medical devices there may be learning effects or behaviours associated with their use that may not be captured using an RCT.

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- Some technologies may also be better suited to alternative study designs (for example, histology-independent cancer treatments may be suited to being studied in basket trials including a heterogeneous population of patients).

  When an RCT is not available or appropriate, justification should be provided for the source and methods used to generate evidence on the relative effects. Any potential bias arising from the design of the studies used in the evaluation should be explored and documented in a formal, transparent and pre-specified manner.

Non-randomised studies

3.3.9 Non-randomised studies can be interventional (but without randomisation) or observational. They include observational database studies with concurrent control, and single-arms trials using external control. Non-randomised studies tend to be at high risk of bias because the factors influencing treatment assignment may be predictive of the outcomes (that is, confounding). Other forms of bias may arise because of limitations in data quality, detection bias, or patient entry into or exit from studies (that is, selection bias). Inferences about relative effects drawn from studies without randomisation will often be more uncertain than those from RCTs. Technical support document 17 provides guidance on methods for addressing for confounding using individual patient level data from observational studies.

3.3.10 The potential biases of observational studies should be identified and quantified and adjusted for when possible. Choice of data, study design and analysis should be selected to minimise the risk of bias. Bias should be evaluated using validated tools specific to the study design and use case. It should be recognised that no single tool covers all relevant domains of bias. Stakeholders should take comprehensive approaches to assessing study quality and should note limitations of tools used when relevant.

3.3.11 Evidence from non-randomised studies may be beneficial in supplementing and supporting RCT data, or substituting for RCT data if there is none. Non-randomised data may also be used to contextualise results from RCTs by, for instance, understanding differences in patient populations, treatment patterns, or

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outcomes. For example, non-randomised evidence may be used to:

- assess the generalisability of results from RCTs
- show effectiveness of interventions over longer time horizons
- describe the characteristics of real-world populations of interest
- understand differences in treatment patterns or outcomes
- provide information on the natural history of the condition to supplement trials
- provide evidence on real-world safety and adverse events
- provide estimates of resource use for populating economic models
- provide information about the experience of people having treatments or using a medical device, diagnostic or digital technology.

3.3.12 Non-randomised studies are usually at higher risk of bias than RCTs because of confounding (that is, systematic differences between treatment groups, and association of those differences with the outcome of interest), selection bias, or informational biases from limitations of the data or differential data collection. It is therefore essential to assess the risk of bias in each study using a validated tool (for example, ROBINS-I). Use of some tools may require sufficient knowledge and experience for application. Alternative tools are available for less experienced authors but justification for their use and any limitations should be presented.

3.3.13 An assessment of the quality of the data should consider completeness, validity, consistency, and accuracy which can be done using an appropriate checklist. As with RCT evidence, it is also important to consider the external validity of the evidence. When possible, more than 1 independent source of such evidence should be examined to gain some insight into the validity of any conclusions. The following principles should guide the generation of the highest quality evidence from non-randomised studies and when using real-world data:

- 1. Evidence should be developed in a fully transparent and reproducible way from study planning through study conduct to the reporting of results.
- 2. Data sources should be identified through systematic, transparent and

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reproducible approaches. The origin of any data source should be shown, and its quality and relevance in relation to the intended applications shown.

- 3. Data should be analysed using appropriate analytical strategies. Bias and uncertainty should be fully characterised and ideally quantified. Extensive sensitivity analyses should be done, covering all key risks of bias.

3.3.14 Additional guidance on the design, conduct and reporting of non-randomised and real-world studies is provided on the NICE website (see the preliminary version of the NICE real-world evidence framework; a link to the final version will be added when available).

3.3.15 Study quality can vary, and so systematic review methods, critical appraisal and sensitivity analyses are as important for review of this data as they are for reviews of data from RCTs.

Diagnostic accuracy studies

3.3.16 Diagnostic test accuracy studies compare test results of people with a disease or condition to those of people without it. Designs are generally prospective cohort or cross-sectional studies, or retrospective case-control studies. Most compare a single index test of interest with a reference standard to calculate the accuracy. Paired design studies compare 2 index tests with each other, and often also with a reference standard. These studies are less prone to bias resulting from confounding.

Impact of technology on clinical pathway

3.3.17 Devices or diagnostics may affect outcomes because of their effect on the clinical pathway. For example, the technology may produce results more quickly, reducing the need for the patient to attend extra appointments or reducing the time to treatment. These outcomes can be included in the evaluation but are sometimes associated with uncertainty. As such, clinical expert opinion or expert elicitation is likely to be important.

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Qualitative research

3.3.18 Qualitative research can explore areas such as values, preferences, acceptability, feasibility and equity implications. Many elements of the decision problem can be informed by qualitative evidence. When this evidence is submitted it can be particularly useful to assess aspects including, but not limited to:

- patients' experience and quality of life as a result of having a disease or condition
- patients' experience and quality of life as a result of having a treatment or test
- any subgroups of patients who may need special consideration in relation to the technology
- any subgroups defined by social characteristics relating to health inequalities
- patients' view on the acceptability of different types of treatment, device or test
- views of carers
- views of people with experience using the device or a comparator device
- views of treating clinicians
- views on the feasibility of guidance implementation.

3.3.19 Qualitative data may be collected ad hoc or opportunistically, through formal qualitative research studies or from a systematic review of relevant qualitative research.

3.3.20 When qualitative evidence is extensive and is appropriate to inform decision making, recognised methods of analysing, synthesising, and presenting qualitative evidence is preferred. For example, rapid review, framework synthesis, narrative summary and synthesis, meta-synthesis and thematic synthesis.

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Expert elicitation or expert opinion

3.3.21 In the absence of empirical evidence from RCTs, non-randomised studies, or registries, or when considered appropriate by the committee taking into account all other available evidence, expert elicitation can be used to provide evidence. Expert elicitation may use either structured or unstructured methods. Evidence generated by expert elicitation, either using structured or unstructured methods, is subject to risk of bias and high uncertainty. Structured methods are preferred because they attempt to minimise biases and provide some indication of the uncertainty. Structured approaches should adhere to existing protocols (such as the Medical Research Council protocol). They typically involve assessing probability distributions, usually after training the responders about the various types of common cognitive biases.

3.3.22 Clinical experts and patient experts can also provide opinions (both quantitative and qualitative). This is different to the methods applied for expert elicitation. This could be used to supplement, support, or refute any observed data from RCTs or non-randomised studies (including drug usage evaluations, cross-sectional studies or case studies). Expert opinion may include any information relevant to the evaluation, including the technology, the comparators and the conditions for which the technology is used. For devices or diagnostics, such information can relate to the technical characteristics, such as their design, if this might affect its capability in delivering the intended benefits; or the training and experience needed to use the technology; or organisational factors that might influence the technology's technical performance or use in clinical practice.

3.3.23 Clear reporting of the methods used for expert elicitation or expert opinion (quantitative) is needed from study planning to conduct. This includes the identification and selection of experts, and the reporting of results including the consensus of opinions or data aggregation. This should follow existing reporting guidelines when possible.

Care management

3.3.24 Clinical guidelines from NICE and other organisations can provide a good source of evidence for care management and the care pathway. When this is not clear or

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not available, expert clinical input of the usual care pathway can be used. Diagnostic before-and-after studies also provide useful information on any change in management after the introduction of an index test to clinical practice. However, these studies are often not available, especially when assessing a new test that is not in routine clinical use. As such, expert clinical input on the usual care pathway is likely to be important.

Unpublished and part-published evidence

3.3.25 To ensure that the evaluation does not miss important relevant evidence, it is important that attempts are made to identify evidence that is not in the public domain. Such evidence includes unpublished clinical trial data and clinical trial data that are in abstract form only or are incomplete, and post-marketing surveillance data. However, this evidence should still consider the key principles of design, analysis and reporting. Such information must be critically appraised, transparently reported and adjusted for bias. When appropriate, sensitivity analysis should examine the effects of its incorporation or exclusion.

Economic evaluations

3.3.26 Economic evaluations may be based on new analyses. However, a review of published, relevant economic evaluations of interventions should also be done. Search for economic evaluations using transparent and reproducible approaches until sufficient appropriate and relevant evidence has been identified. Reviews may not be exhaustive if additional studies identified would merely provide further support that is consistent with the already-identified evidence (rather than necessarily identifying all relevant studies). Once identified, critically assess economic evaluations using a suitable tool and assess external validity related to the decision problem. Clearly state and rationalise if no relevant economic evaluations are found.

3.3.27 Existing economic evaluations can be used as an alternative to de novo modelling if the existing economic evaluations are adequate and appropriate.

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Health inequalities

3.3.28 Evidence on health inequalities in England can be provided to help the committee understand their impacts on eligible populations in NICE's guidance programmes. Analysis of health inequality impacts may be presented as an additional non-reference case analysis.

3.3.29 If a company or stakeholder identifies health inequalities that are relevant to the eligible population, they can provide robust qualitative and quantitative evidence to show that a technology will have a substantial impact. Supporting materials can include:

- descriptive statistics on disease burden
- information on social or structural barriers that are specific to the technology's eligible population and prevent people from accessing care or being included in research.

3.3.30 Important context on health inequalities can be provided by data that shows:

- differences in health outcomes between social groups in the eligible population
- that specific conditions are more common in disadvantaged groups.

3.4 Synthesis of evidence

3.4.1 The aim of clinical-effectiveness analysis is to get precise, relevant and unbiased estimates of the mean clinical effectiveness of the technologies being compared. Consider all relevant studies in the assessment of clinical effectiveness and base analyses on studies of the best available quality. Consider the range of typical patients, normal clinical circumstances, clinically relevant outcomes, comparison with relevant comparators, and measures of both relative and absolute effectiveness with appropriate measures of uncertainty. NICE prefers RCTs directly comparing the intervention with 1 or more relevant comparators and, if available, these should be presented in the reference-case analysis.

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Systematic review

3.4.2 Identify and quantify all health effects, and clearly describe all data sources. Evidence on outcomes should come from a systematic review, defined as systematically locating, including, appraising and synthesising the evidence to give a reliable and valid overview of the data related to a clearly formulated question.

3.4.3 Search strategies for reviews of diagnostic test accuracy tend to be longer and more complex than search strategies to identify treatment effects. Filters should not be used to narrow the search to diagnostic studies because indexing of these types of studies is often poor.

Study selection and data extraction

3.4.4 Do a systematic review of relevant studies of the technology being evaluated according to a previously prepared protocol to minimise the potential for bias. This should include studies investigating relevant comparators.

3.4.5 Compile a list of possible studies once the search strategy has been developed and literature search completed. Each study must be assessed to determine if it meets the inclusion criteria of the review. Keep a log of ineligible studies, with the rationale for why studies were included or excluded. More than 1 reviewer should assess all records retrieved by the search strategy to increase the validity of the decision. Clearly report the procedure for resolving disagreements between reviewers.

Critical appraisal

3.4.6 The quality of a study's overall design, its execution, and the validity of its results determines its relevance to the decision problem. Critically appraise each study that meets the criteria for inclusion. Whenever possible, use the criteria for assessing published studies to assess the validity of unpublished and part-published studies.

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Factors that affect the effectiveness

3.4.7 Many factors can affect the overall estimate of relative effectiveness from a systematic review. Some differences between studies happen by chance, others from differences in the patient characteristics (such as age, sex, severity of disease, choice and measurement of outcomes), care setting, additional routine care and the year of the study. Identify such potential effect modifiers before data analysis, either by a thorough review of the subject area or discussion with experts in the clinical discipline.

Pairwise meta-analysis

3.4.8 The combination of outcome data through meta-analysis is appropriate if there are enough relevant and valid data using outcome measures that are comparable.

3.4.9 Fully report the characteristics and possible limitations of the data (that is, population, intervention, setting, sample size and validity of the evidence) for each study included in the analysis and include a forest plot.

3.4.10 Accompany statistical pooling of study results with an assessment of heterogeneity (that is, any variability in addition to that accounted for by chance). This can, to some extent, be taken into account using a random (rather than fixed) effects model. However, the degree of heterogeneity and the reasons for this should be explored as fully as possible. Known clinical heterogeneity (for example, because of patient characteristics) may be explored by using subgroup analyses and meta-regression. When there is doubt about the relevance of a particular study, a sensitivity analysis should exclude that study. If the risk of an event differs substantially between the control groups of the studies in a meta-analysis, assess whether the measure of relative effectiveness is constant over different baseline risks. This is especially important when the measure of relative effectiveness will be used in an economic model and the baseline rate of events in the comparator arm of the model is very different to the corresponding rates in the meta-analysis studies.

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Indirect comparisons and network meta-analyses

3.4.11 When technologies are being compared that have not been evaluated within a single RCT, data from a series of pairwise head-to-head RCTs should be presented together with a network meta-analysis if appropriate. Fully describe the network meta-analysis and present it as an additional analysis. The committee will consider the additional uncertainty associated with the lack of direct evidence when considering relative-effectiveness estimates derived from indirect sources only. NICE prefers the methods for network meta-analysis set out in the technical support document evidence synthesis series.

3.4.12 The term 'network meta-analysis' includes adjusted indirect comparisons, but also refers to more complex evidence analysis such as mixed treatment comparisons. An 'adjusted indirect comparison' refers to data synthesis from trials in which the technologies of interest have not been compared directly with each other but have been compared indirectly using a common comparator. Mixed treatment comparisons include both head-to-head trials of technologies of interest (both interventions and comparators) and trials that include 1 of the technologies of interest.

3.4.13 Ideally, the network meta-analysis should contain all technologies that have been identified either as an intervention or as appropriate comparators in the scope. Therefore, trials that compare at least 2 of the relevant (intervention or comparator) technologies should be incorporated, even if the trial includes comparators that are not relevant to the decision problem. Follow the principles of good practice for doing systematic reviews and meta-analyses when doing mixed and indirect treatment comparisons. In brief, a clear description of the synthesis methods and the rationale for how RCTs are identified, selected and excluded is needed. Document the methods and results of the individual trials included in the network meta-analysis and a table of baseline characteristics for each trial. If there is doubt about the relevance of a particular trial or set of trials, present sensitivity analysis in which these trials are excluded (or included if the trials are not in the base-case analysis).

3.4.14 In networks consisting of a small number of trials, indirect comparisons are highly vulnerable to systematic bias. Population adjustment methods in connected networks can be considered when effect modifiers between trials may be

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imbalanced. Population adjustment methods need individual patient data to be available from at least 1 trial in the comparison or network. Recognise the limitations of using these methods and, if possible, the likely size of any systematic bias reported (see technical support document 18).

3.4.15 Report the heterogeneity between results of pairwise comparisons and inconsistencies between the direct and indirect evidence on the technologies. If inconsistency within a network meta-analysis is found, then attempt to explain and resolve these inconsistencies.

3.4.16 Use external information to help estimate the between-study heterogeneity to improve the precision of the estimates. In networks with few included studies, it may be preferable to use informative prior distributions for the between-study heterogeneity parameter.

3.4.17 Distributions tailored to particular outcomes and disease areas are recommended.

3.4.18 Note the source of the prior distribution for the between-study heterogeneity and provide justification for its use. Present a sensitivity analysis assessing the impact of using different candidate prior distributions.

3.4.19 Informative prior distributions for relative effectiveness are not recommended unless under very specific circumstances (for example, very sparse adverse event data) and need additional justification.

3.4.20 In all cases when evidence is combined using adjusted indirect comparisons or network meta-analysis frameworks, trial randomisation must be preserved. It is not acceptable to compare results from single treatment arms from different randomised trials. If this type of comparison is presented, the data will be treated as observational in nature and associated with increased uncertainty. Present evidence from a network meta-analysis in both tables and graphical formats such as forest plots. Clearly identify the direct and indirect components of the network meta-analysis and state the number of trials in each comparison. Present results from pairwise meta-analyses using the direct comparisons alongside those based on the full network meta-analysis.

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3.4.21 Bias adjustments should be considered if there are concerns about methodological quality or size of included studies in a network meta-analysis (see technical support document 3). When there is not enough relevant and valid data for including in pairwise or network meta-analyses, the analysis may have to be restricted to a narrative overview that critically appraises individual studies and presents their results. In these circumstances, the committee will be particularly cautious when reviewing the results and drawing conclusions about the relative clinical effectiveness of the options.

Evidence synthesis challenges

3.4.22 Evidence synthesis methods should be appropriate to the evaluation context. The underlying assumptions, purpose and strengths and limitations of the chosen method should be described and justified.

3.4.23 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.

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4 Economic evaluation

4.1 Introduction

4.1.1 This section details methods for assembling and synthesising evidence on the technology in an economic evaluation. This is needed to estimate the technology's relative clinical effectiveness and value for money compared with established practice in the NHS. NICE promotes high-quality analysis and encourages consistency in analytical approaches, but also acknowledges the need to report studies in other ways to reflect particular circumstances.

4.2 The reference case: framework

The concept of the reference case

4.2.1 NICE makes decisions across different technologies and disease areas. So, it is crucial that analyses done to inform the economic evaluation are consistent. NICE has defined a reference case that specifies the methods that are appropriate for the committee's purpose. Economic evaluations considered by NICE should include an analysis of results using these reference-case methods. This does not prevent additional analyses being presented when 1 or more aspects of methods differ from the reference case. However, these must be justified and clearly distinguished from the reference case.

4.2.2 Although the reference case specifies the methods preferred by NICE, it does not prevent the committee's consideration of non-reference-case analyses if appropriate. The key elements of analysis using the reference case are summarised in table 4.1.

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Table 4.1 Summary of the reference case

Element of health technology assessment	Reference case	Section providing details
Defining the decision problem	The scope developed by NICE	4.2.4 to 4.2.6
Comparator(s)	As listed in the scope developed by NICE	2.2.12 to 2.2.16, 4.2.6, 4.2.13
Perspective on outcomes	All health effects, whether for patients or, when relevant, carers	4.2.7, 4.2.8
Perspective on costs	NHS and personal social services (PSS)	4.2.9 and 4.2.10
Types of economic evaluation	Cost-utility analysis with fully incremental analysis Cost-comparison analysis	4.2.14 to 4.2.17 4.2.18 to 4.2.21
Time horizon	Long enough to reflect all important differences in costs or outcomes between the technologies being compared	4.2.22 to 4.2.25
Synthesis of evidence on health effects	Based on systematic review	3.4
Measuring and valuing health effects (see note)	Health effects should be expressed in quality-adjusted life years (QALYs). The EQ-5D is the preferred measure of health-related quality of life in adults	4.3.1, 4.3.6
Source of data for measurement of health-related quality of life (see note)	Reported directly by patients or carers, or both	4.3.3

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Element of health technology assessment	Reference case	Section providing details
Source of preference data for valuation of changes in health-related quality of life (see note)	Representative sample of the UK population	4.3.4
Equity considerations (see note)	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit, except in specific circumstances	6.2.10
Evidence on resource use and costs	Costs should relate to NHS and PSS resources and should be valued using the prices relevant to the NHS and PSS	4.4.1
Discounting	The same annual rate for both costs and health effects (currently 3.5%)	4.5.1

Note: Elements of health technology assessment relevant to a cost-utility analysis and not a cost-comparison analysis.

4.2.3 Clearly specify and justify reasons for not applying reference-case methods and quantify the likely implications. The committee will discuss the weight it attaches to the results of such a non-reference-case analysis.

Defining the decision problem

4.2.4 The economic evaluation should start with a clear statement of the decision problem that defines the technologies being compared and the relevant patient groups. The decision problem should be consistent with the scope for the evaluation; any differences must be justified.

4.2.5 The main technologies of interest, their expected place in the care pathway, the comparator(s) and the relevant patient groups will be defined in the scope developed by NICE (see section 2).

4.2.6 Consider the scope (see section 2), and the evidence available for the technology

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under evaluation and its comparator(s) to allow a robust economic evaluation.

Perspective

4.2.7 For the reference case, the perspective on outcomes should be all relevant health effects, whether for patients or, when relevant, other people (mainly carers). The perspective adopted on costs should be that of the NHS and PSS.

4.2.8 Some features of healthcare delivery (often referred to as process characteristics) may indirectly affect health. For example, the way a technology is used might affect effectiveness, or a diagnostic technology may improve the speed of correct diagnosis. The value of these benefits should be quantified if possible, and the nature of these characteristics should be clearly explained. These characteristics may include convenience and the level of information available for patients.

4.2.9 NICE does not set the budget for the NHS. The objective of NICE's evaluations is to offer guidance that represents an efficient use of available NHS and PSS resources. For these reasons, the reference-case perspective on costs is that of the NHS and PSS. Productivity costs should not be included.

4.2.10 Some technologies may have substantial benefits to other government bodies (for example, treatments to reduce drug misuse may also reduce crime). These issues should be identified during the scoping stage of an evaluation. Evaluations that consider benefits to the government outside of the NHS and PSS will be agreed with the Department of Health and Social Care and other relevant government bodies as appropriate. They will be detailed in the remit from the Department of Health and Social Care and the final scope. For these non-reference-case analyses, the benefits and costs (or cost savings) should be presented in a disaggregated format and separately from the reference-case analysis.

Type of economic evaluation

4.2.11 Two forms of economic evaluation are available for guidance-producing

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programmes in the Centre for Health Technology Evaluation.

4.2.12 A cost-utility analysis is used when a full analysis of costs and health benefits is needed. It is used to establish the level of health benefit and costs of the technology(s) compared with relevant comparator(s).

4.2.13 A cost-comparison analysis is for technologies that are likely to provide similar or greater health benefits at similar or lower cost than the relevant comparator(s). For technologies evaluated using a cost-comparison analysis in the technology appraisal programme, relevant comparators are those recommended in published NICE guidance for the same population.

Cost-utility analysis

4.2.14 Cost-effectiveness (specifically cost-utility) analysis is used to determine if differences in expected costs between technologies can be justified in terms of changes in expected health effects. Health effects should be expressed in terms of quality-adjusted life years (QALYs).

4.2.15 Using cost-effectiveness analysis is justified by NICE's focus on maximising health gains from a fixed NHS and PSS budget. QALYs are the most appropriate generic measure of health benefit that reflects both mortality and health-related quality-of-life effects. If the assumptions that underlie the QALY (for example, constant proportional trade-off and additive independence between health states) are inappropriate in a particular case, then evidence of this should be produced. Analyses using alternative measures may be presented as an additional non-reference-case analysis.

4.2.16 Follow standard decision rules when combining costs and QALYs. When appropriate, these should reflect when dominance or extended dominance exists, presented thorough incremental cost-utility analysis. Incremental cost-effectiveness ratios (ICERs) reported must be the ratio of expected additional total cost to expected additional QALYs compared with alternative technologies. As well as ICERs, expected net health benefits should be presented; this may be particularly informative when applying decision making modifiers, if there are several technologies or comparators, when the differences in costs or QALYs

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between technologies is small, or when technologies provide less health benefit at lower costs. Net health benefits should be presented using values placed on a QALY gain of £20,000 and £30,000 (see section 4.10.8). Net monetary benefits can also be shown alongside ICERs and net health benefits.

4.2.17 In exceptional circumstances, if the technologies form part of a class of treatments, and evidence is available to support their clinical equivalence, estimates of QALYs gained for the class as a whole can be shown.

Cost-comparison analysis

4.2.18 A cost-comparison analysis comprises an analysis of the costs and resource use associated with the technology compared with that of the comparator(s). This type of analysis is usually used when developing medical technologies guidance or a cost-comparison technology appraisal.

4.2.19 The costs associated with differing health outcomes and resource consequences from the technology and the comparator(s) should be captured in the cost-comparison analysis (for example, managing adverse events or impacts on the care pathway), when relevant.

4.2.20 Cost-comparison analyses in a technology appraisal should be used for technologies likely to provide similar health benefits at similar or lower cost than comparator(s) that are recommended in published NICE guidance for the same population. For these analyses, the effects of the intervention and comparator(s) on health outcomes are captured in the clinical-effectiveness evidence and are not included in the cost-comparison analysis. Substantial differences between technologies in costs directly relating to health outcomes (such as adverse events) indicate that the technology and comparator(s) may not provide similar overall health benefits, so any such cost differences must be clearly justified. Whenever possible and appropriate, cost data and data sources should be consistent with any corresponding data and sources that were considered appropriate in the published NICE guidance for the comparator(s) for the same population.

4.2.21 Some technologies may have only a healthcare system benefit. For example, a

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test which rules out disease more quickly but has similar diagnostic performance to the existing and slower test. If there is evidence that existing approaches are similar, the evaluation may concentrate on the health and social care system outcomes.

Time horizon

4.2.22 The time horizon for estimating clinical effectiveness and value for money should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

4.2.23 Many technologies have effects on costs and outcomes over a patient's lifetime. In these circumstances, a lifetime time horizon is usually appropriate. A lifetime time horizon is needed when alternative technologies lead to differences in survival or benefits that last for the remainder of a person's life.

4.2.24 For a lifetime time horizon, it is often necessary to extrapolate data beyond the duration of the clinical trials, observational studies or other available evidence and to consider the associated uncertainty. When the effect of technologies is estimated beyond the results of the clinical studies, analyses that compare several alternative scenarios reflecting different assumptions about future effects using different statistical models are desirable (see section 4.7). These should include assuming the technology does not provide further benefit beyond the technologies' use, as well as more optimistic assumptions. Analyses that limit the time horizon to periods shorter than the expected effect of the technology do not usually provide the best estimates of benefits and costs.

4.2.25 A time horizon shorter than a patient's lifetime could be justified if there is no differential mortality effect between technologies and the differences in costs and clinical outcomes relate to a relatively short period.

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4.3 Measuring and valuing health effects in cost-utility analyses

4.3.1 Express health effects in QALYs for cost-effectiveness analyses. For the reference case, report the measurement of changes in health-related quality of life directly from patients. The utility of these changes should be based on public preferences using a choice-based method.

4.3.2 A QALY combines both quality of life and life expectancy into a single index. In calculating QALYs, each of the health states experienced within the time horizon of the model is given a utility reflecting the health-related quality of life associated with that health state. The time spent in each health state is multiplied by the utility. Deriving the utility for a particular health state usually comprises 2 elements: measuring health-related quality of life in people who are in the relevant health state and valuing it according to preferences for that health state relative to other states (usually perfect health and death).

4.3.3 Health-related quality of life, or changes in health-related quality of life, should be measured directly by patients. When it is not possible to get measurements of health-related quality of life directly from patients, these should come from the person who acts as their carer rather than healthcare professionals.

4.3.4 The valuation of health-related quality of life measured by patients (or their carers) should be based on a valuation of public preferences from a representative sample of the UK population using a choice-based method. This valuation leads to the calculation of utility values.

4.3.5 Different methods used to measure health-related quality of life produce different utility values. Therefore, results from different methods or instruments cannot always be compared.

4.3.6 Given the need for consistency across evaluations, the EQ-5D measurement method is preferred to measure health-related quality of life in adults. Preference values from the EQ-5D should be applied to measurements of health-related quality of life to generate health-related utility values.

4.3.7 In some circumstances adjustments to utility values may be needed, for example

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for age or comorbidities. If baseline utility values are extrapolated over long time horizons, they should be adjusted to reflect decreases in health-related quality of life seen in the general population and to make sure that they do not exceed general population values at a given age. Adjustment should be based on a recent and robust source of population health-related quality of life. If this is not considered appropriate for a particular model, the supporting rationale should be provided. A multiplicative approach is generally preferred. Clearly document the methods used for adjusting utility values.

4.3.8 If not available in the relevant clinical trials, EQ-5D data can be sourced from the literature. When taken from the literature, the methods for identifying the data should be systematic and transparent. Clearly explain the justification for choosing a particular data set. When more than 1 plausible set of EQ-5D data is available, sensitivity analyses should be done to show the effect of the alternative utility values.

4.3.9 When EQ-5D data is not available, this data can be estimated by mapping other health-related quality-of-life measures or health-related benefits seen in the relevant clinical trials to EQ-5D. This is considered to be a departure from the reference case. The mapping function chosen should be based on data sets containing both health-related quality-of-life measures and its statistical properties. It should be fully described, its choice justified, and it should be adequately shown how well the function fits the data. Present sensitivity analyses to explore variation in using mapping algorithms on the outputs.

4.3.10 In some circumstances the EQ-5D may not be the most appropriate measure. To make a case that the EQ-5D is inappropriate, provide qualitative empirical evidence on the lack of content validity for the EQ-5D, showing that key dimensions of health are missing. This should be supported by evidence that shows that EQ-5D performs poorly on tests of construct validity (that is, it does not perform as would be expected) and responsiveness in a particular patient population. This evidence should be derived from a synthesis of peer-reviewed literature. In these circumstances alternative health-related quality-of-life measures may be used. These must be accompanied by a carefully detailed account of the methods used to generate the data, their validity, and how these methods affect the utility values.

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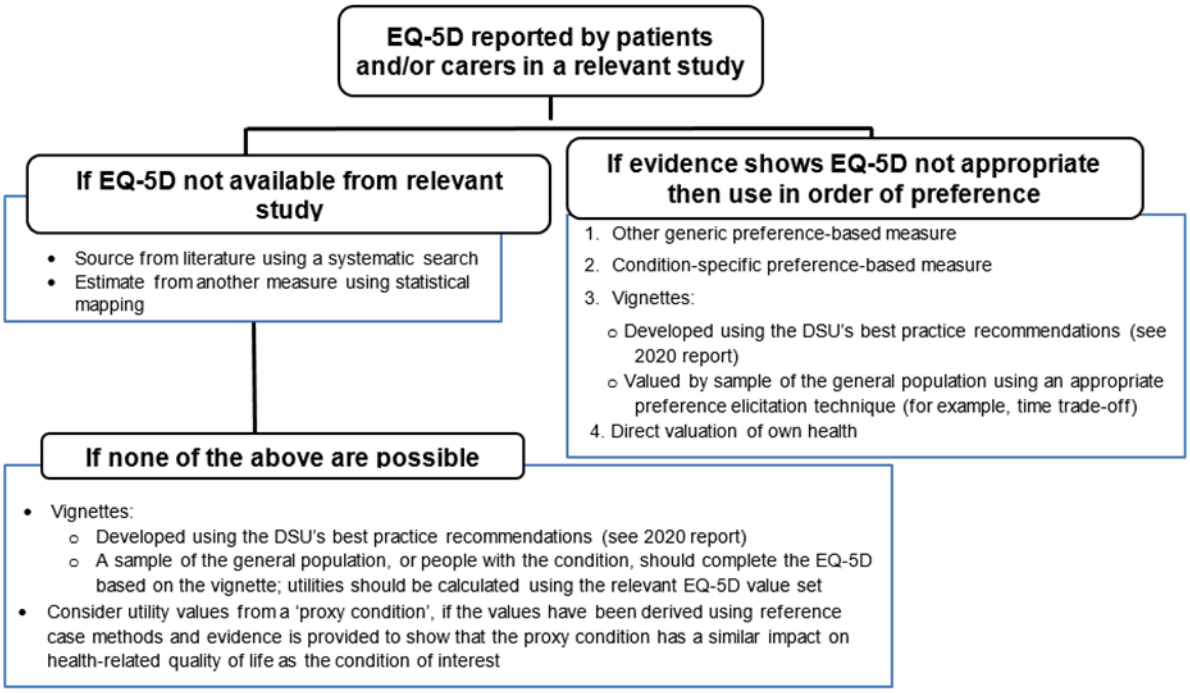
4.3.11 In circumstances when evidence generation is difficult (for example, for rare diseases), when there is insufficient data to assess whether the EQ-5D adequately reflects changes in quality of life, evidence other than psychometric measures may be presented and considered to establish whether the EQ-5D is appropriate.

4.3.12 A hierarchy of preferred health-related quality-of-life methods is presented in figure 4.1. Use figure 4.1 for guidance when the EQ-5D is not available or not appropriate.

Figure 4.1 Hierarchy of preferred health-related quality-of-life methods



4.3.13 For evaluations in which the population includes children and young people (that is, people aged under 18) consider alternative measures of health-related quality of life for children.

4.3.14 NICE does not recommend specific measures of health-related quality of life in children and young people. A generic measure that has been shown to have good psychometric performance in the relevant age ranges should be used. Not all paediatric health-related quality-of-life instruments have a UK value set, and there are methodological challenges when developing value sets for children and young people. Nonetheless, generic measures give valuable descriptive information about the effect of the condition and technology on children and

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young people's health-related quality of life. If data from a paediatric health-related quality-of-life instrument are used to generate utility values, explain how this was done. If there is evidence that generic measures are unsuitable for the condition or technology, refer to the hierarchy of preferred sources for health-related quality of life. A report by the Decision Support Unit summarises the psychometric performance of several preference-based measures.

4.3.15 Report if measures of health-related quality of life were completed by adults with the condition, children and young people themselves, or on their behalf (for example, by parents, carers or clinicians). Report the age of the children and young people. If multiple data sources are available, report what data was used in the economic model and the rationale behind this choice.

4.3.16 The EQ-5D-5L is a new version of the EQ-5D, with 5 response levels. NICE does not recommend using the EQ-5D-5L value set for England published by Devlin et al. (2018). Companies, academic groups and others preparing evidence submissions for NICE should use the 3L value set for reference-case analyses. If data was gathered using the EQ-5D-5L descriptive system, utility values in reference-case analyses should be calculated by mapping the 5L descriptive system data onto the 3L value set. If analyses use data gathered using both EQ-5D-3L and EQ-5D-5L descriptive systems, the 3L value set should be used to derive all utility values, with 5L mapped onto 3L when needed. The mapping function developed by the Decision Support Unit (Hernández Alava et al. 2017), using the 'EEPRU dataset' (Hernández Alava et al. 2020), should be used for reference-case analyses. We support sponsors of prospective clinical studies continuing to use the 5L version of the EQ-5D descriptive system to collect data on quality of life.

4.3.17 Evaluations should consider all health effects for patients, and, when relevant, carers. When presenting health effects for carers, evidence should be provided to show that the condition is associated with a substantial effect on carer's health-related quality of life and how the technology affects carers.

4.3.18 For diagnostics evaluations, linked-evidence modelling is usually needed to measure and value health effects, because 'end-to-end' controlled trials with follow up through the care pathway are uncommon (see section 4.6.14).

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4.3.19 The analysis should include all relevant patient outcomes that change in the care pathway because of the diagnostic test or sequence of tests. The nature, severity, time and frequency of occurrence, and the duration of the outcome may all be important in determining the effect on quality of life and should be considered as part of the modelling process.

4.4 Evidence on resource use and costs

NHS and PSS costs

4.4.1 For the reference case, costs should relate to resources that are under the control of the NHS and PSS. Value these resources using the prices relevant to the NHS and PSS. Present evidence to show that resource use and cost data have been identified systematically.

4.4.2 Estimates of resource use should include the comparative costs or saving of the technologies and changes in infrastructure, use and maintenance. If appropriate, staff training costs should be included.

4.4.3 Estimates of resource use may also include the comparative value of healthcare service use outcomes (such as length of hospital stay, number of hospitalisations, outpatient or primary care consultations) associated with the technology or its comparators.

4.4.4 Reference-case analyses should be based on prices that reflect as closely as possible the prices that are paid in the NHS for all evaluations. Analyses should be based on price reductions when it is known that some form of price reduction is available across the NHS. Sources of prices may include: patient access schemes, commercial access agreements, NHS Supply Chain prices, the Drugs and Pharmaceutical electronic Market Information Tool (eMIT), the drugs tariff or through negotiated contracts such as Commercial Medicines Unit (CMU). When judgement on the appropriate price is needed, the committee should consider the limitations around the price source in its deliberations. This should consider transparency to the NHS and the period for which the prices are guaranteed. Any uncertainty should be acknowledged and explored. If the acquisition price paid

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for a resource varies substantially (for example, the diagnostic technology or consumables may be sold at reduced prices to NHS institutions) the reference-case analysis should be based on costs that reflect as closely as possible the prices that are paid in the NHS. Any uncertainty in price may be incorporated into the modelling and should follow a consistent approach as for other uncertain or variable parameters.

4.4.5 When contracts are awarded by the CMU, the prices for a medicine can differ between regions. This means that, although a discounted price is available across the NHS, there is no single price that is universally available across the NHS. When CMU prices are considered most appropriate for an evaluation, the committee should be aware that prices may not be consistently available across the NHS. The committee should consider analyses based on both the lowest and the highest available CMU prices in its decision making. For pragmatism, sensitivity and scenario analyses for other parameters should use the midpoint (the value between the highest and lowest CMU prices).

4.4.6 When eMIT or confidential CMU prices are used by the committee, it will be aware that those prices are not guaranteed for the duration of the guidance.

4.4.7 For medicines that are mainly prescribed in primary care, base prices on the drugs tariff.

4.4.8 When there is no form of price reduction available across the NHS, or a price agreed by a national institution for the technology(s) (as may be the case for some devices and diagnostic technologies), analyses may use the list price or the price that is generally available to the NHS as submitted by the company (if it is reported transparently).

4.4.9 Healthcare resource groups (HRGs) are a valuable source of information for estimating resource use. HRGs are standard groupings of clinically similar treatments that use common levels of healthcare resources. The national average unit cost of an HRG is reported as part of the annual mandatory collection of reference costs from all NHS organisations in England. Using these costs can reduce the need for local micro-costing (costing of each individual component of care related to a technology). Carefully consider all relevant HRGs. For example, the cost of hospital admission for a serious condition may not account for time

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spent in critical care, which is captured and costed as a separate HRG. It may also be necessary to consider other costs that are unbundled and not included in the core HRG.

4.4.10 Data based on HRGs may not be appropriate in all circumstances. For example, when the new technology and the comparator both fall under the same HRG, or when the mean cost does not reflect resource use in relation to the new technology under evaluation. In such cases, other sources of evidence, such as micro-costing studies, may be more appropriate. In all cases, include all relevant costs such as the costs of the test, follow up, treatment, monitoring, staffing, facilities, training and any other modifications needed. When cost data is taken from literature, the methods used to identify sources of costs and resource use should be defined (preferably through systematic review). When multiple or alternative sources are available, the choice for the base case should be justified, the discrepancies between the sources should be explained and sensitivity analyses explored when appropriate implications for results of using alternative data sources.

4.4.11 Include costs related to the condition of interest and incurred in additional years of life gained because of technology in the reference-case analysis. Exclude costs that are unrelated to the condition or technology of interest. For diagnostic technologies, if the prognostic information generated increases the cost or allows cost savings in unrelated conditions, include these changes in a non-reference-case analysis but explain and justify them.

4.4.12 In cases when current costs are not available, costs from previous years should be adjusted to present value using inflation indices appropriate to the cost perspective, such as the NHS cost inflation index and the PSS pay and prices index, available from the PSS Research Unit report on unit costs of health and social care or the Office for National Statistics consumer price index.

4.4.13 Whenever possible, costs relevant to the UK healthcare system should be used. However, in cases when only costs from other countries are available these should be converted to Pounds Sterling using an exchange rate from an appropriate and current source (such as HM Revenue and Customs or Organisation for Economic Co-operation and Development).

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4.4.14 The reference case should include the full additional costs associated with introducing a technology.

4.4.15 The committee should consider the specific circumstances and context of the evaluation. It should consider alongside the reference-case analysis a non-reference-case analysis in which a particular cost is apportioned or adjusted when:

- there is an established plan to change practice or service delivery in the NHS
- there is a formal arrangement with relevant stakeholders that the full costs should not be attributed to the new technology
- the technology has multiple uses beyond the indication under evaluation
- introducing the new technology will lead to identifiable benefits that are not captured in health technology evaluations.

4.4.16 In cases where a technology increases survival in people for whom the NHS is currently providing care that is expensive or would not be considered cost effective at NICE's normal levels, the committee may consider alongside the reference-case analysis a non-reference-case analysis with the background care costs removed. The committee will consider in its decision making both the reference-case and non-reference-case analyses, taking into account the nature of the specific circumstances of the evaluation including the population, care pathway and technology, as well as:

- the extent to which the cost effectiveness of the technology is driven by factors outside its direct costs and benefits
- if the NHS is already providing care that would not be considered cost effective at NICE's normal levels
- if the high-cost care is separate from direct, intrinsic consequences of the technology (such as a side effect or administration cost)
- the extent to which commercial solutions would address the issue.

4.4.17 When developing technology appraisal guidance, if a technology is administered in combination with another technology, the company may propose commercial

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solutions.

4.4.18 When a group of related technologies is being evaluated as part of a 'class', an analysis using the individual unit costs specific to each technology should normally be presented in the reference case. Exceptionally, if there is a very wide range of technologies and costs to be considered, then present analyses using the weighted mean cost and the highest and lowest cost estimates.

4.4.19 Exclude value added tax (VAT) from all economic evaluations but include it in the calculation of the budgetary impact when the resources in question are liable for this tax.

4.4.20 For technologies with multiple uses that are already being used in the NHS, for example diagnostic tests that could identify multiple markers, and when not all of its uses are being evaluated, the average cost should initially be identified based on the expected use or throughput of the device for only the uses being evaluated. In some cases, if a technology is already recommended for another purpose and enough spare capacity exists to allow the use for the condition in the current evaluation, an analysis using marginal costs may be supplied in addition to the analysis based on average costs.

4.4.21 Additional sensitivity analyses may be done using average costs computed through assigning some of the fixed costs to other uses of the technology, if there is evidence that the other uses also provide good value for money.

Non-NHS and non-PSS costs

4.4.22 Some technologies may have a substantial effect on the costs (or cost savings) to government bodies other than the NHS. Exceptionally, these costs may be included if specifically agreed with the Department of Health and Social Care. When non-reference-case analyses include these broader costs, explicit methods of valuation are needed. In all cases, these costs should be reported separately from NHS and PSS costs, and not included in the reference-case analysis.

4.4.23 Costs paid by patients may be included when they are reimbursed by the NHS or PSS. When the rate of reimbursement varies between patients or geographical

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regions, such costs should be averaged across all patients. When there are costs paid by patients that are not reimbursed by the NHS and PSS, these may be presented separately. Productivity costs should be excluded from the reference case. They can be presented separately, as additional information for the committee, if such costs may be a critical component of the value of the technology.

4.4.24 When care by family members, friends or a partner might otherwise have been provided by the NHS or PSS, it may be appropriate to consider the cost of the time of providing this care, even when adopting an NHS or PSS perspective. All analyses including the time spent by family members providing care should be shown separately. A range of valuation methods exists to cost this type of care. Methods chosen should be clearly described and sensitivity analyses using other methods should be presented. PSS savings should also be included.

4.5 Discounting

4.5.1 Cost-effectiveness results should reflect the present value of the stream of costs and benefits accruing over the time horizon of the analysis. For the reference case, costs and health effects should be discounted at the same rate of 3.5% per year.

4.5.2 Alternative analyses using rates of 1.5% for both costs and health effects may be presented alongside the reference-case analysis, in specific circumstances.

Non-reference-case discounting

4.5.3 The committee may consider analyses using a non-reference-case discount rate of 1.5% per year for both costs and health effects, if, in the committee's considerations, all of the following criteria are met:

- The technology is for people who would otherwise die or have a very severely impaired life.
- It is likely to restore them to full or near-full health.

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- The benefits are likely to be sustained over a very long period.

4.5.4 When considering analyses using a 1.5% discount rate, the committee must take account of plausible long-term health benefits in its discussions. The committee will need to be confident that there is a highly plausible case for the maintenance of benefits over time when using a 1.5% discount rate.

4.5.5 Further, the committee will need to be satisfied that any irrecoverable costs associated with the technology (including, for example, its acquisition costs and any associated service design or delivery costs) have been appropriately captured in the economic model or mitigated through commercial arrangements.

4.6 Modelling methods

4.6.1 The models used to generate estimates of clinical and cost effectiveness and cost comparison should follow accepted guidelines. Provide full documentation and justification of structural assumptions and data inputs. When there are alternative plausible assumptions and inputs, do sensitivity analyses of their effects on model outputs.

4.6.2 Modelling provides an important framework for synthesising available evidence and generating estimates of clinical and cost effectiveness, and cost comparison, in a format relevant to the committee's decision-making process. Models are needed for most evaluations.

4.6.3 Providing an all-encompassing definition of what constitutes a high-quality model is not possible. In general, estimates of technology performance should be based on the results of the systematic review and modelling when appropriate. Structural assumptions should be fully justified, and data inputs should be clearly documented and justified in the context of a valid review of the alternatives. The conceptual model development process used to inform the choice of model structure should be transparent and justified. This should include details of expert involvement in this process (for example, number of experts, details of their involvement, how they were chosen). It is not enough to state that the chosen model structure has previously been used in published model reports or

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accepted in submissions to NICE. The chosen type of model (for example, Markov cohort model, individual patient simulation) and model structure should be justified for each new decision problem.

4.6.4 Detail the methods of quality assurance used in the development of the model and provide the methods and results of model validation. Also, present the results from the analysis in a disaggregated format and include a table of key results. For cost-utility analyses, this should include estimates of life years gained, mortality rates (at separate time points if appropriate) and the frequency of selected outputs predicted by the model.

4.6.5 For cost-utility analyses, clinical end points that reflect how a patient feels, functions, or how long a patient lives are considered more informative than surrogate outcomes. When using 'final' clinical end points is not possible and data on other outcomes are used to infer the effect of the technology on mortality and health-related quality of life, evidence supporting the outcome relationship must be provided together with an explanation of how the relationship is quantified for use in modelling.

4.6.6 Three levels of evidence for surrogate relationships can be considered in decision making (Ciani et al. 2017):

- Level 3: biological plausibility of relation between surrogate end point and final outcomes.
- Level 2: consistent association between surrogate end point and final outcomes. This would usually be derived from epidemiological or observational studies.
- Level 1: the technology's effect on the surrogate end point corresponds to commensurate effect on the final outcome as shown in randomised controlled trials (RCTs).

4.6.7 For a surrogate end point to be considered validated, there needs to be good evidence that the relative effect of a technology on the surrogate end point is predictive of its relative effect on the final outcome. This evidence preferably comes from a meta-analysis of level 1 evidence (that is, RCTs) that reported both the surrogate and the final outcomes, using the recommended meta-analytic

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methods outlined in technical support document 20 (bivariate meta-analytic methods). Show biological plausibility for all surrogate end points, but committees will reach decisions about the acceptability of the evidence according to the decision context. For example, for certain technologies indicated for rare conditions, and some diagnostic technologies and medical devices, the level of evidence might not be as high.

4.6.8 The validation of a surrogate outcome is specific to the population and technology type under consideration.

4.6.9 Thoroughly justify extrapolating a surrogate to final relationship to a different population or technology of a different class or with a different mechanism of action.

4.6.10 Extrapolation should be done using the recommended meta-analytic methods that allow borrowing of information from similar enough classes of technologies, populations, and settings, as outlined in technical support document 20. Existing relevant meta-analytical models may be used. However, when historical models are based on data collected in a different setting, then development of a new model using appropriate meta-analytic techniques is recommended. This may include network meta-analysis or hierarchical methods reflecting differences in mechanism of action between classes of technologies or for first-in-class scenarios.

4.6.11 In cost-utility analyses, the usefulness of the surrogate end point for estimating QALYs will be greatest when there is strong evidence that it predicts health-related quality of life or survival. In all cases, the uncertainty associated with the relationship between the surrogate end points and the final outcomes should be quantified and presented. It should also be included through probabilistic sensitivity analysis and can be further explored in scenario analysis.

4.6.12 Diagnostics evaluations may include intermediate outcomes. Diagnostic test accuracy statistics are intermediate measures, and when incorporated into models, can be used as predictors of future health outcomes of patients. Other intermediate measures include radiation exposure from an imaging test or pathogenicity of specific genetic mutations identified by a genetic test. In all cases, the uncertainty associated with the intermediate measure should be

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quantified and presented.

4.6.13 The scientific literature for diagnostics largely consists of studies of analytical and clinical validity. Data on the impact of diagnostic technologies on final patient outcomes is limited. The benefits from diagnostic testing generally arise from the results of treatment or prevention efforts that take place based on the testing. There may be some direct benefits from the knowledge gained and some direct harm from the testing, but most of the outcomes are indirect and come downstream. To assess these outcomes, consider not only the diagnostic process itself, but also treatment and monitoring. A new diagnostic technology can affect the care pathway in 2 major ways. The first is how the test is used in the diagnostic process. The second is the impact of changed diagnostic information on subsequent disease management. A new technology can be a like-for-like replacement for an existing test or test sequence, or it can be an addition to an existing test or test sequence. New diagnostics can be integrated together with parts of the existing diagnostic process to create a new sequence. Once the diagnostic process options are defined, the health outcomes from identified technologies or changes in technology based on test results should be assessed. Often the technology may be some form of treatment. The diagnostic technology may result in treatment being started, modified or stopped. Ensure the populations assessed in the studies of diagnostic test accuracy are comparable with those in the evaluation of the technology.

4.6.14 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. Specify the links used, such as between diagnosis, treatment and final outcomes. Obtain and review the relevant data about those links.

4.6.15 Clinical trial data generated to estimate treatment effects may not quantify the risk of some health outcomes or events for the population of interest well enough or may not provide estimates over a sufficient duration for the economic analysis. The methods used to identify and critically evaluate sources of data for economic models should be stated and the choice of particular data sets should be justified with reference to their suitability to the population of interest in the evaluation.

4.6.16 Quantifying the baseline risk of health outcomes and how the condition would

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naturally progress with the comparator(s) can be a useful step when estimating absolute health outcomes in the economic analysis. This can be informed by observational studies. Relative treatment effects seen in randomised trials may then be applied to data on the baseline risk of health outcomes for the populations or subgroups of interest. State and justify the methods used to identify and critically evaluate sources of data for these estimates.

4.6.17 When outcomes are known to be related, a joint synthesis of structurally related outcomes is recommended whenever possible, to increase precision and robustness of decision making.

4.6.18 Models used for cost-utility analyses should be informed by knowledge of the natural history of the disease and checked for clinical plausibility. The underlying assumptions should be checked statistically whenever possible.

4.6.19 Assumptions included in models should, when appropriate, be validated by a user of the technology who has experience of using it in the NHS or a user with appropriate expertise that can be applied to the technology. This is particularly relevant for the evaluation of medical devices.

4.6.20 Modelling is often needed to extrapolate costs and health benefits over an extended time horizon. Assumptions used to extrapolate the treatment effect over the relevant time horizon should have both external and internal validity and be reported transparently. The external validity of the extrapolation should be assessed by considering both clinical and biological plausibility of the inferred outcome as well as its coherence with external data sources, such as historical cohort data sets or other relevant studies. Internal validity should be explored and when statistical measures are used to assess the internal validity of alternative models of extrapolation based on their relative fit to the observed trial data, the limitations of these statistical measures should be documented. Alternative scenarios should also be routinely considered to compare the implications of different methods for extrapolation of the results. For example, for duration of treatment effects, scenarios in the extrapolated phase might include:

- treatment effect stops or diminishes gradually over time
- treatment effect is sustained for people who continue to have treatment

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- treatment effect (or some effect) is sustained beyond discontinuation for people who stop treatment, when it is clinically plausible for lasting benefit to remain.

4.6.21 Synthesis of survival outcomes needs individual patient level data. When this is not available, methods such as the Guyot et al. (2012) method can be used to reconstruct Kaplan–Meier data as referenced in technical support document 14.

4.6.22 Studies using survival outcomes, or time-to-event outcomes, often measure the relative effects of treatments using hazard ratios (HRs), which may either be constant over time (proportional hazards) or change over time. The proportional hazards assumption should always be assessed (see technical support document 14), preferably using:

- log-cumulative hazard plots (as advised in technical support document 14)
- visual inspection of the hazard plots or HRs over time, and
- interpretation of tests for proportional hazards reported in the original trial publications.

4.6.23 If the proportional hazards assumption holds within the trial and is clinically plausible during extrapolation, then HRs may be pooled using standard code for treatment differences (see technical support document 2). Correlations need to be accounted for in trials with 3 or more arms.

4.6.24 If the proportional hazards assumption does not hold in some of the studies, then alternative methods should be considered, as described in technical support document 21.

4.6.25 When extrapolating time-to-event data, various standard (for example, parametric) and more flexible (for example, spline-based, cure) approaches are available. Their appropriateness and the validity of their extrapolations should routinely be considered. When comparing alternative models for extrapolating time-to-event data, the clinical plausibility of their underlying hazard functions should routinely be assessed. Uncertainty in the extrapolated portion of hazard functions should also be explored. Functions that display stable or decreasing variance over time are likely to underestimate the uncertainty in the extrapolation.

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4.6.26 In RCTs, patients in the control group are sometimes allowed to switch treatment group and have the technology being investigated. In these circumstances, when intention-to-treat analysis is considered inappropriate, statistical methods that adjust for treatment switching can also be presented. Avoid simple adjustment methods such as censoring or excluding data from patients who crossover, because they are very susceptible to selection bias. Explore and justify the relative merits and limitations of the methods chosen to explore the effect of switching treatments, with respect to the method chosen and in relation to the specific characteristics of the data set in question. These characteristics include the mechanism of crossover used in the trial, the availability of data on baseline and time-dependent characteristics, expectations around the treatment effect if the patients had stayed on the treatment they were allocated and any or residual effect from the previous treatment. When appropriate, the uncertainty associated with using a method to adjust for trial crossover should be explored and quantified.

4.6.27 In general, all model parameter values used in base-case, sensitivity, scenario and subgroup analyses should be both clinically plausible and should use methods that are consistent with the data. Results from analyses that do not meet these criteria will not usually be suitable for decision making.

4.6.28 Sometimes it may be difficult to define what is plausible and what is not, for example, in very rare conditions or for innovative medical technologies, when the evidence base may be less robust. In such situations, consider expert elicitation to identify a plausible distribution of values.

4.6.29 If threshold analysis is used, the parameter value at which a cost-effectiveness estimate reaches a given threshold may be implausible. In this case, it is still appropriate to present the results of the threshold analysis, alongside information on the plausible range for the parameter.

4.7 Exploring uncertainty

4.7.1 Present an overall assessment of uncertainty to committees to inform decision making. This should describe the relative effect of different types of uncertainty (for example, parameter, structural) on cost-effectiveness estimates, and an

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assessment of whether the uncertainties that can be included in the analyses have been adequately captured. It should also highlight the presence of uncertainties that are unlikely to be reduced by further evidence or expert input.

4.7.2 The model should quantify the decision uncertainty associated with a technology. That is, the probability that a different decision would be reached if the true cost effectiveness of each technology could be ascertained before making the decision.

4.7.3 Models are subject to uncertainty around the structural assumptions used in the analysis. Examples of structural uncertainty may include how different states of health are categorised and how different pathways of care are represented.

4.7.4 Clearly document these structural assumptions and provide the evidence and rationale to support them. Explore the effect of structural uncertainty on cost-effectiveness estimates using separate analyses of a representative range of plausible scenarios that are consistent with the evidence. Analyses based on demonstrably implausible scenarios are only useful if they are used to show that cost-effectiveness estimates are robust to a source of uncertainty. For example, if the resource use associated with a procedure is uncertain, a useful exploratory analysis might show that the implausible assumptions of no resource use and very large amounts of resources do not materially affect the cost-effectiveness conclusion. The purpose of such analyses should be clearly presented. This will allow a committee to focus on other key uncertainties in its decision making.

4.7.5 It may be possible to incorporate structural uncertainty within a probabilistic model (for example, by model averaging or assigning a probability distribution to alternative structural assumptions). If structural uncertainty is parameterised, consider the alternative assumptions and any probabilities used to 'weight' them. This should be transparently documented, including details of any expert advice.

4.7.6 Examples of when this type of scenario analysis should be done are:

- if there is uncertainty about the most appropriate assumption to use for extrapolation of costs and outcomes beyond trial follow up
- if there is uncertainty about how the care pathway is most appropriately represented in the analysis

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- if there may be economies of scale (for example, in evaluations of diagnostic technologies).

4.7.7 Uncertainty about the appropriateness of the methods used in the reference case can also be dealt with using sensitivity analysis but present these analyses separately.

4.7.8 A second type of uncertainty arises from the choice of data sources to provide values for the key parameters, such as different costs and utilities, relative-effectiveness estimates and their duration. Reflect the implications of different key parameter estimates in sensitivity analyses (for example, through the inclusion of alternative data sets). Fully justify inputs and uncertainty explored by sensitivity analysis using alternative input values.

4.7.9 The choice of data sources to include in an analysis may not be clear. In such cases, the analysis should be done again, using alternative data sources or excluding the study about which there is doubt. Report the results separately. Examples of when this type of sensitivity analysis should be done are:

- if alternative sets of plausible data on the health-related utility associated with the condition or technology are available
- if there is variability between hospitals in the cost of a particular resource or service, or the acquisition price of a particular technology
- if there are doubts about the quality or relevance of a particular study in a meta-analysis or network meta-analysis.

4.7.10 A third source of uncertainty comes from parameter precision, once the most appropriate sources of information have been identified (that is, the uncertainty around the mean health and cost inputs in the model). Assign distributions to characterise the uncertainty associated with the (precision of) mean parameter values. The distributions chosen for probabilistic sensitivity analysis should not be chosen arbitrarily but chosen to represent the available evidence on the parameter of interest, and their use should be justified. Formal elicitation methods are available if there is a lack of data to inform the mean value and associated distribution of a parameter. If there are alternative plausible distributions that could be used to represent uncertainty in parameter values,

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explore using separate probabilistic analyses of these scenarios.

4.7.11 When doing a probabilistic analysis, enough model simulations should be used to minimise the effect of Monte Carlo error. Reviewing the variance around probabilistic model outputs (net benefits or ICERs) as the number of simulations increases can provide a way of assessing if the model has been run enough times or more runs are needed.

4.7.12 The committee's preferred cost-effectiveness estimate should be derived from a probabilistic analysis when possible unless the model is linear. If deterministic model results are used, this should be clearly justified, and the committee should take a view on if the deterministic or probabilistic estimates are most appropriate. However, in general, uncertainty around individual parameters is not a reason to exclude them from probabilistic analyses; rather, that uncertainty should be captured in the analysis.

4.7.13 In general, scenario analyses should also be probabilistic. When only deterministic base-case or scenario analyses are provided, this should be justified. For example, it may be impractical to get probabilistic results for many plausible scenarios. This may be less influential for decision making if the base-case analysis is shown to be linear, or only moderately non-linear (when 'non-linear' means that there is not a straightforward linear relationship between changes in a model's inputs and outputs).

4.7.14 For evaluations based on cost-utility analyses, the committee's discussions should consider the spread of results.

4.7.15 Appropriate ways of presenting uncertainty in cost-effectiveness data parameter uncertainty include confidence ellipses and scatter plots on the cost-effectiveness plane (when the comparison is restricted to 2 alternatives) and cost-effectiveness acceptability curves (a graph that plots a range of possible maximum acceptable ICERs on the horizontal axis against the probability (chance) that the intervention will be cost effective at that ICER on the vertical axis). The presentation of cost-effectiveness acceptability curves should include a representation and explanation of the cost-effectiveness acceptability frontier (a region on a plot that shows the probability that the technology with the highest expected net benefit is cost effective). Present results exploring uncertainty in a

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table, identifying parameters that have a substantial effect on the modelling results. As well as details of the expected mean results (costs, outcomes and ICERs), also present the probability that the treatment is cost effective at maximum acceptable ICERs of £20,000 to £30,000 per QALY gained and the error probability (that the treatment is not cost effective), particularly if there are more than 2 alternatives.

4.7.16 For evaluations based on cost-comparison analyses, the level of complexity of the sensitivity analysis should be appropriate for the model being considered in terms of the pathway complexity and available data. It is likely scenario-based sensitivity analysis will be important to help identify parameters that have a substantial effect on the modelling results. Threshold analysis is also useful to identify relevant parameter boundaries.

4.7.17 Deterministic sensitivity analyses exploring individual or multiple correlated parameters may be useful for identifying parameters to which the decision is most sensitive. 'Tornado' histograms may be a useful way to present these results. Deterministic threshold analysis might inform decision making when there are influential but highly uncertain parameters. However, if the model is non-linear, deterministic analysis will be less appropriate for decision making.

4.7.18 Accuracy parameters for diagnostic technologies (usually sensitivity and specificity) present a special case. Because sensitivity and specificity are usually correlated and may vary based on how a test is used or interpreted, point estimates with distributions are not usually appropriate.

4.7.19 Consider evidence about the extent of correlation between individual parameters and reflect this in the probabilistic analysis. When considering relationships between ordered parameters, consider approaches that neither artificially restrict distributions nor impose an unsupported assumption of perfect correlation. Clearly present assumptions made about the correlations.

4.7.20 The computational methods used to implement an appropriate model structure may occasionally present challenges in doing probabilistic sensitivity analysis. Clearly specify and justify using model structures that limit the feasibility of probabilistic sensitivity analysis. Models should always be fit for purpose and should allow thorough consideration of the decision uncertainty associated with

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the model structure and input parameters. The choice of a 'preferred' model structure or programming platform should not result in the failure to adequately characterise uncertainty.

4.7.21 Using univariate and best- or worst-case sensitivity analysis is an important way of identifying parameters that may have a substantial effect on the cost-effectiveness results and of explaining the key drivers of the model. However, such analyses become increasingly unhelpful in representing the combined effects of multiple sources of uncertainty as the number of parameters increase. Using probabilistic sensitivity analysis can allow a more comprehensive characterisation of the parameter uncertainty associated with all input parameters. Probabilistic univariate sensitivity analysis may be explored to incorporate the likelihood of a parameter taking upper and lower bound values, rather than just presenting the effect of it taking those values.

4.7.22 Threshold analysis can be used as an option to explore highly uncertain parameters when identifying a parameter 'switching value' may be informative to decision makers. A switching value is the value an input variable would need to take for 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) to change. The threshold analysis should indicate how far the switching value is from the current best estimate of a parameter value.

4.7.23 Threshold analysis is not suitable for exploring uncertainty around parameters that are highly correlated with other influential parameters. Threshold analysis should also not be used to justify restricting the population of interest to a subgroup based on cost effectiveness.

4.7.24 The report should include descriptions and analysis about additional factors that are not part of the reference case and that may be relevant for decision making. These may include discussions of issues such as costings of long-term health states or health states associated with low health-related quality of life, incremental improvements, system and process improvements and patient convenience and cost improvements.

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4.8 Companion diagnostics

4.8.1 Using a treatment may be conditional on the biological characteristics of a disease or the presence or absence of a predictive biomarker (for example a gene or a protein) that helps to assess the most likely response to a particular treatment for the individual patient. If a diagnostic test to identify patients or establish the presence or absence of a particular biomarker is not routinely used in the NHS but is introduced to support the treatment decision for the specific technology, include the associated costs of the diagnostic in the assessments of clinical and cost effectiveness. Provide a sensitivity analysis without the cost of the diagnostic test. When appropriate, examine the diagnostic accuracy of the test for the particular biomarker of treatment efficacy and, when appropriate, incorporate it in the economic evaluation.

4.8.2 The evaluation will consider any requirements of the regulatory approval, including tests to be completed and the definition of a positive test. In clinical practice in the NHS, it may be possible that an alternative diagnostic test procedure to that used in the clinical trials of the technology is used. When appropriate, the possibility that using an alternative test (which may differ in diagnostic accuracy from that used in the clinical trials) may affect selection of the patient population for treatment and the cost effectiveness of the treatment will be highlighted in the guidance.

4.8.3 It is expected that evaluations of multiple companion diagnostic test options will generally be done in the NICE diagnostics assessment programme.

4.9 Analysis of data for patient subgroups

4.9.1 For many technologies, the level of benefit will differ for patients with differing characteristics. In cost-utility analyses, explore this as part of the analysis by providing clinical- and cost-effectiveness estimates separately for each relevant subgroup of patients.

4.9.2 For evaluations using cost-comparison analyses, if a technology is found to affect more than 1 disease area or patient group, clearly present the assumptions and calculations used to calculate acquisition and infrastructure costs for different

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indications and uses of the technology.

4.9.3 The characteristics of patients in the subgroup should be clearly defined and should preferably be identified based on an expectation of differential clinical or cost effectiveness because of known, biologically plausible mechanisms, social characteristics or other clearly justified factors. When possible, potentially relevant subgroups will be identified at the scoping stage, considering the rationale for expecting a subgroup effect. However, this does not prevent the identification of subgroups later in the process; in particular, during the committee discussions.

4.9.4 Given NICE's focus on maximising health gain from limited resources, it is important to consider how clinical and cost effectiveness may differ because of differing characteristics of patient populations. Typically, the level of benefit will differ between patients, and this may also affect the subsequent cost of care. There should be a clear justification and, if appropriate, biological plausibility for the definition of the patient subgroup and the expectation of a differential effect. Avoid post hoc data 'dredging' in search of subgroup effects, this will be viewed sceptically.

4.9.5 The estimate of the overall net treatment effect of a technology is determined by the baseline risk of a particular condition or event or the relative effects of the technology compared with the relevant comparators. The overall net treatment effect may also be determined by other features of the people comprising the population of interest. It is therefore likely that relevant subgroups may be identified in terms of differences in 1 or more contributors to absolute treatment effects.

4.9.6 For subgroups based on differences in baseline risk of specific health outcomes, systematic identification of data to quantify this is needed. It is important that the methods for identifying appropriate baseline data for the purpose of subgroup analysis are provided in enough detail to allow replication and critical appraisal.

4.9.7 Specify how subgroup analyses are done, including the choice of scale on which any effect modification is defined. Reflect the statistical precision of all subgroup estimates in the analysis of parameter uncertainty. Clearly specify the characteristics of the patients associated with the subgroups presented to allow

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the committee to determine the appropriateness of the analysis about the decision problem.

4.9.8 The standard subgroup analyses done in RCTs or systematic reviews seek to determine if there are differences in relative treatment effects between subgroups (through the analysis of interactions between the effectiveness of the technology and patient characteristics). Consider the high possibility of differences emerging by chance, particularly when multiple subgroups are reported. Pre-specification of a particular subgroup in the study or review protocol, with a clear rationale for anticipating a difference in efficacy and a prediction of the direction of the effect, will increase the credibility of a subgroup analysis.

4.9.9 In considering subgroup analyses, the committee will take specific note of the biological or clinical plausibility of a subgroup effect as well as the strength of the evidence in favour of such an effect (for example, if it has a clear, pre-specified rationale and is consistent across studies). Fully document the evidence supporting biological or clinical plausibility for a subgroup effect, including details of statistical analysis. Consider using an established checklist (for example, the 10 credibility criteria by Sun et al. 2012) when differences in relative effects of the technology are identified.

4.9.10 Individual patient data is preferred, if available, for estimating subgroup-specific parameters. However, as for all evidence, the appropriateness of such data will always be assessed by considering factors such as the quality of the analysis, how representative the available evidence is to clinical practice and how relevant it is to the decision problem.

4.9.11 Consideration of subgroups based on differential cost may be appropriate in some circumstances. For example, if the cost of managing a particular complication of treatment is known to be different in a specific subgroup.

4.9.12 Types of subgroups that are not considered relevant are those based solely on the following factors:

- subgroups based solely on differential costs for individuals according to their social characteristics

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- subgroups specified in relation to the costs of providing a technology in different geographical locations in the UK (for example, when the costs of facilities available for providing the technology vary according to location)
- individual utilities for health states and patient preference.

4.9.13 Analysis of 'treatment continuation rules', whereby cost effectiveness is maximised based on continuing treatment only for people whose condition achieves a specified 'response' within a given time, should not be analysed as a separate subgroup. Rather, analyse the strategy involving the 'continuation rule' as a separate scenario, by considering it as an additional treatment strategy alongside the base-case interventions and comparators. This allows the costs and health consequences of factors such as any additional monitoring associated with the 'continuation rule' to be incorporated into the economic analysis. Additional considerations for continuation rules include:

- the robustness and plausibility of the end point on which the rule is based
- if the 'response' criteria defined in the rule can be reasonably achieved
- the appropriateness and robustness of the time at which response is measured
- if the rule can be incorporated into routine clinical practice
- if the rule is likely to predict people for whom the technology is particularly cost effective
- considerations of fairness about withdrawal of treatment for people whose condition does not respond.

4.10 Presentation of data and results

Presenting data

4.10.1 Presentation of results should be comprehensive and clear. All parameters used to estimate clinical and cost effectiveness should be presented in tables and

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include details of data sources. Evidence should be presented following the guidance in technical support document 1 for summaries of key characteristics and results of included studies. Data from the individual trials should be in tables and a narrative summary of the clinical evidence provided.

Model inputs

4.10.2 For the model, input data should be tabulated with the central value, measures of precision and sources. Details on how bias was assessed and addressed should be presented for each source used.

4.10.3 For cost-utility analyses, when presenting health-related quality of life, a table of each value, its source and the methodology (for example, EQ-5D-5L, EQ-5D-3L, standard gamble) used to derive it should be provided.

4.10.4 Present a table including:

- disaggregated costs by health state and resource category
- benefits, QALYs and life years by health state
- decrements associated with further interventions and adverse events.

These results should be presented with and without discounting.

Survival estimates

4.10.5 For cost-utility analyses, Kaplan–Meier and parametric curves, and hazard plots based on observed data and model predictions should be represented both using graphs and tables. Survival analyses should be presented showing the number at risk for each Kaplan–Meier curve at each time point.

Presenting expected cost-effectiveness results

4.10.6 Present the expected value of each component of cost and expected total costs.

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Detail expected QALYs for each option compared in the analysis in terms of their main contributing components. Calculate ICERs as appropriate.

4.10.7 Present separately the life-year component of QALYs as well as the costs and QALYs associated with different stages of the condition.

4.10.8 Economic evaluation results should be presented in a fully incremental analysis with technologies that are dominated (that is, more costly and less effective than another technology in the analysis) and technologies that are extendedly dominated (that is, a combination of 2 or more other technologies would be more cost effective) removed from the analysis. Pairwise comparisons may be presented when relevant and justified (for example, when the technology is expected to specifically displace individual comparators). Expected net health benefits should also be presented when appropriate, using values placed on a QALY gain of £20,000 and £30,000; net health benefits may be particularly informative when:

- there are several interventions or comparators
- the differences in costs or QALYs between comparators is small
- there are subgroup considerations
- technologies provide less health benefit at lower costs (that is, in the south-west quadrant of the cost-effectiveness plane).

Evidence over time

4.10.9 A graphical presentation of the evidence generation process for a technology over time, including planned future evidence generation, can be included in the submission or report. This should show the expected time points of interim and final data readouts from ongoing clinical studies and planned additional studies. It should also indicate the key sources of uncertainty that might be reduced at each evidence-generating time point. For example, a forthcoming readout for a clinical trial may inform all aspects of relative effectiveness, while a future single-arm extension study may inform long-term survival outcomes for the technology under evaluation.

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4.11 Impact on the NHS

Implementation of NICE guidance

4.11.1 Information on the impact of the implementation of the technology on the NHS (and PSS, when appropriate) is needed. This should be appropriate to the context of the evaluation.

4.11.2 When possible, the information on NHS impact should include details on key epidemiological and clinical assumptions, resource units and costs with reference to a general England population, and patient or service base (for example, per 100,000 population or per region).

Implementation or uptake and population health impact

4.11.3 Use evidence-based estimates of the current baseline treatment rates and expected appropriate implementation or uptake or treatment rates of the evaluated and comparator technologies in the NHS. Also, when appropriate, attempts should be made to estimate the resulting health impact (for example, QALYs or life years gained) in a given population. These should take account of the condition's epidemiology and the appropriate levels of access to diagnosis and treatment in the NHS. It should also highlight any key assumptions or uncertainties.

Resource impact

4.11.4 Implementation of a new technology will have direct implications for the provision of units of the evaluated and comparator technologies (for example, doses of drugs or theatre hours) by the NHS. Also, the technology may have a knock-on effect (increase or decrease) on other NHS and PSS resources, including alternative or avoided treatment and resources needed to support using the new technology. These might include:

- staff numbers and hours

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- training and education
- support services (for example, laboratory tests)
- service capacity or facilities (for example, hospital beds, clinic sessions, diagnostic services and residential home places).

4.11.5 Highlight any likely constraints on the resources needed to support the implementation of the technology under evaluation, and comment on the affect this may have on the implementation timescale.

Costs

4.11.6 Provide estimates of net NHS (and PSS, when appropriate) costs of the expected resource impact to allow effective national and local financial planning. The costs should be disaggregated by appropriate generic organisational (for example, NHS, personal and social services, hospital or primary care) and budgetary categories (for example, drugs, staffing, consumables or capital). When possible, this should be to the same level and detail as that adopted in resource unit information. If savings are anticipated, specify the extent to which these finances can be realised. Supplied costs should also specify whether VAT is included. The cost information should reflect as closely as possible the prices that are paid in the NHS, and should be based on published cost analyses, recognised publicly available databases, price lists, or when appropriate, confidential or known price reductions.

4.11.7 If implementing the technology could have substantial resource implications for other services, explore the effects on the submitted cost-effectiveness evidence for the technology.

4.11.8 NICE produces costing tools to allow individual NHS organisations and local health economies to quickly assess the effect guidance will have on local budgets. Details of how the costing tools are developed are available in NICE's assessing cost impact: methods guide.

4.11.9 Committees may consider budget impact analyses when exploring the level of

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decision-making uncertainty associated with the evaluation of the technology(s) (see section 6.2.33).

4.12 Impact on health inequalities

4.12.1 The benefits and costs of new health technologies may not be equally distributed across social groups, which can impact health inequalities. Distributional cost-effectiveness analysis (DCEA) is an economic evaluation framework for synthesising evidence on health inequalities. It determines how costs and benefits vary across population groups. It can be used to show the potential impact of a new technology on health inequalities and specifically the health inequality gap in the general population.

4.12.2 DCEA should only be included in a company submission if there is clear evidence of a significant burden of health inequalities in the eligible population. This should be supported by quantitative evidence (see the technology evaluation methods support document on health inequalities).

4.12.3 DCEA should only be used as supporting evidence of the potential for a technology to impact health inequalities. Cost-effectiveness results by subgroups based solely on social characteristics should not be part of the base-case analysis or presented as non-reference case scenarios.

4.12.4 DCEAs will not be done in economic evaluations produced by EAGs on behalf of NICE for HealthTech guidance and multiple technology appraisals. For these types of evaluations, DCEA evidence can be provided by companies as part of the information requested on the evidence base and their technology.

4.12.5 NICE's technology appraisals and highly specialised technologies recommendations do not include guidance on service delivery or to support implementation for disadvantaged groups. The committee can only recommend technologies as options for use in the NHS. Differences in uptake may determine health inequality impacts and be relevant to the committee's deliberations, but they cannot be addressed by the committee's recommendations.

4.12.6 The committee should be aware of the remit of their guidance programme and

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consider how any variations in modelled uptake would be addressed by the new technology.

4.12.7 The results of the DCEA should not weigh the costs or benefits of a technology differently based on the social characteristics of the people affected by the recommendation.

4.12.8 Health inequalities may be relevant to a range of technologies and diseases. So, it is important that DCEAs that support decision making are consistent. The key components of DCEAs and NICE's preferred methods are summarised in the technology evaluation methods support document on health inequalities. Other approaches can be presented if appropriate, but deviations from the specified methods must be clearly justified and supported by evidence.

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5 Developing the guidance

5.1 Starting the evaluation process

5.1.1 NICE sends the name and contact details of the project manager assigned to an individual evaluation to all stakeholders. Stakeholders should send all correspondence about an individual evaluation to the project manager, unless requested otherwise.

5.1.2 NICE sends correspondence for an evaluation electronically (or in other formats on request) to key contacts identified by each stakeholder organisation. Stakeholders must notify the project manager of any change in contact details, or in organisation or company name, during the evaluation.

5.1.3 NICE charges companies for technology appraisal and highly specialised technologies evaluations. NICE reserves the right to pause the evaluation if payment is not received by the due date. See our published information on charging for more detail.

5.2 Evaluation timelines

5.2.1 It is not possible to set absolute timelines for all stages of the evaluation. The length of time needed for each stage can vary depending on the nature of the particular evaluation. Additional time may be given to particular stages if they coincide with public holidays.

5.2.2 Throughout an evaluation, up-to-date information about timelines and progress will be published on the NICE website.

5.2.3 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.

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5.2.4 For technology appraisals and highly specialised technologies, scheduling of topics into the NICE work programme will be managed using information on expected regulatory approval dates and submission readiness. These will be provided through horizon scanning and topic prioritisation activities, and directly to NICE by the company.

5.2.5 Topics in the same disease area, following the same regulatory timelines and so scheduled into the same (or closely aligned) committee meeting, may benefit from aligned internal processes. When appropriate, NICE may decide to hold a joint committee meeting covering more than 1 appraisal. A joint committee meeting is when the discussion of 2 separate topics is held in 1 committee session. Confidentiality will be strictly preserved. Also, the topics will remain as separate appraisals and considered independently, and recommendations will be made individually for each appraisal. Any regulatory changes or topic delays will result in the cancellation of internal process alignment.

5.3 Information handling – general considerations

5.3.1 NICE adheres to the principles and requirements of data protection legislation, including the General Data Protection Regulation and the Freedom of Information Act, when dealing with information received during an evaluation.

5.3.2 Organisations who want to be involved in an evaluation must sign a confidentiality agreement first (formally known as the confidentiality acknowledgement and undertaking) to be considered a participating stakeholder. After this, NICE can release evaluation documents to them.

5.3.3 NICE needs to meet the requirements of copyright legislation. If a company cites journal articles in its submission, it must include the full articles in its submission and have copyright clearance to do so.

5.3.4 If NICE needs journal articles for its own use during the evaluation, it will obtain the article, paying a copyright fee when necessary.

5.3.5 For company submissions, the medical director (or equivalent senior officer) of the company must sign a statement confirming that all clinical trial data

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necessary to address the scope has been disclosed to NICE or its authorised agents, as issued by the Department of Health and Social Care and NICE. This applies to data within the company's or any of its associated companies' possession, custody, or control in the UK or elsewhere in the world, within the meaning of section 256 of the Companies Act.

5.3.6 For technology appraisals and highly specialised technology guidance, companies must consent to regulatory authorities providing NICE directly with all clinical trial data necessary to address the scope of the evaluation. This includes all data that has been submitted to the regulatory authorities by the company or any of its associated companies and that was relevant to the granting of regulatory approval. Companies must also consent to NICE using that data to do the evaluation. NICE will only ask regulatory authorities directly after having first approached the company for the information if the company is unable or unwilling to provide the information in a timely manner.

5.3.7 Stakeholders should take care when submitting information about individual people. Personal and sensitive information, for example, the name of a person's clinician, should be removed from submissions. It is the responsibility of the submitting organisation to assess the risk of subject identification and handle depersonalised data accordingly. Further information on depersonalised data and how to assess the risk of identification can be found in the Information Commissioner's Office guide to data protection.

5.3.8 All evidence submissions and other information supplied as part of the evaluation process will be published on the NICE website and must therefore meet legislation to ensure content is accessible to everyone including users with impairments to vision, hearing, mobility, thinking and understanding. NICE requires stakeholders to ensure their submissions meet formal accessibility standards.

5.3.9 NICE also encourages stakeholders to make their submissions publicly available, for example, by putting them on their own websites after they have sent their submission to NICE.

5.3.10 NICE may comment publicly on the content of an evaluation during the process and when draft or final guidance has been published. The following

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circumstances may also apply:

- NICE reserves the right to comment publicly if there has been an unauthorised disclosure from a confidential NICE document before it has been published on the NICE website. NICE will inform stakeholders of this decision as soon as possible.
- NICE reserves the right to issue a correction if a public comment is made on draft guidance or final draft guidance that could mislead, misinform or offend.

5.3.11 Stakeholders are responsible for treating evaluation documents that are not in the public domain as confidential until NICE makes those documents, or the data within them, public. NICE considers individuals in a stakeholder organisation who views evaluation documents to be bound by the terms of the confidentiality agreement signed by the stakeholder organisation.

5.3.12 Any organisation or individual not directly employed by the stakeholder organisation is a third party. Stakeholders may release evaluation documents to third parties when:

- it is necessary so the stakeholder can contribute to the evaluation and
- the third party has seen and agreed to be bound by the terms of the NICE confidentiality agreement.

5.3.13 Stakeholders may discuss confidential evaluation documents with other stakeholders but, before doing so, they must be satisfied that the other parties have signed and returned their confidentiality agreement to NICE.

5.3.14 In the committee papers, draft guidance and final guidance, NICE reserves the right to use any material submitted during the evaluation that is not marked as confidential, or which ceases to be confidential. All confidential information will be clearly marked in the committee papers.

5.3.15 If changes are made to the technology's regulatory approval, NICE will discuss the implications with the external assessment group (EAG) and the company. NICE will agree how to incorporate the changes into any evidence submission and external assessment report.

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5.3.16 NICE will not publish final guidance on a technology until UK regulatory approval has been granted and the technology's price is known or can be determined. NICE may share documents with participating stakeholders who have signed and returned a confidentiality agreement to NICE.

5.4 Information handling – confidential information

5.4.1 It is essential that as much of the evidence as possible informing the committee's decision making is made available to stakeholders and is publicly available. This is to ensure that the evaluation process is as transparent as possible. In some circumstances, NICE will accept evidence and information not in the public domain under agreement of confidentiality. NICE defines 3 categories of confidential information; commercial-in-confidence, academic-in-confidence and depersonalised data. Academic-in-confidence is not used for medicines evaluated through the technology appraisals or highly specialised technologies programmes.

5.4.2 There are broad categories of data and information that are redactable and non-redactable. Evidence and information not in the public domain that may be redacted includes:

- evidence that is commercially sensitive, including but not limited to, confidential price discounts, confidential information on market share and confidential regulatory or clinical trial timelines, and data that allows back calculation of commercially sensitive data (see section 5.4.9 for more information on confidential discounts)
- clinical data that is not intended for publication in a scientific paper or in a publicly available regulatory document: the rationale for redacting this data should be explained and consideration should be given to the expected impact on the ability of NICE to explain the evidence that the committee's decisions are based on to stakeholders and the public (see section 5.4.4)
- data provided to the stakeholder submitting to NICE by a third-party organisation, if there are stipulations from the third-party organisation on how the data may be disseminated by the stakeholder. For example, registry data or data from a trial when the stakeholder is not the sponsor; in these

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cases, the redaction stipulations of the third-party organisation will be adhered to

- data that allows for subject identification, including depersonalised data (data that is stripped of direct identifiers) but for which there is still a high risk of subject identification.

5.4.3 Categories of information that cannot be redacted include:

- methods used to do a study or to analyse data from a study
- clinical data that is available in the public domain
- clinical data awaiting publication, including in a journal or in documents supporting authorisations by regulatory agencies that are released at the time of marketing authorisation
- data collected in NHS clinical practice as part of a managed access agreement and cannot be considered confidential unless it meets other criteria, for example, allows for subject identification
- critical appraisal of clinical studies and indirect comparison
- clinical opinion and assumptions (which are not based on empirical data).

5.4.4 The principles for handling confidential information are described in sections 5.4.4 to 5.4.21. Information marked as confidential should be kept to an absolute minimum and reasons for confidentiality must be stated clearly. Marking must allow evidence and information that is likely to be fundamental to the committee's decision making to be sufficiently explained to stakeholders and users of NICE guidance.

5.4.5 Data that is likely to be fundamental to committee's decision making includes:

- cost-effectiveness (incremental cost-effectiveness ratio, ICER) or cost-comparison (incremental cost) estimates
- data informing the case for decision modifiers to be applied in technology appraisals and highly specialised technology evaluations

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- evidence allowing consideration of items listed in section 6.2.28 of the manual and, mainly, the generalisability, reliability and robustness of evidence informing an evaluation and plausibility of assumptions or model outcomes.

  It is recognised that some of this evidence may fall under the categories of redactable data in section 5.4.2 such as:

- data allowing back calculation of a confidential price discount (for example, price related to a patient access scheme [PAS] or a commercial access agreement, or from the Commercial Medicines Unit)

- unpublished clinical data not intended for publication.

  In most instances in which the stakeholder considers it necessary to mark this data as confidential, as a minimum, an accompanying descriptive summary of what the data shows must be provided. This is so that NICE can explain committee decision making to stakeholders and the public. Guidance is given in the principles for confidential information marking and redacting document. There are instances in which numerical data rather than a descriptive summary is needed to explain committee decision making. This includes data informing the case for decision modifiers and also health-state utility values, on-treatment utility increments or decrements, and utility decrements associated with adverse events. In these cases, numerical values should be shown. New flexibility on the redaction of ICERs has been introduced to allow the transparency of these numerical values to be prioritised.

5.4.6 There are instances in which the exact decision-making ICER, or incremental costs in cost-comparison analyses, cannot be published in NICE documentation or in public committee meetings. This includes when there are confidential PAS for combination treatments, comparators and subsequent treatments. In these cases, NICE will state in its public committee meetings and postmeeting documentation whether the values are above or below a level at which the technology may provide value for money. Given the high proportion of evaluations in which this is the case, NICE will consider this approach across all technology and highly specialised technologies evaluations. This means that there is flexibility that allows redaction of ICERs and incremental costs if:

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- there are confidential PAS for combination treatments used alongside the intervention under evaluation, comparators or subsequent treatments
- a new confidential price for the intervention under evaluation is expected or the confidential price is expected to change over the course of the evaluation, and reporting of results including different prices will allow calculation of the final confidential price
- a case for a severity modifier is being made, or
- it allows utility values to be transparent.

When ICERs are redacted, incremental quality-adjusted life year (QALYs) should not be redacted.

5.4.7 If NICE wishes to publish or publicly share data regarded by the data owner as confidential, both NICE and the data owner will negotiate to find a mutually acceptable solution. This will recognise the need for NICE to support its recommendations with evidence and the data owner's right to confidentiality. But, by adhering to the principles for confidential information handling, the need for negotiation is considered exceptional. The data owner retains the right to make a final decision about the release of confidential information into the public domain.

5.4.8 NICE could be challenged that confidential information it has received should be publicly released in the interests of fairness during an evaluation, at appeal or resolution, through judicial review or otherwise. If this happens then data owners must, on request, promptly reconsider whether it is necessary to maintain confidentiality. If disclosure is not possible, the data owner must be prepared to assert publicly that the information is confidential and must submit evidence justifying why NICE should maintain that confidentiality. Without such assertion and evidence, NICE is entitled to conclude that the information is no longer confidential.

5.4.9 Details of a PAS, once referred to NICE for consideration in an evaluation, are not confidential except when NHS England has agreed that a simple discount PAS is confidential. All other types of commercial access agreements, once referred to NICE for consideration in an evaluation, are confidential. In these cases (as outlined in section 5.4.2), the discount and any data that could lead to back-

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calculation of the discount will not be shared with stakeholders or released into the public domain.

5.4.10 When the details of the PAS are not published in final NICE guidance, the NHS must have access to the details. This is so providers and commissioners can properly account for the PAS and commercial agreement. Details of commercial access agreements will not be published in final guidance. When an element(s) of a commercial access agreement needs to be known to the NHS for the agreement to be operationalised, the NHS must have access to the details.

5.4.11 NICE will not share confidential details of confidential price discounts for other medicines with the company for a new technology being evaluated. For each medicine, and for each indication included in the treatment pathway, the company must include a 'discount' field in its economic model. This should allow the user to input any value between 0% and 100%, which is then applied as a percentage discount to the list price of the medicine. By providing this feature in its model, the company will be responsible for the initial programming, which the EAG will check. All parties should then be confident that the discount is programmed correctly. The EAG will be authorised to know the exact level of discount for commercial arrangements in the evaluation.

5.4.12 The EAG will use the list price, or alternative publicly available price such as eMIT price, for any other technologies with confidential price discounts in its external assessment report when reproducing the company's analyses and for any exploratory analyses. To allow the committee to explore the effect of using the actual cost of the technologies in the analyses, the EAG will also create a confidential appendix to its report. This will reproduce all analyses from the external assessment report using the exact level of discount. When the results of the EAG analyses are classed as confidential because of existing confidential commercial mechanisms including, but not limited to, PAS and commercial access agreements, NICE will state whether the ICERs are above or below a decision-making threshold in its public committee meetings and post meeting documentation (section 5.4.6).

5.4.13 Executable economic models used in the evaluation will be made available on request to stakeholders who have signed a confidentiality agreement.

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5.4.14 Committee and EAG members attending the committee meeting will be provided with all confidential information submitted.

5.4.15 The clinical and patient experts who attend the committee will be provided with all confidential information submitted, except confidential PAS for combination treatments, comparators and subsequent treatments, and commercial access agreements (or other similar confidential price arrangements).

5.4.16 In committee meetings, confidential information will be redacted from the slides. Committee and EAG members, clinical and patient experts, and company representatives will also be given an unredacted version of the slides presented in the public part of the meeting. When necessary, for appraisals in which more than 1 technology is being evaluated, NICE may agree with the relevant data owners' additional arrangements for handling clinical data not intended for publication during public meetings, to enable effective and transparent discussions.

5.4.17 If a technical engagement happens, all information marked as confidential will not be released to stakeholders even though they have signed a confidentiality agreement. Patient, clinical and commissioning experts will be able to see unredacted documents.

5.4.18 If an evidence submission or a statement from a non-company stakeholder contains confidential information, it is the responsibility of the submitting organisation to provide 2 versions:

- a version for NICE, the committee, the EAG, experts and the NHS England clinical leads and commissioning experts with all the confidential information marked with turquoise highlighting and underlined
- a version in which all the confidential information is redacted.

5.4.19 The stakeholder must complete a confidential information checklist at the time of submission. This should list all confidential information included in the submission or statement and the reason for its confidentiality. If NICE does not receive a completed checklist with a document, none of the information will be considered confidential.

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5.4.20 Data owners may be asked to check that confidential information is correctly marked in documents created by others in the evaluation before release.

5.4.21 NICE releases all documents that are presented to committee in committee papers to stakeholders during the evaluation. NICE publishes these documents on its website within 7 days after they have been sent to stakeholders. After NICE has published these documents on its website, they are no longer confidential. Confidential information within published documents is redacted.

5.5 Start of the evaluation and evidence submission

5.5.1 After scoping, the guidance development process consists of 3 distinct phases: start of the evaluation and evidence submission, evidence review, and evaluation.

5.5.2 It is the responsibility of the company to inform NICE as soon as possible of any potential related regulatory developments or delays by contacting the project manager.

5.5.3 Before the start of the evaluation, for technology appraisals and highly specialised technologies, the company has the opportunity to discuss the decision problem that follows from the draft scope with the NICE team and EAG representatives. The company must submit an outline of how it intends to approach the decision problem when preparing the evidence submission. This outline should include, but is not limited to:

- evidence sources to be used
- evidence likely to become available during the evaluation and how this might be managed
- any plans to submit quantitative evidence on health inequalities issues
- the planned approach to disease and economic modelling
- potential challenges in interpreting the evidence
- the proposed approach to handling of uncertainty.

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The meeting will also allow companies to discuss potential handling of patient access schemes or commercial access agreements and proposals for using the cost-comparison evaluation process. Changes to the scope will not be considered.

5.5.4 NICE will publish the final scope, the name of the EAG and the stakeholder list on its website at the start of an evaluation.

5.5.5 NICE sends stakeholders the invitation to participate and a list of key dates in the evaluation.

5.5.6 NICE aims to make sure that companies bringing technologies forward for possible use in the NHS can make the best plausible case for its product, to the ultimate benefit of the NHS and patients. Therefore, NICE works closely with relevant stakeholders at key stages of the NICE technology appraisal and highly specialised technologies processes to inform their commercial activities and allow timely discussions between NHS England and NHS Improvement and the company. This interaction between NICE, NHS England and NHS Improvement and the company is key to ensuring the guidance is produced as quickly as possible allowing faster patient access to cost-effective technologies.

5.5.7 From this stage forward in the evaluation, companies are expected to proactively pursue an appropriate commercial arrangement to ensure their technology is cost effective when evaluated (see section 5.9).

Evidence submission from the company

5.5.8 NICE invites the company to provide an evidence submission using a detailed submission template.

5.5.9 For topics identified as cost comparison, submissions should be made using the cost-comparison submission template. Submissions made using the single technology appraisal template after cost comparison has been referred will be rejected and the topic may be delayed.

5.5.10 For technology appraisals and highly specialised technologies, the deadline for

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receipt of the evidence submission is:

- 28 calendar days from the invitation to participate for cost-comparison evaluations
- 56 calendar days from the invitation to participate for single technology evaluations
- 84 calendar days from the invitation to participate for multiple technology evaluations.

5.5.11 For medical technologies evaluations, the evidence submission is provided 42 days from the publication of the final scope.

5.5.12 For diagnostic technologies, the company is not asked to provide a formal evidence submission, but the company is asked to provide information on its technology and evidence base to allow the EAG to prepare its report accurately.

5.5.13 After receiving the submission, NICE sends it to the EAG for review.

5.5.14 The information needed for the evidence submission is derived from the approach NICE uses to evaluate the clinical and economic value of health technologies.

5.5.15 The evidence must be submitted in the template provided by NICE for the type of evaluation selected.

5.5.16 NICE will provide an opportunity for the company to discuss key issues with NICE and, if needed, the EAG before the company's submission date. NICE will ask the company to provide an update on their submission before the meeting. This engagement will also allow companies to discuss potential regulatory developments during the evaluation and the potential inclusion and handling of commercial proposals. Before the company evidence submission deadline, companies can request additional engagement with NICE. Engagement will depend on availability of the NICE team at the time of request.

5.5.17 If the company plans to submit an economic model or is required to do so, it should inform NICE which software will be used. NICE accepts fully executable

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economic models using standard software, that is, Excel, DATA/Treeage, R or WinBUGs. If the company plans to submit a model in a different software package, it should tell NICE in advance. NICE, with the EAG, will investigate if the requested software is acceptable. When the company submits a fully executable electronic copy of the model, it must give NICE full access to the programming code. It should ensure that the submitted versions of the model program and the written content of the evidence submission match.

5.5.18 NICE offers to send the economic model (in its executable form) to stakeholders during any technical engagement or consultation. If the model contains confidential material that the data owner is unwilling to share with stakeholders, despite the assurances provided through the signed confidentiality agreements, NICE will ask the company to redact the model if this can be done without severely limiting the model's function. Stakeholders must make requests for a copy of the model in writing. NICE provides the model on the basis that the stakeholder agrees, in writing, to the following conditions of use:

- The economic model and its contents are confidential and are protected by intellectual property rights, which are owned by the relevant company or EAG. It cannot be used for any purpose other than to inform understanding of the committee papers.
- The economic model cannot be published by stakeholders (except by the company who owns the model), in whole or in part, or be used to inform the development of other economic models.
- The model must not be run for purposes other than to test its reliability.
- The model is deleted from the stakeholder's records upon publication of final NICE guidance.

5.5.19 When technologies are being evaluated at the same time as regulatory approval, sufficient details of the clinical trial evidence should be made available so NICE can do the evaluation according to the defined scope. For medical devices and diagnostic technologies with limited published evidence, unpublished data could support the evidence base.

5.5.20 If the company wishes to include a patient access scheme or commercial access agreement proposal as part of its submission, specific requirements apply (see

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section 5.8).

Managed access proposals (technology appraisals and highly specialised technologies only)

5.5.21 Managed access is only for medicines evaluated through technology appraisals and highly specialised technologies. For medicines where immature evidence or evidence gaps are likely to result in significant uncertainty for committee decision making and the company wishes to have the option of a recommendation with managed access, a managed access proposal should be included within their submission.

5.5.22 A company may opt to make a managed access proposal for any medicines that may be considered eligible through the Cancer Drugs Fund or the Innovative Medicines Fund. Early engagement with NICE about a managed access proposal is encouraged to allow exploration of the potential for further data collection to address significant uncertainties in the evidence. Multiple touch points within the evaluation process provide opportunities for NICE, the company and other stakeholders to identify if a medicine may be suitable for managed access, and that a managed access proposal could be submitted, including:

- At scoping, during the decision-problem stage where the company is considering making a managed access proposal.
- At submission, a managed access proposal as part of the company's submission.
- At technical engagement (if held) when significant uncertainties are highlighted, and a managed access proposal could be submitted.

5.5.23 Managed access proposals should be submitted at the evidence submission stage. A managed access proposal has 2 components:

- a data collection proposal
- a commercial access proposal.

5.5.24 The committee will always first consider whether a case for recommendation (as

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an option) is met. If the committee concludes that recommendation (as an option) is not supported, then it will consider whether a recommendation with managed access is appropriate. To consider this, a committee will need a managed access proposal, along with a feasibility assessment from NICE.

5.5.25 The company must submit a commercial access proposal with its data collection proposal. The process for submitting a PAS or commercial access agreement is outlined in section 5.9.

Managed access data collection proposal (technology appraisals and highly specialised technologies only)

5.5.26 A feasibility assessment will be done by NICE to identify if the proposed data collection can produce new evidence to address the significant uncertainties, without undue burden on the NHS. The feasibility assessment process will involve engagement with a range of stakeholders, including the company, clinicians, patients and their representatives, and NHS data custodians. The extent of engagement activities will be proportionate to the complexity of the data collection proposal.

5.5.27 The feasibility assessment will be shared with the committee, company, and stakeholders 28 days before the committee meeting.

5.5.28 The data collection proposal should identify:

- The key clinical uncertainties that might result in the committee concluding that the case for adoption cannot be supported.
- The outcome data that may be needed to sufficiently support the case for adoption.
- The potential data sources that could be used to collect this outcome data.
- The proposed duration of the data collection period.
- How the data collected would be analysed and incorporated for a NICE guidance update.

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- Any considerations around information governance and data sharing that may need to be addressed.

5.5.29 NICE will assess whether:

- it is feasible to collect and analyse the proposed outcome data within a reasonable timeframe.
- the additional burden of data collection on patients, clinicians, and the NHS is proportionate.
- there is a reasonable likelihood that the proposed outcome data will be sufficient to support the case for adoption at the guidance update.
- the data collection can be started when patients get access to the technology.
- there are any ethical, equality, or patient safety concerns with the proposed data collection and analysis.
- there are other substantive barriers to implementing managed access.

5.5.30 The company will have the opportunity to amend its managed access proposal, before the first committee meeting to address issues identified during the feasibility assessment or in response to EAG feedback. However, substantial revisions or a new proposal during or after technical engagement are likely to delay the evaluation process.

Managing company submissions with high base-case ICERs (technology appraisals and highly specialised technologies only)

5.5.31 If a company submission includes a base-case ICER that is significantly higher than the standard threshold, and this level of ICER has not been sufficiently addressed through a PAS or commercial discussions between the company and NHS England and NHS Improvement, NICE may pause progression of the topic to consider the most efficient and appropriate course of action. NICE will discuss with the company how to progress the evaluation but reserves the right to make

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the final decision about progressing to the next stage of the evaluation. NICE will also ensure that all other stakeholders involved in the process are fully informed of the rationale for the decision.

Evidence submissions from non-company stakeholders

5.5.32 NICE invites non-company stakeholders to make a submission providing information on the potential clinical effectiveness and value for money of a technology, using the appropriate templates available on the NICE website. The submission should reflect the experience of patients, healthcare professionals and commissioners of current standard treatment in the NHS in England. It should also reflect the potential impact of using the new technology on health-related quality of life. If appropriate, it may also demonstrate any potential impacts on health inequalities. Implementation issues, such as staffing and training needs, should also be included. Stakeholders are given the same number of days and deadline to provide their submission to NICE after the invitation to participate. After receiving the evidence submissions, NICE sends them to the EAG and technical team for consideration.

5.6 Evidence review

Developing a protocol

5.6.1 For multiple technology evaluations, the EAG develops an assessment protocol, derived 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.

Initial clarification and additional analysis

5.6.2 After receiving the company's evidence submission (when needed), the NICE technical lead and the EAG assess whether the submission is complete and whether the decision problem is specified appropriately with reference to the

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final scope.

5.6.3 If the company evidence submission is incomplete or the decision problem is not specified appropriately, the technical lead consults with the EAG and sends a letter of clarification and any requests for additional analyses to the company within 21 days of receiving the submission. The company has 14 days from the date of the correspondence to respond to points of clarification and provide any additional analyses. When the company provides additional analyses, it should include full descriptions of the analyses as appendices to the original submission. If necessary, NICE will organise a clarification meeting between the NICE team, the company and the EAG to resolve any issues.

5.6.4 For cost-comparison evaluations, the company has 10 working days from the date of the correspondence to respond to the points of clarification and provide any additional analyses.

5.6.5 If requests for clarification and any additional analyses delay the published timelines, NICE will inform stakeholders and publish the reason for the delay on its website.

5.6.6 At the same time as the response to the clarification request, the company should review the confidential status of information in its evidence submission before the committee meeting.

5.6.7 The company should not submit additional evidence during the evidence review phase unless NICE requests or agrees to this in advance.

Terminating an evaluation

5.6.8 NICE aims to ensure that the company prepares the best possible evidence submission for the committee. NICE will not validate the submission, but it will help to clarify substantive issues. NICE will consider whether the evaluation should be terminated if, after all reasonable requests for clarification, NICE is not satisfied that the evidence submission is adequate for the committee to make a decision.

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5.6.9 NICE will also consider whether to terminate an evaluation if no evidence submission has been received or, for a technology appraisal or highly specialised technologies evaluation, payment has not been received.

5.6.10 When an evaluation is to be terminated, NICE will share termination publication timings and agree appropriate wording with the company. NICE will advise the NHS that it is unable to make a recommendation about using the technology because no evidence submission was received from the company and the evaluation has been terminated. NICE will also provide an explanation to help the NHS make local decisions on making the technology available.

5.6.11 For evaluations that are terminated after a period of managed access because of non-submission, the company will be required to participate in an engagement event with all stakeholders and provide information about the reasons for not proceeding with the guidance update.

5.6.12 NICE may also use the termination process to manage a company submission with a significantly high ICER.

5.6.13 A terminated evaluation can be restarted if the company indicates that it will make a full evidence submission.

External assessment report

5.6.14 The EAG prepares a report on the clinical and cost effectiveness or cost savings of the technology. The report is usually based on a review of the company's evidence submission (except for diagnostics guidance and multiple technology evaluations in technology appraisals and highly specialised technologies) and advice from the EAG's clinical experts. The EAG prepares the report using a template agreed with the NICE team. The EAG is responsible for the content and quality of the report for all guidance types.

5.6.15 The EAG critically evaluates any evidence submissions. If the EAG, as part of exploratory analyses, amends the company's model, NICE will make the analyses available to the company at any technical engagement stage. All other stakeholders may request, in writing, the EAG analyses during technical

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engagement or consultation.

5.6.16 For diagnostic guidance, companies do not normally provide an evidence submission. For multiple technology evaluations in technology appraisals and highly specialised technologies, the companies are invited to provide an evidence submission but are not formally required to do so. The EAG does an assessment of the clinical outcomes and cost effectiveness of the technologies, and diagnostic test accuracy where relevant. The assessment is based on systematic reviews of the literature, data provided by the companies, information from the experts or specialist committee members, and modelling of patient outcomes, costs and cost effectiveness. The EAG's assessment highlights the uncertainties in the evidence and may include an analysis of the value of reducing those uncertainties.

5.6.17 After receiving the external assessment report, NICE will share a copy with the company for fact checking. This will allow the company time to prepare for any technical engagement. NICE may seek advice from experts at this stage if additional clarification on the submitted individual expert statement is needed. There is no fact checking stage in diagnostics evaluations.

5.6.18 If sent out for technical engagement, the external assessment report will be accompanied by:

- any company submission (and model when appropriate)
- any clarification questions and company responses
- any external assessment report factual accuracy check.

5.7 Topic progression – single technology appraisal

5.7.1 After receiving the external assessment report, NICE will assess the evidence submissions and external assessment report and make a decision on how the appraisal will progress. At this stage an appraisal can:

- continue as a single technology appraisal and progress to committee preparation

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- continue as a single technology appraisal and progress to technical engagement before committee preparation
- be appropriate for a streamlined committee decision process in selected low-risk circumstances, with a committee decision outside of a formal meeting
- pause while NICE considers the most efficient and appropriate course of action (see section 5.5.31: managing company submissions with high base-case ICERs).

5.7.2 Technical engagement will only be included if NICE considers that it is appropriate, helpful and proportionate, taking into account whether the technical engagement process is likely to resolve key issues before the committee meeting.

5.7.3 If technical engagement is included, timelines will be amended to allow for engagement time with stakeholders.

5.7.4 Decisions to streamline topics into a committee decision outside of a formal meeting will be made by NICE.

5.7.5 When deciding on the suitability for streamlined decision making, NICE will take into account the risks associated with the evaluation and the decision to streamline. This may include:

- the likelihood of decision error in the guidance, and its consequences
- the complexity of the technology, clinical pathway or evidence, and associated uncertainties
- the potential impact of the decision to streamline on:
  - resources for NICE, committees and stakeholders
  - service readiness
  - consistency and predictability of NICE decision making
  - openness and transparency in decision making.

5.7.6 The progression decision and relevant timelines will normally be communicated to

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stakeholders within 14 days of receipt of the external assessment report into NICE. Information will also be published on the NICE website once stakeholders have been informed.

Technical engagement

5.7.7 The purpose of the technical engagement is to note and consider any evidence gaps and potential resolution ahead of the committee meeting and to consider any commercial or managed access proposals. Technical engagement is not normally needed in medical technologies evaluations.

5.7.8 Technical engagement is not a mandatory stage of the evaluation process. When it is identified that the evaluation would benefit from additional engagement before the committee meeting, NICE may decide that the technical engagement process step should be included. A decision to progress to technical engagement will be discussed in advance with the company and communicated to stakeholders.

5.7.9 The external assessment report is sent to stakeholders for comment within 21 days of NICE receiving the external assessment report and after completion of any factual accuracy check. NICE will notify stakeholders if a delay is expected.

5.7.10 Stakeholders have 28 days to submit comments on the external assessment report for technology appraisals and highly specialised technologies or 14 days for diagnostics or medical technologies evaluations. Comments must be submitted electronically. During the engagement period, NICE may meet with any company who has made an evidence submission and with selected experts when the technical team thinks this is necessary.

5.7.11 NICE will ask the company to re-confirm the expected timing of regulatory approval in the UK (if not already received).

5.7.12 If a comment contains confidential information, the organisation or person who submitted the comment should provide 2 versions; one with all confidential information marked and another with the confidential information redacted (to be published on NICE's website), with a checklist of the confidential information.

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Detailed instructions on sending NICE confidential information are available from the project manager.

5.7.13 During technical engagement, new evidence and analyses can only be accepted if the NICE technical team agrees that this information is likely to affect the committee's judgements. The new evidence must be presented in a separate appendix to the comments on the external assessment report. NICE may need to extend timelines and reschedule the subsequent committee meeting to allow the new evidence to be considered. The company must inform NICE, in writing, of its intention to submit new evidence and analyses, as early as possible and before the deadline for comments on the external assessment report.

5.7.14 Any EAG review of new evidence will not normally be sent out for additional technical engagement before the committee meeting.

5.7.15 If comments received on the economic model need a company or EAG response, NICE sends those comments to the company or EAG. Their responses will be tabled at the next committee discussion.

5.8 Evaluation

5.8.1 The evaluation phase of the process has 4 possible stages:

- consideration of the evidence at a committee meeting to discuss the content of either the draft guidance or final draft guidance
- development of, and consultation on, the draft guidance (if needed)
- review of the draft guidance (if produced) after comments from consultation at a second committee meeting, if needed
- development of the final draft guidance.

Preparing for the committee meeting

5.8.2 The technical team and the EAG may meet to discuss the results of any technical

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engagement, if needed, and prepare for the committee meeting.

5.8.3 The committee papers are usually circulated to all attendees (except members of the public) 2 weeks before the first committee meeting, and consist of:

- A link to the final scope of the evaluation and the stakeholder list.
- The external assessment report, clarification comments and responses, comments from technical engagement (if held) and the technical team's summary of them.
- The evidence submissions from organisations and experts.
- If produced, the managed access or further evidence generation assessment report.
- If produced, the draft data collection agreement.

5.8.4 Committee meetings are primarily held virtually and usually open to members of the public, stakeholders and the press. This supports NICE's commitment to openness and transparency. It allows stakeholders and the public to understand how evidence is evaluated and interpreted and how consultation comments are considered. Some committee discussions take place in private when there is a need to discuss confidential data and when a technology has not yet received regulatory approval.

5.8.5 To promote public attendance, the meetings in public team at NICE publish a notice and draft agenda on the website at least 21 days before the committee meeting. Members of the public and stakeholders who wish to attend as observers can register on NICE's website. The closing date for registration is 7 days before the meeting and late registrations may not always be accepted. NICE aim to contact registrants with the joining links and joining instructions 1 to 2 days before the meeting and publish the final agenda on its website 7 days before the meeting.

Committee meeting

5.8.6 When the committee meets for the first time to discuss the technology, final draft

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guidance will be developed when it is possible to do so. Sometimes the committee may develop draft guidance if recommendations meet the criteria set out in section 5.7.41. The committee will consider the written evidence and verbal evidence, drawn from discussions with experts, EAG representatives, specialist committee members, and national clinical directors or advisers.

5.8.7 Committee decisions are normally based on consensus. If a vote is taken, it will be noted in the minutes.

Part 1 (public session)

5.8.8 Members of the committee and people having direct input into the discussions declare their interests, which are recorded in the minutes.

5.8.9 The lead team committee members present the topic to the other committee members and attendees. This introduction does not pre-empt the committee's debate or drafting of the guidance.

5.8.10 Clinical experts, patient experts and any NHS commissioning experts will be encouraged to help clarify issues about the evidence presented, including responding to and raising questions, but they do not make a presentation to the committee.

5.8.11 Company representatives respond to questions from the committee and comment on any matters of factual accuracy.

5.8.12 The committee considers the evidence during the public session. However, it will not discuss commercial-in-confidence information, or information contained in a statement from a clinical expert, NHS commissioning expert or patient expert that has been marked as confidential during this part of the meeting.

5.8.13 The EAG representatives answer questions from the committee and provide clarification on the external assessment report.

5.8.14 Representatives from other guidance-producing teams (for example, guidelines and public health) at NICE who are responsible for developing NICE guidance in

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areas related to the evaluation may also attend the meeting to observe and advise the committee. These representatives must declare their interests.

5.8.15 NICE staff may present additional evidence, provide advice on NICE policies and procedures, and respond to questions from the committee.

Part 2 (private session)

5.8.16 During the private session, the committee considers commercial-in-confidence information and agrees the recommendations. All other attendees, except the NICE team, are asked to leave the meeting before this discussion takes place.

5.8.17 The chair may ask certain experts, company representatives or EAG representatives to remain when confidential information is discussed but the chair will ask them to leave before the committee agrees the recommendations.

5.8.18 A patient expert can ask to have any personal, sensitive or confidential information heard by the committee in private. The patient expert should formally request this through the project team at NICE and it must be agreed with the chair of the committee before the meeting.

5.8.19 NICE staff remain at the meeting while the committee agree the recommendations, but they play no part in decision making.

5.8.20 The committee concludes the discussions and agrees the content of either the draft guidance, which sets out its draft recommendations, or the final draft guidance, which sets out its final recommendations (subject to fact checking, appeal or resolution). After the meeting, the guidance is drafted based on the discussions at the meeting. NICE may issue draft guidance or final draft guidance on a technology before that technology receives final UK regulatory approval.

5.8.21 The outcome of the committee meeting will be shared with stakeholders within 7 days of the committee meeting. This will be a brief statement of the committee decision.

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Minutes

5.8.22 NICE publishes unconfirmed minutes of the committee meeting on its website within 28 days of the meeting. When the committee has approved them, NICE publishes the confirmed minutes on its website normally within 6 weeks of the meeting. The minutes of a committee meeting provide a record of the proceedings and a list of the issues discussed.

Committee decisions outside of formal meetings (technology appraisals only)

5.8.23 For cost-comparison appraisals and those streamlined for committee decision outside of a formal meeting, a subset of committee members will review the evidence. They will be able to make a recommendation outside of a full committee meeting and no stakeholders will be asked to attend a meeting.

5.8.24 Experts who have been selected to take part in the appraisal (see sections 1.3.17 to 1.3.19) or other members of the committee may be invited to contribute on a case-by-case basis. This will be if, in the opinion of the subset of committee or the NICE team, they are needed to address specific questions.

5.8.25 If the subset of committee concludes it cannot make a recommendation, this will result in a full committee meeting. This will not alter standard governance or appeal processes, and maintains the independence of the committee as a decision-making body.

5.8.26 If a full committee meeting is needed for a streamlined appraisal, then clinical experts, patient experts and non-company stakeholders will not normally be invited to take part in the committee meeting discussion. In exceptional circumstances, the committee chair and NICE may agree to invite clinical or patient experts to the meeting to help address specific uncertainties.

5.8.27 If the subset of committee concludes that a cost-comparison recommendation cannot be made, then they have the option of proceeding to a full committee meeting or rerouting to the standard process. The company will then need to provide a new evidence submission using the full cost-utility template provided

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by NICE. The topic will be rescheduled into the work programme at the earliest opportunity.

Commercial opportunities after the first committee meeting (technology appraisals and highly specialised technologies only)

5.8.28 If the committee do not recommend the technology at the first committee meeting and the committees' preferences and assumptions are clear, NICE will provide the opportunity for companies to improve their commercial offer in certain circumstances.

Increasing the PAS or proceeding to draft guidance after the first committee meeting (technology appraisals and highly specialised technologies only)

5.8.29 Shortly after the committee meeting, NICE will inform the company of the committees' recommendation and key assumptions. The company will confirm to NICE within 7 days of the first committee meeting whether they accept the committees' preferences and assumptions and if they will increase their simple PAS discount in line with those preferences.

5.8.30 Companies will have a single opportunity to increase their simple discount PAS at this stage in the process.

5.8.31 When an increased simple discount PAS has been submitted and is regarded as low risk by NICE, the committee chair can review and decide on behalf of the committee, whether the company's proposal is likely to result in a recommendation as an option.

5.8.32 This review may result in:

- a recommendation (as an option) or an optimised recommendation that is in line with company and expert opinion. In these circumstances, the chair may decide that another committee meeting is not needed. Final draft guidance is drafted, and the final recommendations are agreed by the committee

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electronically. The final recommendations will be shared with stakeholders within 7 days of sign-off. This will be a brief statement of the committee's decision.

- the chair being unable to make a recommendation without a full committee meeting. NICE will proceed to a second committee meeting. NICE will be unable to accommodate any further requests for delay to its process to accommodate PAS discussions for these topics.
- a technology being not recommended, recommended only in a research context, recommended (as an option) or an optimised recommendation that is not in line with company or expert opinion. NICE will issue draft guidance and will be unable to commit to a date for a subsequent committee meeting for the topic. NICE will be unable to accommodate any further requests for delay to its process to accommodate PAS discussions for these topics.

5.8.33 If a company informs NICE that it does not accept the committees' preferences and assumptions, the draft guidance will be published for consultation. The subsequent committee meeting will be scheduled according to normal NICE timelines. NICE will be unable to accommodate any further requests for delay to its process to accommodate PAS discussions for these technologies.

Pausing publication of the draft guidance after the first committee meeting to allow a commercial access agreement to be agreed (technology appraisals and highly specialised technologies only)

5.8.34 If NHS England and NHS Improvement confirm before the first committee meeting that they are willing to engage in discussions about a commercial access agreement after the meeting, NICE may also agree to pause publication of the draft guidance to allow the company and NHS England and NHS Improvement to negotiate on a commercial access agreement so that, subject to subsequent committee approval, final draft guidance may be issued.

5.8.35 NICE will inform the company of the committees' recommendation and key assumptions. The company will confirm to NICE within 14 days of the first

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committee meeting whether they accept the committees' preferences and assumptions and if they wish to request a delay to publication of the draft guidance for up to 42 days to allow discussions with NHS England and NHS Improvement.

5.8.36 NICE will provide a commercial briefing to NHS England and NHS Improvement and the company within 7 days of the company confirming it is willing to accept the committees' preferences and assumptions. The briefing includes the committee's preferred assumptions for the evaluation and the implications for the company's value proposition.

5.8.37 The final commercial access agreement must be in line with the committee's preferred assumptions as documented in the NICE commercial briefing.

5.8.38 NHS England and NHS Improvement will confirm to NICE within 49 days of the committee meeting if a commercial access agreement has been agreed in principle.

5.8.39 If NHS England and NHS Improvement and the company are unable to agree a commercial access agreement within the above timescale, or earlier, NICE will issue draft guidance for consultation. NICE will be unable to accommodate any further requests for delay to its process to accommodate PAS or commercial access agreement discussions for these topics.

5.8.40 When a commercial access agreement has been agreed in principle and is regarded as low risk by NICE, the committee chair can review and decide on behalf of the committee, whether the company's proposal is likely to result in a recommendation as an option. The potential outcomes of this review are the same as those listed in section 5.8.43, with the conditions applying to PASs also applying to commercial access agreements.

5.8.41 If NHS England and NHS Improvement and the company are unable to finalise any arrangement within 21 days of an agreement in principle being confirmed, NICE will proceed to issue draft guidance. NICE will be unable to commit to a date for a subsequent committee meeting for topics proceeding to draft guidance at this point. NICE will also be unable to accommodate any further requests for delay to its process to accommodate PAS or commercial access agreement discussions

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for these topics.

5.8.42 If a company informs NICE that it does not accept the committees' preferences and assumptions, the subsequent committee meeting will be scheduled according to normal NICE timelines. NICE will be unable to accommodate any further requests for delay to its process to accommodate a PAS or commercial access agreement discussions for these technologies.

Consultation on the draft guidance (if produced)

5.8.43 Normally, consultation on draft guidance takes place only if the draft recommendations for the technology are either:

- not recommended
- recommended only in a research context
- recommended for data collection
- recommended (as an option) in specific circumstances, which is not in line with the company submission and expert opinion
- there is sufficient uncertainty in the cost case for a cost-saving technology or
- if the company is asked to provide further clarification on the commercial arrangements in their evidence submission.

5.8.44 NICE usually circulates the draft guidance to stakeholders for consultation within 21 days of the committee meeting. NICE informs stakeholders if a delay is expected.

5.8.45 The draft guidance summarises the evidence and views that have been considered by the committee and sets out preliminary recommendations. The draft guidance is not NICE's final guidance on a technology. The recommendations may change after consultation. The draft guidance usually contains:

- the committee's preliminary recommendations to the NHS on the technology

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and how it should be used

- a description of the technology, including its licensed indication and dosage or intended use and cost
- a description of how the committee has interpreted the evidence together with the key issues raised by experts
- the committee's preferred assumptions and maximum acceptable ICER, if appropriate
- expectations about implementation of the recommendations, if appropriate
- proposed recommendations for further research, if appropriate.

5.8.46 When a technology has the potential to be recommended with managed access, the committee will state the conditions for its use in the draft or final draft guidance and will identify the nature of the clinical uncertainty that should be addressed through data collection. Details of data collection, including a protocol and analysis plan (when applicable), will be set out in a data collection arrangement.

5.8.47 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.

5.8.48 The purpose of the consultation is to seek views on the draft recommendations and to determine whether they are an appropriate interpretation of the evidence considered. NICE invites comments on whether:

- all the evidence available to the committee has been appropriately taken into account
- the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence
- the draft recommendations are sound and constitute a suitable basis for guidance to the NHS

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- there are any equality issues that need special consideration that are not considered in the draft guidance.

5.8.49 Stakeholders have 28 days from the date of sending to submit comments on the draft guidance. They must submit their comments in writing, preferably electronically.

5.8.50 NICE publishes the draft guidance and any additional committee papers not already shared on its website with an electronic comment facility within 7 days of circulation to stakeholders. Confidential information is redacted for public consultation.

5.8.51 If a comment contains confidential information, the organisation or person who submitted the comment should provide 2 versions, a complete version and another with the confidential information redacted (to be published on NICE's website), with a checklist of the confidential information. Detailed instructions on sending NICE confidential information about an evaluation are available from the project manager.

5.8.52 After the draft guidance has been developed, new evidence will not be accepted unless 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. It is preferrable for available additional evidence to be submitted in response to the technical engagement stage (when held).

5.8.53 The committee may be unable to develop recommendations for the technology without further scrutiny or further evidence submission. If this is the case, the evaluation can be paused. NICE may request that the company or EAG submit specific information, further analyses or an updated economic model. When the committee seeks such clarification, NICE will inform stakeholders within 7 days of the committee meeting. After this pause, the committee will make a recommendation.

5.8.54 For cost-comparison evaluations with a funding requirement, final draft guidance will normally be developed after committee ratification or a full meeting. In exceptional circumstances, the committee may be unable to develop recommendations for the technology without further scrutiny or further evidence

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submission. If this is the case, NICE will publish a statement advising that the committee is unable to make a recommendation. If a company wishes to resubmit after the committee has stated that it is unable to make a recommendation, the topic will be rescheduled into the committee work programme. It will not always be possible to prioritise the topic for immediate review.

5.8.55 Where the committees' preferences and key assumptions are clear after the first committee meeting and a pause implemented to allow for further commercial consideration, NICE will issue final draft guidance after a second committee meeting according to its normal timelines. NICE will be unable to accommodate additional requests for delay to accommodate PAS or commercial access agreement discussions at this final stage of guidance production.

Committee meeting to develop the final draft guidance

5.8.56 If draft guidance is produced the committee usually meets again, with members of the public and press observing. This is 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 the stakeholders.

5.8.57 Representatives from the company, the EAG and from other teams at NICE (for example, guidelines and public health) who are responsible for developing NICE guidance in areas related to the evaluation, may attend the meeting. The chair of the committee may invite 1 or more of the clinical experts, NHS commissioning experts or patient experts to attend.

5.8.58 The committee discusses the responses to the draft guidance consultation in the public part of the meeting and moves to a private session to consider any confidential information and to agree the content of the final draft guidance, which sets out the final recommendations. After the meeting, the final draft guidance is drafted based on the discussions at the meeting and the final recommendations agreed by the committee.

5.8.59 When stakeholders submit comments that lead to a substantial revision of the committee's previous decision, involving a significant change in the

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recommendations, discussions or the evidence base, NICE and the chair of the committee will decide whether it is necessary to repeat the draft guidance consultation. The decision to hold another consultation will extend the timelines for the evaluation. NICE will distribute the committee papers with the second draft guidance, together with consultation comments and any new evidence not circulated with the previous draft guidance.

5.8.60 For technology appraisals and highly specialised technologies, the company can respond to the consultation by making an updated commercial offer. If the revised ICER is below the maximum acceptable ICER specified by the committee in the draft guidance, the chair can decide on behalf of the committee whether the company's proposal is likely to result in the technology being recommended as an option. In these circumstances, the chair may decide that another committee meeting is not needed. Final draft guidance is drafted, and the final recommendations are agreed by the committee electronically.

5.8.61 For technology appraisals and highly specialised technologies, when the committee has requested new analyses, this has been provided using the committee's preferred assumptions, and if the revised ICER is below the maximum acceptable ICER specified by the committee in the draft guidance, the chair may decide that another committee meeting is not needed. Final draft guidance is drafted, and the final recommendations are agreed by the committee electronically.

5.8.62 For medical technologies and diagnostics guidance, the 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. Factual changes and corrections to the guidance are made and final draft guidance and recommendations are agreed by the committee electronically.

5.8.63 The chairs decision will be shared with stakeholders within 7 days of sign-off. This will be a brief statement of the decision.

Developing final draft guidance

5.8.64 The final draft guidance contains:

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- the committee's final recommendations to the NHS on the technology and how it should be used
- a description of the technology, its cost and, when relevant, its licensed indication and dosage
- a description of how the committee has interpreted the evidence together with the key issues raised by experts
- the committee's preferred assumptions and maximum acceptable ICER, when applicable
- expectations about implementation of the recommendations, if appropriate
- proposed recommendations for further research, if appropriate.

5.8.65 After internal sign off of the final draft guidance, a report is submitted to NICE's guidance executive. The guidance executive checks that the committee has evaluated the technology in accordance with the terms of the Secretary of State for Health and Social Care's referral (for technology appraisal and highly specialised technologies) and the scope. If satisfied, the guidance executive approves the final draft guidance for publication on behalf of the NICE Board.

5.8.66 NICE issues the final draft guidance to consultees so that they can consider whether to appeal or raise a resolution request against the final recommendations. They can also highlight any factual errors. Other stakeholders receive the final draft guidance for information and can also highlight any factual errors. Details of the appeal and resolution processes are set out in finalising and publishing the guidance chapter.

5.8.67 When NICE sends the final draft guidance to stakeholders, any further analysis done by the company, NICE or the EAG during development of the final draft guidance will be made available to stakeholders. Comments received on the draft guidance (if produced), together with NICE's responses to them are also provided.

5.8.68 NICE usually sends the final draft guidance within 35 days of the committee meeting to stakeholders. NICE notifies stakeholders if a delay is expected. NICE publishes the final draft guidance and the committee papers on its website, with

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confidential material redacted, within 7 days of circulation to stakeholders. NICE notifies stakeholders if a delay is expected.

5.8.69 In exceptional circumstances NICE may do further analysis. The EAG or Decision Support Unit normally does this further analysis before NICE circulates the final draft guidance. This is to ensure that NICE can provide robust guidance to the NHS. The centre director or programme director decides whether this is needed, with the chair of the committee and the NICE team. If further analysis is done, NICE will inform stakeholders. NICE will distribute any such analysis to stakeholders and publish it on the website at the same time as the final draft guidance.

Finalising a managed access data collection agreement (technology appraisal and highly specialised technologies only)

5.8.70 After a medicine is recommended with managed access by the committee, the data collection agreement must be finalised between the relevant stakeholders for publication alongside the final draft guidance 35 days after the committee meeting.

5.8.71 NICE will invite the company to provide a draft data collection agreement document using a proforma template. NICE may ask the company to begin developing this document at any point during its assessment of the managed access proposal.

5.8.72 Depending on the complexity of the topic, the data collection agreement will be developed in collaboration with stakeholders. It will set out:

- the key clinical uncertainties identified by the committee
- eligibility of the patient population
- outcome data that could sufficiently support the case for adoption
- sources of data
- the duration of data collection

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- the analytical outputs needed
- information governance, ethics and data sharing considerations
- monitoring arrangements
- publication considerations.

5.9 Patient access schemes and commercial access agreements (technology appraisals and highly specialised technologies)

Introduction

5.9.1 The NHS commercial framework for new medicines enables companies to submit proposals for patient access schemes (PAS) and, in addition, allows NHS England and NHS Improvement to offer companies the potential opportunity to enter into complex confidential agreements. NICE endorses the principles outlined in the framework in its commercial and managed access activities.

5.9.2 These arrangements allow companies to improve their value proposition as part of the evaluation process when NICE's assessment of value, on the current evidence base, is unlikely to support the list price.

5.9.3 The NHS commercial framework for new medicines describes 2 key types of commercial arrangement:

- Patient access schemes (PAS)
- Commercial access agreements

5.9.4 A PAS can be proposed by a member company of the 2019 voluntary scheme for branded medicines pricing and access. A PAS proposal is submitted to NHS England and NHS Improvement. This is then referred to NICE for advice on the feasibility of implementing the scheme in England. The advice from NICE informs NHS England and NHS Improvement's decision on whether the proposed PAS can

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be considered in the NICE evaluation. The PAS review process is not part of the NICE evaluation process.

5.9.5 Unlike a PAS, a commercial access agreement is only expected to be used in specific circumstances. The feasibility of implementing a commercial access agreement is assessed directly by NHS England and NHS Improvement, with a commercial access agreement being agreed between NHS England and NHS Improvement and the company. This includes commercial access agreements contained within managed access agreements.

5.9.6 NICE will only consider a PAS or commercial access agreement proposal after NHS England and NHS Improvement approval.

5.9.7 All references to the NHS are to the NHS in England and Wales.

Patient Access Schemes

5.9.8 A PAS is the starting point or default option for companies to consider when developing their value proposition for evaluation by NICE. Unless a technology is to be considered at list price, companies should always include a PAS when making their initial evidence submission to NICE. This is to ensure enough time for full consideration in advance of the committee meeting.

5.9.9 There are 2 types of PAS:

- simple discount patient access scheme (confidential)
- complex patient access scheme (non-confidential).

For further details, see NICE's arrangements for patient access schemes.

5.9.10 A simple discount PAS scheme must meet the simple discount criteria which ensure that a PAS does not cause a significant ongoing additional burden on the NHS, as set out in the NICE's arrangements for patient access schemes and the relevant PAS proposal template.

5.9.11 A complex PAS scheme includes all other type of PAS and can include a wide

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range of mechanisms. In contrast to a simple PAS, a complex PAS is non-confidential. This is because transparency is needed to make sure the administrative burden and cost to the service of implementing such schemes within the NHS is minimised and helps to make sure the value of the treatment, as determined by NICE, is achieved. A complex PAS scheme must meet the criteria which ensure that a PAS should be operationally manageable for the NHS without unduly complex monitoring, disproportionate additional costs and bureaucracy, as set out in the NICE's arrangements for patient access schemes and the relevant PAS proposal template.

5.9.12 NHS England and NHS Improvement is unlikely to agree to more than 1 PAS for a single technology, because of the complexity this would introduce for the NHS. Therefore, a PAS proposal should be designed so that it could apply across all relevant indications of a technology.

5.9.13 In line with the 2019 voluntary scheme for branded medicines pricing and access, simple confidential and complex non-confidential PASs continue to be available in accordance with the criteria and terms as originally set out in the 2014 Pharmaceutical Price Regulation Scheme. NICE considers the key principles contained in this document when assessing a PAS.

5.9.14 Changes may be made to a PAS proposal after NHS England and NHS Improvement has referred it to NICE, but these must be discussed and agreed with NHS England and NHS Improvement.

Commercial Access Agreements

5.9.15 As described in NHS commercial framework for new medicines, a commercial access agreement is a confidential agreement and is agreed at NHS England and NHS Improvement's discretion, with the default arrangement of offering a PAS (simple or complex) always being available to companies.

5.9.16 As stated in the NHS commercial framework for new medicines, a PAS is the starting point or default option for companies developing their value proposition for evaluation by NICE; therefore a commercial access agreement may build upon a PAS included in a company's initial evidence submission to NICE.

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5.9.17 For further details of the circumstances in which NHS England and NHS Improvement may consider a commercial access agreement, please see the NHS commercial framework for new medicines.

Timing of PAS and commercial access agreement proposals

5.9.18 The process for assessing the impact of a PAS or commercial access agreement proposal on the cost effectiveness of a technology depends on when the proposal is submitted to NICE. When proposing a PAS or commercial access agreement as part of a NICE evaluation, companies should make sure that:

- Unless a treatment is to be considered at list price, a PAS should always be included in the initial evidence submission to NICE to ensure enough time for full consideration and approval in advance of the first committee meeting.
- In certain circumstances, a revision to an existing simple discount PAS proposal or a new commercial access agreement proposal may be accepted at other times during the NICE evaluation process. A revision can be proposed:
  - in response to technical engagement (when held)
  - in response to the draft guidance
  - at the end of the process, once any appeals have been heard and NICE's final guidance has been issued to the NHS. This may generate a rapid review of the published guidance.

5.9.19 There will be a single opportunity to revise a simple discount PAS or propose a commercial access agreement at each of these points.

5.9.20 The approval of a complex PAS may be possible when proposed in response to technical engagement (when held) or the draft guidance. It is the company's responsibility to ensure that NHS England and Improvement has enough time to complete its consideration in time for the committee meeting. Please note, for cost-comparison evaluations companies must include an NHS England and NHS Improvement approved PAS or commercial access agreement proposal in their initial evidence submission.

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5.9.21 Significant or structural changes to, or new proposals for a PAS or commercial access agreement will not be accepted after release of the final draft guidance.

5.9.22 A company interested in submitting a PAS or discussing a commercial access agreement proposal should first contact the NICE commercial liaison team. The company should also consult the Commercial Medicines Directorate at NHS England and NHS Improvement.

5.9.23 In line with the NHS commercial framework for new medicines, initial discussions with NICE will focus on submission of a simple PAS proposal, as the default commercial proposal.

5.9.24 If at any point in the evaluation process, NICE identifies that a technology is not likely to be cost effective with a simple or complex PAS, NICE and NHS England and NHS Improvement will liaise to assess the potential for a commercial access agreement proposal. A commercial access agreement proposal can only be considered if a PAS proposal has been fully explored.

PAS revisions or new commercial access agreement proposals submitted during an evaluation

5.9.25 The committee can consider a revised simple or complex PAS proposal before formal approval from NHS England and NHS Improvement when the risk of non-approval is considered low (for example when the NICE advice to NHS England and NHS Improvement supports the proposal). A new commercial access agreement can only be considered when NHS England and NHS Improvement informs NICE that a deal in principle has been agreed. NICE will not release draft or final draft guidance until formal approval of the PAS increase or commercial access agreement is received from NHS England and NHS Improvement.

5.9.26 If a company submits a revised simple discount PAS proposal or NHS England and NHS Improvement approve a commercial access agreement proposal after the initial evidence submission, the following conditions apply:

- For a simple discount PAS revision, the company must inform the project team in writing of its intention to submit an amended proposal, as early as

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possible.

- For a commercial access agreement, NHS England and NHS Improvement must inform the NICE commercial liaison team in writing of its intention to agree a commercial access agreement, as early as possible.
- The company must provide information on the revised proposal in a separate submission, using the NICE PAS submission template.
- The revised proposal must be received by NICE at least 14 days before the next committee meeting, to allow time for review.

Interaction with technology evaluation processes

5.9.27 NICE's commercial liaison team activities are aligned with key steps in the technology evaluation processes and focus on key commercial checkpoints. The procedures and minimum timescales are summarised below. This information is for guidance only because the time needed for each stage can vary.

5.9.28 If NICE's commercial liaison team identifies that a technology is unlikely to be cost effective with a simple or complex PAS alone at checkpoints 1 to 4, it will liaise with NHS England and NHS Improvement to assess the potential for a commercial access agreement proposal. This may result in NHS England and NHS Improvement contacting the company directly. A commercial access agreement proposal can only be considered if a PAS proposal has been fully explored.

Checkpoint 1: Pre-invitation to submit evidence

5.9.29 This checkpoint allows for early engagement. NICE's commercial liaison team uses this checkpoint to have informal discussions with a company about their commercial intentions. The team will:

- explore the need for submission of a simple discount PAS as the starting point or default option
- explore any commercial challenges that mean the technology may not be

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cost effective with a simple or complex PAS.

Checkpoint 2: Invitation to participate and decision-problem meeting

5.9.30 NICE's commercial liaison team reviews the decision-problem meeting documents submitted by the company for details of the company's commercial intentions. This review is usually a few weeks before the invitation to participate is issued. The team will:

- assess whether the company intends to submit a simple discount PAS as the starting point or default option
- assess any commercial challenges that mean the technology may not be cost effective with a simple or complex PAS.

Checkpoint 3: Company submission of evidence to NICE

5.9.31 When the company's evidence submission is made, NICE's commercial liaison team:

- checks that a simple discount PAS proposal has been submitted
- checks that a budget impact test submission has been made
- assesses any commercial challenges that mean that the technology may not be cost effective with a simple or complex PAS or is likely to breach the budget impact test.

Checkpoint 4: Technical engagement (when held)

5.9.32 When the EAG report is received, NICE's commercial liaison team re-assesses any commercial challenges the company may have that mean the technology is not likely to be cost effective with a simple or complex PAS or is likely to breach the budget impact test.

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5.9.33 NICE's commercial liaison team may join the project team at the technical engagement meeting with the company.

Checkpoint 5: Preparation and release of pre-committee commercial summary

5.9.34 NICE's commercial liaison team prepares a commercial summary which is shared with the project team, the company, and NHS England and NHS Improvement. This summary is usually available 4 weeks before the committee meeting.

5.9.35 If the topic is identified as high risk of not being cost effective with a simple or complex PAS alone, NICE's commercial liaison team will seek formal confirmation from NHS England and NHS Improvement that they would be willing to discuss a commercial access agreement after the committee meeting if necessary.

5.9.36 The commercial summary covers the following points:

- confirms the commercial arrangement that will be considered by committee
- identifies any risks relating to cost effectiveness in the evaluation or budget impact test that the arrangement may carry
- confirms NHS England and NHS Improvement's position on their willingness to offer commercial discussions about a commercial access agreement after the committee meeting.

5.9.37 There is no opportunity for a company to change the structure of its PAS or commercial access agreement proposal or to make substantial revisions after this point and before the committee meeting. In exceptional cases, minor revisions to the structure of an existing PAS or commercial access agreement may be considered.

Checkpoint 6: First committee meeting

5.9.38 The NICE commercial liaison team will attend committee meetings for topics where NHS England and NHS Improvement's indicate they are willing to offer commercial discussions about a commercial access agreement after the

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committee meeting.

Checkpoint 7: After the committee meeting

5.9.39 When a company and NHS England and NHS Improvement agree to enter additional commercial discussions (see sections 5.8.33 to 5.8.41) NICE's commercial liaison team will provide a commercial briefing to NHS England and NHS Improvement and the company within 7 days of the company confirming it is willing to accept the committees' main assumptions. The briefing includes the committee's preferred assumptions for the evaluation and the implications for the company's value proposition.

5.9.40 Any commercial access agreement agreed must be in line with the committee's preferred assumptions in the commercial briefing.

PAS revisions or new commercial access agreements submitted after guidance publication

5.9.41 Within 16 weeks of publication of the final guidance, companies can request a rapid review to consider new PAS or commercial access agreement proposals. The rapid review of the guidance is planned into the work programme. NICE can only consider a new PAS or commercial access agreement proposal with NHS England and NHS Improvement's agreement. The committee will usually consider the proposal within 6 months of the company request.

5.9.42 The rapid review of guidance will normally be used to consider a new approved PAS or commercial access agreement only. If the company wishes to submit additional new evidence other than a new approved PAS or commercial access agreement proposal, NICE will consider whether this would be acceptable in the context of a rapid review or whether it would trigger a full review proposal.

5.9.43 The company must provide details of the new proposal, a revised economic model incorporating the proposal, and an updated checklist of confidential information, if necessary. This is in addition to the information that must be submitted to NHS England and NHS Improvement as part of a submission for a

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PAS or commercial access agreement proposal.

5.9.44 When a new PAS or commercial access agreement proposal has been approved and is regarded as low risk by NICE, a subset of the committee will review the evidence and will be able to make a recommendation outside of the context of a full committee meeting. The full committee will be asked to ratify the decision ahead of the release of any draft guidance document. Any concerns from the lead team or committee, or classification of high risk will result in a full committee meeting.

5.9.45 Although NICE will include a PAS or commercial access agreement proposal submitted for rapid review on the relevant committee meeting agenda, NICE makes no public announcement about the specific topics and will hold the committee meeting in private. PAS and commercial access agreement proposals submitted as a rapid review are treated by NICE as commercial in confidence and all matters about the proposed scheme (except the existence of the scheme proposal) will usually remain confidential unless consideration by the committee results in a change to guidance recommendations. In this situation, NICE will issue final draft guidance for appeal. NICE releases information with the final draft guidance so that the proposed scheme and its impact on the clinical effectiveness, cost effectiveness and the recommendations can be understood.

5.9.46 If, in exceptional circumstances, NHS England and NHS Improvement approves a PAS or commercial access agreement proposal more than 16 weeks after guidance publication, the topic could be considered under the rapid review arrangements. However, it would not be prioritised in the work programme and NICE would need to be assured that the principles of rapid review apply.

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OBSOLETE: REPLACED BY THE UPDATE TO PMG36 ON 14 JULY 2025

5.10 Varying the funding requirement to take account of net budget impact (technology appraisals and highly specialised technologies)

Policy context

5.10.1 As referred to in sections 1.3 to 1.5, of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (the 'Regulations'), expect NICE to:

- "recommend [...] that relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients" and
- "specify in a technology appraisal recommendation the period within which the recommendation [...] should be complied with", which "must be a period that begins on the date the recommendation is published by NICE and ends on the date 3 months from that date".

5.10.2 The regulations state that if NICE considers it appropriate, NICE must specify a longer period, when:

- the health technology cannot be appropriately administered until:
  - training is given to staff involved in the delivery of the drug to patients
  - certain health service infrastructure needs including goods, materials or other facilities are in place
  - other appropriate health services resources, including staff, are in place; or
- the health technology is not yet available in England.

5.10.3 The regulations require NICE, when it is minded to specify a longer period, to consult with "such persons with an interest in the appraisal of a health technology...about the appropriate period that may be specified in a technology

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appraisal recommendation", and that this consultation must include "the Secretary of State and the [Commissioning] Board [now referred to as NHS England and NHS Improvement]".

5.10.4 NHS England and NHS Improvement may request a longer time to implement the statutory funding requirements for technologies funded through its specialised commissioning budgets. This may happen when the potential net budget impact is expected to exceed £40 million per year in any of the first 3 financial years of its use in the NHS. NHS England and NHS Improvement will also do this on behalf of clinical commissioning groups, for locally commissioned technologies that NICE has evaluated.

5.10.5 If the potential net budget impact is expected to exceed £40 million per year in any of the first 3 financial years of a technology's use in the NHS, NHS England and NHS Improvement will offer to engage in commercial discussions with companies whose technologies are being evaluated by NICE before requesting a variation to the funding requirement.

5.10.6 A commercial discussion may not result in a budget impact of less than £40 million per year in each of the first 3 financial years of the technology's use in the NHS in England. In such cases, and when NHS England and NHS Improvement requests a variation to the funding requirement, NICE will take into account any relevant aspects of the commercial discussion in responding to the variation request.

Evidence submission

5.10.7 After receiving submissions from the company and NHS England and NHS Improvement, NICE will assess the potential budget impact of the technology by estimating the net annual cost to the NHS (see the assessing resource impact process manual for further details).

5.10.8 Where submissions have been received from both the company and NHS England and NHS Improvement, NICE will also share the initial company budget impact test submission with NHS England and NHS Improvement. Conversely NICE will share any budget impact test submission from NHS England and NHS

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Improvement with the company.

5.10.9 NICE will share a draft budget impact test with the company and NHS England and NHS Improvement, normally within 17 days after receiving the company submission.

5.10.10 NHS England and NHS Improvement and the company will have 7 days to comment on the draft budget impact test.

5.10.11 NICE will update and finalise the budget impact test within 7 days of receiving any additional information and re-issue a final budget impact test to NHS England and NHS Improvement and the company.

5.10.12 Within 7 days after receiving the final net budget impact estimate, NHS England and NHS Improvement must inform NICE whether it intends to have a commercial discussion with the company. This will allow NICE to plan for potential changes to the timelines of a technology evaluation.

5.10.13 If there remains a material difference of opinion between NHS England and NHS Improvement, the company and the NICE budget impact test, details will be submitted to the NICE executive team for resolution. NHS England and NHS Improvement and the company will be informed of progression to this step, and anticipated timelines for the decision.

5.10.14 NHS England and NHS Improvement and the company will be informed of the final decision with 7 days of NICE's executive team discussion. The budget impact test approved by NICE's executive team will be used for commercial negotiations and should any variation to the funding requirement be sought by NHS England and NHS Improvement.

5.10.15 The budget impact commercial discussion between the company and NHS England and NHS Improvement will be done in parallel with the evaluation timescales. NHS England and NHS Improvement must provide a progress update to NICE at least 7 days before the first committee meeting. Any budget impact commercial agreements confirmed at this point will be to specifically manage the net budget impact of the technology and will not be reviewed by the committee.

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5.10.16 For a rapid review, the time frame for the budget impact commercial discussion between the company and NHS England and NHS Improvement will be readjusted accordingly.

Draft guidance issued for consultation after the committee meeting

5.10.17 If the committee recommends the technology as an option or makes a recommendation for optimised use of the technology, NICE will update its budget impact assessment of the technology.

5.10.18 When draft guidance is issued for consultation after the committee meeting NICE will inform the company and NHS England and NHS Improvement of the (new) estimate for budget impact, at the same time the draft guidance or final draft guidance is published.

5.10.19 If NHS England and NHS Improvement and the company intend to pursue a commercial access agreement after the first committee meeting, and they anticipate that it will need more time than the next phase of the NICE process provides, NHS England and NHS Improvement must formally notify NICE. They must do this 7 days after receiving details of the potential budget impact of the committee's recommendations. NICE will suspend the evaluation for a maximum of 12 weeks, to allow a second opportunity for commercial engagement and inform stakeholders. NICE will decide when the evaluation will restart. The subsequent committee meeting will be rescheduled in line with the time needed for concluding the commercial engagement.

5.10.20 If NHS England and NHS Improvement intends to apply for a variation to the funding requirement after the first committee meeting, it must do so at the earliest opportunity, and no later than the end of the suspension period.

Final draft guidance issued after committee meeting

5.10.21 If the committee chooses to alter the draft recommendations, NICE will update its assessment of the budget impact of the technology, when appropriate (see

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NICE's assessing resource impact process manual). NHS England and NHS Improvement and the company will be informed of the updated budget impact before the release of the final draft guidance and will have an opportunity for commercial engagement before final draft guidance is issued to stakeholders.

5.10.22 If the potential net budget impact is expected to significantly exceed £40 million per year in any of the first 3 financial years of a technology's use in the NHS, NICE may consider a request from NHS England and NHS Improvement to allow a pause after release of the final draft guidance to stakeholders before publication of the final guidance.

5.10.23 Requests will be considered on a case-by-case basis and must be received within 7 days of NHS England and NHS Improvement and the company being informed of the net budget impact.

5.10.24 If NHS England and NHS Improvement intends to apply for a variation to the funding requirement, it must do so at the earliest opportunity, and no later than the end of the period for consideration and lodging an appeal.

Guidance executive and applying to vary the funding requirement

5.10.25 NHS England and NHS Improvement can advise NICE that it may need to apply to vary the funding requirement directly after receiving the estimate of the net budget impact at the evidence submission stage or at later stages in the evaluation.

5.10.26 When requesting a variation to the funding requirement, NHS England and NHS Improvement should provide:

- the duration of, and the justification for, the proposed variation.
- the relevant provisions of any commercial arrangement reached with the company.
- in the case of a technology funded from the national specialised commissioning budgets, the amount and phasing of funding that will be made available and how this will be applied to patients eligible for treatment.

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- in the case of technologies funded by clinical commissioning groups, the direction it intends to give about the phasing of funding during the deferred funding period.
- an assessment of the impact on patients who are eligible for treatment under the guidance, but whose treatments will be delayed because of the funding variation, taking into account NHS England and NHS Improvement's and NICE's responsibilities under equalities legislation.
- details of the interim commissioning policy that would be applied to phase in funding and to manage access to the technology during the extended funding variation period.

5.10.27 NICE will present the application for a variation to the funding requirement to NICE's guidance executive at the earliest opportunity. This can be at the stage of developing the draft guidance (to allow for consultation on guidance executive's decision to vary the timescale for the funding requirement at the same time as consultation on draft recommendations), with final draft guidance, or during the appeal period.

5.10.28 At each of these stages, guidance executive will decide whether it will vary the timescale for the funding requirement taking into account whether:

- the budget impact test has been met
- all reasonable opportunities for reaching a commercial arrangement have been pursued
- the request is in proportion to the size of the budget impact
- the request takes account of the severity and acuity of the condition that the guidance relates to
- NHS England and NHS Improvement's and NICE's duties under equalities legislation have been considered
- an interim commissioning policy has been developed to provide phased funding for, and access to, the technology during the extended funding period.

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5.10.29 Regardless of the duration of the variation requested, all applications will need to contain proposals for a phased allocation of funding.

5.10.30 For technologies for which the budget impact test is met, guidance executive will consider applications to vary the funding requirement, normally for up to a maximum of 3 years. In exceptional circumstances, a longer period may be considered.

5.10.31 Applications to vary the funding requirement are specific to each evaluation. However, when considering technologies with indications for which a treatment has already been recommended and a funding variation is in place, NICE will take into account the combined budget impact for both technologies when considering an application for a funding variation for the second (and subsequent) technologies.

5.10.32 When guidance executive decides to vary the timescale for the funding requirement, this decision will be shared with stakeholders, including NHS England and NHS Improvement and the Secretary of State for Health and Social Care, for a 21-day consultation period. The provisional decision will be published for information on the NICE website 7 days later.

5.10.33 Comments received during consultation from stakeholders will be presented to guidance executive to reach a final decision on the timescale for the funding requirement. The decision and comments received will be published on the NICE website at the next appropriate step in the process.

5.10.34 The final guidance will refer to the variation to the funding requirement (when appropriate).

5.11 Rapid updates to guidance after loss of market exclusivity (technology appraisals only)

5.11.1 After the completion of surveillance in section 8.7, NICE will schedule a rapid update of the guidance to coincide with NHS Commercial Medicines Unit tenders for these technologies. The rapid update will focus on the active substance

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rather than the individual products. A rapid update cannot be used to update terminated guidance.

5.11.2 Companies that produce the biosimilar or generic technologies (including the originator company) will not need to provide an evidence submission to support a rapid update to guidance after loss of marketing exclusivity.

5.11.3 An EAG will develop a report that evaluates the economic model against a predetermined checklist. The report will include a targeted literature review and clinical expert engagement. It will determine whether:

- there have been changes to the evidence base since the guidance was published
- there have been changes to the care pathway since the guidance was published
- cost was the key factor resulting in the technology not being recommended or recommended for optimised use.

5.11.4 NICE will not issue the report for technical engagement.

5.11.5 Participating companies will have 14 days to consider the report before it is considered by representatives of the committee who will act on behalf of the full committee. This will normally be the committee chair and a 3-member lead team.

5.11.6 The committee representatives will use the report to assess if there have been significant changes since the original guidance and whether the economic model can still be used for decision making. They will also decide on the threshold ICER for the technology to be considered cost effective, if this is not clearly identified in the original guidance.

5.11.7 If the committee concludes that the economic model can be used for decision making, final draft guidance will be developed using standard development timelines. New guidance will be published that will replace the original guidance.

5.11.8 If the committee concludes that the economic model cannot be used for decision making, no updated guidance will be produced. NICE will produce a statement

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indicating that the committee is unable to update the recommendations for the technology.

5.12 Tools and resources

5.12.1 The implementation of the budget impact assessment within the evaluation will not affect publication of the advice and tools to support the local implementation of NICE guidance. This includes resource impact tools or statements for most evaluations and additional tools for some technology evaluations.

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6 Committee recommendations

6.1 Evaluation of the evidence and structured decision making

6.1.1 The committee makes recommendations to NICE about the clinical effectiveness and value for money of technologies for use within the NHS. The committee will not recommend technologies if the benefits to patients are unproven, or if the technologies are not considered to be a good use of NHS resources. NICE is responsible for publishing the final guidance.

6.1.2 When forming its recommendations to NICE, the committee considers those factors it believes are most appropriate for each evaluation. In doing so, the committee takes into account the provisions and regulations of the Health and Social Care Act 2012 relating to NICE, and NICE's legal obligations on equality and human rights. The Act expects NICE, when doing its general duties, to be aware of:

- the broad balance between the benefits and costs of providing health services or social care in England.
- the degree of need of people in England for health services or social care.
- the desirability of promoting innovation when providing health services or social care in England.

6.1.3 In reaching its decision, the committee bases its recommendations on the evidence presented, including statements from stakeholders and, when relevant, the views expressed by experts at the committee meeting. Formulating the committee discussion section of the guidance is an important component of the committee's work. These sections identify the key evidence considered by the committee and its views on this evidence. They highlight any areas of contention and uncertainty that have arisen during the committee's discussions of the evidence. They also present a general description of the committee's views on the written and oral inputs that have informed its decision.

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6.1.4 The committee's provisional recommendations may be released for widespread consultation with stakeholders and the public. In reviewing responses to consultation, the committee is most interested in comments on its preliminary recommendations within the context of the evidence base reviewed at its first meeting and its consideration of that evidence. The comments received on the key issues identified at the first meeting are carefully reviewed.

6.1.5 The committee considers the effect of the consultation comments on:

- the preliminary recommendations on the use of the technology
- the other sections of the consultation document
- recommendations for further research
- issues for implementation, including:
  - resource availability to support implementation (for example, workforce planning and training, and new clinics)
  - the extent of any changes in current clinical practice
  - any implementation criteria agreed between NICE and the Department of Health and Social Care
- the timing and potential impact of research in progress (for example, new randomised controlled trials [RCTs]).

6.1.6 The committee considers the comments and, if appropriate, amends its recommendations. The committee discussion section is modified to reflect any issues that have arisen from consultation.

6.1.7 The committee considers advice from NICE on the appropriate approach to making scientific and social value decisions. Advice on social value judgements is informed by the work of the NICE listens, NICE's advisory bodies, and the NICE Board, as well as legislation on human rights, discrimination and equality as reflected in NICE's equality scheme. Principles that describe the social value judgements that should, generally, be considered by the committee are in our principles on the NICE website.

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6.1.8 The credibility of the guidance produced by NICE depends on the transparency of the committee's decision-making process. The committee's decisions must be explained clearly with reference to all the available evidence, the contributions of experts, and comments received during consultation. The reasoning for the committee's decision will be explained, with reference to the factors that have been considered, in the committee discussion section of the guidance.

6.1.9 The language and style used in the documents produced by the committee are governed by the following principles:

- The need for clarity in explaining how the committee has come to its conclusions. The committee discussion section of the guidance document is particularly important. This summarises the key issues that have been debated and the rationale for the conclusions.
- The understanding that the text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful consideration so that enough information and justification is given in the draft guidance document or final guidance to allow the reader to understand what evidence the committee considered and, if appropriate, who provided that evidence.

6.1.10 The committee is not empowered to alter any direction from the Secretary of State for Health and Social Care for guidance with a funding requirement that requires commissioners to make funds available for the implementation of relevant NICE guidance within 3 months of publication. However, the committee may consider circumstances in which this implementation period should be varied and advise NICE accordingly. When appropriate, the committee's consideration is limited to those circumstances in which it is apparent that either the technology cannot be acquired or the NHS will not be in a position to use it within the 3-month period, or both.

6.1.11 The committee does not normally make recommendations on using a technology outside the terms of its regulatory approval. Exceptionally, the Department of Health and Social Care may direct NICE to develop guidance on a technology outside of its regulatory approval.

6.1.12 Evidence relating to the technology being evaluated that is outside the terms of

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its regulatory approval may be considered during the assessment phase of the evaluation. This may inform the committee's discussions about the use of the technology within the scope.

6.1.13 The committee may consider factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the cost analysis, such as improved processes.

6.1.14 Patient access schemes, commercial access agreements, managed access proposals and any related process and documents apply to technology appraisals and highly specialised technologies only, unless specifically stated otherwise. For diagnostics guidance please refer to the interim addendum on access proposals.

6.1.15 The committee is not able to make recommendations on the pricing of technologies to the NHS, but can consider a commercial arrangement or managed access proposal.

6.2 Assessing the evidence

Comparators

6.2.1 The committee must make decisions on the appropriateness and relevance of comparator technologies because this is crucial to considering the clinical and economic evidence.

6.2.2 When selecting the most appropriate comparators, the committee will consider:

- established NHS practice in England
- the natural history of the condition without suitable treatment
- existing NICE guidance
- cost effectiveness of the comparator
- the licensing or regulatory status of the comparator.

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6.2.3 The committee will normally be guided by established practice in the NHS when identifying the appropriate comparators. When the evaluation suggests that an established practice may not be considered a good use of NHS resources relative to another available treatment, the committee will decide whether to include it as an appropriate comparator in the evaluation, after reviewing an incremental economic analysis. The committee's overall decision on whether a cost-ineffective practice is a valid comparator will be guided by whether it is recommended in other NICE guidance, or whether its use is so embedded in clinical practice that this will continue unless it is replaced by a new technology.

6.2.4 The committee can consider as comparators technologies that do not have regulatory approval for the population defined in the scope when they are considered to be part of established clinical practice for the population in the NHS. Long-standing treatments often do not have a company to support the regulatory process. Specifically, when considering an 'off-label', 'unlicensed' or 'unregulated' comparator technology, the committee will take into account the extent and quality of evidence, particularly for safety and efficacy, for the unregulated use.

Structured decision making: clinical effectiveness

6.2.5 The committee can consider the full range of clinical studies that have been done and is not expected to restrict itself to considering only certain categories of evidence. This means the committee considers all of the evidence presented to it. This includes RCTs, non-randomised studies and test accuracy studies. It also includes any qualitative evidence related to the experiences of patients, carers and experts who have used the technology being evaluated or are familiar with the relevant condition.

6.2.6 The importance given to these various kinds of evidence depends on both the overall balance and quality of the evidence from different sources, the suitability of a particular type of evidence to address issues under consideration, and the particular evaluation context (including, for example, the type of technology, evaluation or population). In general, greater importance is given to evidence from studies of higher quality with methods designed to minimise bias. NICE expects high-quality evidence to be presented, and will assess it proportionately

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according to each circumstance, context, and decision problem.

6.2.7 The committee's decisions on clinical effectiveness take account of the following factors:

- The nature and quality of the evidence derived from:
  - the written evidence submissions
  - the analysis of the external assessment group
  - the views expressed by the clinical experts and, if relevant, specialist committee members, particularly their experience of the condition and the technology in clinical practice
  - the experience of the patient experts, carers and specialist lay committee members of living with the condition and using the technology being considered.
- Uncertainty generated by the evidence and differences between the evidence submitted for regulatory approval and that relating to effectiveness in clinical practice.
- The possible differential benefits or adverse outcomes in different groups of patients.
- The impact of benefits and adverse outcomes associated with the technology as seen from the patient's perspective.
- The position of the technology in the overall care pathway and the alternatives to the technology that are established in clinical practice.

For highly specialised technologies, the committee will consider the following additional factors in its deliberations around clinical effectiveness:

- The overall size of health benefits to patients and, when relevant, carers.
- Robustness of the current evidence and the contribution the guidance might make to strengthen it.
- Extent of disease morbidity and patient clinical disability with current

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standard care.

6.2.8 The extent to which these factors are taken into account in making decisions about the clinical-effectiveness evidence is at the committee's discretion.

6.2.9 For technologies evaluated using cost-comparison analysis, conclusions on the similarity of health benefits will be based on a pragmatic view of all available evidence for the technology compared with the relevant comparators. Clinical, technological, biological, or pharmacokinetic evidence can be used to support such a conclusion. Ideally, a non-inferiority or equivalence study with appropriate non-inferiority margins should be presented. Alternative methods, such as meta-analysis and indirect comparisons (including, for example, observational studies with a comparator drawn from the population through a matching-adjusted indirect comparison) may be considered when an RCT was not possible. The methods used to do the analysis must be rigorous and transparent.

Decision modifiers

6.2.10 In the reference case, the committee will regard all quality-adjusted life years (QALYs) as being of equal weight. However, when considering the overall health benefits, the committee can consider other factors and decision-making modifiers. Also, when relevant and in exceptional circumstances, it can accept analysis that explores a QALY weighting that is different from that of the reference case. Deviating from the reference case and applying modifiers should be morally and ethically supported by reason, coherence, and available evidence.

6.2.11 Decision-making modifiers are factors that have not been included in the estimated QALY because they cannot be (that is, they are factors that go beyond QALYs), and value judgements. Modifiers can be taken into account qualitatively through committee discussion or quantitatively through QALY weighting.

Decision modifiers: severity

6.2.12 The committee will consider the severity of the condition, defined as the future

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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.

6.2.13 When assessing the severity of the condition in technology appraisals, the committee will consider the associated absolute and proportional QALY shortfall.

6.2.14 Absolute QALY shortfall is the future health, including quality and length of life, that is lost by people living with a condition, compared with the expected future health without the condition over the remaining lifetime of the patients. Absolute QALY shortfall is calculated as the expected total QALYs that people living with a condition would be expected to have with current treatment over their remaining lifetime subtracted from the total QALYs that the general population with the same age and sex distribution would be expected to have. The expected QALYs for the condition with current treatment is equivalent to the total QALYs gained with established practice in the NHS.

6.2.15 Proportional QALY shortfall represents the proportion of future health, including quality and length of life, that is lost by people living with the condition. Proportional QALY shortfall is calculated by taking the absolute QALY shortfall and dividing it by the remaining QALYs that the general population with the same age and sex distribution would be expected to have over their remaining lifetime.

6.2.16 The committee may apply a greater weight to QALYs if technologies are indicated for conditions with a high degree of severity. The data used to estimate both absolute and proportional QALY shortfall should focus on the specific population for which the new technology will be used and be based on established clinical practice in the NHS.

6.2.17 Absolute and proportional shortfall calculations include an estimate of the total QALYs for the general population with the same age and sex distribution as those with the condition. The population EQ-5D data and survival data used for the estimates should be based on a recent and robust source. Absolute and proportional shortfall calculations should include discounting at the reference-case rate.

6.2.18 The QALY weightings for severity are applied based on absolute and proportional

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shortfall, whichever implies the greater severity level. If either the proportional or absolute QALY shortfall calculated falls on the cut-off between severity levels, the higher severity level will apply.

Table 6.1 QALY weightings for severity

QALY weight	Proportional QALY shortfall	Absolute QALY shortfall
1	Less than 0.85	Less than 12
x1.2	0.85 to 0.95	12 to 18
x1.7	At least 0.95	At least 18

6.2.19 For medical technologies evaluated through the medical technologies evaluation programme, the concept of a quantitative QALY weight is not applicable. The severity of the condition should be considered deliberatively within decision making.

6.2.20 For diagnostics, a QALY weight for severity based on absolute and proportional QALY shortfall is unlikely to reflect the societal value and severity of disease in a way that is relevant to the diagnostics context. Therefore, the severity modifier will not normally be applicable in diagnostic evaluations.

6.2.21 For highly specialised technologies, the severity of the condition is already implicitly captured in the selection of technologies for evaluations. No additional QALY weighting for the severity of disease is applied.

6.2.22 Technologies recommended after applying the severity modifier will be considered as relevant comparators for future evaluations of new technologies introduced for the same condition. They must have been recommended for routine use and represent established practice in the NHS at the time of evaluating the new technology. Second and subsequent extensions to the regulatory approval for the same technology will be considered on their individual merits.

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Decision modifiers: size of benefit for highly specialised technologies

6.2.23 For highly specialised technologies, the committee will consider the size of the incremental QALY gain in relation to the additional weight that would need to be assigned to the QALY benefits for the cost effectiveness of the technology to fall within the highly specialised technologies £100,000 cost per QALY level.

6.2.24 For this weight to be applied, there will need to be compelling evidence that the treatment offers significant QALY gains. Depending on the number of QALYs gained over the lifetime of patients, when comparing the new technology with its relevant comparator(s), the committee will apply a weight between 1 and 3, using equal increments, for a range between 10 and 30 QALYs gained.

6.2.25 The weighting is applied as described in table 6.2 below.

Table 6.2: QALY weightings for size of benefit for highly specialised technologies

Incremental QALYs gained (per patient using lifetime horizon)	Weight
Less than or equal to 10	1
11 to 29	Between 1 and 3 (using equal increments)
Greater than or equal to 30	3

Structured decision making: value for money

6.2.26 NICE considers the overall resources available to the NHS when determining value for money. Therefore, decisions about a new technology must consider implications for healthcare programmes for other patient groups that may be displaced by the adoption of the new technology; the opportunity cost, including those programmes or technologies not evaluated by NICE.

6.2.27 As far as possible, the committee will make sure that its decisions about what constitutes good value for money are consistently applied between evaluations.

6.2.28 The committee's decisions on cost effectiveness or cost savings are influenced

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by the following factors:

- The strength of the supporting clinical-effectiveness evidence.
- The robustness and appropriateness of the structure of the economic models. In particular, the committee considers carefully whether the model reflects the decision problem at hand and the uncertainties around the assumptions on which the model structure is based.
- The position in the care pathway.
- The plausibility of the inputs, and the assumptions made, in the economic models.
- The committee's preferred modelling approach, taking into account all of the economic evidence available.
- The range and plausibility of the incremental cost-effectiveness ratios (ICERs), net health benefits (if appropriate) or cost savings generated by the models reviewed.
- The likelihood of decision error and its consequences.

6.2.29 The committee will consider carefully which individuals benefit most from the technology and whether there are subgroups of individuals for whom the effectiveness evidence suggests differential cost effectiveness or cost savings. The committee may recommend a technology for subgroups of the population only if there is clear evidence that the characteristics defining the subgroup influence the effectiveness or value for money of the technology. It can only do this based on an appropriate consideration of subgroups, to make sure that the decision is clinically justifiable, methodologically robust, ethical, and lawful under equalities legislation. The committee should be particularly aware of the benefits and harms (to individuals and to the NHS as a whole) of including or excluding a given subgroup. If considering excluding a subgroup, the committee must be convinced the harm to the NHS of including it is great enough to justify this decision. If appropriate, the committee may decide to not recommend a technology in a particular subgroup (that is, to exclude a subgroup from the recommendation), even if the technology is clinically and cost effective in the whole population, if they consider it appropriate. When considering subgroups, the committee pays particular attention to its legal obligations with respect to

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legislation on human rights, discrimination and equality when considering subgroups.

6.2.30 When the evidence on key parameters used to estimate cost effectiveness or cost savings has serious limitations, or when a variety of assumptions have been necessary in the economic modelling, the additional uncertainty this creates is a key factor in the committee's decisions.

6.2.31 The committee should consider the reliability and generalisability of the evidence presented when considering cost-effectiveness estimates. In its consideration, the committee will decide whether to recommend or not recommend a technology based on both the evidence presented and the impact of the evidence on key decision uncertainties. When the evidence is highly uncertain and leads to a high degree of decision uncertainty, the committee may consider making recommendations that include managed access, data collection or research (see section 6.4).

6.2.32 The committee considers how its advice may allow more efficient use of available healthcare resources. In general, it will want to be increasingly certain of the cost effectiveness or cost savings of a technology as the impact of the adoption of the technology on NHS resources increases. Therefore, the committee may need more robust evidence on the effectiveness and cost effectiveness or cost savings of technologies that are expected to have a large impact on NHS resources.

6.2.33 When considering uncertainty, the committee should take into account the likelihood of decision error and its consequences for patients and the NHS. There should be an explicit reference to the potential benefits and risks to patients based on the level of decision uncertainty and whether this can or cannot be mitigated. The committee should also consider the risks to the NHS of using the technology, based on the most plausible ICER and the impact of adopting the technology on NHS resources.

6.2.34 Decisions about the acceptability of the technology as an effective use of NHS resources will specifically take account of the degree of certainty around the value for money. In particular, the committee will normally be more cautious about recommending a technology if they are less certain about the evidence

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presented. However, the committee will be mindful that there are certain technologies or populations for which evidence generation is particularly difficult because they are:

- rare diseases
- for use in a population that is predominantly children (under 18 years old)
- innovative and complex technologies.

In these specific circumstances, the committee may be able to make recommendations accepting a higher degree of uncertainty. The committee will consider how the nature of the condition or technology(s) affects the ability to generate high-quality evidence before applying greater flexibility.

6.2.35 In all cases, the committees must consider the nature, scale and consequences of the decision uncertainty and the risks to patients and the NHS. It should be cautious in accepting a higher degree of uncertainty in circumstances when the highest standard of evidence generation that should be expected in the circumstances has not been achieved. Uncertainty will be considered proportionately for the evaluation context (including, for example, the type of technology, evaluation, or population).

Structured decision making: health inequalities

6.2.36 If robust evidence shows that the technology substantially affects health inequalities, the committee will consider how this impacts its decision on whether the technology is an effective use of NHS resources (see sections 6.2.38 and 6.2.39).

6.2.37 Consideration of the health inequality impacts of a technology is separate from NICE's legal obligations on equality and human rights, including under the Equality Act 2010.

6.2.38 When assessing the relevance of health inequality impacts on the value of the technology, the committee will consider any uncertainty associated with the health inequality evidence and analysis. If robust condition- or disease-specific

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evidence shows that uncertainty or biases in the health inequality evidence are caused by structural or social barriers to accessing care or participating in research, the committee may accept a higher level of uncertainty in the health inequality evidence and analysis.

6.2.39 When considering the relevance of health inequality impacts on the value of the technology, the committee can apply flexibility to the range normally considered a cost-effective use of NHS resources. But, it must consider the effects of healthcare displacement and opportunity cost and provide a rationale for stakeholders. This flexibility should be applied to the most appropriate acceptable ICER decided by the committee for the reference case analysis, as described in sections 6.3.4 to 6.3.8. It should only be applied when the size of the health inequality impacts of a technology are substantial. It should not be used to justify restricting the population of interest to a subgroup based on cost effectiveness (see section 4.9). The committee will not use evidence on health inequality impacts to make optimised recommendations for subgroups based solely on social characteristics.

Structured decision making: uncaptured benefits and non-health factors

6.2.40 In general, the committee uses the most plausible ICER or most plausible level of cost savings as the primary consideration when making decisions about the acceptability of technologies as a cost-effective use of NHS resources. However, its overall conclusions are also affected by the following additional considerations:

- 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 and may therefore misrepresent the health utility gained.
- If a substantial proportion of the costs (savings) or benefits are incurred outside of the NHS and personal and social services, or are associated with

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significant benefits other than health, only when requested specifically by the Department of Health and Social Care as part of the remit.

6.3 Decision making

Economic evaluations based on cost-utility analyses

6.3.1 The committee does not use a precise maximum acceptable ICER above which a technology would automatically be defined as not cost effective or below which it would. Given the fixed budget of the NHS, the appropriate maximum acceptable ICER to be considered is that of the opportunity cost of programmes displaced by new, more costly technologies. NICE does not have complete information about the costs and QALYs from all competing healthcare programmes to define a precise maximum acceptable ICER. However, NICE considers that it is most appropriate to use a range as described in sections 6.3.4 to 6.3.8. Also, consideration of the cost effectiveness of a technology is necessary but is not the only basis for decision making. Consequently, NICE considers technologies in relation to this range of maximum acceptable ICERs, so that the influence of other factors on the decision to recommend a technology is greater when the ICER is closer to the top of the range.

6.3.2 To be transparent in decision making, when applying decision-making modifiers, net health benefits should be routinely presented to show the effect on opportunity costs of recommending a technology that meets specific decision-making modifiers. Net health benefits should be presented using values placed on a QALY gain of £20,000 and £30,000, both with and without the QALY weighting applied. Positive net health benefits mean that overall population health is increased because of the new technology. Negative net health benefits mean that the health benefits associated with the new technology are not large enough to prevent overall health loss because of healthcare not being funded elsewhere in the system. Technologies associated with negative unweighted net health benefits may still be recommended when decision-making modifiers have been applied. This is because there is an ethical and moral rationale to value the health benefits gained with these technologies more than those gained by technologies not meeting decision-making modifiers.

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6.3.3 When multiple technologies are being compared, cost-effectiveness rankings may be used to present the results of probabilistic model analyses. This should show the probability that each technology is ranked highest (produces the highest net benefit). It may also help to know the probability that each technology is ranked second, last, and all positions in between. Ranking-based histograms ('rankograms') may be used to present this information in a simple way, alongside the expected net benefit of each technology.

6.3.4 Below a most plausible ICER of £20,000 per QALY gained, or £100,000 per QALY gained for highly specialised technologies, the decision to recommend a technology is normally based on the cost-effectiveness estimate and the acceptability of a technology as an effective use of NHS resources. When the estimated ICERs are less than £20,000 per QALY gained, or £100,000 per QALY gained for highly specialised technologies, and the committee decides that the technology should not be recommended, the committee will make specific reference to its view on the plausibility of the inputs to the economic modelling, or the certainty around the estimated ICER, or both. This might be affected, for example, by sensitivity analysis or limitations to the generalisability of findings about effectiveness.

6.3.5 Above a most plausible ICER of £20,000 per QALY gained, or £100,000 per QALY gained for highly specialised technologies, decisions about the acceptability of the technology as an effective use of NHS resources will specifically consider the following factors:

- the degree of certainty and uncertainty around the ICER
- aspects that relate to uncaptured benefits and non-health factors
- aspects that relate to health inequalities.

6.3.6 For highly specialised technologies the committee may give particular consideration to:

- The impact of the technology on the overall delivery of the specialised service
- Additional staffing and infrastructure requirements, including training and planning for expertise.

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6.3.7 As the ICER for a technology increases in the range of £20,000 to £30,000 per QALY gained, the committee's decisions about the acceptability of the technology as an effective use of NHS resources will make explicit reference to the relevant factors listed in section 6.3.5.

6.3.8 Above a most plausible ICER of £30,000 per QALY gained or £100,000 per QALY gained for highly specialised technologies, 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 sections 6.3.5 and 6.3.6.

6.3.9 For technologies that provide less health benefit at a lower cost compared with the relevant comparator(s) (that is, that fall in the south-west quadrant of a cost-effectiveness plane), cost-effectiveness considerations should consider the usual cost-effectiveness levels of £20,000 to £30,000 per QALY. Any relevant additional factors and modifiers should also be taken into account.

6.3.10 Recommendations for using a diagnostic test may also be limited to specific circumstances such as: the patient's characteristics, aetiology of the disease, the training and skills of those providing the test, availability of equipment, and the availability of other portions of the care pathway.

6.3.11 A technology may have multiple uses and not all of these may be explored in the evaluation. The committee forms recommendations only for the use of the technology described in the scope.

6.3.12 When a technology has already been purchased, the committee may take into account that its recommendations are made in the context of additional use of existing equipment.

Economic evaluations based on cost-comparison analyses

6.3.13 The committee's main considerations when making its decisions are:

- Benefit to patients – if the technology has measurable benefit to patients over currently available health and social care system technologies, measured by relevant outcome indicators.

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- Benefit to the health and social care system – if the technology is likely to reduce costs or resource use (for example staff or facilities) compared with current management.

6.3.14 The committee makes its recommendations based on the clinical and economic evidence, informed by contributions from experts and stakeholders. The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to make robust recommendations. If there are any uncertainties, the committee makes informed judgements and describes its uncertainties in the guidance. The committee should also consider the degree of severity of the condition when evaluating cost-saving technologies and may take that into account when assessing the level of uncertainty of the evidence presented.

6.4 Types of recommendation

6.4.1 The committee produces recommendations based on the extent to which the potential patient and health and social care system benefits are supported by evidence.

Table 6.3 Committee recommendations

Case for adoption and potential benefits	Type of recommendations that are normally made	New recommendation wording 2025	For details see section
Case is fully supported.	Recommended (as an option)	[Technology] can be used (within its marketing authorisation)	6.4.2 to 6.4.5
Case is partially supported – for example, it is supported for specific circumstances or populations.	Recommended (as an option) in specific circumstances ('optimised recommendation')	[Technology] can be used as an option	6.4.4

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Case for adoption and potential benefits	Type of recommendations that are normally made	New recommendation wording 2025	For details see section
The case is not currently supported but the technology has the plausible potential to be cost effective and has potential to provide significant patient or healthcare system benefits if the uncertainties in the clinical evidence are addressed.	Recommended with managed access	[Technology] can be used during the managed access period as an option	6.4.6 to 6.4.11
Case is currently not fully supported but the technology has potential to provide significant patient or healthcare system benefits if the uncertainties in the evidence are addressed.	Recommended with data collection	[Technology] can be used as an option in the NHS during the evidence generation period	6.4.12 to 6.4.15
Case is not currently supported because the clinical effectiveness or evidence on the impact on other health outcomes is absent or uncertain, but the technology has potential to provide significant patient or healthcare system benefits and a recommendation in a research context is considered appropriate.	Recommended only in a research context	More research is needed on [technology] before it can be funded in the NHS	6.4.16 to 6.4.17
Case is not supported.	Not recommended	[Technology] should not be used	6.4.18

Recommending a technology

6.4.2 The committee will recommend 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 and so should be made available in the NHS.

6.4.3 For technologies evaluated using cost-comparison analysis, the committee

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usually recommends a technology can be used when it considers that:

- there is enough certainty that the technology has at least equivalent clinical or health and social care system benefits compared with current management, and overall uses less resources or
- there is enough certainty that the technology has significantly greater clinical or health and social care system benefits compared with established practice in the NHS, and overall uses similar resources.

6.4.4 The committee may recommend the technology can be used only under specific circumstances (sometimes referred to as an 'optimised recommendation'). For example, only for patients with a particular condition who meet specific clinical eligibility criteria, only for a specific subgroup of people, or that the treatment must be given by staff with certain training or in a particular care setting.

6.4.5 When recommending technologies that are one of several similar options, committees may specify what should be taken into account when choosing between them, if it considers this appropriate. These considerations may include cost, if appropriate.

Recommendation with managed access (technology appraisals and highly specialised technologies only)

6.4.6 When a committee is unable to recommend a medicine because there is still significant resolvable uncertainty, it can make a recommendation for further evidence to be gathered subject to managed access. The committee can consider a recommendation with managed access when:

- the medicine has not been recommended, it has the plausible potential to be cost effective at the currently agreed price, but the evidence is currently too uncertain, and
- new evidence that could sufficiently support the case for recommendation is expected from ongoing or planned clinical trials, or could be collected from patients having the medicine in clinical practice, and
- these data could feasibly be collected within a reasonable timeframe (up to a

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maximum of 5 years) without undue burden.

6.4.7 The committee may also make recommendations with managed access for a medicine in specific circumstances only. For example, only for patients with a particular condition who meet specific clinical eligibility criteria, or that the medicine must be given by staff with certain training or in a particular care setting.

6.4.8 A recommendation with managed access is intended to reduce uncertainty about specific evidential issues identified by the committee.

6.4.9 Medicines recommended with managed access are not commissioned routinely by the NHS but are made available to patients for a time-limited period. Patient access is determined by the terms of the managed access agreement between NHS England and NHS Improvement and the company.

6.4.10 A recommendation with managed access is not considered established practice in the NHS because:

- the committee has found that a recommendation cannot be supported, until further evidence is available
- the committee has made a recommendation with managed access using a temporary price to mitigate the uncertainty
- the funding during the evidence generation period for these medicines is made available from dedicated managed access funds, rather than routine NHS funding
- if, once further evidence is available, the committee does not recommend the medicine, the medicine will then not be available in the NHS for people who have not yet had treatment
- although there is plausible potential to satisfy the criteria for a recommendation, the uncertainty in the clinical data (and consequently the cost-effectiveness estimates) was too great to make such a recommendation at the time of the evaluation.

6.4.11 A recommendation with managed access is distinct from a recommendation only

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in a research context because managed access is designed to allow further evidence generation in the NHS, in addition to current or ongoing clinical research. A recommendation only in a research context, however, comes without a requirement for NHS funding.

Recommendation with evidence generation (diagnostics guidance and medical technologies guidance only)

6.4.12 For devices and diagnostics, when a committee is unable to recommend a technology because more research or evidence generation is needed, the committee may make recommendations with evidence generation if:

- the technology could provide substantial benefits to patients or may release significant resources but
- there is substantial uncertainty about whether the potential clinical and system benefits are realisable in clinical settings in the NHS; uncertainties may relate to whether clinical outcomes will be achieved, or to service impact (for example, the likelihood of the technology being introduced in a way that leads to the claimed benefit of released resources).

6.4.13 The committee considers the following factors when deciding whether to make a recommendation with evidence generation:

- the most important clinical, economic, technical or other evidence gaps relating to use of the technology in the health and social care system
- the research questions that future studies could address
- the likely net benefits for all NHS patients of only using the technology in research during the time that the recommended research is being done
- irrecoverable costs incurred from introducing the technology
- the likely costs and benefits of the research (to ensure that a research recommendation does not become a barrier to innovation).

6.4.14 Research recommendations may focus on the care pathway after the use of a

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diagnostic test if uncertainties about the pathway affect the value of testing.

6.4.15 A recommendation with future evidence generation is not intended to prevent the use of the technology in the health and social care system but to identify further evidence which, after evaluation, could support a wider recommendation. Evaluations that include a recommendation with evidence generation will normally be reviewed at an appropriate time, to reconsider the evidence and value of the technology.

Recommendation for more research

6.4.16 When the evidence of clinical effectiveness or impact of a technology on other health outcomes is either absent, weak or uncertain, the committee may recommend that the technology is used while more research is done. Before issuing such recommendations, the committee will consider the following points:

- The need for and potential value to the NHS of additional evidence that can inform the development of NICE guidance and clinical practice on the use of the technology.
- The uncertainty in the analysis and what could be gained by reconsidering the decision in the light of research findings.
- The impact of recommendations on the feasibility of doing the research.
- Information about ongoing or planned relevant research, or the likelihood that the research needed will be commissioned and successfully reported.
- The time it is likely to take for research findings to be available to inform subsequent NICE guidance and clinical practice.
- Ethical or practical aspects of doing further research.

In considering these factors the committee may seek advice from research commissioners, the wider research and clinical communities and stakeholders. The committee will consider these factors to balance the potential net benefits to current patients in the NHS of a recommendation not restricted to research with the potential net benefits to both current and

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future patients in the NHS of producing guidance and basing clinical practice on a more secure evidence base.

6.4.17 A recommendation for more research is not considered established practice in the NHS.

Not recommended, should not be used

6.4.18 If the benefits and value for money delivered by 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. The committee's rationale is described in the committee discussion section of the guidance.

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7 Finalising and publishing the guidance

7.1 Finalising the guidance

7.1.1 For technology appraisals and highly specialised technologies guidance, consultees can appeal the final draft guidance, or the process followed using the appeal process. For medical technologies and diagnostics guidance, stakeholders can use the resolution process on the final draft guidance and the process followed.

7.2 Resolution for medical technologies and diagnostic guidance

7.2.1 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.

7.2.2 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.

7.2.3 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.

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Grounds for resolution

7.2.4 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.

7.2.5 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

7.2.6 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.

7.2.7 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

7.2.8 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.

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Ground 1: breach of process

7.2.9 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.

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

Ground 2: factual errors

7.2.11 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.

7.2.12 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.

7.2.13 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.

7.2.14 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 7.1 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

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Outcome of initial scrutiny	NICE action
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

7.2.15 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.

7.2.16 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.

7.2.17 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.

7.2.18 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.

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Resolution outcome

Ground 1: breach of process

7.2.19 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

7.2.20 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.

7.2.21 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 7.2 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

7.2.22 NICE implements the panel's decision and informs everyone who made resolution

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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.

7.3 Publishing the guidance

7.3.1 Once the appeal or 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'.

7.3.2 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 technical engagement 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.

7.3.3 If NICE is advised of any potential errors in the guidance or the supporting

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documents after publication, these are dealt with according to NICE's standard procedures.

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8 Guidance surveillance

8.1 Making sure the guidance is current and accurate

8.1.1 The aim of surveillance is to monitor guidance to make sure it is up to date and decide what action to take if it is no longer valid or accurate. NICE will regularly monitor its published technology guidance to check for any new evidence or information that could affect the recommendations. Guidance will not have a fixed review date, except for guidance with recommendations for use with managed access, when a surveillance review will be scheduled at the end of the data collection period.

8.2 Surveillance monitoring

8.2.1 NICE will monitor the following information and sources to decide when a guidance topic should be reviewed:

- changes in the evidence base
- changes to regulatory status
- guidance age
- the safety of the recommendations
- changes in the care pathway
- changes to costs
- ongoing and completed data collections for technologies recommended with managed access.

8.2.2 NICE is keen to hear about any new evidence or other information that could affect the recommendations (please send information to nice@nice.org.uk,

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stating the guidance topic it relates to). NICE will assess the likely effect of the new evidence on the recommendations and will start a surveillance review if needed. NICE may proactively contact companies and other stakeholders requesting information as a normal part of its monitoring activities.

8.2.3 NICE will regularly review the information it receives through monitoring activities. When monitoring information indicates that the guidance recommendations are likely to be unsafe, invalid or inaccurate, NICE will do a more detailed surveillance review.

8.3 Surveillance review

8.3.1 NICE develops a surveillance proposal after gathering relevant information. The proposal is used as the basis for a decision on whether the guidance should be amended, updated, withdrawn or not updated.

8.3.2 NICE will publish on its website when a surveillance review has started and contact stakeholders and any specialist committee members involved in the original guidance development as needed to gather information to develop the surveillance review. NICE will update the stakeholder list from the original guidance.

8.3.3 To develop the surveillance proposal NICE will aim to identify the following information as appropriate:

- changes to the evidence base or other sources (including asking companies or stakeholders to provide new evidence that has become available since publication of the guidance)
- changes to the care pathway
- changes to costs, prices and other factors that affect the financial information in the guidance
- changes in the regulatory status of the technology or regulatory extensions to its approved indication.

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8.3.4 If, while developing the surveillance review, NICE becomes aware of ongoing studies or other information that is likely to be an important or significant consideration when reaching a surveillance decision, NICE may defer its review to a later date when the relevant information is available.

8.4 Surveillance decision options

8.4.1 NICE considers the surveillance review and determines if it should have a public consultation. A consultation will only take place when the review has identified significant uncertainty in the appropriate decision option. NICE expects that consultations will not be needed routinely.

8.4.2 When a consultation takes place, NICE asks stakeholders to comment on the surveillance review. NICE publishes the surveillance review, together with the list of stakeholder organisations, on its website.

8.4.3 The consultation will be open for 28 days.

8.4.4 NICE will consider the surveillance review and any consultation comments received and approve the final surveillance decision. Stakeholders are informed of the surveillance decision. The surveillance decision is published on the NICE website 7 days after stakeholders are informed. If a consultation has taken place, NICE also publishes the comments and NICE's response to them.

No update to guidance

8.4.5 Guidance will remain unchanged if:

- the evidence base, clinical pathway and costs are similar to those NICE considered when developing the original guidance and are unlikely to change the recommendations, and
- the guidance is factually correct.

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Publish a technical supplement

8.4.6 If the guidance remains valid but newer versions of the technology (often diagnostic or digital) are available, NICE may develop a technical supplement.

8.4.7 A technical supplement may be developed outside of a surveillance review when new versions of technologies become available shortly after guidance is published.

8.4.8 Technical supplements are normally developed for NICE by an external assessment group and:

- provide up-to-date technical information about newer versions of 1 or more of the technologies covered in the guidance
- are factual, do not make recommendations or evaluate if technologies are comparable in performance
- only contain publicly available information
- do not update or change the guidance recommendations.

8.4.9 Technical supplements contain the following information for each technology, in a way that allows different technologies and versions to be compared:

- technology name and version
- regulatory information
- technical specification
- cost.

8.4.10 The external assessment group contacts companies to get technical and pricing information, and use information obtained during the surveillance process. NICE sends the draft technical supplement to the company for a factual accuracy check.

8.4.11 The technical supplement is updated and published on the website alongside the existing guidance.

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Amending the guidance

8.4.12 Guidance will be amended if:

- the technology name, owner, version or functionality has changed but the recommendations and evidence used in the original evaluation are still valid
- the costs have changed but the cost effectiveness or cost-saving outcome in the guidance remains broadly valid
- the terminology has changed or to make sure the language is consistent with other guidance.

8.4.13 As part of the review process, NICE may reassess how the costs in the original guidance have changed. This is usually done on guidance that is cost saving.

8.4.14 The proposed guidance amendments are set out in the surveillance decision. The amendments to the guidance will be made when the surveillance decision is published.

Updating the guidance

8.4.15 Guidance will be updated by the committee if there are changes to the evidence base, clinical pathway or economic case that are likely to have a material effect on the recommendations.

8.4.16 Guidance can be updated in the following ways:

- through an evaluation, publishing new guidance to replace the existing guidance
- within an evaluation of other technologies
- within another guidance-producing centre (for example in a NICE guideline).

8.4.17 The surveillance decision will clearly state how the guidance will be updated, using which guidance type and process, and what will happen to the original guidance once the updated guidance is published.

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Withdrawing the guidance

8.4.18 Guidance will be permanently or temporarily withdrawn if:

- the technology or the recommendations are no longer considered safe, or their safety becomes uncertain
- NICE issues new guidance that replaces the existing guidance
- the technology is withdrawn from the market or loses its regulatory approval for the populations or uses in the guidance
- advice or guidance from professional societies, evidence or other accredited sources that lead NICE to conclude that the recommendations on the technology are no longer aligned with accepted clinical practice
- changes to the technology or the care pathway are such that the original guidance cannot be updated
- after a period of managed access if:
  - commitments in the data collection agreement have not been met and corrective actions will not address the issues arising
  - a guidance update would be futile (for example, the assumptions that led to the original recommendation for use with managed access are not supported in the new evidence being generated)
  - the company has not made a complete submission to NICE to enable a guidance update
  - the company has not paid the relevant fee for the guidance update process.

8.4.19 Guidance will be withdrawn from the NICE website when the surveillance decision is published. The reason for withdrawal will be published on the website.

8.4.20 NICE may withdraw guidance in exceptional circumstances at any point during or outside of the surveillance process when the technology no longer has regulatory approval for use, or the technology or guidance are considered unsafe.

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8.4.21 If guidance is withdrawn for a technology with managed access, the company will submit the clinical evidence collected during the managed access period to NICE and NHS England and NHS Improvement. It will then take part in an engagement meeting convened by NICE with attendance from NHS England and NHS Improvement, and professional, patient and carer organisation stakeholders. The company will present the clinical evidence collected during the managed access period and an explanation of reasons for the guidance being withdrawn.

8.5 Surveillance of managed access data collections (including interim evidence reviews)

8.5.1 NICE will convene technology-specific managed access oversight groups to oversee each data collection agreement, with representation from NICE, NHS England and NHS Improvement, data custodians and the company. The role, responsibilities and meeting frequency of each managed access oversight group is described in a terms of reference document issued by NICE.

8.5.2 For complex data collection agreements (for example, when real-world data is the primary data source or when a new service is needed to deliver the technology), clinical experts and patient and carer organisations may also be invited to provide representation on the managed access oversight group.

8.5.3 The number of managed access oversight group members will be decided on a case-by-case basis depending on the needs of the topic. In certain circumstances, NICE will issue an expression of interest notification to stakeholders and request application forms to shortlist and confirm the final managed access oversight group membership list after assessing all applications.

8.5.4 The managed access oversight group will regularly review the progress of managed access data collections. Regular reports provided by the company or the data custodian will be submitted to NICE (at a frequency agreed within the data collection agreement). These reports will confirm that the data collection is on track and to assess whether any corrective action is needed to achieve the objectives of the data collection agreement.

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8.5.5 Any issues with the performance of managed access data collection or decisions that could impact the final outputs of managed access data collection will be escalated by the managed access oversight group to the joint NICE and NHS England and NHS Improvement managed access governance group. This group will make final recommendations and agree actions to address arising issues.

8.5.6 Managed access data collections may be subject to an interim evidence review, when needed (for example, for agreements longer than 2 years, or complex arrangements). An interim evidence review provides a midpoint opportunity to assess the performance of the data collection and the effect of any changes in clinical pathways. It may involve, but is not limited to, a review of data quality and completeness, and reporting on outcomes and interim or planned analyses. The interim evidence review can address whether the data collection, and therefore the managed access period, should continue for the full duration, or identify corrective actions that need to be addressed, or both.

8.5.7 When an interim evidence review is indicated, the scope and timing of the review will be agreed by the data collection working group and detailed in the data collection agreement.

8.5.8 The interim evidence review will be coordinated by NICE and may involve an external assessment group. NICE will produce recommendations for the consideration of the joint NICE and NHS England and NHS Improvement managed access governance group. This will include whether:

- to continue data collection as planned or with corrective actions needed, or
- to update the guidance early (for example, when new evidence is available sooner than anticipated), or
- to withdraw the guidance (only under exceptional circumstances, see sections 8.4.18 to 8.4.21).

8.5.9 NICE will publish the outcome of the interim evidence review on the NICE website, along with any reports from the external assessment group.

8.6 Updating guidance after a period of managed

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access

8.6.1 NICE will update its guidance for a technology recommended for use with managed access at the end of the data collection period as specified in the data collection agreement. The aim of the guidance update is to decide whether the technology can be recommended (as an option). The technology cannot be recommended with managed access as part of the guidance update.

8.6.2 NICE may consider a guidance update earlier than the published review date in the data collection agreement, if the joint NICE and NHS England and NHS Improvement managed access governance group agrees. For example, if there is significant new evidence that supports the original case for clinical and cost effectiveness.

8.6.3 NICE will schedule guidance updates into the work programme to coincide with the end of the data collection period determined by the data collection agreement.

8.6.4 NICE will apply the process and methods in place at the time of the invitation to participate to a guidance update after a period of managed access, unless explicitly stated in the data collection arrangement.

8.6.5 A guidance update after a period of managed access will be done through NICE's processes for developing guidance (that is, a single technology appraisal, a multiple technology appraisal or a cost-comparison evaluation) unless otherwise specified by NICE in the data collection agreement. The preferred evaluation type will be confirmed by NICE before the end of the data collection period specified in the data collection agreement.

8.6.6 The guidance update will include the scoping step, making sure that the evolution of the treatment pathway has been considered appropriately during the period of managed access.

8.6.7 Companies must provide an evidence submission to support a guidance update after a period of managed access. If the company does not make an evidence submission, NICE will withdraw the guidance.

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8.7 Surveillance of guidance after loss of market exclusivity (technology appraisals only)

8.7.1 NICE will do surveillance of guidance because of loss of marketing exclusivity when:

- the original guidance (including for technologies that are used in combination with other technologies) resulted in the technology being recommended (as an option) in specific circumstances (optimised use), recommended only in research context or not recommended
- the biosimilars or generics of the technology are licensed for the same indication
- the original economic model can be used for the purpose of the update and consent has been received from the originator company for the model to be used for this purpose.

8.7.2 NICE will work with the NHS Commercial Medicines Unit and decide whether to start a rapid update of the guidance.

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Update information

May 2025: This manual was updated to include guidance on the evidence and impact of health inequalities and how this affects decision making. For more information on this modular update, please see the support document published alongside the updated manual.

October 2023: This manual was updated to include guidance on the cost-comparison process, streamlined decision making and operating efficiently. For further information on this modular update please see the accompanying report published alongside the updated manual.

Minor changes since publication

June 2025: Sections 5.10.4, 5.10.5, 5.10.6 and 5.10.22 were updated to note that the threshold for the budget impact test has now increased from £20 million to £40 million.

December 2024: In the section on types of recommendation, minor updates were made to the terminology now used by a committee when making a recommendation.

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