

Proposed changes to NICE health technology evaluations: the manual (PMG36)

25 September 2025

Proposed amendments

Existing [NICE health technology evaluations: the manual](#).

Table 1 Proposed amendments to NICE health technology evaluations: the manual

Existing wording	Section	Proposed change
NICE health technology evaluations: the manual	Title	Replace with: NICE technology appraisal and highly specialised technologies: the manual
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:	Introduction to health technology evaluation	Replace with: Introduction to technology appraisal and highly specialised technologies guidance This guide describes the methods and processes, including expected timescales, that NICE follows when producing technology appraisal and highly specialised technologies guidance. The methods and processes are designed to produce robust guidance for the NHS in an open, transparent and timely way, with appropriate contribution from stakeholders. Organisations invited to contribute to guidance development should read this manual alongside the NICE-wide topic prioritisation process. All documents are available on the NICE website. The methods and processes are designed to provide recommendations for the NHS, in the form of NICE guidance, on the use of new and existing

• HealthTech 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 • 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.		medicinal products and HealthTech, including medical devices, diagnostics and digital technologies. When necessary, this manual distinguishes health technologies as being medicines or HealthTech. If not indicated otherwise, 'health technologies' refers to both medicines and HealthTech. Some of these technologies will also be considered in other NICE guidance (without mandated funding associated with recommendations for use), such as NICE guidelines or HealthTech guidance, or will have medicines and prescribing support from the Medicines Optimisation Team. This manual relates only to technologies evaluated for technology appraisal and highly specialised technologies guidance.
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	Introduction to health technology evaluation	Replace with: To support the robustness of NICE's processes, our programmes and processes comply with the principles underpinning the UK government's review of quality assurance of government models (the Macpherson recommendations). NICE

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.		Directors have 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.
Service-level agreements are in place to help disseminate NICE technology evaluation guidance in the devolved administrations in Wales and Northern Ireland. 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	Introduction to health technology evaluation	Replace with: Service-level agreements are in place to help disseminate guidance in the devolved administrations in Wales and Northern Ireland. Technology appraisal and highly specialised technologies guidance Assessments for technology appraisal and highly specialised technologies guidance assess technologies using clinical utility and cost-effectiveness analysis. The process normally covers new technologies 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 (this is the most common process across the programmes and is used for the first assessment of a medicine and updates to existing medicines guidance) • the multiple technology appraisal • cost comparison • rapid review • update after loss of market exclusivity of a technology. For technology appraisal and highly specialised technologies guidance, the National Institute for Health and Care Excellence (Constitution and Functions)

and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 indicate that NICE may make a recommendation:		and the Health and Social Care Information Centre (Functions) Regulations 2013 indicate that NICE may make a recommendation:
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.	Introduction to health technology evaluation	Replace with: 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 this 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 evaluations.
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	How to use this manual	Replace with: How to use this manual This manual explains how NICE does evaluations for Technology Appraisal and Highly Specialised Technologies guidance. 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.

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.		You can use this manual to find out how 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.
1. Involvement and participation Describes who is involved in health technology evaluations, at different stages, and how they participate.	How to use this manual	Replace with: 1. Involvement and participation Describes who is involved in evaluations at different stages, and how they participate.
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.	How to use this manual	Replace with: 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 opportunity to challenge the guidance through the appeal process. Details of the appeals process are presented in NICE's guide to the technology appraisal and highly specialised technologies appeal process.
1.2.7 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 Involvement and participation (section 1.2.7)	Replace with: 1.2.7 The technical team is responsible for considering any 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.
Clinical experts and patient experts	1 Involvement and participation (section 1.2.10)	Replace with: Clinical experts and patient experts

1.2.10 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.		1.2.10 Clinical experts and patient experts are selected from those nominated by consultee organisations or by NICE, or from expressions of interest, taking into account the NICE policy on declaring and managing interests for NICE advisory committees . Experts may be 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.
NHS commissioning experts 1.2.12 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.	1 Involvement and participation (section 1.2.12)	Replace with: NHS commissioning experts 1.2.12 NICE invites NHS commissioning experts from NHS England and NHS Improvement and relevant commissioning organisations to help clarify issues about the submitted evidence.
NICE Decision Support Unit 1.2.18 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.	1 Involvement and participation (section 1.2.18)	Replace with: NICE Decision and Technical Support Unit 1.2.18 The Decision and Technical Support Unit is commissioned by NICE to provide a research and training resource to support NICE's guidance programmes and the methods of evaluation.
Centre director 1.2.20 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.	1 Involvement and participation (section 1.2.20)	Replace with: Director 1.2.20 Directors are responsible for delivering all outputs and ensures that evaluations are done in line with the published process and methods.
Public Involvement Programme (PIP) adviser 1.2.29 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	1 Involvement and participation (section 1.2.29)	Replace with: People and Communities Team (PaCT) adviser 1.2.29 PaCT is the team at NICE that supports and develops public involvement across NICE's work programme . The public

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.		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.
Adoption lead 1.2.32 The adoption and implementation team may produce an adoption report at the scoping stage for HealthTech 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.	1 Involvement and participation (section 1.2.32)	Replace with: Adoption lead 1.2.32 The adoption and implementation team may produce an adoption report at the scoping stage. 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.
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 Involvement and participation (section 1.3.1)	Replace with: Companies 1.3.1 For medicines evaluations, 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. For HealthTech evaluations companies can provide responses to requests for information to provide information and evidence about their technology.
1.3.2 At the earliest opportunity, NICE will ask companies for details of the studies they intend to include in their submission. If	1 Involvement and participation (section 1.3.2)	Replace with: 1.3.2 At the earliest opportunity, NICE will ask companies for details of the studies they intend

information is unpublished, companies should include the study reports.		to include in their submission (if this will be made). If information is unpublished, companies should include the study reports.
1.3.3 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 Involvement and participation (section 1.3.3)	Replace with: 1.3.3 In a single technology evaluation for medicines, 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 .
1.3.8 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 Involvement and participation (section 1.3.8)	Bold text added: 1.3.8 Stakeholder organisations are invited to nominate clinical experts, patient experts and commissioning experts, who 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. When necessary, NICE may ask for expressions of interest to identify potential experts, particularly for patient experts.
1.3.12 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 Involvement and participation (section 1.3.12)	Replace with: 1.3.12 NICE asks NHS England and NHS Improvement and 2 clinical commissioning groups selected at random to nominate NHS commissioning experts.
1.3.14 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...	1 Involvement and participation (section 1.3.14)	Replace with: 1.3.14 NICE selects experts from the nominations received or expressions of interest. Clinical and patient experts are chosen based on their experience of the technology and the condition that the technology is designed for...
1.3.16 Usually, a maximum of 2 clinical experts or 2 patient experts are selected for each evaluation. NHS commissioning	1 Involvement and participation (section 1.3.16)	Replace with: 1.3.16 Usually, a maximum of 2 clinical experts or 2 patient

experts are selected for technology appraisals and highly specialised technologies guidance and for other guidance when needed.		experts are selected for each evaluation. But this can be higher if needed, at the discretion of the committee chair and NICE. NHS commissioning experts are selected when needed. For evaluations that focus on HealthTech a greater number of clinical experts will typically be needed to ensure that knowledge of the care pathway and user experience is fully captured.
1.3.17 NICE asks experts to submit written evidence on the technology, the way it should be used in the NHS in England, and current management of the condition...	1 Involvement and participation (section 1.3.17)	Replace with: 1.3.17 NICE may ask experts to submit written evidence on the technology, the way it should be used in the NHS in England, and current management of the condition...
1.3.20 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...	1 Involvement and participation (section 1.3.20)	Bold text added: 1.3.20 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 and any expressions of interest received, taking into account any declared conflicts of interest...
1.3.25 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 Involvement and participation (section 1.3.25)	Bold text added: 1.3.25 For a single technology evaluation for medicines , 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.
1.3.26 For a multiple technology evaluation, 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	1 Involvement and participation (section 1.3.26)	Bold text added: 1.3.26 For a multiple technology evaluation for medicines and all evaluations of HealthTech , the EAG creates a report that independently synthesises the evidence from published information and any evidence submissions or returned

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.		requests for information 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.
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 The scope (section 2.1.4)	Bold text added: 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). For example, HealthTech topics selected by the NICE Prioritisation Board for guidance development using NICE's technology appraisal process may be re-routed for HealthTech guidance to be produced instead, following the NICE HealthTech manual (PMG48), potentially for early use assessment if there is limited evidence available. Routing decisions are not subject to appeal.
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	2 The scope (section 2.2.3)	Replace with: 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. 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

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.		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 The scope (section 2.2.4)	Replace with: 2.2.4 For assessment of HealthTech multiple technologies are usually included. These can include alternative technologies that are not in common use or are newly available (or soon to be) Alternative technologies are normally similar in action or intent to each other. 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 The scope (section 2.2.5)	Replace with: 2.2.5 A medicine 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.
2.5.2 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 The scope (section 2.5.2)	Bold text added: 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 provisional 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	2 The scope (section 2.5.3)	Replace with: 2.5.3 Consultations are either 28 days (long) or 14 days (medium). Long consultations will be used if there is a reasonable degree of uncertainty about elements of

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.		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 consultation may be used. Please see the consultation lengths table below for distinctions between the consultation lengths.
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 The scope (section 2.5.4)	Replace with: 2.5.4 NICE can ask companies 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.
2.6 Consultation on the draft scope – determining cost-comparison suitability	2 The scope (section 2.6)	Bold text added: 2.6 Consultation on the draft scope – determining cost-comparison suitability (for medicines only)
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 The scope (section 2.6.3)	Bold text added: 2.6.3 During scope consultation for medicines topics , 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	2 The scope (section 2.6.4)	Bold text added: 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, for evaluations of medicines NICE will invite stakeholders to make a cost-

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.		comparison submission. If cost comparison is not appropriate, for evaluations of medicines 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.
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 The scope (section 2.7.3)	Bold text added: 2.7.3 At the scoping workshop, the company can provide preliminary details of the evidence it will submit, or provide in response to a request for information for HealthTech topics , 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.
2.8 Scoping a technology after a period of managed access	2 The scope (section 2.8)	Bold text added: 2.8 Scoping a technology after a period of managed access (for medicines only)
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 The scope (section 2.9.2)	Replace with: 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 a director or the prioritisation board. Stakeholders are told about the decision and the reason why.
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 Evidence (section 3.3.14)	Replace with: 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 NICE's real-world evidence framework).
3.4.6 The quality of a study's overall design, its execution, and the validity of its results determines its relevance to the	3 Evidence (section 3.4.6)	Bold text added: 3.4.6 The quality of a study's overall design, its execution,

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.		and the validity of its results determines its relevance to the decision problem. Critically appraise each study that meets the criteria for inclusion. But, when there are large numbers of studies, critical appraisal may be prioritised for studies considered key for decision making, particularly those providing data used for economic models. When possible, use the criteria for assessing published studies to assess the validity of unpublished and part-published studies.
4.2.11 Two forms of economic evaluation are available for guidance-producing programmes in the Centre for Health Technology Evaluation.	4 Economic evaluation (section 4.2.11)	Replace with: 4.2.11 Two forms of economic evaluation are available for technology appraisals and highly specialised technologies assessments.
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.	4 Economic evaluation (section 4.2.13)	Replace with: 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 medicines evaluated using a cost-comparison analysis in the technology appraisal programme, relevant comparators are those recommended in published NICE guidance for the same population.
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).	4 Economic evaluation (section 4.3.18)	Replace with: 4.3.18 For evaluations of diagnostics technologies, 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).
Sections 4.4.4, 4.4.5 and 4.4.6	4 Economic evaluation (sections 4.4.4, 4.4.5 and 4.4.6)	References to the Commercial Medicines Unit (CMU) framework are replaced with the Medicines Procurement and

		Supply Chain (MPSC) framework.
4.4.17 When developing technology appraisal guidance, if a technology is administered in combination with another technology, the company may propose commercial solutions.	4 Economic evaluation (section 4.4.17)	Bold text added: 4.4.17 When developing technology appraisal guidance for medicines , if a technology is administered in combination with another technology, the company may propose commercial solutions.
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 Economic evaluation (section 4.12.4)	Replace with: 4.12.4 DCEAs will not be done in economic evaluations produced by EAGs on behalf of NICE for all appraisals of HealthTech and multiple technology appraisals for medicines. 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.
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 Developing the guidance (section 5.2.4)	Bold text added: 5.2.4 For technology appraisals and highly specialised technologies for medicines , 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...	5 Developing the guidance (section 5.2.5)	Replace with: 5.2.5 For single technology appraisals 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...
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	5 Developing the guidance (section 5.3.6)	Replace with: 5.3.6 Companies must consent to regulatory authorities providing NICE directly with all clinical trial data necessary to

necessary to address the scope of the evaluation...		address the scope of the evaluation...
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 Developing the guidance (section 5.3.8)	Replace with: 5.3.8 All evidence submissions and other information supplied as part of the evaluation process can 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 .
5.4.8 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...	5 Developing the guidance (section 5.4.8)	Replace with: 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, through judicial review or otherwise...
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 Developing the guidance (section 5.4.10)	Bold text added: 5.4.10 When the details of the PAS or any confidential price arrangements 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.
5.4.12 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	5 Developing the guidance (section 5.4.12)	Bold text added: 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

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).		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). This approach will also be taken when the EAG do the economic evaluation and economic model.
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...	5 Developing the guidance (section 5.5.3)	Bold text added: 5.5.3 Before the start of the evaluation, for technology appraisals and highly specialised technologies for which an evidence submission can be made , the company has the opportunity to discuss the decision problem that follows from the draft scope with the NICE team and EAG representatives...
Evidence submission from the company 5.5.8 NICE invites the company to provide an evidence submission using a detailed submission template .	5 Developing the guidance (section 5.5.8)	Bold text edited in header and added to normal text: Evidence submission from the company (for medicines only) 5.5.8 For evaluations of medicines , NICE invites the company to provide an evidence submission using a detailed submission template .
5.5.15 If the company plans to submit an economic model or is required to do so, it should inform NICE which software will be used...	5 Developing the guidance (section 5.5.15)	Bold text added: 5.5.15 If the company plans to submit an economic model (or provide one with a returned request for information) or is

		required to do so, it should inform NICE which software will be used...
Managed access proposals (technology appraisals and highly specialised technologies only) 5.5.19 Managed access is only for medicines evaluated through technology appraisals and highly specialised technologies...	5 Developing the guidance (section 5.5.19)	Bold text edited: Managed access proposals (technology appraisals and highly specialised technologies for medicines only) 5.5.19 Managed access is only for medicines evaluated through technology appraisals and highly specialised technologies...
Managed access data collection proposal (technology appraisals and highly specialised technologies only) 5.5.24 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...	5 Developing the guidance (section 5.5.24)	Bold text edited: Managed access data collection proposal (technology appraisals and highly specialised technologies for medicines only) 5.5.24 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...
Managing company submissions with high base-case ICERs (technology appraisals and highly specialised technologies only) 5.5.29 If a company submission includes a base-case ICER that is significantly higher than the standard threshold, and...	5 Developing the guidance (section 5.5.29)	Replace with: Managing company submissions with high base-case ICERs 5.5.29 If a company submission includes a base-case ICER that is significantly higher than the standard threshold, and...
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.	5 Developing the guidance (section 5.6.1)	Bold text added: 5.6.1 For multiple technology evaluations for medicines and all evaluations of HealthTech , 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 Developing the guidance (section 5.6.2)	Bold text edited:

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 final scope.		Initial clarification and additional analysis (for medicines only) 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 final scope.
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 Developing the guidance (section 5.6.9)	Replace with: 5.6.9 NICE will also consider whether to terminate an evaluation if an evidence submission (for medicines only), completed requests for information (for HealthTech only) or payment have not been received.
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 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 Developing the guidance (section 5.6.14)	Bold text added: 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 multiple technology evaluations in technology appraisals and highly specialised technologies or evaluations of HealthTech), returned requests for information (for HealthTech evaluations) 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.
5.6.16 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. The	5 Developing the guidance (section 5.6.16)	Bold text added: 5.6.16 For multiple technology evaluations in technology appraisals and highly specialised technologies for medicines , the companies are invited to provide an evidence submission but are not formally required to do so. For evaluations of HealthTech ,

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.		companies are not invited to provide an evidence submission but instead can provide information in response to requests for information. The EAG does an assessment of the clinical outcomes and cost effectiveness of the technologies. 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.
5.7 Topic progression – single technology appraisal	5 Developing the guidance (section 5.7)	Bold text edited: 5.7 Topic progression – single technology appraisal (for medicines only)
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.	5 Developing the guidance (section 5.7.7)	Bold text edited in header and added to normal text: Technical engagement (for medicines only) 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 will not be held for evaluations of HealthTech.
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,	5 Developing the guidance (section 5.8.3)	Replace with: 5.8.3 The committee papers are usually circulated to all attendees (except members of the public) 1 to 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 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.		comments and responses, fact check comments and responses, comments from technical engagement (if held). • 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.
5.8.6 When the committee meets for the first time to discuss the technology, final draft 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 5.8.43. 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 Developing the guidance (section 5.8.6)	Replace with: 5.8.6 When the committee meets for the first time to discuss the technology, final draft 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 5.8.43. The committee will consider the written evidence and verbal evidence, drawn from discussions with experts, EAG representatives, and national clinical directors or advisers.
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 Developing the guidance (section 5.8.10)	Bold text added: 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 typically do not make a presentation to the committee.
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	5 Developing the guidance (section 5.8.20)	Replace with: 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 or appeal). After the meeting, the guidance is

or final draft guidance on a technology before that technology receives final UK regulatory approval.		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.	5 Developing the guidance (section 5.8.21)	Bold text added: 5.8.21 The outcome of the committee meeting will be shared with stakeholders within 7 days of the committee meeting. When this is not possible, stakeholders will be informed of this within 7 days of the committee meeting, and the outcome will be shared when available. This will be a brief statement of the committee decision.
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.	5 Developing the guidance (section 5.8.28)	Bold text edited: Commercial opportunities after the first committee meeting (technology appraisals and highly specialised technologies for medicines 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...	5 Developing the guidance (section 5.8.29)	Bold text edited: Increasing the PAS or proceeding to draft guidance after the first committee meeting (technology appraisals and highly specialised technologies for medicines only) 5.8.29 Shortly after the committee meeting, NICE will inform the company of the committees' recommendation and key assumptions...
Pausing publication of the draft guidance after the first committee meeting to allow a	5 Developing the guidance (section 5.8.34)	Bold text edited: Pausing publication of the draft guidance after the first

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...		committee meeting to allow a commercial access agreement to be agreed (technology appraisals and highly specialised technologies for medicines only) 5.8.34 If NHS England and NHS Improvement confirm before the first committee meeting that they are willing to engage in discussions...
5.8.62 The chair's decision will be shared with stakeholders within 7 days of sign-off. This will be a brief statement of the decision.	5 Developing the guidance (section 5.8.62)	Replace with: 5.8.62 The decision will be shared with stakeholders within 7 days of sign-off. This will be a brief statement of the decision.
5.8.65 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 Developing the guidance (section 5.8.65)	Replace with: 5.8.65 NICE issues the final draft guidance to consultees so that they can consider whether to appeal 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 process is set out in finalising and publishing the guidance chapter.
5.8.68 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.	5 Developing the guidance (section 5.8.68)	Replace with: 5.8.68 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. A 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) 5.8.69 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 Developing the guidance (section 5.8.69)	Bold text edited: Finalising a managed access data collection agreement (technology appraisal and highly specialised technologies for medicines only) 5.8.69 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.
5.9 Patient access schemes and commercial access agreements (technology appraisals and highly specialised technologies) Introduction The NHS commercial framework for new medicines enables companies to submit proposals for patient access schemes (PAS) and...	5 Developing the guidance (section 5.9)	Bold text edited: 5.9 Patient access schemes and commercial access agreements (technology appraisals and highly specialised technologies for medicines only) Introduction The NHS commercial framework for new medicines enables companies to submit proposals for patient access schemes (PAS) and...
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 Developing the guidance (section 5.10.4)	Bold text added: 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 for medicines 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	5 Developing the guidance (section 5.10.5)	Bold text added: 5.10.5 For medicines if the potential net budget impact is

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.		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.
5.11 Rapid updates to guidance after loss of market exclusivity (technology appraisals only)	5 Developing the guidance (section 5.11)	Bold text edited: 5.11 Rapid updates to guidance after loss of market exclusivity (technology appraisals for medicines only)
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....	6 Committee recommendations (section 6.2.7)	Replace with: 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, particularly their experience of the condition and the technology in clinical practice ○ the experience of the patient experts and carers of living with the condition and using the technology being considered....
Decision modifiers: severity 6.2.12 The committee will consider the severity of the condition, defined as the future health lost by people living with the condition with standard care in the NHS (including use of other available treatments,	6 Committee recommendations (section 6.2.12)	Bold text added: Decision modifiers: severity 6.2.12 The committee will consider the severity of the condition, defined as the future health lost by people living with the condition with standard care in the NHS (including use of

diagnostics, or best supportive care). The extent of unmet health need is reflected within the severity definition.		other available treatments, diagnostics, or best supportive care). The extent of unmet health need is reflected within the severity definition. Initially, the severity modifier will not be applied to technology appraisals of HealthTech. Here the severity of the condition should be captured within the QALY benefits and then deliberately within decision making. We are currently exploring approaches on how the severity modifier could be applied for technology appraisals of HealthTech.
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 Committee recommendations (section 6.2.20)	Replace with: 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 evaluations of diagnostic technologies.
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 Committee recommendations (section 6.2.31)	Replace with: 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 (for medicines only) or research (see section 6.4).

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...	6 Committee recommendations (section 6.4.6)	Bold text edited: Recommendation with managed access (technology appraisals and highly specialised technologies for medicines only) 6.4.6 When a committee is unable to recommend a medicine because there is still significant resolvable uncertainty...
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 interventional procedures and HealthTech guidance, stakeholders can use the resolution process on the final draft guidance and the process followed.	7 Finalising and publishing the guidance (section 7.1.1)	Replace with: 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.
The whole of section 7.2. (that is, sections 7.2.1 to 7.2.22)	7 Finalising and publishing the guidance (section 7.2)	This text will be removed from PMG36 and moved to the NICE HealthTech programme manual (PMG48).
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 Finalising and publishing the guidance (section 7.3.1)	Replace with: 7.3.1 Once the appeal process is complete and any changes to guidance following this process 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'.
8.5 Surveillance of managed access data collections (including interim evidence reviews)	8 Guidance surveillance (section 8.5)	Add bold text: 8.5 Surveillance of managed access data collections (including interim evidence reviews, for medicines only)
8.6 Updating guidance after a period of managed access	8 Guidance surveillance (section 8.6)	Add bold text: 8.6 Updating guidance after a period of managed access (for medicines only)
8.7 Surveillance of guidance after loss of market exclusivity (technology appraisals only)	8 Guidance surveillance (section 8.7)	Add bold text: 8.7 Surveillance of guidance after loss of market exclusivity

		(technology appraisals for medicines only)
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Proposed new content

Existing [NICE health technology evaluations: the manual](#).

Table 2 Proposed new content to add to NICE health technology evaluations: the manual

New content	Proposed position to add in manual
For assessments of HealthTech, requests for information may be sent to companies during scoping if they have technologies that could be included in the assessment or otherwise be relevant to it. A request for information does not mean that a technology will be included in the scope for the assessment. Information provided is often used to determine if a technology is suitable to include in the scope.	After section 2.1.5
- Company evidence submissions are not made for evaluations of HealthTech. Instead, companies can be asked to provide responses to requests for information from NICE. Requests for information may be made as needed throughout the guidance development process, including during the scoping stage. - Unpublished evidence can be provided with a request for information. - A completed checklist of confidential information must be provided with a returned request for information. - Economic models can be provided as part of the response to a request for information. The same requirements apply as for models provided with an evidence submission (see section 5.5.15). - HealthTech will not automatically be withdrawn from a scope or guidance because a response to a request for information has not been received. But not providing information needed by NICE may affect the assessment of a technology or procedure and consequently the recommendation.	After section 5.5.18
Commercial opportunities for HealthTech (HealthTech only) NICE's commercial liaison team (CLT) activities will be aligned with key steps in the evaluation processes. The procedures are summarised below.	After section 5.12

This information is for guidance only because the time needed, and information available, for each stage may vary for some evaluations. • If the NICE CLT identifies that a technology or technologies is/are unlikely to be cost effective at the existing price before the first committee meeting, liaison can take place with relevant NHS bodies and companies to explore any commercial challenges. • The NICE CLT attend committee meetings for topics where a risk has previously been identified relating to cost-effectiveness in the evaluation. • After the committee meeting the NICE CLT provides further information to the company(s) and relevant NHS bodies, to support further commercial activity if required. Additional time may be granted at this stage of the process to allow further commercial activity. • Companies can provide prices relevant to using their technology in their response to a request for information and updated costs at consultation on draft guidance. Outside of these times it may not be possible to consider new or updated prices. • Section 4.4.4 describes considerations for prices used in reference case analyses. If companies believe there are extenuating circumstances for why the technology cost cannot be disclosed in public documents, further information on these circumstances must be provided for NICE to consider whether this is acceptable. In circumstances when NICE agrees to accept a price marked as confidential, a further price that can be publicly disclosed should also be provided. • Section 4.4.5 details how prices that differ between regions are handled. This is in the context of the MPSC prices, however the principles of handling a situation where there is no single price that is universally available across the NHS applies to HealthTech. • The committee will be made aware when confidential prices are used that are not guaranteed for the duration of the guidance.	
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