

# Guide to the processes of technology appraisal

2 September 2014

## Acknowledgements

NICE is very grateful to everyone who contributed to the development of this guide (see [section 7.1](#)).

## Foreword

The National Institute for Health and Care Excellence (NICE, or the Institute) provides guidance to the NHS in England on the clinical and [cost effectiveness](#) of selected new and established technologies. The Institute carries out appraisals of health technologies at the request of the [Department of Health](#). Guidance produced by the Institute on health technologies is also applied selectively in Northern Ireland, Scotland and Wales.

The Institute regularly reviews its processes and methodology. This document replaces the 'Guide to the single technology appraisal process' and the 'Guide to the multiple technology appraisal process' published in October 2009.

This document is one of a series describing the processes and methods that NICE uses to carry out [technology appraisals](#). It focuses on the single technology appraisal (STA) and multiple technology appraisal (MTA) processes and provides an overview for organisations invited to contribute to an appraisal.

The documents in the series are:

- 'Guide to the processes of technology appraisal' (this document).
- [Guide to the methods of technology appraisal](#).
- [Guide to the technology appraisal and highly specialised technologies appeal process](#).

Organisations invited to contribute to NICE technology appraisals ([consultees](#) and [commentators](#)) should read this guide with the other documents listed above. All documents are available on the NICE website.

# 1 Introduction

- 1.1 This guide describes the processes, including expected timescales, that NICE follows when carrying out a [technology appraisal](#). The processes are designed to produce robust guidance for the NHS with appropriate contribution from stakeholders. This guide should be read with NICE's [Guide to the methods of technology appraisal](#), which describes the methods of appraisal for single and multiple technology appraisals.
- 1.2 Technology appraisals are developed by the Centre for Health Technology Evaluation (CHTE), within NICE.
- 1.3 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 technology recommendation:
- in relation to a [health technology](#) identified in a direction by the Secretary of State
  - that recommends 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.
- 1.4 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.
- 1.5 The Regulations require clinical commissioning groups, NHS England 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. The Institute provides advice and tools to support the local implementation of its guidance. This includes costing tools or statements for most technology appraisals and additional tools, including clinical audit tools, for selected technology appraisals.

1.6 The technology appraisals 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 referred to the NICE technology appraisals programme include:

- medicinal products
- medical devices
- diagnostic techniques
- 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 the clinical guidelines programme, the medical technologies evaluation programme, the diagnostics assessment programme or the interventional procedures programme, or will have medicines and prescribing support from the Medicines and Prescribing Centre at NICE. This process guide relates only to technologies appraised through the technology appraisals programme.

- 1.7 The single technology appraisal (STA) process is specifically designed to appraise a single product, device or other technology, for a single [indication](#). 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. NICE seeks relevant [evidence](#) from several sources. The [company](#) submits the principal evidence. The [Evidence Review Group](#) (ERG), an external academic organisation independent of NICE, produces a review of the evidence submission (see [section 3.3.8](#)). [Consultees](#) provide information (see table 1) and selected [clinical experts](#), NHS commissioning experts and [patient experts](#) also give evidence (see [section 3.6](#)).
- 1.8 The multiple technology appraisal (MTA) process is designed to appraise single or multiple products, devices or other technologies, with 1 or more related indications. NICE seeks relevant evidence from several sources. An independent academic group (the [Assessment Group](#) [AG]; see table 1) carries out a health [technology assessment](#) (see [section 3.4](#)). Consultees provide information (see table 1) and selected clinical experts, NHS commissioning experts and patient experts also give evidence (see [section 3.6](#)).
- 1.9 The decision on which process will be used to appraise a technology is made during topic selection or the review proposal process. Once published, NICE technology appraisal guidance has the same status, regardless of whether it was produced by the STA or the MTA process.
- 1.10 An STA is based on a review of clinical and economic evidence, mainly provided by the company. An MTA is based on a review by an independent assessment group of clinical and economic evidence from a variety of sources. Clinical evidence shows how well the technology works – the health benefits. The evidence includes the impact on quality of life (for example, pain and disability), and the likely effects on mortality. Economic evidence shows how well the technology works in relation to how much it costs the NHS and whether it represents value for money. In both processes, NICE also considers estimates of the associated costs,

concentrating on costs to the NHS and personal social services (for example, social services).

- 1.11 The [Appraisal Committee](#) (see table 1) considers the evidence and makes a judgement on whether or not the technology should be recommended as a clinically-effective and cost-effective use of NHS resources, or whether it should only be recommended for specific subgroups of people.
- 1.12 The Appraisal Committee submits its recommendations to NICE in either an [appraisal consultation document](#) (ACD) or a [final appraisal determination](#) (FAD). Normally, the Appraisal Committee produces an ACD only if its preliminary recommendations are substantially more restrictive than the terms of the [marketing authorisation](#) (or equivalent, for example, [CE marking](#) for devices) of the technology being appraised or do not recommend use of the technology. If the Committee produces an ACD, then NICE invites consultees, [commentators](#) and the public to comment on the ACD. After considering these comments, the Committee finalises its recommendations and submits them to NICE in the form of a FAD. The FAD forms the basis of the guidance that NICE issues to the NHS in England.
- 1.13 The NICE technology appraisal process complies 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 is the model senior responsible owner with overall responsibility for assuring the quality of models developed in their areas of responsibility. The quality of models is assured through the requirements for the development of evidence submissions (see the [Guide to the methods of technology appraisal](#)) and the process used to involve stakeholders in testing the reliability of models (see [sections 3.2.8 and 3.5.6](#)).
- 1.14 NICE is committed to advancing equality of opportunity, eliminating unlawful discrimination and fostering good relations between people who share a protected characteristic and society as a whole, and to complying

fully with its legal obligations on equality and human rights. NICE's [equality scheme](#) describes how the Institute meets these commitments and obligations.

- 1.15 In formulating its recommendations, the Appraisal Committee will have regard to the provisions and regulations of the Health and Social Care Act 2012 relating to NICE. The Appraisal Committee will also take into account the Institute's guidance on social value judgements described in 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 Appraisal Committees, should apply when making decisions about the effectiveness and [cost effectiveness](#) of interventions.
- 1.16 Service level agreements are in place to help disseminate NICE technology appraisal guidance within the devolved administrations; Wales, Northern Ireland and Scotland.

### **Table 1 Participants in the technology appraisal processes**

---

Appraisal Committee      The Appraisal Committee is an independent standing committee that produces recommendations. NICE recruits Committee members through open, competitive advertising and appoints members initially for a 3-year term. Committee members are from:

- the NHS
- lay backgrounds (with an understanding of patient and public perspectives on healthcare issues)
- academia
- pharmaceutical and medical devices industries.

Full details of how NICE recruits members can be found in the [advisory body recruitment pack](#).

NICE is committed to equality and diversity and welcomes applications for membership from all sectors of the community.

NICE allocates Committee members to 1 of 4 standing Appraisal Committees. Members will normally remain in the same Committee for the duration of their membership.

Although the Appraisal Committee seeks the views of organisations representing healthcare professionals, patients, [carers](#), companies and government, its advice is independent. Names of Appraisal Committee members are posted on NICE's website.

See the [Appraisal Committee's standing orders and terms of reference](#).

---

Consultees      NICE invites consultees to take part in the appraisal. They include:

- national groups representing patients and carers
  - organisations representing healthcare professionals
  - the company that manufactures or sponsors the technology
  - the [Department of Health](#)
  - the Welsh Government
-

- 
- NHS England as a specialised commissioning group
  - clinical commissioning groups.

As part of the scoping process, NICE invites consultees to comment on draft [remits](#) and draft [scopes](#).

Consultees can make a submission and participate in the [consultation](#) on the appraisal consultation document (ACD; if produced). All non-company consultees can nominate clinical experts and/or patient experts to verbally present their personal views to the Appraisal Committee. Company consultees can also nominate clinical experts. Representatives from NHS England and clinical commissioning groups invited to participate in the appraisal may also attend the Appraisal Committee as NHS commissioning experts. All consultees have the opportunity to consider an appeal against the final recommendations, or report any factual errors, within the final appraisal determination (FAD).

Consultees can also comment on the proposal for reviewing the guidance.

---

Commentators NICE invites commentator organisations with an interest in the technology to take part in the appraisal. They include, but are not restricted to:

- relevant [comparator](#) technology companies
  - Healthcare Improvement Scotland
  - any relevant National Collaborating Centres (groups commissioned by NICE to develop clinical guidelines) and/or the relevant Programme Development Group for 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 Unit, the Scottish
-



---

Medicines Consortium, the Medicines and Healthcare Products Regulatory Agency, the Department of Health, Social Services and Public Safety for Northern Ireland).

As part of the scoping process, NICE invites commentators to comment on draft remits and draft scopes.

Commentators can participate in the consultation on the ACD (if produced), but NICE does not ask them to make any submission for the appraisal. Non-company commentator organisations can nominate clinical experts and patient experts to verbally present their personal views to the Appraisal Committee. Commentator organisations representing relevant comparator technology companies can also nominate clinical experts. These organisations receive the FAD and have the opportunity to report any factual errors.

Commentators can also comment on the proposal for reviewing the guidance.

---

Clinical experts and patient experts

The Chair of the Appraisal Committee and the NICE project team select clinical experts and patient experts from nominations by non-company consultees and commentators. They attend the Appraisal Committee meeting as individuals to answer questions to help clarify issues about the submitted evidence and to provide their views and experiences of the technology and/or condition. Before they attend the meeting, all experts must either submit a written statement (using a template) or indicate they agree with the submission made by their nominating organisation.

---

NHS commissioning experts	NICE selects at random 2 clinical commissioning groups and NHS England to be consultees. NICE invites 2 of their representatives to attend the Appraisal Committee meeting to offer their views, answer questions and help clarify issues about the submitted evidence and the impact of the technology on the NHS. Before they attend the meeting, NICE asks them to submit a written statement explaining their views and experiences of the technology and/or condition from an NHS perspective.
Evidence Review Group (ERG) <b>STA process only</b>	The ERG is an independent (academic) group that reviews the company's evidence submission. The ERG may also prepare some additional analyses. The ERG is normally commissioned by the <a href="#">National Institute for Health Research – Health Technology Assessment programme</a> .
Assessment Group (AG) <b>MTA process only</b>	The Assessment Group is an independent (academic) group (commissioned by the National Institute for Health Research – Health Technology Assessment programme) that prepares a review of the clinical and cost effectiveness of the technology(ies). This review is based on a <a href="#">systematic review</a> of the literature and a review of submissions from the company(s), known as the <a href="#">assessment report</a> (see <a href="#">section 3.5</a> for further details).
<a href="#">Decision Support Unit</a> (DSU)	The DSU is commissioned by NICE to provide a research and training resource to support the Institute's technology appraisal programme.
<b>NICE staff</b>	The DSU is a collaboration between the Universities of Sheffield, York and Leicester. It also has members at the University of Bristol, London School of Hygiene and Tropical Medicine and Brunel University.

---

<a href="#">Centre Director</a>	The Centre Director is responsible for delivering all outputs of the CHTE. The Centre Director must also ensure that appraisals are conducted in accordance with the published appraisal process and methods.
Programme Director	The Programme Director is responsible for all aspects of managing and delivering the appraisal work programme. The Programme Director interacts with the NICE sponsor branch at the Department of Health and other national bodies, and with healthcare industry bodies. The Programme Director is responsible for signing off guidance at specific stages of an individual appraisal. The Programme Director is also responsible for ensuring that appraisals are conducted in accordance with the published appraisal process and methods.
Associate Director	The Associate Director is responsible for developing individual appraisals within the appraisal programme and has delegated responsibility, from the Programme Director, for approving documentation for consultation at specific stages of an individual appraisal.
Project manager	The project manager is responsible for planning individual appraisal timelines, ensuring the timelines and process are followed, and liaising with consultees, commentators and other individuals and organisations contributing to the appraisal.
Administrator	The administrator is responsible for supporting the project manager in the planning and management of individual appraisals, including ensuring the timelines and process are followed, and liaising with consultees, commentators and other individuals and organisations.

---

Technical lead	The technical lead is the analyst responsible for the technical aspects of the appraisal, including liaising with the ERG or AG, scoping the appraisal, preparing drafts of guidance and advising the Appraisal Committee. There may be more than 1 technical lead for an appraisal.
Technical adviser	The technical adviser is responsible for the technical quality of the appraisal. This involves providing leadership on technical issues, and reviewing and quality assuring the work of the technical lead. The technical adviser also ensures a consistent approach is taken across the appraisal programme.
Executive lead	The executive lead is allocated from NICE's Executive Directors. It is an advisory role and involvement is limited to dealing with particularly complex issues.
Communications lead	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.
Guidance Information services lead	The guidance information services lead is responsible for supporting the technical lead in scoping the appraisal. The information services lead gathers information to support the production of a draft scope and continues to track key information throughout the life cycle of the appraisal to support the work of the technical lead.
Editorial lead	The editorial lead is responsible for ensuring that all guidance documents are accurate, clear and consistent. The editorial lead prepares the final versions of the guidance for healthcare professionals and patients and carers ('Information for the public'), and works with the implementation, audit and costing leads to make sure the tools that help the NHS put the guidance into practice are clear and understandable.

---

Public Involvement Programme (PIP) public involvement adviser	The PIP is the team at NICE that supports and develops public involvement across NICE's work programme. A PIP public involvement adviser is assigned to each appraisal and supports patient and carer consultee organisations, their representatives, and individual patients or carers throughout the appraisal. This may include making it easier to attend workshops or meetings, giving advice on completing submissions and statements, consultation responses or other documentation, and nominating experts. The PIP public involvement adviser also supports the <a href="#">lay members</a> of the Appraisal Committees and supplies the patient and carer group information for the 'Information for the public'.
Costing lead	The costing lead works with the technical lead and clinical experts to produce guidance-related costing tools. The costing tools consist of a costing report and template to help organisations assess the financial impact of implementing NICE guidance. They are published at the same time as the appraisal and are subject to a limited consultation. The costing lead also provides input at the topic selection stage, assessing the potential financial impact of each topic scoped.
Audit lead	The audit lead is responsible for developing clinical audit tools through the provision of ready-to-use standards, including exceptions and definitions, and a data collection tool. Audit support is externally validated and developed in collaboration with the technical lead.
Implementation adviser	The implementation adviser provides support from the scoping stage through to post-publication activities, liaising with the internal NICE teams, development teams and external organisations to support the implementation of NICE guidance, including the development of implementation support tools.

---

---

Pathways lead	The pathways lead is responsible for ensuring there is a process in place for making guidance accessible via NICE Pathways. This includes ensuring that new guidance is considered in terms of appropriate inclusion and presentation in new or existing NICE Pathways with agreement from the CHTE management team.
Health Technology Adoption Programme lead	The Health Technology Adoption Programme (HTAP) lead will work with the NHS to provide a systematic approach to the adoption of new technologies such as pharmaceuticals, diagnostic and monitoring devices, surgical implants and other technologies that improve the care given to patients.

---

## 2 Selection of technologies

### 2.1 *Overview*

2.1.1 Topic selection is the process for deciding which topics NICE will produce [technology appraisal](#) guidance on. NICE aims to consider all new significant drugs and [indications](#). Health technologies referred to the NICE technology appraisals programme include:

- medicinal products
- medical devices
- diagnostic techniques
- surgical procedures or other therapeutic techniques
- therapeutic technologies other than medicinal products
- systems of care
- screening tools.

2.1.2 The topic selection process has been designed to support the technology appraisal process so that topics chosen will add value and support healthcare professionals and others to provide care of the best possible quality, which offers the best value for money. The steps involved are shown in figure 1.

2.1.3 NICE manages this process on behalf of the [Department of Health](#). NICE can only begin to appraise a technology when it has been formally referred by the Secretary of State for Health.

2.1.4 The aims of the topic selection process are to:

- ensure NICE addresses topics of importance to patients, [carers](#), healthcare professionals, commissioners, providers and public health
- help make the best use of NHS resources
- coordinate the selection of topics using a standard selection process
- make topic selection as rapid as possible to minimise the period of uncertainty before guidance is issued
- ensure that all topic selection activities are inclusive, open, transparent and consistently applied
- ensure that all stages of the process are well documented with clear operating procedures and responsibilities and that throughout there is clear and visible progress tracking for all topics considered
- ensure there are appropriate governance structures and arrangements in place with all relevant parties.

2.1.5 Most topics are identified by the [National Institute for Health Research Innovation Observatory \(NIHRIO\)](#). This centre notifies NICE about key, new and emerging healthcare technologies that might be suitable for NICE technology appraisal. It aims to notify NICE of new drugs in development 20 months before [marketing authorisation](#) and new indications 15 months before marketing authorisation. These time frames are required by NICE to enable guidance to be published as close as possible to product launch. Suggestions for technology appraisal guidance on a new medicinal product (that has not yet received a marketing authorisation) should be made by the relevant [company](#) through [UKPharmaScan](#). Healthcare professionals, researchers and patients can also suggest potential technologies for NICE to appraise by contacting NIHRIO.

## 2.2 ***Elimination and filtering***

2.2.1 Topic selection decisions are based on the consideration of each potential topic against elimination and prioritisation criteria. The elimination criteria filter out topics unsuitable for guidance development through the technology appraisal programme. A topic will not be considered if the technology has not been granted a marketing authorisation (or equivalent) or if there are no plans for it to receive a marketing authorisation (or equivalent) or if it is identical to:

- NICE guidance that has been published
- NICE guidance that is in development
- a topic currently in the topic selection process
- a topic that has been considered and eliminated from the topic selection process
- a topic that has been considered in the last 3 years and not been prioritised
- a topic widely accepted and implemented on the basis of existing published guidance from the Department of Health, Arm's Length Body or other government departments (excluding national service frameworks, white papers and planning priorities guidance).

2.2.2 The following topic areas are also outside the [remit](#) of technology appraisal guidance development at NICE:

- Population screening – falls under the remit of the UK National Screening Committee.
- Vaccination – generally falls under the remit of the Joint Committee on Vaccination and Immunisation. However, NICE does consider therapeutic vaccines.
- HIV technology or therapy – falls under the remit of the British HIV Association. However, there may be situations when the Department of Health considers that a NICE appraisal of an HIV technology or therapy would be helpful to the NHS and these will be dealt with on a case-by-case basis.



### 2.2.3 Topics are not considered unless:

- there is likely to be significant benefit to patients in terms of administration, efficacy or improved side-effect profile and
- the new formulation or technology is likely to be at a significantly different price to current standard treatment and
- there is appropriate [evidence](#), either available or anticipated to be available in the near future, to support the appraisal (refer to section 3.3 of the [Guide to the methods of technology appraisal](#)) and
- the relevant clinical question(s) can be addressed by applying the technology appraisal methodology. This may mean excluding topics on which technology appraisal guidance would not add value without broader guidelines on the clinical pathway.

2.2.4 Elimination and filtering is done by the Consultant Clinical Adviser in the topic selection team and includes seeking expert opinion and engaging with the relevant National Clinical Directors. The filtering recommendations are considered by an internal group at NICE, and shared with the Department of Health and NHS England.

## 2.3 **Prioritisation**

2.3.1 The importance of each topic is considered against [prioritisation criteria](#) that help the Secretary of State for Health decide which topics should be referred to NICE for guidance development through the technology appraisal programme. This includes consideration of the population size, disease severity, resource impact and the value that NICE could add in carrying out a technology appraisal. The prioritisation criteria are:

- Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
- Is the technology likely to result in a significant impact on other health-related Government policies?
- Is the technology likely to have a significant impact on NHS resources if given to all patients for whom it is indicated?

- Is there significant inappropriate variation in the use of the technology across the country?
- Is NICE likely to be able to add value by issuing national guidance? For example, without such guidance is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and [cost effectiveness](#)?

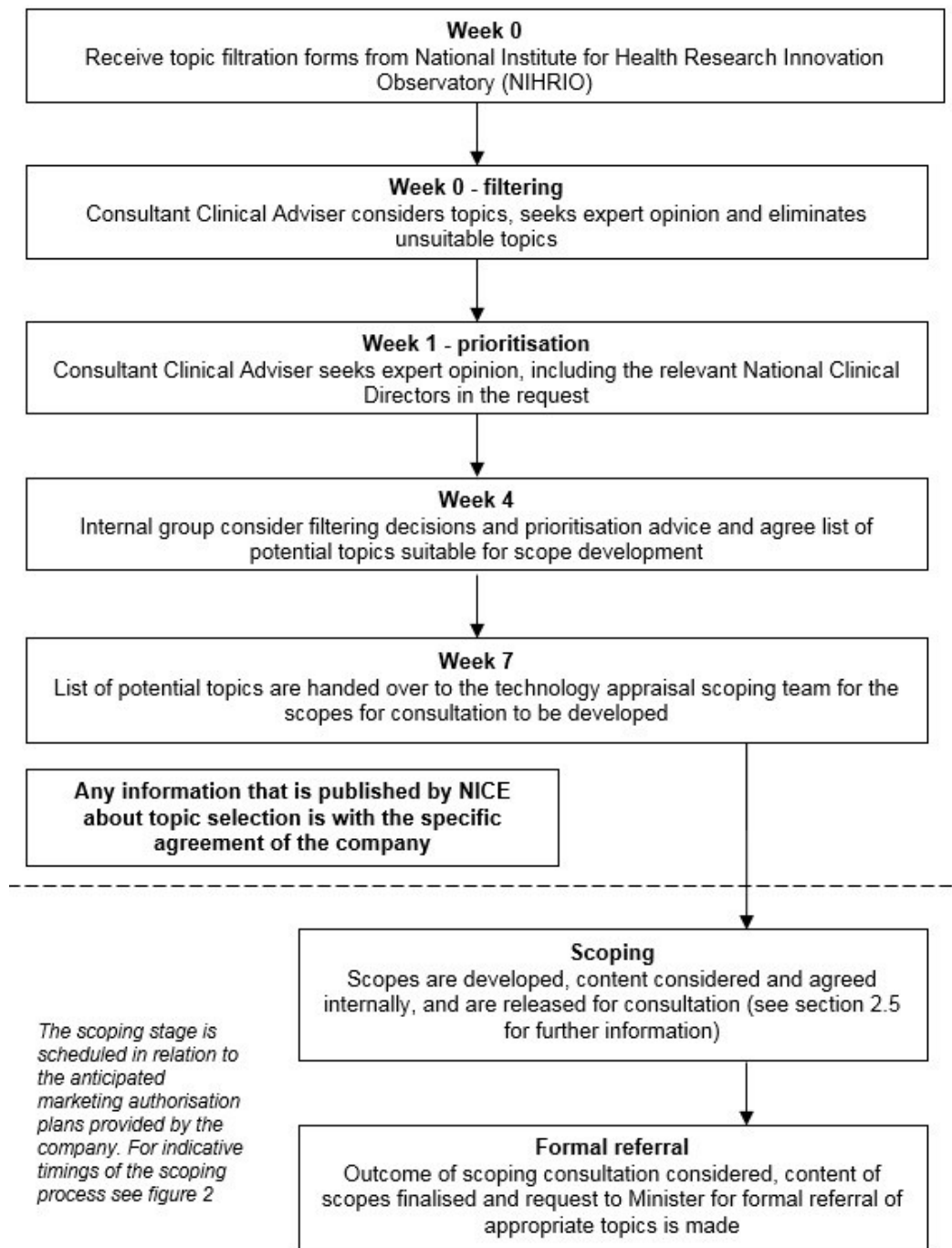
2.3.2 Prioritisation is also done by the Consultant Clinical Adviser in the topic selection team and is informed by the external expert opinion already sought during filtering. [NIHRIO](#) develops technology briefings for potential appraisal topics. Relevant companies have the opportunity to comment on these technology briefings before the prioritisation recommendations are considered by an internal group at NICE, and shared with the Department of Health and NHS England. The group at NICE meets to decide the next steps for each topic being considered, to ensure the timely production of guidance. The group considers each topic and decides whether it is potentially suitable for NICE appraisal and as a result, whether the [scope](#) should be sent out for [consultation](#).

2.3.3 Summary information on topic progress is published on the NICE website. The list of potential topics is handed over to the technology appraisal scoping team to develop the draft scopes for consultation.

2.3.4 Medicinal products marketed in England that do not meet the criteria for referral into the technology appraisal programme can be considered for the highly specialised technologies programme or for a new medicines evidence summary to help inform local decision-making.

## 2.4 Process

Figure 1 Overview of the topic selection stages



## 2.5 *Developing the remit and scope*

### Developing the draft scope

2.5.1 After identifying topics through the topic selection programme, NICE seeks the views of interested parties. At this stage, NICE develops a draft remit and draft scope for each potential appraisal. The steps involved are shown in figure 2.

2.5.2 The draft scope sets out what questions the appraisal will address. It will steer and focus the appraisal if the technology is formally referred to NICE for appraisal.

2.5.3 The first step in the scoping process is to identify information about the technology. NICE's information specialists, working with the appraisal team's technical leads, do this task, which includes literature searching, checking the availability of relevant evidence, and contacting the company. NICE uses this information, along with the technology briefing prepared by the National Institute for Health Research Horizon Scanning Centre, to prepare a draft scope.

2.5.4 The draft scope defines a number of elements, including:

- the population, in whom treatment with, or use of, the technology would be appraised
- the potential [comparators](#)
- the potential subgroups
- the health [outcome](#) measures
- any other special considerations and issues that are likely to affect the potential appraisal, including equality and diversity issues.

For further information on how scopes are developed, see NICE's [Guide to the methods of technology appraisal](#).

2.5.5 Unless the Department of Health specifically indicates otherwise, NICE will not publish guidance on the use of 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 the technology’s marketing authorisation).

### **Identifying interested parties**

- 2.5.6 Identifying interested parties (known as [consultees](#) and [commentators](#); see table 1) is an important stage of the process. NICE identifies consultees and commentators before it consults on the draft remit and draft scope.
- 2.5.7 A patient or professional group can be a consultee 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 consultees include specialised commissioning groups – NHS England and 2 clinical commissioning groups (CCGs) and the company. The 2 CCGs are selected at random from the pool of CCGs operating in the NHS in England.
- 2.5.8 Commentators include research organisations with an interest in the technology being considered, 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 commentators when appropriate.
- 2.5.9 During the scoping phase, NICE aims to identify the widest range possible of relevant consultees and commentators 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, people with disabilities, mental health problems and/or learning disabilities.
- 2.5.10 Any organisation meeting the criteria outlined in sections **2.5.7–2.5.9** that wishes to become a consultee or commentator for a proposed appraisal can contact the relevant project manager (see the [NICE website](#) for details). A request to join the appraisal as a consultee or commentator can

be made at any point during the scoping and appraisal phases of the process.

### **Consultation on the draft remit and draft scope**

- 2.5.11 NICE sends the draft remit and draft scope to the identified provisional consultees and commentators, together with the list of consultees and commentators (known as a 'matrix'), for comment. The aim of this consultation is to gather views on whether NICE should appraise the technology, as well as ensuring all the relevant areas and issues are covered if the technology is referred to NICE for appraisal. It is important that all the relevant organisations and interested parties are included in these consultations. NICE therefore asks identified provisional consultees and commentators if there are other organisations that need to be included in the consultation. Consultees and commentators have 20 working days from the date of sending to submit comments.
- 2.5.12 NICE asks the company to provide information about the expected timing of pending marketing authorisation applications (or equivalent) for their technology in the UK. This must include, if applicable, the date on which the Committee for Medicinal Products for Human Use of the [European Medicines Agency](#) is expected to publish an opinion on the granting of the marketing authorisation for the technology, and the expected date of receipt of the final marketing authorisation from the European Commission or the Medicines and Healthcare Products Regulatory Agency. The company should also state whether they expect the launch date for their technology in the UK to differ from the regulatory approval date. Medical devices go through a different regulatory approval process to pharmaceuticals with different timelines and data requirements. It is important that the company informs NICE of any change in the regulatory approval timelines as soon as possible. NICE uses this information to plan the appraisal.
- 2.5.13 NICE publishes the draft remit, draft scope and list of consultees and commentators on its website, for information, 5 working days after it sends these documents to the provisional consultees and commentators.

## **The scoping workshop**

2.5.14 After the provisional consultees and commentators have submitted their comments on the draft remit, draft scope and list of consultees and commentators, NICE normally holds a meeting called the scoping workshop. NICE invites all provisional consultees and commentators, and the [Assessment Group](#) (for MTAs only), to send up to 2 representatives to this meeting.

2.5.15 The aims of the workshop are to:

- briefly explain the appraisal process
- ensure the scope is appropriately defined
- discuss the issues raised by provisional consultees and commentators during consultation on the draft remit and draft scope
- discuss the appropriateness of completing an appraisal and the appropriate appraisal process
- identify important evidence and any other issues relevant to the potential appraisal.

2.5.16 It is important that sufficient expertise is fed into the development of the scope. NICE welcomes and values all specialist input from patient groups, NHS commissioners and healthcare professionals provided at consultation and during the workshop discussions.

2.5.17 At the scoping workshop, NICE encourages the company to provide preliminary details of the evidence it would submit if NICE were asked to appraise the technology. This may include details of trials in progress, for example the inclusion and exclusion criteria used. At the end of the workshop, the company can discuss commercially sensitive information and technical issues about the proposed appraisal with NICE, in confidence.

## **Final scope**

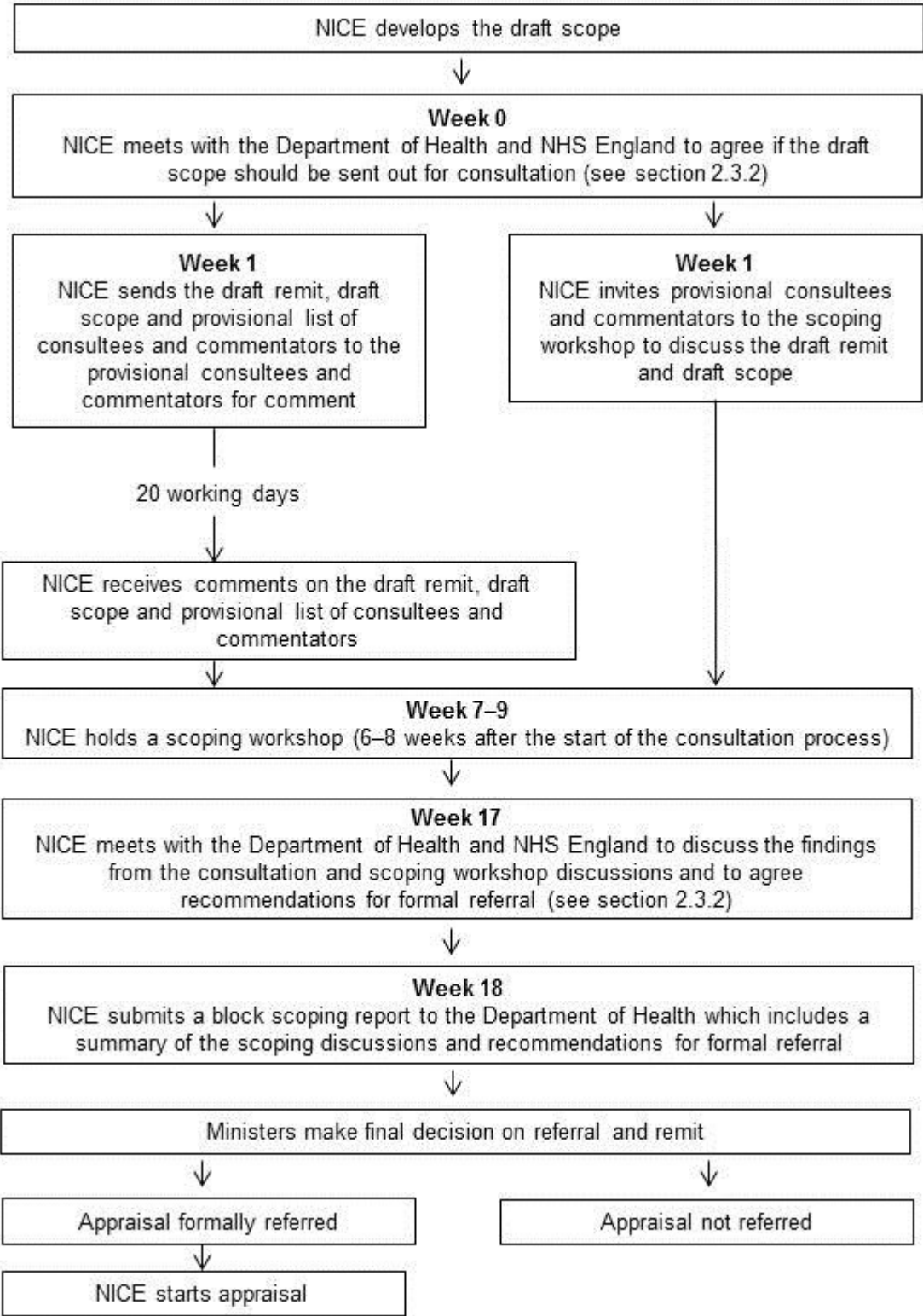
2.5.18 NICE updates the scope, taking into account comments received during the draft remit and draft scope consultation, and the discussions at the

scoping workshop. This is in anticipation of receiving a formal referral to appraise the technology from the Secretary of State for Health.

- 2.5.19 NICE submits a report to the Department of Health summarising the results of the consultation and scoping workshop discussions (known as the block scoping report). This information helps ministers to decide whether or not the technology should be formally referred to NICE for appraisal and whether it should be referred as an MTA or an STA. If ministers decide to refer a technology, it is formally referred to NICE for appraisal along with the final remit.
- 2.5.20 NICE publishes the block scoping report (with any [commercial in confidence](#) information [redacted](#)) on its website after formal referral.
- 2.5.21 If there is a significant length of time between scoping and the start of the appraisal, NICE may need to update the scope to ensure it is still relevant. Depending on the extent of this update, NICE may carry out further consultation with consultees and commentators. An additional scoping workshop is not routinely held.
- 2.5.22 NICE may need to refine the remit and scope further at the request of ministers.



**Figure 2 Steps in developing the scope**



## Planning the referred appraisals into the work programme

- 2.5.23 After formal referral, NICE plans the topic into the work programme, and normally publishes the detailed timelines on its website within 6 weeks. Occasionally, timelines have to change, either before or during the appraisal. NICE will inform consultees and commentators about these changes and, if possible, explain the reasons for the changes. NICE works with the company to release as much information as possible to interested parties.
- 2.5.24 An appraisal may begin before UK regulatory approval for the technology has been granted.
- 2.5.25 For an STA, NICE aims to hold the first [Appraisal Committee](#) meeting as soon as possible after the technology gains a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency, or equivalent from the Medicines and Healthcare Products Regulatory Agency. It is therefore essential that the company informs NICE of all developments in the regulatory approval process. This ensures that NICE publishes guidance on the use of the new technology as soon as possible after receipt of the marketing authorisation and/or its introduction into the UK.
- 2.5.26 During the referral process of an appraisal, NICE asks the [National Institute for Health Research – Health Technology Assessment programme](#) (NIHR HTA programme) to formally commission the ERG or AG to produce a report.

## 3 The appraisal process

Although there are many similarities between the [single technology appraisal \(STA\)](#) and [multiple technology appraisal](#) (MTA) processes, they differ in terms of process steps and timelines between the start of the appraisal and the first [Appraisal Committee](#) meeting. Differences between the processes are described in sections 3.2–3.5.

### 3.1 **General points**

- 3.1.1 NICE sends the name and contact details of the project manager assigned to an individual appraisal to all [consultees](#) and [commentators](#). Consultees and commentators should send all correspondence, including [consultation](#) responses about an individual appraisal, to the project manager to make sure it is dealt with effectively.
- 3.1.2 NICE sends correspondence for an appraisal electronically (or in other formats on request) to key contacts identified by each consultee and commentator organisation. It is therefore essential that consultees and commentators notify the project manager of any change in contact details, or in organisation or [company](#) name, during the appraisal process.
- 3.1.3 The [Public involvement programme](#) (PIP) at NICE offers support throughout the appraisal process to patient and [carer](#) consultee organisations and [patient experts](#) (see table 1).

#### **Process timelines**

- 3.1.4 It is not possible to set absolute timelines for all stages of the appraisal process. The length of time needed for each stage can vary depending on the nature of the particular appraisal. The timelines set out in tables 3–6 and [sections 7.2–7.3](#) indicate the minimum number of weeks for each stage of the appraisal process. Additional time may be given to particular stages if they coincide with public holidays.
- 3.1.5 Throughout an appraisal, up-to-date information about timelines and progress is available on the NICE website. Further information is available from the project manager.
- 3.1.6 If possible, NICE informs consultees and commentators about timeline changes during an appraisal and the reasons for these changes. Sometimes, however, if the reasons are commercially sensitive, NICE cannot disclose them. NICE works with the company to release as much information as possible to interested parties.

## Information handling – general considerations

- 3.1.7 NICE adheres to the principles and requirements of the Data Protection Act and the Freedom of Information Act when dealing with information received during an appraisal.
- 3.1.8 Organisations involved in an appraisal must sign a confidentiality agreement (formally known as the confidentiality acknowledgement and undertaking) before they are recognised as participating consultees and commentators. After this, NICE can release appraisal documents to them.
- 3.1.9 NICE is required to meet the requirements of copyright legislation. If a company cites journal articles in their submission, they must include the full journal articles in their submission and have copyright clearance to allow them to do so. NICE will accept journal articles in electronic format only if they are provided on CD-ROM (or another form of portable data storage) separate to the main submission and economic model. Copyright-controlled material may not be submitted by email or other Internet-based means. NICE will pass journal articles to the ERG or AG in the format they are received (printed or electronic). NICE will not copy, print or store submitted full journal articles because this would breach copyright legislation.
- 3.1.10 If NICE requires journal articles for its own use within the STA or MTA process, NICE will obtain the article itself, paying a copyright fee when necessary.
- 3.1.11 NICE requires the medical director of the company to sign a statement confirming that all clinical trial data necessary to address the [remit](#) and [scope](#) of the [technology appraisal](#) as issued by the [Department of Health](#) and NICE, within the company's or any of its associated companies<sup>1</sup> possession, custody, or control in the UK or elsewhere in the world, have been disclosed to NICE or its authorised agents.

---

<sup>1</sup> within the meaning of s.256 of the Companies Act.

- 3.1.12 NICE requires companies to consent to it being provided directly by European Economic Area regulatory authorities all clinical trial data necessary to address the remit and scope of the technology appraisal as issued by the Department of Health and NICE. This includes all data that have been submitted to the regulatory authorities by the company or any of its associated companies and that were relevant to the granting of a [marketing authorisation](#), and for NICE to use those data in carrying out the technology appraisal. NICE will only ask regulatory authorities directly after having first approached the company for the information and the company is unable or unwilling to provide the information in a timely manner.
- 3.1.13 Care should be taken when submitting information about individual people. Personal and sensitive information, for example, identifying a person's clinician, should be removed from submissions.
- 3.1.14 NICE releases the documents listed in table 2 to consultees and commentators during the appraisal process. NICE publishes these documents on its website at least 5 working days after they have been sent to consultees and commentators. After NICE has published these documents on its website, they are no longer confidential.
- 3.1.15 NICE encourages consultees to make their individual submissions accessible – for example, by putting them on their own websites after they have sent their submission to NICE.
- 3.1.16 NICE will not comment publicly on the content of an appraisal until the process has been completed and its guidance has been produced, except in the following circumstances:
- 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. The Chief Executive of NICE will take this decision. NICE will inform consultees and commentators of this decision as soon as possible.

- NICE reserves the right to issue a correction if a public comment is made on an [appraisal consultation document](#) (ACD) or [final appraisal determination](#) (FAD) that could mislead or misinform.

3.1.17 It is the responsibility of the consultees and commentators, and any other party that has signed a confidentiality agreement for the appraisal, to treat appraisal documents that are not in the public domain as confidential until NICE makes those documents public. NICE considers individuals in a consultee or commentator organisation who see appraisal documents to be bound by the terms of the confidentiality agreement signed by the consultee or commentator organisation.

3.1.18 Any organisation or individual not directly employed by the consultee or commentator organisation is a third party. Consultees and commentators may release the appraisal documents to third parties when:

- it is necessary to enable the consultee or commentator to contribute to the appraisal and
- the third party has seen and agreed to be bound by the terms of the NICE confidentiality agreement.

3.1.19 Consultees and commentators may discuss confidential appraisal documents with other consultees and commentators but, before doing so, they must be satisfied that the other consultees and commentators have signed and returned their confidentiality agreement to NICE.

3.1.20 In the [committee papers](#) (see [section 3.7.3](#)), ACD and FAD, NICE reserves the right to use any material submitted during the appraisal process that is not marked as 'confidential' by the consultee, or which ceases to be so under sections 3.1.18 or 3.1.29. All confidential information should be clearly signposted and marked as such in the committee papers.

3.1.21 If changes are made to the expected therapeutic [indication](#) during the regulatory approval process, NICE will discuss the implications with the

ERG or AG and the company and agree how to incorporate the changes into the submission and the ERG or AG report.

- 3.1.22 With the exception of the draft scope, NICE will not make public, or circulate among consultees and commentators any documents for consultation or guidance on a technology until UK regulatory approval has been granted and the technology's price is known.

### **Information handling – confidential information**

- 3.1.23 To ensure that the appraisal process is as transparent as possible, NICE considers it essential that evidence on which the Appraisal Committee's decisions are based is publicly available. In exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes [commercial in confidence](#) information (for example, the findings of a research project defined as 'confidential' because its public disclosure could have a significant impact on the commercial interests of a particular company) and [academic in confidence](#) information (because public disclosure or publication by NICE would seriously jeopardise the ability of the data owner to publish the information in a scientific paper).

- 3.1.24 NICE has developed the following principles for handling confidential information in the technology appraisal programme:
- Information marked as confidential should be kept to an absolute minimum. Data that are likely to be fundamental to the Appraisal Committee's decision-making cannot be marked as confidential (for example, the list price of a technology after launch and [incremental cost-effectiveness ratio](#) [ICER] estimates).
  - Reasons for confidentiality must be stated clearly, including the date of expected release into the public domain by the data owner, with specific consideration to be given to release of data by regulators as part of granting of the marketing authorisation for a medicinal product.

- When a NICE document quoting evidence from a clinical trial is released before the results are published in a journal, or released via the [European Medicines Agency](#) transparency policy, as a minimum a structured [abstract](#) should be made available for public disclosure. This abstract should follow a recognised format for a full trial report, such as that provided by the [CONSORT statement](#). An equivalent approach is needed for all data and studies that underpin and are included in economic analyses and models.
- Evidence designated as [academic in confidence](#) (but not 'commercial in confidence') can be presented at Appraisal Committee meetings with members of the public and press present.
- Executable [economic models](#) used by companies in their submission for an STA, or by the [assessment group](#) for an MTA, will be made available (on request) to consultees and commentators that have signed a confidentiality agreement.
- All clinical trial information designated confidential at the time of submission to NICE, by companies or other parties, will be shared with those consultees and commentators who have signed a confidentiality agreement before public disclosure.
- If NICE wishes to publish or share data regarded by the data owner as academic or commercial in confidence, both NICE and the data owner will negotiate to find a mutually acceptable solution, recognising the need for NICE to support its recommendations with evidence and the data owner's right to publication. However, the data owner retains the right to make a final decision about the release of confidential information to consultees and commentators and into the public domain.
- Details of a patient access scheme proposal, once referred to NICE for consideration in a technology appraisal, are not confidential except when ministers have agreed that the discount in a simple scheme is confidential. In this case the discount will not be shared with consultees and commentators or released into the public domain.



- When the level of discount of a simple discount patient access scheme is not published in final NICE guidance, the NHS must have access to the discount price, so that providers and commissioners are able to properly account for the patient access scheme.
- NICE will not share confidential details of a simple patient access scheme for a [comparator](#) technology with the company for a new technology being appraised. To allow the Committee to explore the impact of using the actual cost of the comparator in the analyses, the company for the new intervention technology should model the [cost effectiveness](#) of their technology using a range of potential discounts for the comparator. Although this exploration can be marked as commercial in confidence, NICE will have to publish the ICER that informs the recommendation(s), after taking into account the exact level of the discount provided in the patient access scheme for the comparator.
- If NICE is challenged that confidential information it has received should be released in the interests of fairness during an appraisal, at appeal, through judicial review or otherwise, 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 the reasons for NICE maintaining that confidentiality. Without such assertion and evidence, NICE is entitled to conclude that the information is no longer confidential.

3.1.25 If an evidence submission from a company, or a statement from a non-company consultee contains confidential information, it is the responsibility of the submitter to provide 2 versions: a version for NICE to share with the Appraisal Committee and consultees and commentators (including the confidential information marked as per the instructions provided by NICE), and another for release into the public domain (with the confidential information [redacted](#)).

- 3.1.26 A checklist will be provided that must be completed by the consultee at the time of submission, listing all confidential information included in the submission or statement, the reason for its confidentiality, and the date at which it will no longer be considered confidential. If NICE does not receive a completed checklist with a document, none of the information will be considered confidential.
- 3.1.27 The Appraisal Committee and the ERG or AG, the [clinical experts](#), NHS commissioning experts and patient experts invited to attend the Appraisal Committee meeting will be provided with all confidential information submitted.
- 3.1.28 Data owners will be asked to check that confidential information is correctly marked as such in documents created by others in the technology appraisal process at NICE before release to the public; for example, the ERG report and the premeeting briefing.
- 3.1.29 Reasonable amendments to the standard confidentiality agreement will be considered if that would allow release of specific confidential information among the consultees and commentators for an individual technology appraisal.

**Table 2 Documents NICE publishes during the appraisal process**

<b>Document</b>	<b>STA</b>	<b>MTA</b>
Matrix of consultees and commentators	Yes	Yes
Final scope and remit for the appraisal	Yes	Yes
Company's evidence submission(s) (confidential information redacted)*	Yes	Yes
Statements/submissions from non-company consultees and experts*	Yes	Yes
Assessment Group (AG) report*		Yes

Comments from consultees and commentators on the Assessment Group report*		Yes
<a href="#">Evidence Review Group</a> (ERG) report* (including clarification questions and responses)	Yes	
Premeeting briefing*	Yes	Yes
If produced, the appraisal consultation document (ACD)*	Yes	Yes
Comments from consultees and commentators and members of the public on the ACD, if produced, and responses from NICE	Yes	Yes
Final appraisal determination (FAD)*	Yes	Yes

---

\*NICE releases these documents to consultees and commentators who have signed a confidentiality agreement before publishing them on its website (5 working days later).

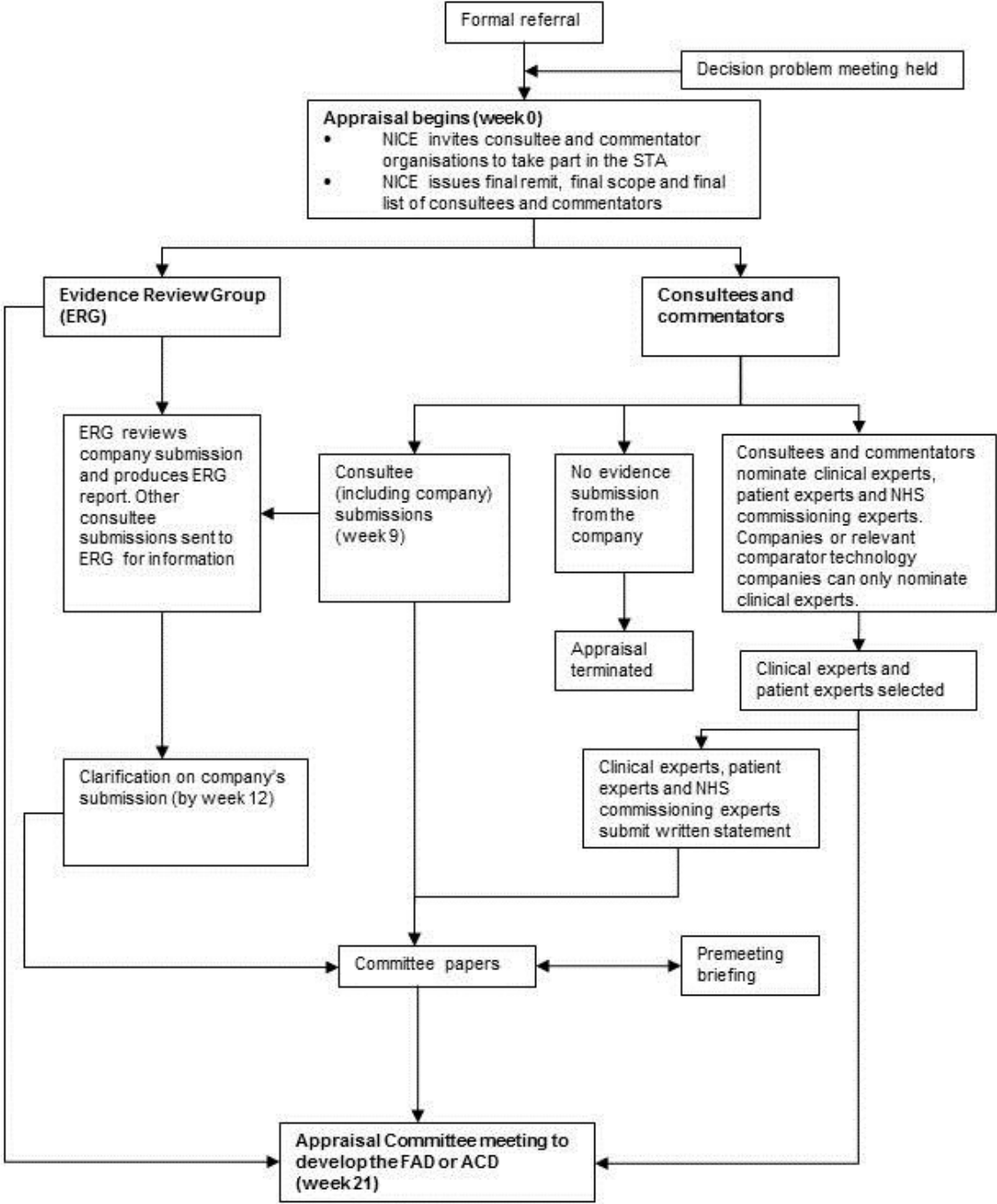
---

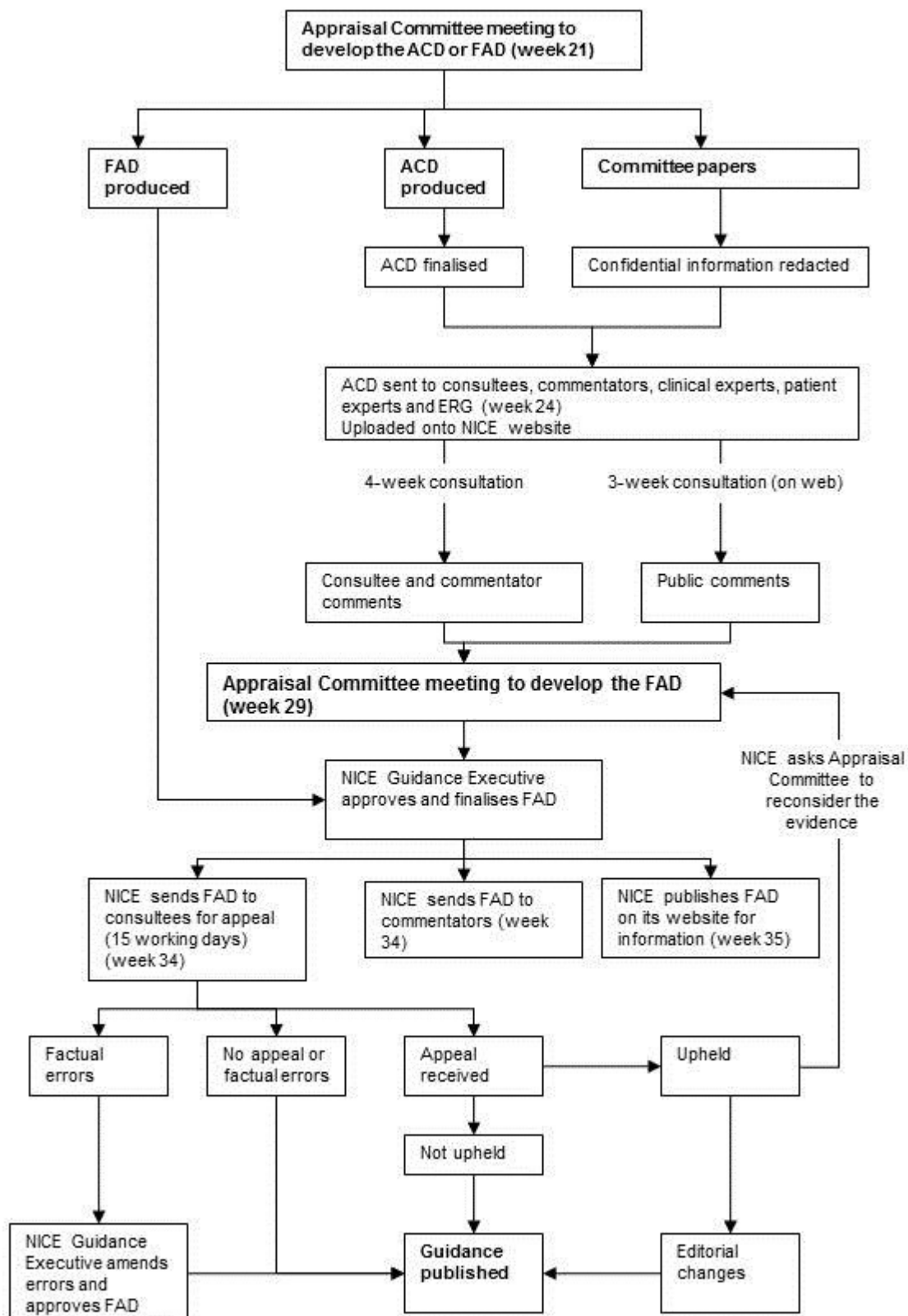
## 3.2 ***STA initiation and evidence submission***

See figure 3 and [section 7.2](#) for an overview of the STA process and timelines.

- 3.2.1 The STA process consists of 3 distinct phases: STA initiation and evidence submission, evidence review (including initial clarification), and appraisal. The first phase can only begin after the scoping phase has been completed and NICE has received formal referral from the Secretary of State for Health.
- 3.2.2 After formal referral, the company has the opportunity to discuss the [decision problem](#) that follows from the draft scope with the NICE team and representatives from the ERG. The company must submit an outline of how it intends to approach the decision problem when invited to prepare the STA evidence submission. This outline is to include, but is not limited to, evidence sources to be used, evidence likely to become available during the appraisal and how this may be managed, the planned approach to disease and economic modelling, potential challenges in interpreting the evidence, and the proposed approach to handling of uncertainty. The meeting will also allow companies to signal potential regulatory developments during the appraisal and the potential inclusion and handling of patient access scheme proposals. The meeting is not intended to provide an opportunity to discuss or request changes to the scope.
- 3.2.3 NICE publishes the final remit and final scope (see [section 2.5](#)), the name of the ERG and the list of consultees and commentators on its website at least 7 weeks before the company's evidence submission deadline. Each STA is assigned to a project team at NICE that is listed on NICE's website. The roles of key members of the project team are summarised in table 1.
- 3.2.4 The appraisal starts when NICE invites consultees and commentators to participate in the STA. NICE sends consultees and commentators a list of key dates for the STA with the invitation to participate.

**Figure 3 Summary of the STA process**





## **Evidence submission from the company**

- 3.2.5 NICE invites the company to provide an evidence submission using a [detailed template](#). The deadline for receipt of the evidence submission is at least 8 weeks from invitation. After receiving this NICE sends it to the ERG for review.
- 3.2.6 The information needed for the evidence submission is derived from the decision-analytical approach NICE uses to evaluate the clinical and cost effectiveness of health technologies. This approach is outlined in NICE's [Guide to the methods of technology appraisal](#). Page limits and instructions on the use of appendices are given for the evidence submission. Submission appendices are not normally provided to the Appraisal Committee or published on the NICE website.
- 3.2.7 If the company plans to submit an economic model, they should inform NICE what software will be used. NICE accepts fully executable economic models using standard software, that is, Excel, DATA/Treeage, R or WinBUGs. If the company plans to submit a model in a non-standard package, it should tell NICE in advance. NICE, in association with the NIHR HTA programme and the ERG, will then investigate whether 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. Care should be taken to ensure that the submitted versions of the model program and the written content of the evidence submission match.
- 3.2.8 NICE offers to send the economic model (in its executable form) to consultees and commentators during consultation on the ACD. If the model contains confidential material that the data owner is unwilling to share with consultees and commentators, 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. Consultees and commentators must make requests for a copy of the model in writing. NICE provides the model on the basis

that the consultee or commentator 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. It cannot be used for any purpose other than to inform the recipient's understanding of the committee papers.
- The economic model cannot be published by consultees or commentators (except by the company who owns the model), in whole or in part, or used to inform the development of other economic models.
- The model must not be run for purposes other than to test its reliability.

3.2.9 If the company wishes to include a patient access scheme proposal as part of its submission, specific requirements apply (see [section 5](#) for more information).

3.2.10 **If the** timelines of the STA are following the anticipated time frame for regulatory approval, the company must notify NICE when it makes a submission for regulatory approval for the technology being appraised. The notification should also specify when an opinion is expected from the Committee for Medicinal Products for Human Use (or equivalent), when it expects to receive regulatory approval, and the expected wording of the marketing authorisation. The company should also state whether they expect the launch date for their technology in the UK to differ from the regulatory approval date. Companies are required to inform NICE immediately if there are changes in the regulatory approval process that will affect the time frame or have implications for the wording of the marketing authorisation.

3.2.11 NICE is unable to comment on submissions during their preparation.



## Statements from non-company consultees

3.2.12 NICE invites all non-company consultees to make a submission providing information on the potential clinical and cost effectiveness of a treatment using the appropriate [templates](#) available on the NICE website. The submission should reflect the experience of patients, clinicians or commissioners of current standard treatment in the NHS in England and the potential impact of treatment on [health-related quality of life](#). Implementation issues, such as staffing and training requirements, should also be included. Consultees have at least 8 weeks to provide their submission to NICE. After receiving the evidence submissions, NICE sends them to the ERG for information.

## 3.3 **STA evidence review**

### Initial clarification

- 3.3.1 After receiving the company's evidence submission, NICE and the ERG assess whether the submission is complete and whether the decision problem is specified appropriately with reference to the final scope.
- 3.3.2 If the evidence submission is incomplete or the decision problem is not specified appropriately, NICE consults with the ERG and sends a letter of clarification to the company within 15 working days of receiving the submission. The company has 10 working days from the date of the correspondence to respond. NICE will organise a face-to-face meeting to discuss any issues that cannot be resolved by other means.
- 3.3.3 If requests for clarification delay the published timelines, NICE informs consultees and commentators, and publishes the reason for the delay on its website.
- 3.3.4 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 Appraisal Committee meeting (see [sections 3.1.23–3.1.29](#) for details on submission of confidential information).

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

### **Terminating an STA**

- 3.3.6 NICE must ensure that the company prepares the best possible evidence submission for the Appraisal Committee. NICE's technical leads do not validate the submission but they help to clarify substantive issues. If, after all reasonable requests for clarification, NICE is not satisfied that the evidence submission is adequate for the Appraisal Committee to make a decision or if no evidence submission has been received, the [Centre Director](#) or Programme Director will recommend to NICE's [Guidance Executive](#) that the STA should be [terminated](#). NICE will return an inadequate evidence submission to the company noting that no submission has been received. NICE will subsequently advise the NHS that the appraisal has been terminated and that NICE is unable to make a recommendation about the use in the NHS of the technology because no evidence submission was received from the company. NICE will also provide an explanation to help the NHS make local decisions on making the technology available.
- 3.3.7 A [terminated appraisal](#) can be restarted if the company indicates that they wish to make a full evidence submission.

### **Evidence Review Group report**

- 3.3.8 The ERG prepares a report on the clinical and cost effectiveness of the technology in line with NICE's [Guide to the methods of technology appraisal](#). The report is based on a review of the company's evidence submission and advice from the ERG's clinical advisers. The ERG prepares the report in accordance with the [NIHR HTA programme quality criteria](#), the scope of work as identified in the service level agreement between the Department of Health, the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) and NICE, and will use an agreed report template. The ERG is responsible for the content and quality of the report.

- 3.3.9 The ERG critically evaluates the evidence submission. The ERG may suggest to NICE, during initial clarification, that the company should carry out additional analyses. In that case, the company should include full descriptions of any additional analyses as appendices to the original submission. If the ERG, as part of exploratory analyses, amends the company's model, it will include technical details of these amendments and their impact in the ERG report. If the ERG carries out significant exploratory analyses of the company's model, which cannot easily be replicated based on the technical details provided in the ERG report, the ERG will provide these analyses to NICE. NICE will make the analyses available to the company at the fact check stage. All other consultees and commentators may request the ERG analyses in writing during the ACD consultation.
- 3.3.10 NICE sends the ERG report to the company before it is presented to the Appraisal Committee. The company has 5 working days from the date of sending to check that the report (including confidential information provided by the company) does not contain factual errors, for example, errors in the figures, incorrect quotes from the evidence submission or text that does not describe the facts accurately. NICE prepares a document highlighting any factual errors for the Appraisal Committee and publishes the document on its website as part of the committee papers. The company cannot submit additional evidence during the evidence review phase unless NICE has agreed to this before the main evidence submission, or NICE asks for more evidence. The company is also required to check that the ERG has accurately marked confidential information within the report. This again provides an opportunity for the company to reconsider and update the confidential status of information before the Appraisal Committee meeting.
- 3.3.11 The ERG report is made available to consultees and commentators, and published on the website (confidential information redacted), with either the ACD or the FAD.

**Table 3 Expected timelines for the STA process: starting the process and preparing the ERG report\***

		<b>Weeks (approx.) since process began</b>
Step 1	NICE invites organisations to participate in the STA as consultees or commentators	0
Step 2	NICE receives evidence submissions from consultees	8
Step 3	NICE requests clarification on the evidence submission	10–11
Step 4	NICE invites selected clinical experts, NHS commissioning experts and patient experts to attend the Appraisal Committee meeting and asks them to submit a written statement	10
Step 5	NICE sends the ERG report to the company for fact checking	18
Step 6	Selected clinical experts, NHS commissioning experts and patient experts submit written statements	18
Step 7	NICE compiles the supporting documentation (see <a href="#">section 3.7.3</a> ) and sends it to the Appraisal Committee	19

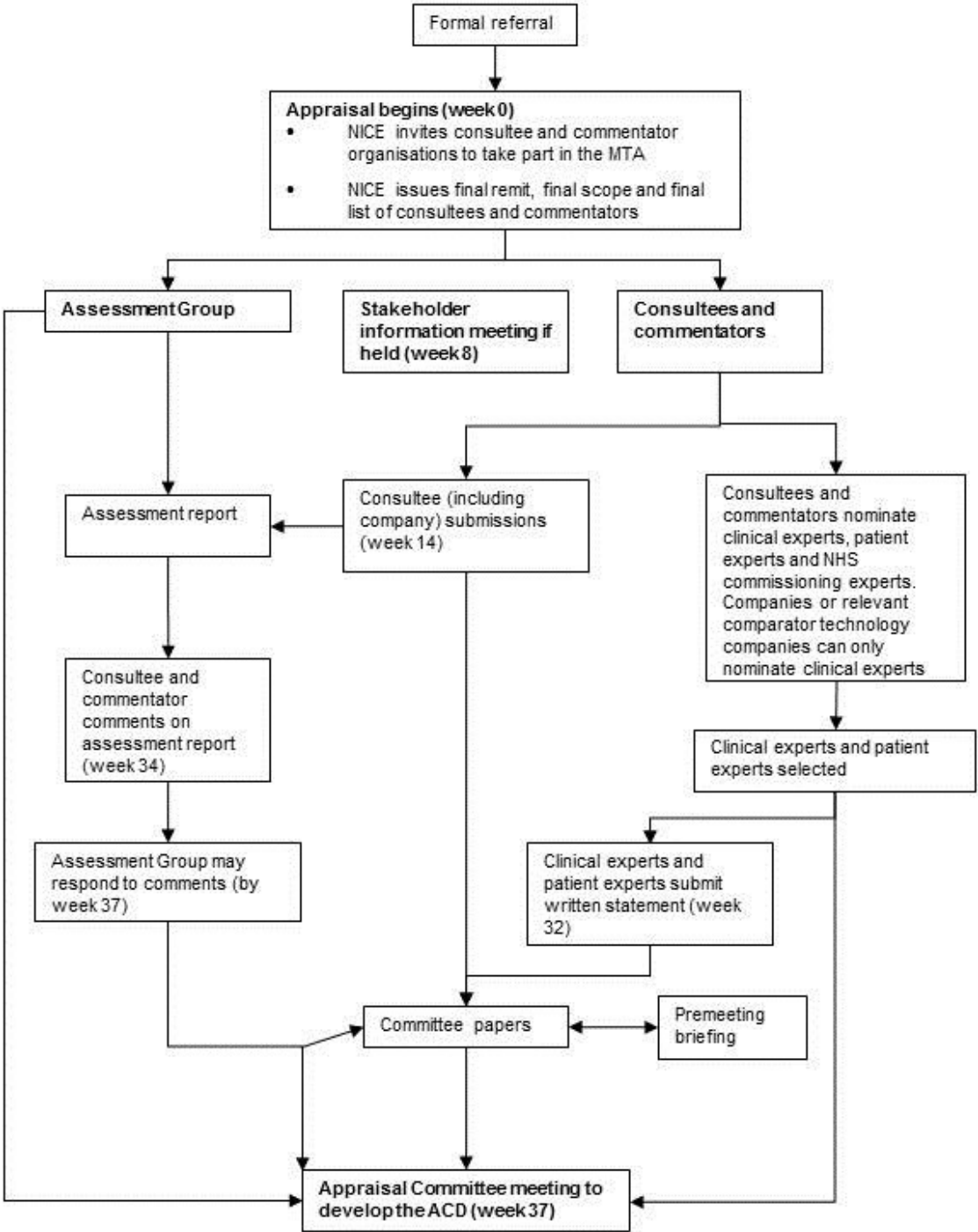
\*Timelines may change in response to individual appraisal requirements.

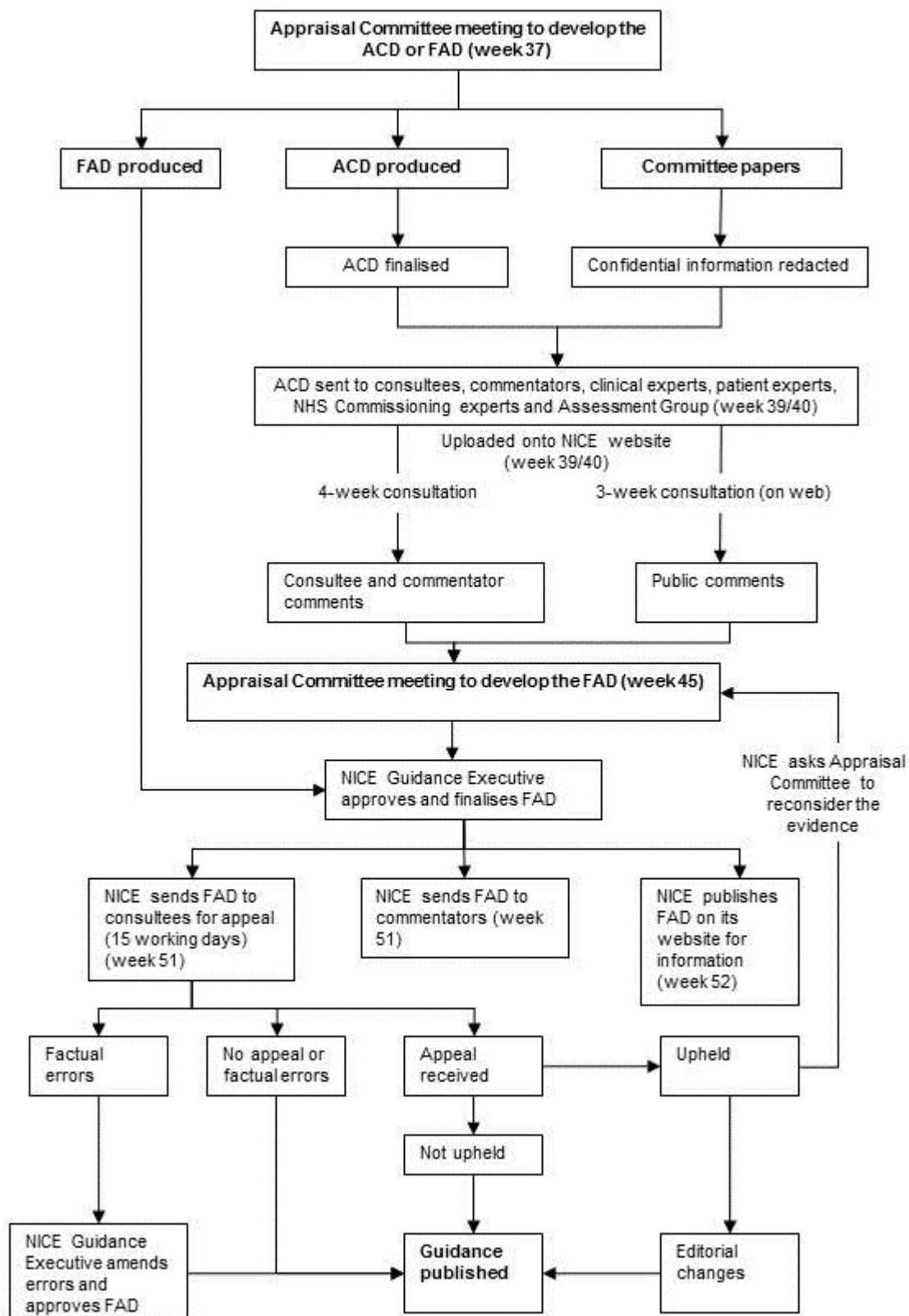
### 3.4 ***MTA initiation and evidence submission***

See figure 4 and [section 7.3](#) for an overview of the MTA process and timelines.

- 3.4.1 The MTA starts when NICE invites consultees and commentators to participate in the appraisal and asks consultees to provide a submission. NICE sends consultees and commentators a list of key dates for the MTA along with the invitation to participate.
- 3.4.2 NICE publishes the final remit and final scope (see [section 2.5.18](#)), the name of the AG and the list of consultees and commentators on its website. Each MTA is assigned to a project team at NICE which is listed on NICE's website. The roles of key members of the project team are summarised in table 1.

**Figure 4 Summary of the MTA process**





## Consultee submissions

- 3.4.3 A submission for an MTA should be a concise, comprehensive and structured report of all relevant information (published and unpublished) for an appraisal. It should address the issues highlighted in the final scope. NICE does not accept unsolicited submissions (that is, from organisations other than consultees).
- 3.4.4 Consultees have at least 14 weeks to prepare their submissions.
- 3.4.5 NICE forwards all submissions, in full, to the AG. The AG uses the information to prepare the [assessment report](#).
- 3.4.6 If consultees plan to submit an economic model, they should inform NICE what software will be used. NICE accepts fully executable economic models using standard software, that is, Excel, DATA/Treeage, R or WinBUGs. If consultees plan to submit a model in a non-standard package, they should inform NICE in advance. NICE, in association with the NIHR HTA programme and the AG, will then investigate whether the requested software is acceptable. When consultees submit a fully executable electronic copy of the model, they must give NICE full access to the programming code. Care should be taken to ensure that the submitted versions of the model program and the written content of the evidence submission match.
- 3.4.7 If the company wishes to include a patient access scheme proposal as part of their submission, specific requirements apply (see [section 5](#) for more information).
- 3.4.8 The AG may contact consultees preparing a submission with queries about their submission. This should be done by email, copied to NICE's technical lead and project manager. In exceptional circumstances, NICE will organise a face-to-face meeting to discuss issues that cannot be resolved by other means.
- 3.4.9 During the submission stage, NICE may organise a stakeholder information meeting. All consultee and commentator organisations are



invited to send up to 2 representatives each to the meeting. The Institute's project team and representatives from the AG also attend. The purpose of the meeting is to:

- explain the appraisal process
- explore technical aspects of the appraisal
- identify important evidence to be included in stakeholder submissions.

3.4.10 NICE is unable to comment on submissions during their preparation.

### 3.5 ***MTA evidence review***

#### **Assessment report**

3.5.1 The AG first develops a protocol. The protocol is derived from the scope of the appraisal, taking into account consultation responses to the draft scope and comments from organisations attending the scoping workshop.

3.5.2 The NIHR HTA programme and NICE approve the final [assessment protocol](#) after the technology has been formally referred to NICE. NICE sends the assessment protocol to consultees and commentators within 3 weeks of the start of the MTA and publishes the protocol on its website 5 working days later.

3.5.3 The AG prepares an assessment report, which is an analysis of the clinical and cost effectiveness of the technology or technologies based on a [systematic review](#) of the literature, examination of submissions, and advice from the clinical advisers. The assessment report may include an assessment of cost effectiveness, separate to that provided by the company(ies). Further details can be found in NICE's [Guide to the methods of technology appraisal](#).

3.5.4 The AG prepares the assessment report in accordance with the NIHR HTA programme [quality criteria](#), the scope of work as identified in the service level agreement between the Department of Health, NETSCC and NICE, and an agreed report template. The AG is responsible for the content and

quality of the report. If the NICE project team (see table 1) and the Appraisal Committee Chair think that the assessment report is not of the required standard, steps will be taken via the NIHR HTA programme to make sure that a satisfactory assessment report is produced. The AG does not propose recommendations on the use of a technology. The AG submits its report to NICE and it forms part of the evidence base for the appraisal. The AG will further develop the report for subsequent publication as a topic in the [HTA programme](#).

- 3.5.5 NICE sends the assessment report to consultees and commentators for comment. NICE publishes the report on its website, with confidential information redacted, 5 working days after it is circulated to consultees and commentators. Consultees and commentators must submit their comments within 20 working days of the date of sending. NICE presents these comments, along with any responses from NICE or the AG, to the Appraisal Committee and later publishes them on its website as part of the committee papers. Comments, therefore, should not contain any confidential information. If a comment does contain confidential information, the responder must provide 2 versions of the comment, a complete version and another with the confidential information redacted (to be published on NICE's website), together with a checklist of the confidential information. Detailed instructions on sending NICE confidential information about an appraisal are available from the project manager. NICE does not anticipate that comments on the assessment report will contain new evidence. Proposals to submit new evidence at this stage must be agreed by the Programme Director or Centre Director before submission.
- 3.5.6 If the AG has produced an economic model in support of the assessment report, NICE offers to send it (in its executable form) to consultees and commentators during consultation on the assessment report. If the model contains confidential material that the data owner is unwilling to share with consultees and commentators, despite the assurances provided through the signed confidentiality agreement, NICE will ask the AG to redact the

model if this can be done without severely limiting the model's function. Depending on the length of this discussion, this may result in the economic model being offered during consultation on the ACD or FAD instead. Consultees and commentators must make requests for a copy of the model in writing. NICE provides the model on the basis that the consultee or commentator 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 AG. It cannot be used for any purpose other than to inform the recipient's understanding of the assessment report.
- The economic model cannot be published by consultees or commentators, in whole or in part, or used to inform the development of other economic models.
- The model must not be run for purposes other than to test its reliability.

3.5.7 NICE sends the assessment report to consultees and commentators again after the Appraisal Committee meeting as part of the committee papers supporting the ACD (see [section 3.7.3](#)). Consultees and commentators may include any further comments on the assessment report with their comments on the ACD, under a separate heading.

3.5.8 After comments are received and considered, the AG may need to carry out additional analysis before the Appraisal Committee meets to develop the ACD. Any additional analysis is included in the committee papers for distribution to consultees and commentators with the ACD.

3.5.9 If possible, additional analysis is completed in time for the scheduled Appraisal Committee meeting. If this is not possible, NICE may extend the timelines for the appraisal. NICE will advise consultees and commentators as soon as possible of any change to the timelines and the reasons for that extension. The decision to carry out additional analysis is not taken

lightly; it is done to ensure that NICE is able to provide robust guidance to the NHS.

**Table 4 Expected timelines for the MTA process: starting the process and preparing the assessment report\***

		<b>Weeks (approx.) since process began</b>
Step 1	NICE invites organisations to participate in the MTA as consultees or commentators	0
Step 2	NICE receives submissions from consultees	14
Step 3	NICE sends submissions from consultees to the Assessment Group	15
Step 4	NICE invites selected clinical experts, NHS commissioning experts and patient experts to attend the Appraisal Committee meeting and asks them to submit a written statement	16
Step 5	NICE receives the assessment report	28
Step 6	NICE sends the assessment report to consultees and commentators for comment	30
Step 7	Selected clinical experts, NHS commissioning experts and patient experts submit written statements	32
Step 8	NICE receives comments on the assessment report from consultees and commentators	34
Step 9	NICE compiles the committee papers (see	35/36

section 3.7.3) and sends to the Appraisal Committee

---

\*Timelines may change in response to individual appraisal requirements.

---

## 3.6 ***External participation in the STA and MTA processes***

### **Participation of clinical, NHS commissioning and patient experts**

- 3.6.1 NICE encourages all consultees and commentators to nominate clinical experts and patient experts to take part in the first Appraisal Committee meeting discussion. NICE asks NHS England and the 2 clinical commissioning groups selected at random to be consultees to nominate NHS commissioning experts to attend the Appraisal Committee meeting.
- 3.6.2 The PIP public involvement adviser gives advice and information to the patient and carer organisations nominating experts and to people interested in becoming patient experts. Patient organisations may nominate both patient and clinical experts.
- 3.6.3 The nominating organisation and the experts (clinical, patient or NHS commissioning) jointly complete a nomination form. The form includes a section asking the expert to provide a 50-word summary describing their experience and knowledge of the condition and, if possible the technology, and describing any previous involvement with NICE.
- 3.6.4 The Chair of the Appraisal Committee, with input from the NICE project and PIP teams, selects clinical experts, NHS commissioning experts and patient experts from the nominations received. The choice of clinical experts and patient experts is based on the nominees' experience of the technology and the condition(s) that the technology is designed to treat. If possible, the clinical experts and patient experts will have complementary rather than similar backgrounds and experiences. NICE uses the following criteria to select clinical experts, NHS commissioning experts and patient experts for Appraisal Committee meetings:

- 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 ACD and/or FAD.
- They have knowledge and/or experience of the condition and/or technology under appraisal and/or the way it is used in the NHS.
- They are willing and able to discuss the condition and the technology with members of a large committee at a meeting where there may be members of the public and press observing.
- They are familiar with the purpose and processes of NICE (the PIP public involvement adviser at NICE can give patient experts an overview that enables them to contribute to the discussions at Appraisal Committee meetings).
- They are prepared to declare any interests they have in the technology under appraisal at Appraisal Committee meetings.

3.6.5 Additionally, the following criteria are used to select clinical experts:

- They are in active clinical practice and have specialist expertise in the subject area of the appraisal.
- Their principal place of work is within the NHS.
- If they have acted as a clinical expert for the company, or the ERG or AG, they agree to declare this in their personal statement and at Appraisal Committee meetings.
- They hold no official office (that is, no paid employment, unpaid directorship or membership of a standing advisory committee) with the technology company or any relevant comparator technology companies.

3.6.6 Usually, 2 clinical experts, 2 patient experts and 2 NHS commissioning experts are selected. NICE asks them to submit a short written personal statement on the technology and the way it should be used in the NHS in England. NICE gives the written statements to the Appraisal Committee and publishes them as part of the committee papers. If the clinical experts

and patient experts support the submission made by their nominating organisation they do not need to submit a statement. Further advice about the contribution of clinical experts, NHS commissioning experts and patient experts is available from the project manager.

- 3.6.7 Clinical experts, NHS commissioning experts and patient experts attend Appraisal Committee meetings as individuals to provide their own views and not as representatives of their nominating organisation. NICE aims to select a cross-section of people from the nominations received for clinical experts and patient experts. 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.
- 3.6.8 NICE publishes details of consultee and commentator organisations, which have provided nominations for clinical experts, NHS commissioning experts and patient experts, on the Appraisal Committee meeting agenda. NICE includes the names and affiliations of the selected clinical experts, NHS commissioning experts and patient experts in the ACD, FAD and in the minutes of Appraisal Committee meetings.
- 3.6.9 It is important that sufficient expertise feeds into the technology appraisal. NICE welcomes and values the input from patient experts, NHS commissioning experts and clinical experts.

### **Participation of company representatives**

- 3.6.10 Two representatives from the company(ies) (normally 1 with health economics expertise and 1 with medical expertise) for the technology(ies) being appraised can attend part 1 of the Appraisal Committee meeting discussions. The Chair will ask these representatives to respond to questions from the Appraisal Committee. The Chair will ask the representatives to comment on any matters of factual accuracy before concluding part 1 of the meeting. The Chair may ask the representatives to remain for part of the closed session (part 2) of the Appraisal 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 developing the company's evidence submission
- have relevant detailed knowledge of the technology under appraisal to engage effectively with the Appraisal Committee
- be able to comment on the clinical and/or cost effectiveness 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 there may be members of the public and press observing
- be familiar with the purpose and processes of NICE.

3.6.11 The ACD, FAD and the minutes of Appraisal Committee meetings will report the industry representation at the Appraisal Committee meetings but will not name the representatives who attended.

### 3.7 ***Appraisal – STA and MTA***

3.7.1 The appraisal phase of the process has 4 possible stages:

- consideration of the evidence at an Appraisal Committee meeting to discuss the content of either the ACD or FAD
- development of and consultation on the ACD (if required)
- review of the ACD (if produced) in the light of comments from consultation at a second Appraisal Committee meeting
- preparation of the FAD.

#### **Preparing for the meeting to develop the ACD or FAD**

3.7.2 A [lead team](#), selected from the Committee members at the start of each appraisal, helps the NICE technical lead prepare a summary of the evidence, known as the premeeting briefing. The lead team consists of 3 committee members; 1 focuses on [clinical effectiveness](#); 1 on cost



effectiveness and 1 on patient and carer evidence (called the lay lead). The ERG or AG also attend a meeting with the Committee Chair, the lead team and the NICE project team to discuss the content of the premeeting briefing.

3.7.3 In preparation for the Appraisal Committee meeting, the committee papers are circulated to all attendees (except members of the public) usually 2 weeks before the meeting. The papers consist of:

- the final scope of the appraisal and the list of consultees and commentators
- STA only:
  - the company's evidence submission plus responses to clarification requests
  - the ERG report and any supplements to it
  - factual errors in the ERG report identified by the company along with the ERG response
- MTA only:
  - the assessment report and any supplements to it
  - comments from consultees and commentators on the assessment report
  - the AG's written response, if any, to the comments on the assessment report
  - the full submissions from the professional, patient/carers and NHS commissioning consultees
  - the executive summaries of the company submissions (the full submissions are available to the Committee)
- submissions from consultees, NHS commissioning experts and statements from clinical and patient experts attending the Appraisal Committee meeting
- a premeeting briefing written by NICE's technical lead for the appraisal.

3.7.4 Appraisal Committee meetings are usually open to members of the public and press. This supports NICE's commitment to openness and

transparency. It enables stakeholders and the public to understand how evidence is assessed and interpreted and how consultation comments are taken into account.

- 3.7.5 To promote public attendance, the meetings in public team at NICE publishes a notice and draft agenda on its website announcing each Appraisal Committee meeting, at least 20 working days before the meeting. At this point, members of the public who wish to attend the meeting can register on NICE's website. Up to 20 places will be available, depending on the size of the venue. In the event that attendance at any meeting is oversubscribed, NICE may need to limit the number of places offered. To allow wide public access, NICE reserves the right to limit attendees to 1 representative per organisation. The closing date for receiving completed application forms is 10 working days before the meeting. NICE publishes the final agenda on its website 5 working days before the meeting. Once registration has closed, NICE will contact applicants to let them know whether they have a place at the meeting.

### **Appraisal Committee meeting to develop the ACD or FAD**

- 3.7.6 When the Appraisal Committee meets for the first time to discuss an appraisal, it may develop an ACD (see [section 3.7.21](#) for an explanation of when an ACD is produced) or FAD. The Appraisal Committee considers and discusses the evidence for a technology. Committee decisions are normally based on consensus. If a vote is taken, it will be noted in the minutes. More information on how the Appraisal Committee considers the evidence and makes its decision is available in NICE's [Guide to the methods of technology appraisal](#). The committee papers include the written evidence (see section 3.7.3). The verbal evidence is drawn from discussions with invited clinical experts, NHS commissioning experts, patient experts and ERG or AG representatives.

### **Part 1 (public session)**

- 3.7.7 Part 1 of NICE Appraisal Committee meetings is usually open to members of the public and press. There may be occasions when a meeting will be entirely closed because it is not possible to conduct its business without

referring to confidential information, or without its discussions being commercially sensitive.

- 3.7.8 Members of the Committee and people having direct input into the discussions declare their interests, which are recorded in the minutes. For further information on how NICE deals with conflicts of interest, please see NICE's [code of practice for declaring and dealing with conflicts of interest](#).
- 3.7.9 The lead team (selected from members of the Appraisal Committee) usually introduces the topic of the appraisal to the other Appraisal Committee members and attendees. The lay lead's role is to include the patient evidence in the lead team's introduction. This introduction does not pre-empt the Committee's debate or the formulation of the guidance.
- 3.7.10 Clinical experts, NHS commissioning experts and patient experts are encouraged to interact fully in the debate with the Committee, including responding to and raising questions, but do not make a formal presentation to the Committee.
- 3.7.11 Company representatives respond to questions from the Appraisal Committee and comment on any matters of factual accuracy.
- 3.7.12 The Appraisal Committee considers the evidence during the public session. However, the Appraisal Committee 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. See [section 3.1.24](#) for further details on how [academic in confidence](#) information is handled at Appraisal Committee meetings.
- 3.7.13 The ERG or AG representatives answer questions from the Appraisal Committee and provide clarification on the ERG or AG report.
- 3.7.14 Representatives from other guidance-producing teams (for example, clinical guidelines and public health) at NICE who are responsible for developing NICE guidance in areas related to the appraisal may also

attend the meeting to observe and advise the Appraisal Committee. These representatives must declare their interests and satisfy NICE's conflict of interest policy as indicated in section 3.7.8.

- 3.7.15 NICE staff may present evidence, provide advice on NICE policies and procedures, and respond to questions from the Appraisal Committee.

## **Part 2 (closed session)**

- 3.7.16 During the closed session, the Appraisal Committee considers 'commercial in confidence' information and agrees the recommendations. Members of the public and press along with the clinical experts, NHS commissioning experts, patient experts, company representatives and the ERG or AG representatives are asked to leave the meeting before this discussion takes place.
- 3.7.17 The Chair may ask clinical experts, NHS commissioning experts, patient experts, company representatives and ERG or AG representatives to remain when confidential information is discussed, but the Chair will ask them to leave before the Committee agree the recommendations in the ACD or the FAD.
- 3.7.18 The 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 via the project team at NICE and it must be agreed with the Chair of the Committee before the meeting.
- 3.7.19 NICE staff and representatives from other guidance-producing teams at NICE who are responsible for developing NICE guidance in areas related to the appraisal may stay at the meeting while the Appraisal Committee agree the recommendations in the ACD or the FAD; however, they play no part in decision-making.
- 3.7.20 The Appraisal Committee concludes the discussions and agrees the content of either the ACD (see section 3.7.23), which sets out its preliminary recommendations, or the FAD (see section 3.7.37), which sets out its final recommendations. After the meeting, the ACD or the FAD is

drafted based on the discussions at the meeting, including the preliminary or final recommendations agreed by the Appraisal Committee.

### **Consultation on the ACD (if produced)**

3.7.21 Normally, formal consultation (when an ACD is produced) takes place only if the preliminary recommendations from the Appraisal Committee do not recommend use of the technology, limit the use of the technology further than the marketing authorisation (or instructions for use) for the indication being appraised, or if (in an STA) the company is asked to provide further clarification on their evidence submission.

3.7.22 NICE usually circulates the ACD to consultees and commentators within 15 working days of the Appraisal Committee meeting. NICE notifies consultees and commentators if a delay is expected. NICE cannot issue an ACD or FAD on a technology before that technology receives UK regulatory approval (see [section 3.1.22](#) for further information).

3.7.23 The ACD summarises the evidence and views that have been considered by the Appraisal Committee and sets out preliminary recommendations. The ACD is not NICE's final guidance on a technology. The recommendations may change after consultation. The ACD usually contains the following elements:

- the Appraisal Committee's preliminary recommendations to the NHS on the technology and how it should be used
- a description of the technology, including its licensed indication and dosage, mode of action and cost
- a summary of the evidence provided by consultees and the ERG or AG
- a description of how the Appraisal Committee has interpreted the evidence together with the key issues raised by clinical experts, NHS commissioning experts and patient experts
- expectations about implementation of the recommendations, if appropriate
- proposed recommendations for further research, if appropriate

- a list of related NICE guidance
- the proposed date for consideration of a review of the guidance.

3.7.24 The ACD and the committee papers are sent to consultees, commentators, the clinical experts, NHS commissioning experts and patient experts for consultation. These documents are confidential until NICE publishes them on its website 5 working days after circulation. The published committee papers will include the full company submissions. Information designated as commercial or [academic in confidence](#) will be redacted from the documentation.

3.7.25 The purpose of the consultation is to seek views on the Appraisal Committee's preliminary 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 Appraisal Committee has been appropriately taken into account
- the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence
- the preliminary recommendations are sound and constitute a suitable basis for guidance to the NHS
- there are any equality issues that need special consideration that are not covered in the ACD.

3.7.26 Consultees and commentators (and the clinical experts, NHS commissioning experts and patient experts) have 20 working days from the date of sending to submit comments on the ACD. They must submit their comments in writing, preferably electronically. They must not use the website comment facility.

3.7.27 NICE publishes the ACD with an electronic comment facility and the committee papers with confidential material redacted on its website for public consultation 5 working days after circulation to consultees and commentators. NICE sends the comments received from this website

consultation (in summary form if there are a large number of comments) to the Appraisal Committee for consideration.

- 3.7.28 If a comment contains confidential information, it is the responsibility of the organisation or person who submitted the comment to provide 2 versions, a complete version and another with the confidential information redacted (to be published on NICE's website), together with a checklist of the confidential information. Detailed instructions on sending NICE confidential information about an appraisal are available from the project manager.
- 3.7.29 After the ACD has been developed, new evidence can only be accepted if the Centre Director or Programme Director agrees that the new evidence is likely to affect the preliminary recommendations in the ACD. The new evidence must be presented as a separate appendix to the comments on the ACD. NICE may need to extend timelines and reschedule the subsequent Committee meeting to allow for new evidence to be considered. The company must inform NICE, in writing, of its intention to submit additional evidence, as early as possible.
- 3.7.30 Any review of such new evidence by the ERG or AG will not be sent for an additional factual error check or for consultation before the subsequent committee meeting.
- 3.7.31 When consultees and commentators submit comments and/or new evidence that lead to a substantial revision of the ACD, involving a major change in the recommendations, considerations and/or evidence base, the Centre Director or Programme Director and the Chair of the Appraisal Committee will decide whether it is necessary to prepare another ACD. If so, the consultation process will be repeated. The decision to produce another ACD will extend the timelines for the appraisal. NICE will distribute the committee papers with the second ACD, together with any new evidence not circulated with the previous ACD and consultation comments on the first ACD.
- 3.7.32 **For STA only:** As part of the ACD, the Appraisal Committee may ask NICE to seek clarification from the company on the key evidence

submitted. NICE will ask the company to submit its response to this request (as a separate appendix) along with its comments on the ACD and the committee papers. If the company has carried out new analyses, it must submit an updated version of the economic model. When the Appraisal Committee seeks such clarification, NICE will inform the company and the ERG before the ACD is released for consultation.

- 3.7.33 **For STA only:** If comments received from the consultation on the economic model need a response from the company, NICE sends those comments to the company to respond. The response will be tabled at the next Appraisal Committee discussion.

### **Appraisal Committee meeting to develop the FAD**

- 3.7.34 If an ACD is produced, the Appraisal Committee meets again, with members of the public and press observing, to consider the preliminary recommendations in the ACD in the light of the comments received. Before the meeting, NICE sends the Appraisal Committee members the full text of the comments from the consultees and commentators and a summary of any comments received from other people or organisations.
- 3.7.35 Representatives from the company, the ERG or AG and from other guidance-producing teams at NICE (for example, clinical guidelines and public health) who are responsible for developing NICE guidance in areas related to the appraisal, may attend the meeting. If clarification of issues raised during the consultation period is needed, the Chair of the Appraisal Committee can, at their discretion, invite 1 or more of the clinical experts, NHS commissioning experts or patient experts to attend.
- 3.7.36 The Appraisal Committee discusses the responses to the ACD consultation in part 1 of the meeting (see section 3.7.7) and moves to a closed session (part 2, see section 3.7.16) to consider any confidential information and to agree the content of the FAD, which sets out the final recommendations. After the meeting, the FAD is drafted based on the discussions at the meeting and the final recommendations agreed by the Appraisal Committee.



3.7.37 The FAD contains:

- the Appraisal Committee's final recommendations to the NHS on the technology and how it should be used
- a description of the technology, including its licensed indication and dosage, mode of action and cost
- a summary of the evidence provided by consultees and the ERG or AG
- a description of how the Appraisal Committee has interpreted the evidence together with the key issues raised by clinical experts, NHS commissioning experts and patient experts
- expectations about implementation of the recommendations, if appropriate
- proposed recommendations for further research, if appropriate
- a list of related NICE guidance
- the proposed date for consideration of a review of the guidance.

3.7.38 The Centre Director or Programme Director signs off the final FAD and submits a report to NICE's Guidance Executive. The Guidance Executive checks that the Appraisal Committee has appraised the technology in accordance with the terms of the Secretary of State for Health's referral and the scope. If satisfied, the Guidance Executive approves the FAD for publication on behalf of the NICE Board.

3.7.39 NICE issues the FAD to consultees so that they can consider whether to appeal against the final recommendations (see [section 4](#)). They can also highlight any factual errors. Commentators receive the FAD for information and can also highlight any factual errors.

3.7.40 NICE distributes any new, non-confidential evidence submitted by consultees and commentators, and further analysis done by NICE or the ERG or AG during development of the FAD, to consultees and commentators. When NICE sends the FAD to consultees and commentators, it also sends the comments received from consultees and commentators on the ACD (if produced), together with NICE's responses

to them, and the comments received from the public via the website. NICE publishes all this information on its website 5 working days after sending it to consultees and commentators.

3.7.41 NICE usually sends the FAD within 25 working days of the Appraisal Committee meeting to consultees and commentators. NICE notifies consultees and commentators if a delay is expected. NICE publishes the FAD and the committee papers with confidential material redacted on its website 5 working days after circulation to consultees and commentators.

3.7.42 In exceptional circumstances, for example, if relevant information is published while the FAD is being developed or because of comments from consultees or commentators, NICE may carry out further analysis. The ERG or AG or [Decision Support Unit](#) (DSU) normally does this further analysis before NICE circulates the FAD. The Centre Director or Programme Director takes this decision in discussion with the Chair of the Appraisal Committee and the NICE project team. The decision is not taken lightly and is made to make sure that NICE is able to provide robust guidance to the NHS. If further analysis is done, NICE will inform consultees and commentators. NICE will distribute any such analysis to consultees and commentators and publish it on the website at the same time as the FAD.

## Minutes

3.7.43 NICE publishes unconfirmed minutes of the Appraisal Committee meeting on its website within 20 working days of the meeting. When the Appraisal Committee has approved them, NICE publishes the confirmed minutes on its website normally within 6 weeks of the meeting. The minutes of an Appraisal Committee meeting provide a record of the proceedings and a list of the issues discussed.

**Table 5 Expected timelines for the appraisal process if an ACD is produced\***

<b>Weeks (approx.) since process</b>
--

		<b>began</b>	
		<b>STA</b>	<b>MTA</b>
Step 8/10	Appraisal Committee meeting to develop an ACD attended by clinical experts, NHS commissioning experts and patient experts	21	37
Step 9/11	The ACD is produced. NICE distributes the ACD and publishes it on the website 5 working days later	24	40
Step 10/12	Fixed 4-week consultation period on the ACD	24–28	40–44
Step 11/13	Appraisal Committee meeting to consider comments on the ACD from consultees and commentators, and comments received through the consultation on the NICE website. Appraisal Committee agrees the content of the FAD	29	45
Step 12/13	The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later	34	50

\*Timelines may change in response to individual appraisal requirements.

**Table 6 Expected timelines for the appraisal process if an ACD is not produced\***

		<b>Weeks (approx.) since process began</b>	
		<b>STA</b>	<b>MTA</b>
Step	Appraisal Committee meeting to develop a FAD,	21	37

8/10	attended by clinical experts, NHS commissioning experts and patient experts		
Step 9/11	The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later	26	42

\*Timelines may change in response to individual appraisal requirements.

### Publication of the guidance

3.7.44 Subject to any appeal by consultees, the FAD forms NICE's guidance on the use of the technology.

3.7.45 After receiving the FAD, any consultee (whether or not they are submitting an appeal) or commentator can request correction of factual errors. Some examples of what might constitute factual errors are:

- wrong names or misspelling of technologies or companies
- errors in figures presented in the FAD
- incorrect or incomplete quotes from marketing authorisations
- text to be changed to ensure that the facts are described appropriately in the FAD.

3.7.46 The Guidance Executive considers all significant requests for correction of factual errors and decides whether to make changes to the FAD. This decision is made after any appeal proceedings have concluded. NICE then publishes the FAD as technology appraisal guidance on its website. NICE also publishes a lay version for patients and carers (known as 'Information for the public') on its website.

3.7.47 When an appraisal is published, NICE provides an opportunity for companies to meet with NICE. This is a debrief meeting for situations when the company wishes to discuss specific issues or questions related to the appraisal and their own evidence submission in the context of the

Appraisal Committee's recommendations. Up to 5 people involved in the development of the company's submission can attend the meeting.

## 4 Appeal

Details of the appeals process are set out in NICE's [Guide to the technology appraisal and highly specialised technologies appeal process](#) and a brief summary is given here (see table 7 for expected steps in the appeals process).

- 4.1 Appeal(s) should be submitted in writing within 15 working days of the FAD being issued. Appeals must fall within 1 or more of the grounds of appeal as outlined in the appeals process guide.
- 4.2 Requests for corrections of minor factual or typographical errors are not normally considered at an appeal and will be considered separately (see [section 3.7.47](#)).
- 4.3 Appellants cannot submit appeals because they do not agree with the recommendations. The Appeal Panel will not rehear [evidence](#) or be persuaded by repetition of points previously made by the appellant, and considered by the [Appraisal Committee](#), unless it can be shown that 1 or more of the grounds of appeal is also valid. New evidence or information that was not presented to the Appraisal Committee, or re-analysis of existing evidence or information, must not be presented in the appeal letter, and will not be considered by the Appeal Panel.
- 4.4 On receipt of appeal(s), the initial and final scrutiny of the appeal is carried out by the vice chair of NICE or another non-executive director of NICE.
- 4.5 If after scrutiny the appeal progresses to an appeal hearing (either an oral or written appeal hearing), an Appeal Panel consisting of the following 5 members is formed:
  - Appeal Panel Chair
  - a non-executive director of NICE
  - a person with experience of the life sciences industry

- a [lay member](#) who may have experience of being a patient or [carer](#) or member of an organisation that represents patients and carers
- a person with experience of the NHS.

4.6 After considering the appeal (either at an oral or written appeal hearing), the Appeal Panel will aim to send its decision in writing to NICE within 15 working days of the appeal hearing. There may be circumstances in which more time is needed. The appeal decision is then considered by NICE's [Guidance Executive](#). The time between the appeal decision and its consideration by the Guidance Executive depends on the time needed to prepare all the final documents, and so will vary.

4.7 If 1 or more of the appeal points are upheld and it is necessary for the Appraisal Committee to reconsider the FAD, the Appeal Panel's decision is published on the NICE website within 15 working days of the Guidance Executive meeting. [Consultees](#) (including appellants) and [commentators](#) are informed of the publication date of the Appeal Panel's decision, sent a copy of the decision and the arrangements for further consideration of the FAD. The appraisal process will resume at an appropriate point as specified in the decision of the Appeal Panel.

4.8 If the Appeal Panel requests that revisions are made to the FAD that do not need further consideration by the Appraisal Committee, the Appeal Panel's decision and the revised final guidance is published on the NICE website within 15 working days of the Guidance Executive meeting. Consultees (including appellants) and commentators are informed of the date of publication, and are sent the Appeal Panel's decision and a copy of the final guidance 2 working days before they are published on the website.

4.9 If the appeal is dismissed and the Appeal Panel has not requested changes to the FAD, the Appeal Panel informs the Guidance Executive of this decision. NICE publishes the Appeal Panel's decision and the final guidance within 10 working days of the Guidance Executive meeting. Consultees (including appellants) and commentators are informed of the

date of publication, and are sent the Appeal Panel's decision and a copy of the final guidance 2 working days before they are published on the website.

**Table 7 Expected steps in the appeals process**

Step 1	Appeal is submitted (15-working-day period)
Step 2	Scrutiny of appeal(s)
Step 3	If necessary, NICE convenes an Appeal Panel
Step 4	NICE notifies appellants and other consultees and commentators of the appeal
Step 5	NICE holds an appeal hearing (oral or written)
Step 6	NICE advises consultees and commentators of the appeal decision
Step 7	NICE publishes the decision on its website

## 5 Patient access schemes and flexible pricing

5.1 The [Pharmaceutical Price Regulation Scheme \(PPRS\) 2014](#) allows companies who are members of the scheme to submit proposals for patient access schemes and flexible pricing proposals as part of an ongoing or published NICE [technology appraisal](#).

### Definitions

5.2 A patient access scheme is a scheme proposed by a [company](#) that is a member of the 2014 PPRS. It is agreed between the [Department of Health](#) (with input from NICE) and the company. Patient access schemes can facilitate patient access to a technology when NICE's assessment of value, on the current [evidence](#) base, is unlikely to support the list price.

5.3 Flexible pricing recognises that the initial launch price of a technology may not fully reflect its longer-term value to patients in the NHS. It therefore allows a company to propose an initial price for a technology that reflects value that can be demonstrated at launch, while retaining the freedom to apply to increase or decrease this original list price either as further evidence or as new [indications](#) emerge and change the effective value that the technology offers to NHS patients.

5.4 NICE can only consider patient access scheme proposals (see figure 5) and flexible pricing proposals (see figure 6) after formal referral by the Department of Health.

### Patient access schemes

5.5 The 2014 PPRS identifies 2 types of patient access scheme (see chapter 5 of the 2014 PPRS for more detail):

- simple discount schemes and
- complex schemes.

5.6 The [Patient Access Scheme Liaison Unit](#) (PASLU) at NICE advises the Department of Health on the feasibility of patient access scheme proposals. When assessing a patient access scheme proposal, the



PASLU considers the key principles for implementing patient access schemes in England as outlined in the 2014 PPRS. The PASLU process is not part of the appraisal process. Changes should not normally be made to a patient access scheme proposal after the Department of Health has referred it to NICE, however, if any changes are proposed, these must be discussed and agreed with the Department.

- 5.7 The [Appraisal Committee](#) considers the effect of the patient access scheme proposal on the clinical and [cost effectiveness](#) of the technology and clarifies relevant points with the company (see [sections 3.3 and 3.5](#)). The ERG or AG assesses the impact of the proposed scheme and submits a report.
- 5.8 The process for reviewing the impact of a patient access scheme proposal on the clinical and cost effectiveness of a technology depends on when the proposal is submitted to NICE. As set out in the 2014 PPRS, when companies wish to propose patient access schemes in the context of a NICE technology appraisal, they should do so either:
- at the outset, when making their initial evidence submission to NICE. This implies that any patient access scheme submission to the Department of Health should precede the evidence submission to NICE or
  - at the end of the appraisal process, once any appeals have been heard and NICE's final guidance has been issued to the NHS, under the rapid review facility.
- 5.9 In exceptional circumstances, a patient access scheme proposal assessed as meeting the simple discount criteria may be accepted at other times in the NICE process, but this would not normally be possible for complex proposals. Appraisal Committee meetings will not be rescheduled to accommodate discussion of a patient access scheme proposal. It is the company's responsibility to ensure that the Department of Health has sufficient time to complete its consideration of the proposed patient access scheme in time for the meeting.

5.10 If the Appraisal Committee recommends a technology after reviewing the impact of an outcomes-based patient access scheme, it is important that the [outcomes](#) of the scheme are formally considered in the future. If the actual outcomes differ sufficiently from those assumed during the original appraisal, NICE may decide to bring forward a review of the recommendations.

### **Patient access scheme proposals submitted during an appraisal**

5.11 When a company submits a patient access scheme proposal with the evidence submission at the outset of an appraisal it is the company's responsibility to ensure that the Department of Health has sufficient time to complete its consideration of the proposed patient access scheme before the first Appraisal Committee meeting. The Appraisal Committee cannot consider a patient access scheme proposal without the formal agreement of the Department of Health.

5.12 If in exceptional circumstances, the company wants to submit a proposal for a simple discount patient access scheme at a different time in the appraisal process, the following conditions apply:

- The company must inform the NICE technology appraisal programme in writing of its intention to submit a patient access scheme proposal, as early as possible.
- The patient access scheme proposal must be submitted to the Department of Health in sufficient time that the Department is able to complete its consideration of the proposed scheme and notify NICE at least 5 working days before the next Committee meeting, to allow sufficient time for the ERG or AG review.
- The company must provide information about the patient access scheme proposal as a separate additional submission to the technology appraisal programme, using the patient access scheme submission template provided by NICE.
- The patient access scheme submission must be submitted to NICE by the ACD [consultation](#) closing date, and if possible earlier.

- 5.13 When a simple discount patient access scheme proposal is submitted after the ACD, NICE may choose to reschedule the subsequent Committee meeting to allow sufficient time to consider and review the proposed scheme. When a simple discount patient access scheme proposal is submitted after the FAD has been released, NICE may hold an additional Committee meeting to allow the Appraisal Committee to consider whether the recommendations should change in light of the patient access scheme proposal.
- 5.14 When the Department of Health refers a simple discount patient access scheme proposal to NICE for consideration after the release of an ACD, the impact of the proposed scheme on the clinical and cost effectiveness of the technology may lead the Appraisal Committee to revise their recommendations. If the technology is recommended, a FAD will be issued for appeal (see [section 3.7.36](#) onwards). Information will be released so that the proposed scheme and its impact on the [clinical effectiveness](#), cost effectiveness and the recommendations can be understood. Subject to any appeal by [consultees](#), the FAD forms the basis of NICE guidance on the technology. In certain circumstances, the [Centre Director](#) or Programme Director and the Chair of the Appraisal Committee may decide that it is necessary to produce another ACD. If so, the consultation process will be repeated. The decision to produce another ACD will extend the timelines for the appraisal.

#### **Patient access schemes submitted after guidance publication**

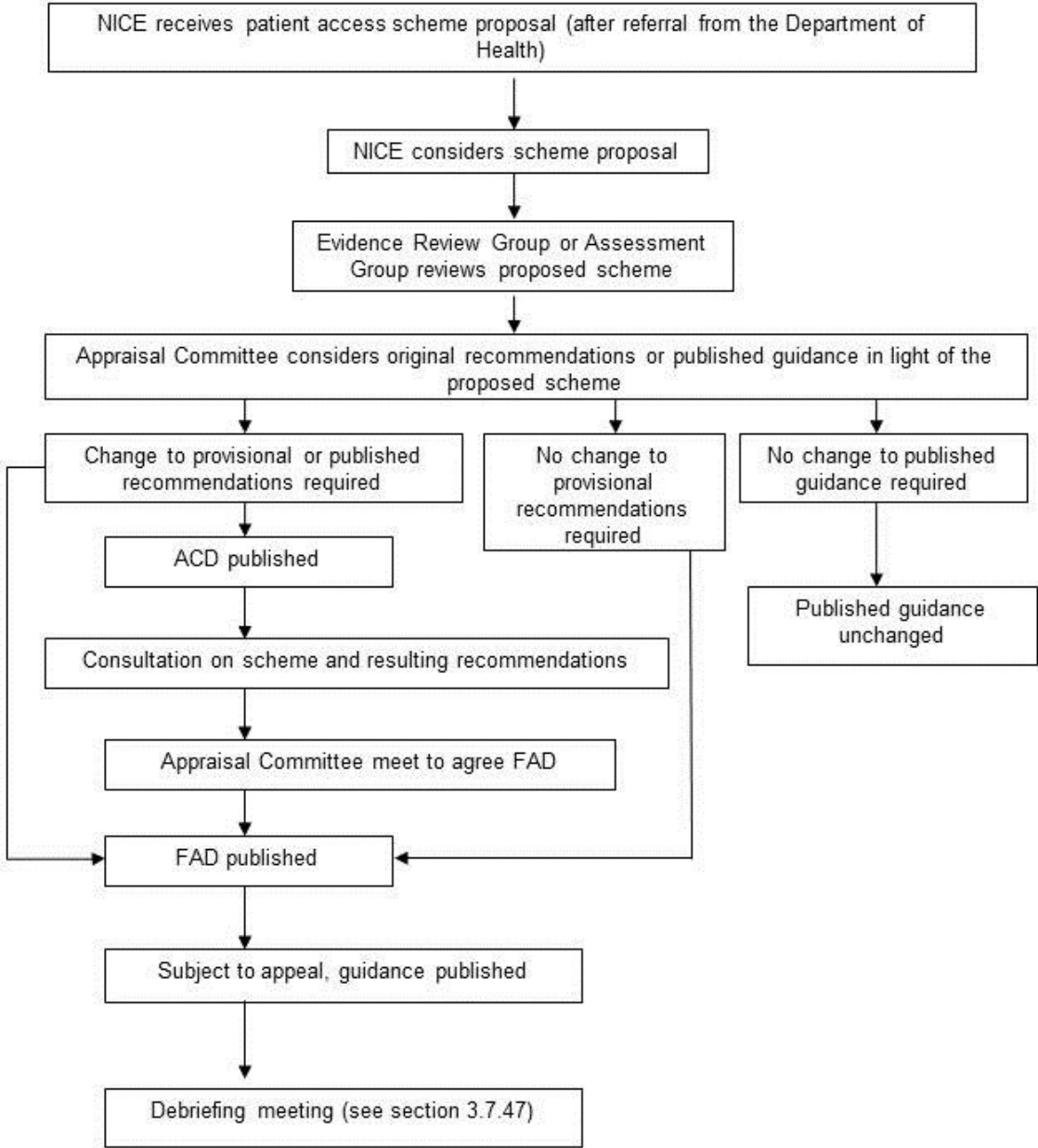
- 5.15 Patient access schemes are designed to maximise the opportunity for cost-effective access to a new technology. Therefore, within 16 weeks of guidance publication, a rapid review facility is available to consider new patient access scheme proposals. NICE can only consider these proposals with the agreement of the Department of Health. After referral by the Department, the rapid review of the guidance is planned, as a priority, into the work programme. The Appraisal Committee will usually consider the proposed scheme within 6 months of its referral.

- 5.16 The rapid review facility will be used for a new patient access scheme proposal only. If the company wishes to submit additional new evidence other than that about a patient access scheme 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 (see [section 6](#)).
- 5.17 The company must use the technology appraisal patient access scheme submission template to provide details of the proposed scheme, a revised [economic model](#) incorporating the patient access scheme proposal, and an updated checklist of confidential information, if necessary. (This is in addition to the information that must be submitted to the Department of Health as part of a submission for a patient access scheme proposal).
- 5.18 Although NICE will include patient access scheme proposals submitted under the rapid review facility on the agenda for the relevant Committee meeting where they are to be considered, NICE makes no public announcement about the specific topics. Scheme proposals submitted through the rapid review facility 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 Appraisal Committee results in a change to guidance recommendations. In this situation, NICE will issue an ACD for consultation (see [section 3.7.21](#) onwards). NICE releases information during the ACD consultation so that the proposed scheme and its impact on the clinical effectiveness, cost effectiveness and the recommendations can be understood.
- 5.19 When a company submits a patient access scheme proposal through the rapid review facility for an MTA, other companies whose products were appraised in the same appraisal also have a single opportunity to propose a scheme.
- 5.20 Appeals following the rapid review of guidance, when consideration of the impact of patient access scheme proposals on current guidance has resulted in a change to the guidance, will only be accepted on points

relating to the new patient access scheme proposal. The Appeal Panel will not consider points previously raised or points that could have been raised at earlier appeals. Subject to any appeal by consultees, the FAD forms the basis of NICE guidance on the use of the technology.

- 5.21 Patient access scheme proposals should be submitted in the context of planned NICE appraisals, within the timings set out above. If, in exceptional circumstances, the Department of Health were to refer a patient access scheme proposal to NICE more than 16 weeks after guidance publication, NICE would consider such a proposal via the standard review process (see [section 6](#)).

**Figure 5 Process for considering a patient access scheme proposal**



**Flexible pricing**

5.22 The 2014 PPRS identifies 2 circumstances in which flexible pricing may be relevant:

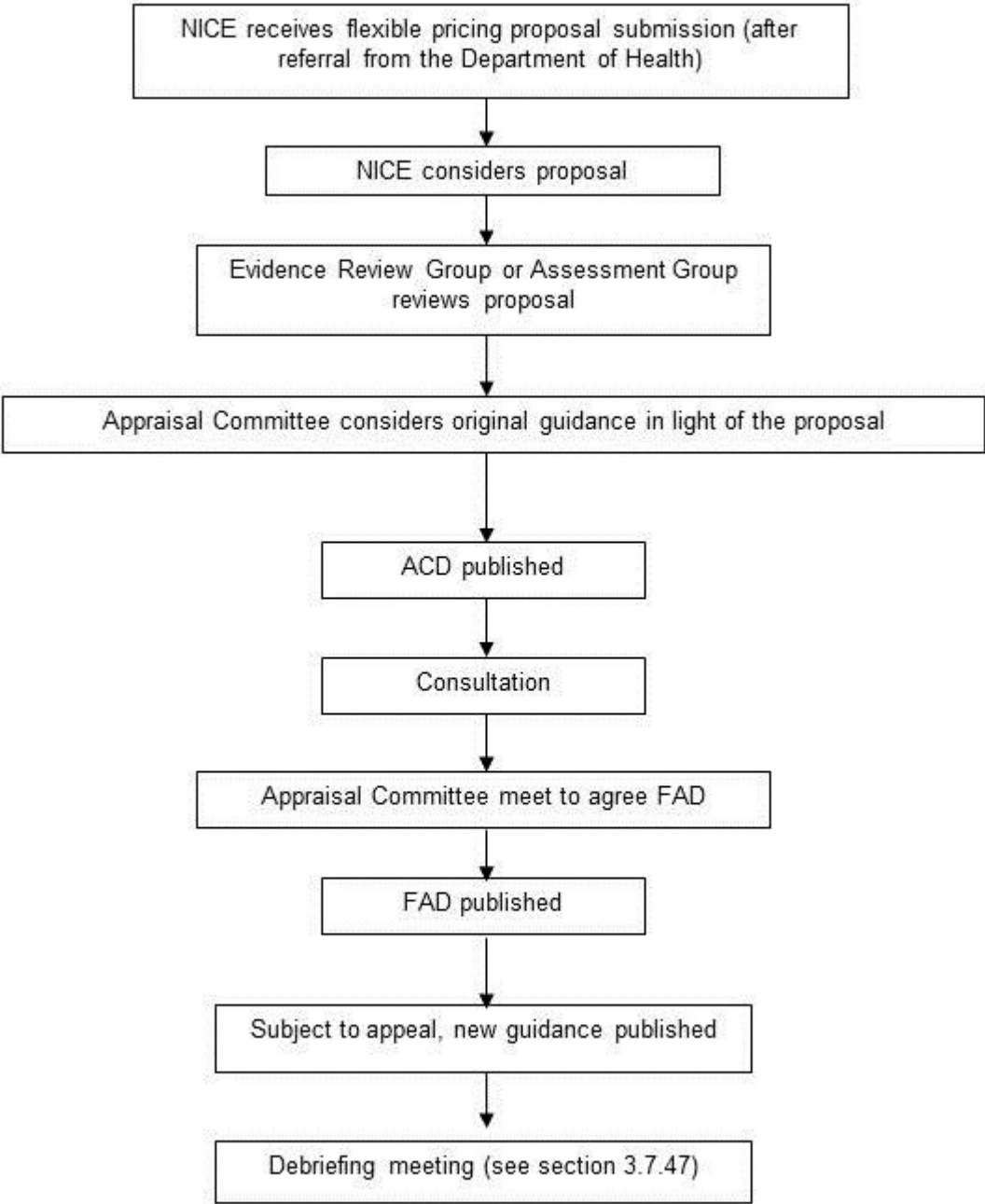
- when significant new evidence is generated that changes the value of an existing indication and
- when a significant new indication is proposed.

- 5.23 Requests to consider a flexible pricing proposal for an existing indication of a technology must be linked to the emergence of new evidence. The company therefore needs time to gather the additional evidence necessary to justify a price change. NICE will consider reviewing the guidance only in the light of significant new evidence that is likely to have an impact on the clinical or cost effectiveness of the technology. This could include: new clinical trial evidence, new evidence on identified subgroups of patients, or significant new evidence supporting additional benefits previously unaccounted for (for example, long-term outcomes). New evidence does not include new analyses of existing data. Flexible pricing proposals that are not supported by new evidence will not be considered.
- 5.24 For technologies launched after 1 January 2009, if NICE receives a flexible pricing proposal for an existing indication within 12 months of guidance publication, NICE will consider the impact of new evidence and the flexible pricing proposal on the clinical and cost effectiveness of the technology. NICE will clarify relevant points with the company before the ERG or AG reviews the proposal. The Appraisal Committee will then consider the proposal together with the independent review from the ERG or AG.
- 5.25 NICE considers flexible pricing proposals for an existing indication submitted more than 12 months after guidance publication via the standard review process (see [section 6](#)).
- 5.26 All flexible pricing proposals for technologies launched before 1 January 2009 are considered via the standard review process (see [section 6](#)).
- 5.27 When the Appraisal Committee considers a flexible pricing proposal for an existing indication, the Committee will review the original guidance in light of the new evidence and the proposed new price. The Committee's assessment of cost effectiveness will be consistent with that used in the original appraisal.

- 5.28 Although NICE includes flexible pricing proposals under consideration on the relevant Committee meeting agenda, NICE makes no public announcement about the specific topics. NICE considers it essential that such proposals can be received and considered in confidence. NICE also understands that companies may suffer commercial and other harm if information on the proposals were to be made public at this point. Therefore, NICE treats all flexible pricing proposals for existing indications as confidential and will not normally release any information about these schemes under the Freedom of Information Act, or for any other purpose at this stage (including during the public part of Appraisal Committee meetings), unless the company has agreed to this.
- 5.29 When the Appraisal Committee has reviewed the existing guidance on the technology in the light of the new evidence and flexible pricing proposal, an ACD will be published for consultation (see [section 3.7.21](#) onwards). Detailed information will be released as part of the ACD consultation so that the proposed new price and its impact on the clinical effectiveness, cost effectiveness and the recommendations can be understood. As with the normal appraisal process, the Appraisal Committee will review consultation responses on the ACD and develop a FAD. NICE will issue the FAD to consultees, along with the consultation response to the ACD, for appeal. Appeals will be accepted only on points relating to the flexible pricing proposal. The Appeal Panel will not consider points previously raised or points that could have been raised at an earlier appeal. Subject to any appeal by consultees, the FAD forms NICE's updated guidance on the use of the technology.
- 5.30 Flexible pricing proposals for new indications of existing technologies are also covered in the 2014 PPRS. New indications are potential new appraisals. Consideration of their suitability for technology appraisal is therefore covered under topic selection (see [section 2](#) onwards).



**Figure 6 Process for considering a flexible pricing proposal**



## 6 Reviews

6.1 When NICE publishes guidance, a suggested time for its review is given. This is the length of time after publication when NICE will consult with relevant organisations on a proposal about whether or not the guidance needs to be updated, and if so, how to update the guidance. The length of

time between guidance publication and review consideration varies depending on the available [evidence](#) for the technology, and knowledge of when ongoing research will be reported.

- 6.2 Guidance may be reviewed before the suggested review time when there is significant new evidence that is likely to change the recommendations. NICE is keen to hear about any new evidence that becomes available before the time of review (please send information to [nice@nice.org.uk](mailto:nice@nice.org.uk)). NICE will assess the likely impact of the new evidence on the recommendations and will propose an update to the published guidance if required. The steps involved are shown in figure 7.
- 6.3 NICE develops the review proposal after gathering relevant information and doing a literature search. NICE identifies new [indications](#) for the appraised technology, searches for new related technologies, assesses the progress of ongoing trials, and gathers new evidence. NICE also asks companies to provide information about the existing [marketing authorisation](#) (or equivalent) or any extensions to the marketing authorisations.
- 6.4 When guidance includes a patient access scheme, the (possible) review provides a useful opportunity to review how the patient access scheme is operating and consider whether it would be appropriate to make any changes to the scheme to simplify and improve its operation. Any changes to a patient access scheme are subject to discussion with, and agreement by, the [Department of Health](#).
- 6.5 NICE's [Guidance Executive](#) uses this information to consider the review proposal and decides if and how the published guidance should be updated.
- 6.6 NICE proposes to update the published guidance if there is new evidence available that is likely to change the existing recommendations. Evidence that may lead to a change in the clinical or [cost effectiveness](#) of the technology, or an extension or revision to the marketing authorisation for

the technology could lead NICE to propose that the guidance should be updated.

6.7 The Guidance Executive decides on one of the following options if the published guidance needs updating:

- Plan an appraisal to update the published guidance.
- Plan an appraisal that combines the published guidance with 1 or more related pieces of published guidance (including [terminated appraisals](#)) or ongoing appraisals.
- Update the published guidance within another guidance-producing centre (for example in a clinical guideline). See [Updating technology appraisals in the context of a clinical guideline](#).

6.8 The Guidance Executive decides on one of the following options if the published guidance does not need updating:

- The guidance is valid and does not need an update because the evidence base is not likely to change substantially. It is therefore designated as static guidance.
- Incorporate the published guidance into guidance from another guidance-producing centre. The [technology appraisal](#) is then designated as static guidance and remains in force.

6.9 When the Guidance Executive has agreed the review proposal, NICE asks [consultees](#) and [commentators](#) to comment on the proposal and to identify any other interested parties that NICE needs to consult with.

6.10 NICE publishes the review proposal, together with the list of consultees and commentators, on its website 5 working days after sending for [consultation](#).

6.11 Consultees and commentators must send comments to NICE within 20 working days of the date of sending for the comments to be considered.

- 6.12 After considering the comments received during consultation, the NICE technology appraisal programme agrees a review decision. If the review decision differs from the original proposal, the Guidance Executive will agree the most appropriate option, taking consultation comments into account.
- 6.13 NICE writes to consultees and commentators informing them of the final decision and attaches a table of responses to the comments on the review proposal for information.
- 6.14 NICE publishes the final decision and the table of comments on its website 5 working days after contacting consultees and commentators.
- 6.15 If guidance needs updating within the appraisal programme, the update is timetabled and it follows either the STA or MTA process. The standard approach will be to update the guidance by the MTA process. The decision is determined by a number of factors, including other relevant technologies or appraisals that may also be considered as part of the update and extensions to the marketing authorisation.
- 6.16 If guidance is designated as static guidance, then NICE considers whether a review is required 5 years after the guidance is added to the static list. This is called a static list review. NICE does a literature search to see if there is any new evidence to update the existing recommendations. If it is decided that the evidence base has changed significantly, then a full review proposal is developed to assess whether an update of the guidance is required.
- 6.17 If a review of the static guidance uncovers no new evidence that is likely to change the existing guidance, it remains on the static list.
- 6.18 NICE notifies consultees and commentators of the outcome of the static list review, and publishes this information on the NICE website 5 working days after sending it to consultees and commentators.

6.19 At any point during the development of a review proposal, NICE may decide that the consideration of a review is not appropriate. This may be because evidence not yet available is considered likely to change the existing recommendations. In this instance, NICE notifies stakeholders of the decision to defer the review proposal. The decision is also published on the NICE website. NICE also identifies the likely time for the next consideration of a review. This is usually within 6 months of the availability of the required evidence.

### **Updating technology appraisals in the context of a clinical guideline**

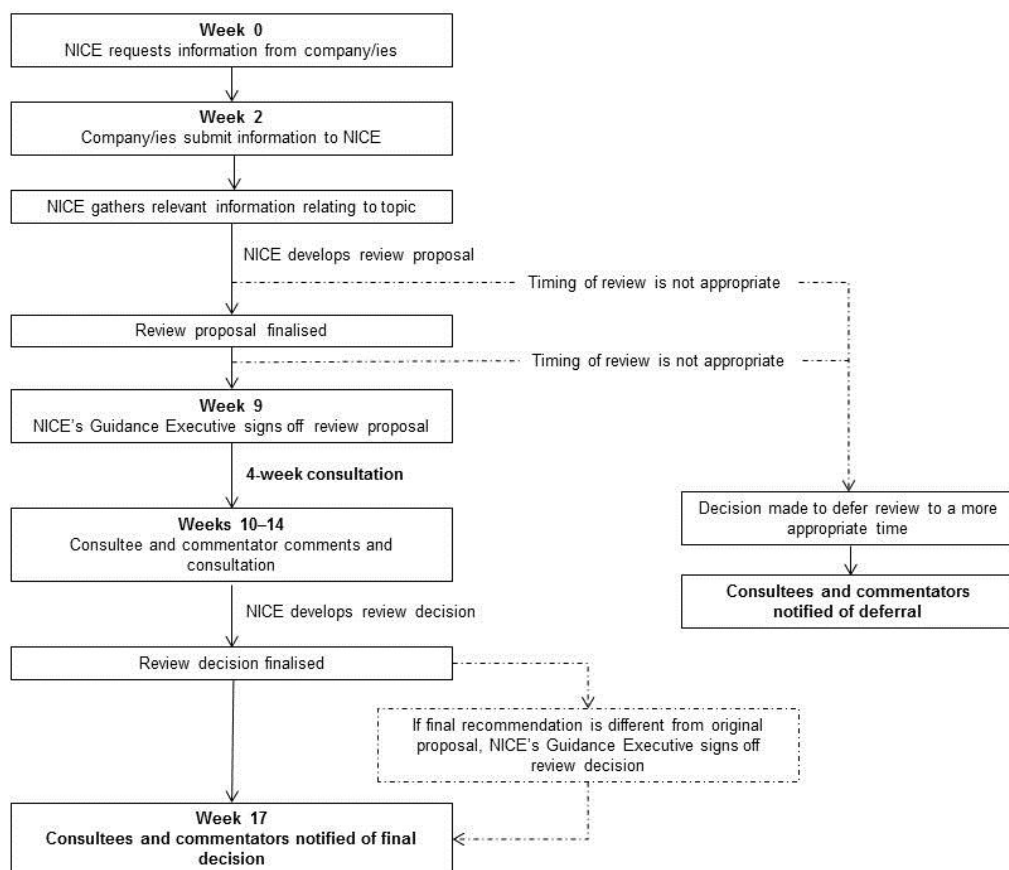
6.20 A technology appraisal is likely to be suitable for updating in the context of a clinical guideline only if all the following conditions are met (see NICE's policy on [updating technology appraisals in clinical guidelines](#)).

- The technology falls within the [scope](#) of the guideline.
- There is no proposed change to an existing patient access scheme or flexible pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement.
- There is no new evidence that is likely to lead to significant changes in the clinical or cost effectiveness of a technology.
- The technology is well established and embedded in the NHS. The following may suggest that it is not well established or embedded:
  - spending on the technology for the indication that was the subject of the appraisal continues to rise
  - there is evidence of unjustified variation across the country in access to the technology
  - there is plausible and verifiable information to suggest that the availability of the technology is likely to be reduced if the funding direction were removed
  - the technology is excluded from the payment by results (PbR) tariff.

- Stakeholder opinion, expressed in response to consultation on a review proposal for the technology appraisal, is broadly supportive of the proposal.

6.21 These criteria relate to technologies covered by an existing technology appraisal. Clinical guidelines will only be used to carry out a first assessment of a significant new technology or significant marketing authorisation extension for an existing technology when it has been agreed by both the Department of Health and the [company](#) that this is appropriate.

**Figure 7 Summary of the review proposal process**



## 7 Further information

### 7.1 *Steering Group and Process Review Group*

A Steering Group and Process Review Group, as set out below, developed this document.

## **Steering Group**

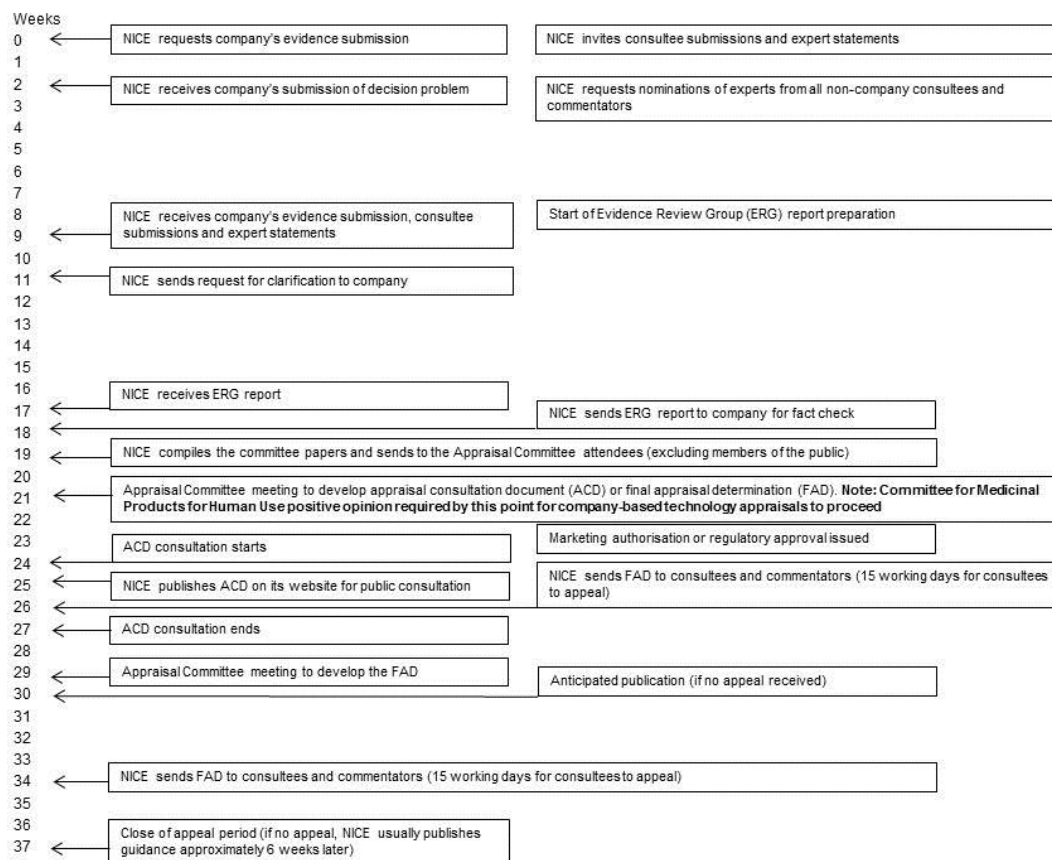
Carole Longson (Chair)	Centre Director, Centre for Health Technology Evaluation (CHTE), NICE
Meindert Boysen (Vice chair)	Programme Director, CHTE, NICE
Jennifer Prescott	Associate Director, CHTE, NICE
Nina Pinwill	Associate Director, CHTE, NICE
Sarah Cumbers	Associate Director, Centre for Clinical Practice (CCP), NICE
Andrew Stevens	Chair, Appraisal Committee
Jane Adam	Chair, Appraisal Committee

## **Process Review Group**

Meindert Boysen (Chair)	Programme Director, CHTE, NICE
Jennifer Prescott (Vice chair)	Associate Director, CHTE, NICE
Elisabeth George	Associate Director, CHTE, NICE
Janet Robertson	Associate Director, CHTE, NICE
Frances Sutcliffe	Associate Director, CHTE, NICE
Helen Knight	Associate Director, CHTE, NICE
Jeremy Powell	Project Manager, CHTE, NICE
Lori Farrar	Project Manager, CHTE, NICE
Bijal Joshi	Project Manager, CHTE, NICE
Kate Moore	Project Manager, CHTE, NICE
Andrew Kenyon	Project Manager, CHTE, NICE

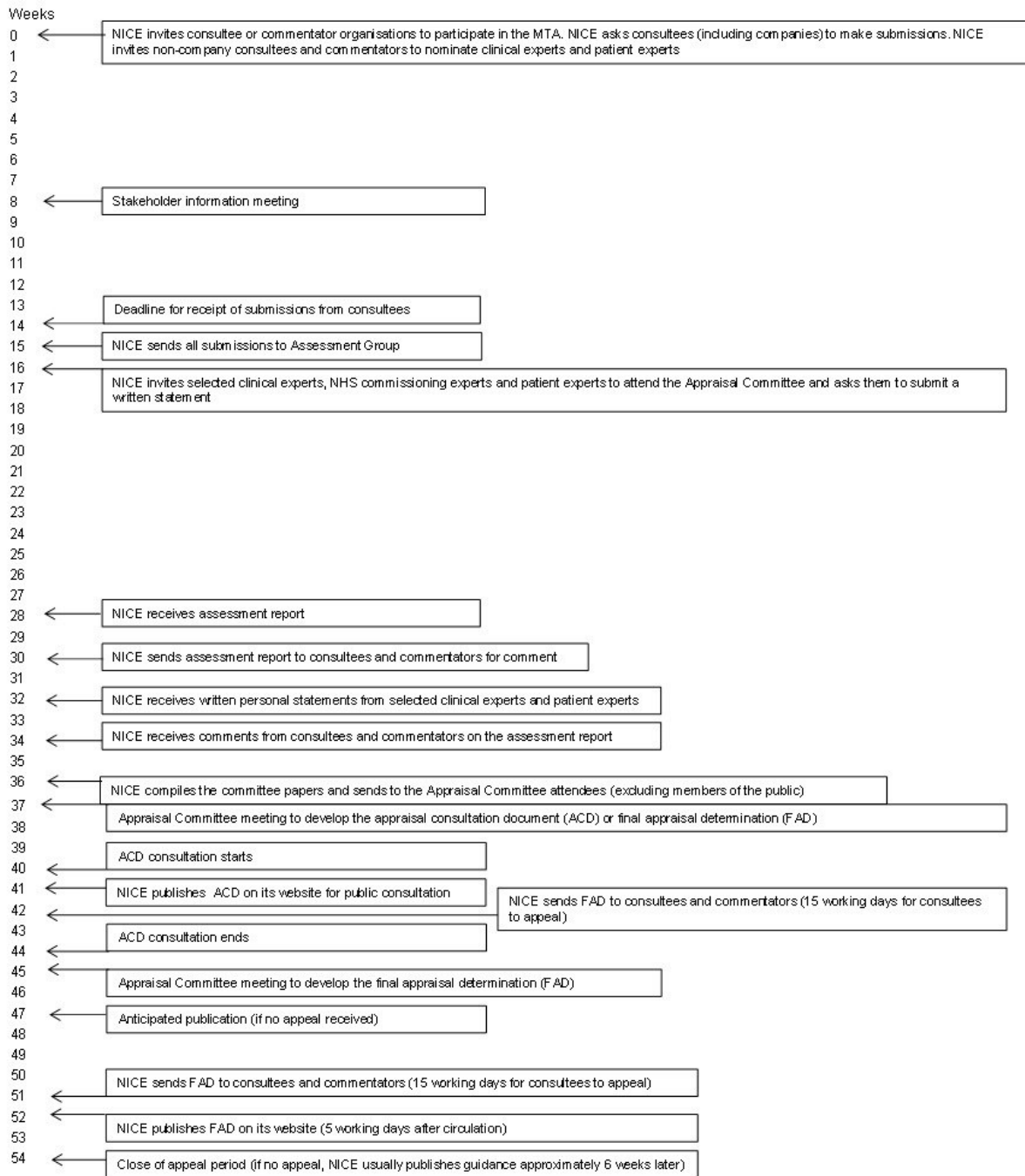
Michelle Adhemar	Project Manager, CHTE, NICE
Ben Hendry	Project Manager, CHTE, NICE
Lynn Woodward	Project Manager, CHTE, NICE
Nicole Fisher	Project Manager, CHTE, NICE
Bruce Smith	Administrator, CHTE, NICE
Joanna Richardson	Technical Adviser, CHTE, NICE
Melinda Goodall	Technical Adviser, CHTE, NICE
Heidi Livingstone	Public Involvement Adviser, Public Involvement Programme (PIP), NICE

## 7.2 STA process timelines





## 7.3 MTA process timelines



# Glossary

## **Abstract**

A summary of a study, which may be published alone or as an introduction to a full scientific paper.

## **Academic in confidence**

See 'In confidence material'.

## **Appraisal**

See [Technology appraisal](#) (single and multiple).

## **Appraisal Committee**

A standing advisory committee of the Institute. Includes people who work in the NHS, people representing patient and [carer](#) organisations, [lay members](#), people from relevant academic disciplines and the pharmaceutical and medical device industries.

## **Appraisal consultation document (ACD)**

Sets out the [Appraisal Committee](#)'s preliminary recommendations to NICE.

## **Assessment Group**

An independent assessment group commissioned by the NHS Research and Development Health Technology Assessment (HTA) programme to produce an independent review of the [evidence](#) for technologies being appraised within the multiple [technology appraisal](#) (MTA) process.

## **Assessment protocol**

The assessment protocol is derived from the [scope](#) of the appraisal, taking into account [consultation](#) responses to the draft scope and comments from organisations attending the scoping workshop. It forms the basis of the assessment report during an appraisal following the MTA process.

## **Assessment report**

A critical review of the clinical and [cost effectiveness](#) of a [health technology](#) or technologies being appraised within the multiple [technology appraisal](#) (MTA) process. It is prepared by the [Assessment Group](#). To prepare the report, the Assessment Group carries out a review of the published literature and the submissions from companies.

## **Carer**

In this guide the term 'carer' refers to a person who provides unpaid care by looking after a relative, friend or partner who needs support because of ill health, frailty or disability.

## **CE mark(ing)**

The CE mark is a mandatory conformity mark on medical device products placed on the single market in the European Economic Area. The CE mark certifies that a product has met EU consumer safety, health or environmental requirements.

## **Centre Director**

The Director of the Centre for Health Technology Evaluation is responsible for the delivery of the [technology appraisal](#) programme. The Director is also responsible for ensuring that appraisals are conducted in accordance with the published appraisal process and methodology.

## **Clinical effectiveness**

The extent to which an intervention produces an overall health benefit, taking into account beneficial and adverse effects, in routine clinical practice. It is not the same as efficacy.

## **Clinical expert**

In [technology appraisals](#), clinical experts act as expert witnesses to the [Appraisal Committee](#). They are selected on the basis of specialist expertise and personal knowledge of the technology and/or other treatments for the condition. They provide a view of the technology within current clinical practice, and insights not typically available in the published literature.

## **Commentator**

An organisation that engages in the appraisal process but is not asked to prepare a submission dossier. Commentators are invited to comment on the draft [scope](#) document, the [assessment report](#) and the [appraisal consultation document](#) (ACD). They receive the [final appraisal determination](#) (FAD) for information only. These organisations are relevant [comparator](#) technology companies, Healthcare Improvement Scotland, the relevant National Collaborating Centre, related research groups, and other groups when appropriate.

## **Commercial in confidence**

See 'In confidence material'.

## **Committee papers**

The committee papers that are issued and published with an ACD or a FAD include all of the [evidence](#) seen by the [Appraisal Committee](#). It is made up of the ERG report, written submissions, and the personal statements of [patient experts](#) and [clinical experts](#), as well as comments received on the ERG report. For second and subsequent committee meetings they will also include [consultation](#) comments and responses.

## **Company**

The company that manufactures or sponsors either the technology being appraised, or the [comparator](#) technology.

## **Comparator**

The standard intervention against which the intervention under appraisal is compared. The comparator can be no intervention, for example best supportive care.

## **CONSORT statement (consolidated reporting of clinical trials)**

Recommendations for improving the reporting of randomised controlled trials in journals. A flow diagram and checklist allow readers to understand how to conduct a study and assess the validity of the results.

## **Consultation**

The process that allows stakeholders and individuals to comment on draft versions of NICE guidance and other documents (for example, the draft [scope](#)) so that their views can be taken into account when the final version is being produced.

## **Consultee**

An organisation that participates in the appraisal of a technology. Consultees can comment on the draft [scope](#), the [Assessment Report](#) and the [appraisal consultation document](#) (ACD) during the [consultation](#) process. Consultee organisations can nominate [clinical experts](#), commissioning experts and patient experts to present their personal views to the [Appraisal Committee](#). All consultees are given the opportunity to appeal against the [final appraisal determination](#) (FAD).

## **Cost effectiveness**

How well a technology works in relation to how much it costs.

## **Decision problem**

A clear description of the interventions, patient populations, outcome measures and perspective adopted in a [health technology](#) evaluation, relating specifically to the decision(s) that the evaluation is designed to inform.

## **Decision Support Unit**

The Decision Support Unit helps the technical team at NICE to meet the information needs of the [Appraisal Committee](#). This is achieved by providing support, as required, to the technical team and the [Evidence Review Group](#) or Assessment Group. The objective of the Decision Support Unit is to enhance the delivery of robust information to support Appraisal Committee decision-making. The Decision Support Unit is a multidisciplinary team, expert in methods of [health technology](#) assessment and capable of providing advice and high-quality analyses to decision-makers within very tight deadlines.

## **Department of Health**

The Department of Health is responsible for standards of healthcare in the UK, including the NHS. The Department sets the strategic framework for adult social care and influences local authority spending on social care. The Department is also

responsible for promoting and protecting the public's health, taking the lead on issues like environmental hazards to health, infectious diseases, health promotion and education, the safety of medicines, and ethical issues.

### **Economic model**

An explicit mathematical framework that is used to represent clinical [decision problems](#). It incorporates [evidence](#) from a variety of sources so that the costs and health outcomes can be estimated.

### **European Medicines Agency (EMA)**

A decentralised agency of the European Union responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.

### **Evidence**

Information on which a decision or guidance is based. Evidence is obtained from a range of sources, including randomised controlled trials, observational studies and expert opinion (of clinical professionals and/or patients/[carers](#)).

### **Evidence Review Group (ERG)**

An independent assessment group commissioned by the NHS Research and Development Health Technology Assessment (HTA) programme to produce an independent assessment of the evidence submitted by the [company](#) with a technology being appraised within the single [technology appraisal](#) (STA) process.

### **Final appraisal determination (FAD)**

The FAD sets out the [Appraisal Committee](#)'s final recommendations to NICE on how the technology should be used in the NHS in England.

### **Guidance Executive**

A team comprising the Executive Directors and [Centre Directors](#) at NICE who are responsible for approving the final appraisal determination before publication.

### **Health-related quality of life**

A combination of a person's physical, mental and social wellbeing.

## **Health technology**

Any method used by those working in health services to promote health, prevent and treat disease, and improve rehabilitation and long-term care. Technologies in this context are not confined to new drugs or medical technologies.

## **In confidence material**

Information (for example, the findings of a research project) defined as 'confidential' because its public disclosure could have an impact on the commercial interests of a particular company or the academic interests of a research or professional organisation, or the policy interests of government.

## **Incremental cost-effectiveness ratio (ICER)**

The ratio of the difference in the mean costs of a technology compared with the next best alternative to the differences in the mean outcomes.

## **Indication**

The defined use of a technology as licensed by the [Medicines and Healthcare Products Regulatory Agency](#) (MHRA) or the European Commission.

## **Lay member**

A lay member is a committee member with a patient, service user, [carer](#) or community background. The lay member's role is the same as other committee members, and additionally includes contributing a lay perspective and highlighting patient and carer issues.

## **Lead team**

The lead team consists of 3 committee members; 1 who focuses on [cost effectiveness](#); 1 on clinical [evidence](#) and 1 on patient and [carer](#) evidence (called the lay lead).

## **Marketing authorisation**

An authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA) or European Commission to market a medicinal product.

## **Medicines and Healthcare Products Regulatory Agency (MHRA)**

The Executive Agency of the [Department of Health](#). It protects and promotes public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

## **National Institute for Health Research – Health Technology Assessment programme**

The National Institute for Health Research – Health Technology Assessment (NIHR HTA) is part of the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton. The NIHR HTA coordinates the Health Technology Assessment (HTA) programme on behalf of the NIHR. The aim of the HTA programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way.

## **Outcome**

A measure of the possible results of a treatment with a preventive or therapeutic intervention. Outcome measures can be either intermediate or final end points.

## **Patient Access Scheme Liaison Unit**

The Patient Access Scheme Liaison Unit (PASLU) at NICE advises the [Department of Health](#) on the feasibility of patient access scheme proposals. When assessing a patient access scheme proposal, the PASLU considers the key principles for implementing patient access schemes in England and Wales as outlined in the 2014 Pharmaceutical Price Regulation Scheme.

## **Patient expert**

Acts as an expert witness to the [Appraisal Committee](#). Patient experts have used the technology either personally or as part of a representative group. Patient experts attend as individuals; they may be either somebody with personal experience of the condition, and if possible the technology, or a member of a patient and [carer](#) organisation for the condition being appraised.



## **Pharmaceutical Price Regulation Scheme (PPRS)**

The 2014 PPRS is a non-contractual voluntary scheme. The parties to this agreement are the Department of Health and the Association of the British Pharmaceutical Industry (ABPI – the trade association for more than 90 companies in the UK producing prescription medicines for human use). The scheme aims to ensure that safe and effective medicines are available on reasonable terms to the NHS.

## **Public involvement programme (PIP)**

The PIP is the team at NICE that supports and develops public involvement across NICE's work programme. A PIP Public Involvement Adviser is assigned to each appraisal and supports patient and [carer consultee](#) organisations, their representatives, and individual patients or carers throughout the appraisal. The PIP public involvement adviser also supports the [lay members](#) of the [Appraisal Committees](#) and supplies the patient and carer group information for the 'Information for the public'.

## **Redacted**

If documents contain confidential information, it must be redacted, that is, [academic in confidence and commercial in confidence](#) information should be replaced with asterisks and then highlighted in black.

## **Remit**

This is the brief the Department of Health gives to NICE when it formally refers a technology for appraisal. Typically, the remit outlines the disease, the patients and the technologies that will be covered by the appraisal.

## **Scope**

Provides a detailed framework for the appraisal and defines the disease, the patients and the technologies that will be covered by the appraisal. The questions the appraisal aims to address are also part of the scope.

## **Systematic review**

Research that summarises the [evidence](#) on a clearly formulated question according to a predefined protocol. Systematic and explicit methods to identify, select and

appraise relevant studies, and to extract, collate and report their findings are used. Statistical meta-analysis may or may not be used.

### **Technology appraisal (single and multiple)**

The process of developing recommendations on the use of new and existing health technologies within the NHS in England. A multiple technology appraisal will normally cover more than 1 technology, or 1 technology for more than 1 [indication](#). A single technology appraisal covers a single technology for a single indication.

### **Technology assessment**

The process of evaluating the clinical, economic and other [evidence](#) about the use of a technology and to formulate guidance on its use.

### **Terminated appraisal**

The single technology appraisal process relies on companies submitting [evidence](#), in line with NICE's specification. Occasionally, they do not make a submission or the submission does not meet the specification. The appraisal is therefore terminated and NICE asks NHS organisations to take into account the reasons why the company did not make an evidence submission when making local decisions on whether to offer the treatment.

## **About this document**

This document is one of a series describing the processes and methods that NICE uses to carry out technology appraisals. For further information, please go to [www.nice.org.uk](http://www.nice.org.uk)

Nothing in this document shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

### **Copyright**

© National Institute for Health and Care Excellence 2014. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-0701-4