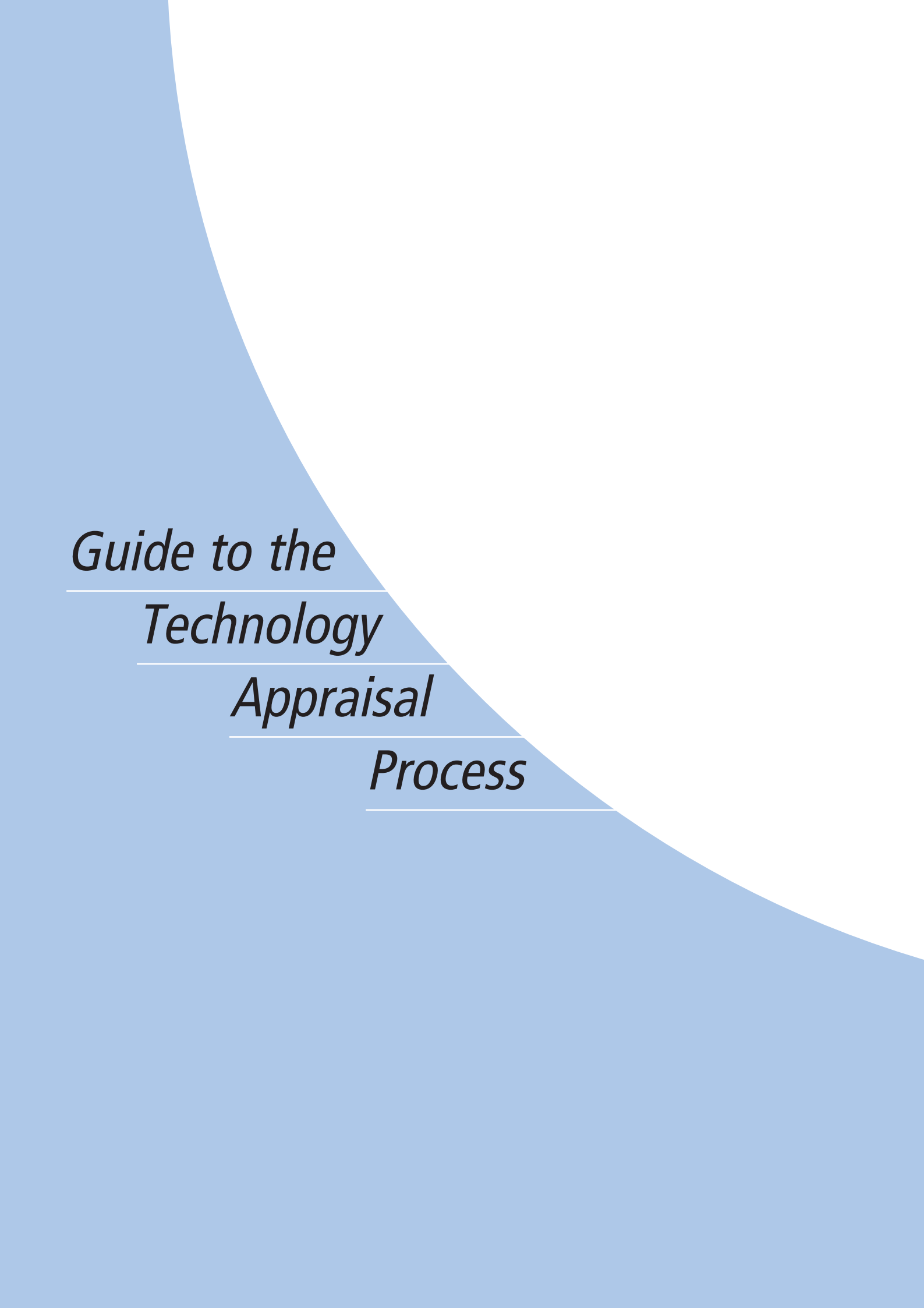




*National Institute for  
Clinical Excellence*

*Guide to the  
Technology  
Appraisal  
Process*



*Guide to the*  

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*Technology*  

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*Appraisal*  

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## Guide to the Technology Appraisal Process

Issue date: June 2001

### About the technology appraisal series

This document is one of a set of five, which describe the process the Institute uses to undertake technology appraisals and provide guidance to the organisations invited to contribute to these appraisals.

When a submission to the Institute is being considered or prepared, the statement of process should be read in conjunction with the guidance documents referred to below. All five documents are available on the Institute's website: [www.nice.org.uk](http://www.nice.org.uk)

**Note:** Documents 1, 2 and 5 replace the Institute's publication entitled *Appraisal of New and Existing Technologies: Interim Guidance for Manufacturers And Sponsors December 1999*.

### Ordering information

These publications can be ordered by telephoning the NHS Response Line on 0870 1555 455 and quoting the relevant reference number below. The price is £10.50 each with a 10% discount for orders between 5 and 50. Discounts for orders over 50 by application to NICE. The five technology appraisal documents are:

Title	Ref. No.
1. Guide to the Technology Appraisal Process	N0010
2. Guidance for Appellants	N0011
3. Guidance for Patient/Carer Groups	N0012
4. Guidance for Healthcare Professional Groups	N0013
5. Guidance for Manufacturers and Sponsors	N0014

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# Guide to the Technology Appraisal Process

## Part I: Introduction and background to the appraisal process

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- a) This document sets out the process, including approximate timescales, that the National Institute for Clinical Excellence (the Institute) follows in undertaking technology appraisals.
- b) This document should be read, where relevant, in conjunction with the related documents that set out guidance for manufacturers and sponsors, patients and carers, and professional groups on submitting evidence to an individual appraisal. These documents are available in PDF format on the Institute's website: [www.nice.org.uk](http://www.nice.org.uk).
- c) The arrangements for selecting technologies for the appraisal programme are outlined in section 3 below but are not set out in detail in this document. Topic selection is undertaken by Ministers responsible for the health service in England and in Wales. Although it is not one of the Institute's functions, the Institute's staff are involved in the arrangements for advising Ministers on topics for referral.

### 1. Introduction

- a) The Institute provides guidance to the National Health Service (NHS) on the use of selected new and established health technologies<sup>1,2</sup>. The guidance is based on an appraisal of those technologies.
- b) The Department of Health (DH) and the National Assembly for Wales (NAW) decide when guidance is needed in relation to a health technology and refer that technology to the Institute for appraisal. The types of technology referred will include the following:
- pharmaceuticals
  - medical devices
  - diagnostic techniques
  - surgical procedures
  - other therapeutic interventions
  - health promotion
- c) The nature of the appraisal carried out by the Institute is as described in the Secretary of State's and the National Assembly for Wales' Directions<sup>3</sup>.  
*"to appraise the clinical benefits and the costs of those interventions notified by the Secretary of State and the National Assembly for Wales and to make recommendations".*

### 2. Background and general principles of the appraisal process

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1 Department of Health. A First Class Service: Quality in the new NHS. Leeds; 1998  
2 Department of Health. Faster Access to Modern Treatment: How NICE Appraisal will Work. Leeds; 1999  
3 National Institute for Clinical Excellence. Framework Document. London; 2000

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This means that the Institute assesses the evidence of all the clinical benefits of an intervention (referred to in this document as a health technology) in the broadest sense. This will include the impact on the quality of life (e.g. relief of pain and disability) as well as likely effects on mortality, and estimates of the associated costs. Evidence is derived from a systematic review and from information provided by the consultees to the appraisal process.

- d) In light of the evidence before it, the Institute's Appraisal Committee (a statutory committee, the membership of which is published on the Institute's website) will reach a judgment as to whether, on balance, the intervention can be recommended as a cost-effective use of NHS resources in general, or for specific indications, or for defined subgroups of patients. Where there is already an intervention for a condition the Appraisal Committee will, as appropriate, estimate the net impact on both costs and benefits of any new intervention under consideration. This judgment is referred to as the appraisal determination, and once the appraisal process is complete (including any appeal) the determination is submitted to the Institute. This determination is then used by the Institute as the basis of its guidance to the NHS in England and Wales.
- e) In reaching its judgment the Institute will have regard to the factors listed in the Secretary of State and National Assembly for Wales' Directions, namely:
- the Secretary of State's and the National Assembly for Wales' broad clinical priorities (as set out for instance in National Priorities Guidance and in National Service Frameworks, or any specific guidance on individual referrals);
  - the degree of clinical need of the patients with the condition under consideration;
  - the broad balance of benefits and costs;
  - any guidance from the Secretary of State and the National Assembly for Wales on the resources likely to be available and on such other matters as they may think fit;
  - the effective use of available resources.
- f) A further factor, which the Institute will take into account in its appraisal, is the wish to be sympathetic to the longer-term interests of the NHS in encouraging innovation of good value to patients.

### 3. Selection of technologies for appraisal

a) The DH and the NAW will select technologies for appraisal based on the following criteria:

- 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 (e.g. reduction in health inequalities)?
- Is the technology likely to have a significant impact on NHS resources (financial or other) if given to all patients for whom it is indicated?
- Is the Institute likely to be able to add value by issuing national guidance? For instance, in the absence of such guidance is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost effectiveness?

b) Before deciding whether to refer a particular health technology to the Institute the DH and NAW consults with relevant patient bodies, professional bodies and manufacturers and sponsors of the technologies in question.

c) Until a technology, or set of technologies, is formally referred to the Institute by the DH or NAW, the Institute cannot commence the appraisal process described below. The Institute will not comment on speculation about possible referrals to NICE.

Further information about the process for selecting technologies for referral to the Institute can be obtained from *Dr Nick Clarke, MPI Division, Department of Health, Quarry House, Quarry Hill, Leeds, LS2 7UE.*

### 4. Confidentiality in the appraisal process

a) The following documents will be released to consultees during the appraisal process:

- Appraisal scope;
- Assessment protocol;
- Assessment report (material provided as 'commercial in confidence' having been removed);
- Evaluation report and any supplement(s) to it ('commercial in confidence' data having been removed);
- Appraisal Consultation Document (ACD);
- Final Appraisal Determination (FAD).

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The ACDs and FADs are not regarded as confidential documents. They will be posted on the Institute's website five working days after they have been sent to consultees.

- b) Other than the ACDs and the FAD, information and documents submitted to or generated by the Institute in the course of its appraisal process are subject to the following policy on confidentiality:
- i) The Institute will not comment on the content of an appraisal until the process has been completed and its guidance has been produced, other than in the circumstances set out in paragraph (ii) below.
  - ii) The Institute reserves the right to comment on an appraisal before the appraisal process has been completed in the event that confidential appraisal documentation is released without the Institute's permission. The decision to make such a comment will be taken by the Chairman or Vice-Chairman of the Institute on the recommendation of two executive directors. Consultees will be informed of this decision as soon as practicably possible.
  - iii) Organisations invited to make submissions to an appraisal ('consultees', see further below) will be required to sign a confidentiality agreement before they will be recognised as consultees and appraisal documentation released to them.
  - iv) Appraisal documents released to consultees by the Institute must be kept securely at all times. The Institute considers that those within the consultees' organisation who see appraisal documentation are bound by the terms of the confidentiality agreement signed by the consultee organisation.
  - v) Consultees may release the appraisal documentation to third parties where:
    - this is clearly necessary to enable the consultee to formulate its contribution to the appraisal; and
    - the third party has seen and agreed to be bound by the terms of the confidentiality agreement.Any organisation or individual not in the direct employment of the consultee organisation is a third party.
  - vi) Consultees may discuss confidential appraisal documentation with other consultees, but before doing so each consultee must satisfy itself that the other has signed and returned their confidentiality agreement to the Institute.

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- vii) Where information submitted to the Institute is designated by a consultee as being 'commercial in confidence', the Institute undertakes not to release this information to a third party. However, the Institute may ask the consultee to forego such restrictions on release where either:
- there appears to be no obvious commercial reason for the restrictions;
  - or
  - such restrictions would make it difficult or impossible for the Institute to show the evidential basis for its guidance.
- viii) The Institute reserves the right to use in its evaluation report, appraisal documents and appraisal determinations any material which is submitted to it during the course of an appraisal which is not designated by the consultee as being "commercial in confidence" or which ceases to be so designated under paragraph (vii) above. However the Institute will not release to a third party any documents received by it from consultees, including submissions, correspondence, responses to formal consultation and statements of appeal against the FAD, unless the originator of the documents consents to the release.
- ix) In the event of an appeal, the names of the appellant(s) will not be released by the Institute, except to other appellants, until the decision of the appeal has been published.

Each appraisal of a technology is assigned to a technical and to an executive lead within the Institute. The technical lead is a member of the Institute's staff who will have responsibility for co-ordinating the technical aspects of the appraisal. The executive lead is a director of the Institute who will have responsibility for piloting the appraisal through its various stages, including the Appraisal Committee.

## 5. Administration of the appraisal within the Institute

## Part II: The appraisal process

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This part of the document sets out the process carried out by the Institute under seven headings:

- The timing of the process (section 6)
- Commencing the appraisal process and scoping (section 7)
- Assessment (section 8)
- Appraisal (section 9)
- Appeal (section 10)
- Publication (section 11)
- Review and updating (section 12)

These sections describe the steps taken at each stage in the appraisal process. Each of these sections contains a corresponding table, which summarises the steps in the process and the approximate timing of the steps.

### 6. The timing of the process

It is not possible to set fixed timescales for the process as the length of time needed for each stage may vary with the nature of the particular appraisal and the position of particular consultees. The figures in the tables in this document and in the complete appraisal timeline that are set out at appendix A are estimates of the number of weeks which will elapse in an average appraisal between the start of the process (when the Institute initiates the appraisal) and that particular step. However certain time limits and consultation periods are referred to in the tables as “fixed”, indicating that they will not be adjusted and will be the same in every appraisal, save in exceptional circumstances.

### 7. Scoping and commencing the appraisal process

- a) When the DH and NAW refer one or more technologies to the Institute under the process described in section 3 above, the Institute has two initial tasks.
- b) First, the Institute must identify the manufacturer(s) or sponsor(s), national professional organisations and national patient organisations whom it is appropriate for them to consult in making its appraisal. Together with the DH and the NAW, the Health Technology Board for Scotland and two health authorities, these bodies are the ‘consultees’. The Health Technology Board for Scotland and the two health authorities will not however have appeal rights.
- c) Second, the Institute has to undertake the scoping process, which sets the parameters of its appraisal. The DH and NAW provide the Institute with a remit for the appraisal. In addition, the Institute will identify the questions which need to be asked about each technology. These questions will focus and steer the appraisal process.

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- d) The first step in the scoping process is a search of the literature relating to the technology which will be undertaken by the Institute's information specialist. The information specialist then works with the relevant technical lead to prepare a draft scope. This draft is sent to all appraisal consultees, relevant NHS disease area National Directors (also known as Czars) and the group producing the assessment report. Comments on the draft scope should be submitted within 10 working days to the Institute, which will then produce the final scope of the appraisal. A list of the consultees to the appraisal will be sent with the scope.
- e) The professional and patient body consultees are asked to nominate experts to attend the first meeting of the Appraisal Committee.
- f) The final scope will be available on the Institute's website around 8 weeks after the referral from the DH/NAW, together with the names of the Institute's technical and executive leads for the appraisal, the assessment group and the list of consultees to the appraisal.
- g) The scope of an appraisal will usually define a number of distinct elements including:
- the patient population involved and any relevant sub-groups;
  - the interventions being examined;
  - the comparisons being made with the referred technology;
  - the relevant outcomes for determining the effectiveness of the technology.
- h) It should be noted that appraisals will not normally include consideration of either off-label prescribing of the technology in question or use of the technology for indications for which it has not been licensed unless the DH/NAW indicates that such consideration is appropriate, in its remit.

Scoping and commencing the appraisal process		Weeks (approx) since process commenced
<b>Step 1</b>	Institute initiates appraisal	0
<b>Step 2</b>	Identification by Institute of consultees	2
<b>Step 3</b>	Literature search and preparation of draft scope	4
<b>Step 4</b>	Fixed two week consultation period on draft scope and timescales for appraisal process, accompanied by a list of consultees to appraisal	4-6
<b>Step 5</b>	Patient body and professional body consultees invited to nominate experts to attend first Appraisal Committee meeting (see further below)	4-7
<b>Step 6</b>	Final scope and timeline produced	7
<b>Step 7</b>	Final scope and list of consultees posted on Institute's website	8

## 8. Assessment

- a) Once the scope of the appraisal has been defined, the next stage (from step 8) of the process is the assessment of the technology. The purpose of the assessment is to bring together the evidence that will be used by the Appraisal Committee in formulating its advice on the technology.
- b) The Institute will then normally commission an assessment report, which is a critical review of the clinical and cost effectiveness of the technology(ies). It will draw, as appropriate, on the submissions from manufacturers or sponsors. The extent to which a manufacturer/sponsor submission is used by the assessment group will depend on whether the data submitted fits with the inclusion and exclusion criteria established in the protocol prepared by the group. This protocol will be available at the initial meeting with consultees. It does not reach any conclusion on the appropriate use of the technology for the NHS. Normally the report will be commissioned by the NHS Co-ordinating Centre for Health Technology Assessment on behalf of the Institute from one of a number of academic centres. Occasionally other sources may be used to provide the assessment report. The body producing the assessment report is referred to in this document as the 'assessment group'. The assessment report is the responsibility of its authors. The Institute is responsible for the guidance document which is derived from it. A version of the assessment report used by the Appraisal Committee to inform its consideration of the technology will be posted on the Institute's website. Any 'commercial in confidence' material will have been removed. The final version of the assessment report will normally appear as part of the NHS Health Technology Assessment Programme Monograph Series.

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- c) All consultees are invited to make submissions to the Institute. They will have not less than 16 weeks to prepare these submissions, which are then available to the assessment group to inform the preparation of the assessment report. All consultees making a submission, must include with their submission (if longer than 10 pages) an executive summary of no more than 3 sides of A4.
- d) During this period all consultees will also be invited as a group to a meeting with the Institute's executive and technical leads and representatives from the assessment group. The purpose of this meeting is to explain the appraisal process and to explore technical aspects of the appraisal. If manufacturer or sponsor consultees wish to discuss 'commercial in confidence' matters at this meeting then the Institute will consider holding a separate meeting with that consultee for the purposes of that confidential discussion.
- e) The Institute prefers that communications with it and with the assessment groups be via e-mail or fax.
- f) The Institute will not review or approve submissions during their preparation. Consultees preparing submissions may contact the assessment group and vice versa, in order to make and respond to technical enquiries. The Institute will be advised, by the assessment group, of the nature of these exchanges.
- g) When the assessment group has produced the assessment report, the Institute will send it for comment to consultees. Any commercial in confidence material will have been removed. Consultees will have 10 working days to comment on the report. The comments received will be put to the Appraisal Committee in the evaluation report (comprising of the assessment report, the full submissions from the professional and patient body consultees, and the executive summaries of the manufacturer or sponsor submissions). The evaluation report is the core evidence which will be put before the Appraisal Committee in the next stage of the process.
- h) While the assessment report is being commissioned and prepared, the Institute begins to organise the next stage of the process, namely the deliberations of the Appraisal Committee. Selected normally from the expert nominations received by the professional and patient bodies, two of the patient bodies are invited to nominate two representatives each and two (in total) of the nominees put forward by the professional bodies are invited to attend. These experts have the opportunity to submit a written perspective of the technology and the way it should be used in the NHS in England and Wales, if they wish to do so. Those documents will be put before the Appraisal Committee and they will be made available to consultees, during the consultation period on the ACD.

Assessment	Weeks (approx) since process commenced
<b>Step 8</b> Consultees invited to make submissions to the Institute. Assessment group advised of confirmed scope and timeline	7
<b>Step 9</b> Clinical experts and patient experts invited to attend first Appraisal Committee meeting and asked to submit a written perspective	7
<b>Step 10</b> Meeting between consultees, Institute leads and assessment group	13-18
<b>Step 11</b> Consultees' submissions received	23
<b>Step 12</b> Experts nominated by patient and professional body consultees submit written perspectives	33
<b>Step 13</b> Assessment report received by Institute	34
<b>Step 14</b> Assessment report sent to consultees for comment	35 to 37
<b>Step 15</b> Evaluation report completed and papers circulated for first Appraisal Committee meeting	38

## 9. Appraisal

a) The Appraisal Committee comprises experts drawn from the health professions, patient-focused organisations, health economists and NHS managers. Information about the composition and membership of the committee is available to the public on the Institute's website.

b) The appraisal stage of the process consists of three elements:

- the first meeting of the Appraisal Committee<sup>4</sup>, at which the committee undertakes its first consideration of the evaluation report, the written perspectives and any other evidence which has been submitted to it with the assistance of the patient and clinical experts. This leads to the production of the ACD, which contains the initial views of the Appraisal Committee;
- a four week period of consultation on the ACD during the final three weeks of which the ACD is posted on the Institute's website;
- further consideration of the evidence and any comments received during the consultation period by the Appraisal Committee leading to the production of the final appraisal determination (FAD) which sets out the final advice of the Appraisal Committee.

### The first meeting of the Appraisal Committee

c) The papers for the first meeting of the Appraisal Committee are circulated to the committee. Others attending the meeting will also receive a version, with

<sup>4</sup> The membership of the Appraisal Committee is listed on the Institute's web site: <http://www.nice.org.uk>

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the 'commercial in confidence' material removed. The papers include the written perspectives submitted by the patient and clinical experts.

- d) As indicated above, the Appraisal Committee invites experts nominated by the consultees to inform their consideration of the technology at their first meeting. Usually four experts nominated by the patient body consultees and two of the experts nominated by professional/clinical body consultees are selected to receive these invitations. Representatives of the assessment group are also invited to attend the meeting.
- e) The selection of patient experts who are invited to the meeting is made by the chairman of the Appraisal Committee, based on the extent and nature of their experience of the technology, the disease and the services provided by the NHS to patients with the condition(s) the technology is designed to treat.
- f) The selection of the clinical experts who are invited to the meeting is made by the chairman of the Appraisal Committee, using the following criteria:
- they are in active clinical practice; and
  - their principal place of work is within the NHS; and
  - they have published in the clinical field to which the technology contributes; and
  - they hold no official office (i.e. no paid employment, unpaid directorship or membership of a standing advisory committee) with any of the manufacturers of the technology or any manufacturer of a directly competing technology.
- g) At the meeting, the patient and clinical experts have the opportunity to make observations about the technology and its use in the NHS. At this stage the observations may include consideration of the wider implications of the technology for the NHS and patients and carers. The committee usually asks questions following their representations, and the experts then withdraw from the meeting. After any further clarification of the assessment report with its authors, the authors withdraw, leaving the committee to discuss the evaluation report and the submissions they have received, and the drafting of the ACD.
- h) The Appraisal Committee may, at its discretion, invite one or more of the manufacturers, or the sponsor, to attend the meeting.
- i) The Institute would normally expect the ACD to be available to consultees within seven days of the Appraisal Committee meeting, although there may be circumstances in which the ACD takes longer to produce.

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j) The ACD will normally contain the following elements:

- The Appraisal Committee's interim views
- A description of clinical need and practice in the relevant disease area
- A description of the technology
- A summary of the evidence referred to by the Appraisal Committee and how it has been interpreted
- The implications of the initial views for the NHS
- Any further research proposed

k) The minutes of the Appraisal Committee meeting will be posted on the Institute's website once they have been confirmed by the committee.

### **The consultation period**

l) The ACD, together with the executive summaries of the manufacturer(s)/ sponsor(s) submissions, the full versions of the patient and professional group submissions, comments received on the assessment report from consultees and the written perspectives of the experts who attended the Appraisal Committee meeting will be sent, by special delivery, in the form of the evaluation report, to consultees, the clinical experts for consultation, and to the assessment group for information. The patient experts will receive it via their nominating consultee organisation. The consultees have four weeks in which to submit their written comments on the ACD. These comments should not contain new evidence, i.e. evidence that has not previously been considered by the Appraisal Committee. The purpose of the consultation is to gather comments on whether the ACD is an accurate reflection of the evidence that has been considered by the Appraisal Committee. The ACD will be placed on the Institute's website five working days after it has been circulated to consultees. Comments on it from non-consultees will be summarised and submitted to the Appraisal Committee for consideration.

m) In exceptional circumstances the Appraisal Committee may consider new evidence submitted by consultees with their comments on the ACD, or evidence which the Institute has drawn to its attention. Where such new evidence has the effect of substantially altering the ACD, the Institute shall prepare a second ACD. The Institute's Guidance Executive shall take the decision as to whether there is a need to prepare a second ACD. A decision to produce a second ACD will extend the timeline for the appraisal. The new evidence will be circulated with the new ACD. The Institute's Guidance Executive consists of the Chief Executive, Clinical Director, Communications Director and Planning and Resources Director with the Appraisal Programme Director, Audit Programme Director and Guidelines Programme Director in

attendance. Its principal function is to approve the Institute's guidance documents for publication.

### The committee's final considerations

- n) The Appraisal Committee meets again to consider the original evidence and the ACD in light of the comments received from the consultees and the summary of any comments received from non-consultees as indicated in paragraph 9(l) above. The committee sees the full text of the comments from the consultees. The committee then prepares the FAD and submits it to the Institute. If satisfied that the Appraisal Committee has properly appraised the technology in accordance with the terms of the DH/NAW's reference and the Institute's scope, the Institute will accept the FAD and, subject to any appeal by consultees, it will be used as the basis of the Institute's guidance on the use of the appraised technology.
- o) The Institute would normally expect the FAD to be produced within seven days of the Appraisal Committee meeting. However there may be circumstances in which it takes longer for the FAD to be produced. The FAD will be despatched to the consultees by special delivery. The FAD will be posted on the Institute's website under the same conditions referred to in paragraph 9(l) above.
- p) The Institute will correct factual errors brought to its attention.

Appraisal		Weeks (approx) since process commenced
<b>Step 15</b>	Evaluation report completed and papers circulated for first Appraisal Committee meeting	38
<b>Step 16</b>	First meeting and consideration of the Appraisal Committee, attended by patient and clinical experts	40
<b>Step 17</b>	ACD produced and distributed. ACD posted on Institute's website five working days later	41
<b>Step 18</b>	Fixed four week consultation period on ACD	41–45
<b>Step 19</b>	Papers circulated for second Appraisal Committee meeting	46
<b>Step 20</b>	Second meeting of Appraisal Committee to consider consultees' comments	48
<b>Step 21</b>	FAD produced and distributed. FAD posted on Institute's website five working days later	49

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## 10. Appeal

- a) Consultees, other than the Health Technology Board for Scotland and the two health authorities are given 15 working days in which to lodge an appeal. Any appeal must be in writing and must be lodged with the Institute by the date and in the manner indicated. The detail of the Institute's appeal process is set out in a separate document<sup>5</sup> and the following is only a brief summary of the process. Appeals are made to the Institute's Appeal Panel.
- b) It is not possible to appeal against the FAD simply because the appellant does not agree with it. The Appeal Panel will not consider appeals unless the grounds for appeal are clearly identified and fall within one or more of the following grounds:
  - The Institute has failed to act fairly and in accordance with its published procedures;
  - The FAD is perverse in the light of the evidence submitted;
  - The Institute has exceeded its powers.
- c) The board of the Institute will appoint the members of the Appeal Panel. The panel will comprise of 5 members drawn from the Institute's Appeals Committee, all of whom will have had no prior involvement in the appraisal in question. The panel will consist of at least one non executive director of the Institute who will chair the appeal, at least one member from within the NHS, one member with experience of the relevant industry or clinical field and one member with experience of patient or carer organisations.
- d) The Institute will inform the appellant(s) of the membership of the Appeal Panel and the confirmed date of the appeal hearing as soon as possible after an appeal has been lodged.
- e) The Appeal Panel will consider the appellants' representations in private and its findings will be made public. The identity of the appellants will not be made public until the outcome of the appeal(s) has been published.
- f) The Institute will endeavour to issue the outcome of an appeal within 21 days of the appeal hearing, but there may be circumstances where a longer interval is necessary. The full text of the appeal decision will be posted on the Institute's website two working days after it is made available to the appellants and the other consultees.

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<sup>5</sup> National Institute for Clinical Excellence. *Guidance for Appellants*. London; May 2000. Available from: <http://www.nice.org.uk>

- g) If the appeal is upheld, the Institute will consider the appropriate course of action. In most cases the Appraisal Committee will be asked to reconsider the evidence and the process will resume at step 20 (second meeting of the Appraisal Committee, following consultation on the ACD).

Appeal		Weeks (approx) since process commenced
<b>Step 22</b>	Any appeals lodged (fixed 15 working day period)	52
<b>Step 23</b>	If necessary, Appeal Panel convened by the Institute	54-56
<b>Step 24</b>	Appellants and other consultees notified of the outcome of the appeal	56-59
<b>Step 25</b>	Appellants provided with the full appeal decision	57-60

- a) If there is no appeal or any appeal is dismissed, the Institute makes arrangements for the outcome of the appeal, based on the FAD, to be issued to the NHS in England and Wales in the form of guidance on the use of the referred health technology.
- b) The DH and NAW may consider issuing complementary guidance to the NHS on the implementation of individual guidance documents.  
*(The figures in brackets in the time column below refer to the time that will have elapsed if there has been an appeal that has been dismissed).*

## 11. Publication

Publication		Weeks (approx) since process commenced
<b>Step 26</b>	The Institute issues guidance to NHS in England and Wales	54 (up to 62)
<b>Step 27</b>	The Institute issues media briefings and provides media with an opportunity to seek further information.	54 (up to 62)

- a) When the Institute issues its technology guidance it will give a date on which the guidance will be reviewed. This date is referred to as the 'review date'. The date refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of the updated assessment report.

## 12. Review and updating technology appraisal guidance

b) The length of time between the issue of the guidance and the review date will vary depending on the anticipated rate of change in the evidence for the technology. Experience to date shows that this period ranges in length from 12 to 36 months. The Institute standardises its arrangements for determining appropriate review dates by reference to the table below. Technologies in the second and third evidence based categories will be automatically phased into the Institute's forward programme.

### Assignment of technology revision date

Evidence base	Nature of review	Review date
Little or no change anticipated	Maintenance review which will result either in updated guidance, made by the Institute without reference to the Appraisal Committee, or the guidance being referred to the Institute's 'static guidance list' with no further review scheduled.	3 years
Change anticipated	Full review, undertaken either by the HTA Programme or by the Institute resulting in an updated assessment report typically referred to the Appraisal Committee, followed by updated guidance.	3 years
Rapid change anticipated	Full review, typically undertaken by the Institute, resulting in an updated assessment report referred to the Appraisal Committee, followed by updated guidance.	1 year

c) It is possible that evidence that may make a substantive contribution to the current guidance will become available at a time prior to the official review date for the guidance. Where such evidence is identified by the Institute or the consultees to the appraisal of the particular health technology, the Institute's guidance executive will consider whether the guidance needs to be updated. If it considers that the guidance may need to be updated then the review date for the guidance will be brought forward. This will be exceptional and the Institute will not review any guidance earlier than 12 months after its original publication date.

d) It is anticipated that, eventually, the evidence base for all technologies and their diffusion into the NHS will have stabilised at a point where no further guidance on its use is required. At this point, the guidance will be placed on the Institute's 'static guidance list'. Topics on this list may be referred back to the Institute for further appraisal, by the DH and the NAW, in the event that new evidence, likely to have a material effect on the last guidance issued, becomes available.

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- e) It is not possible to set fixed timescales for the process as the length of time needed for each stage may vary with the nature of the particular appraisal and the position of particular consultees. The figures in the table are estimates of the number of weeks that will elapse in an average review between the review date and that particular step of the process. However certain time limits and consultation periods are referred to in the tables as “fixed”, indicating that they will not be adjusted and will be the same in every review.
- f) In reviewing its guidance, the Institute will identify and then notify the appropriate consultees that it is undertaking the process of review. The consultees will consist of the patient and professional groups and manufacturers or sponsors who were consultees in the original appraisal, including the DH and the NAW, two health authorities, the Health Technology Board for Scotland and any other organisations whose views are now relevant to the review.
- g) The Institute will have commissioned an update of the original assessment report. Typically, this update will be based on re-running the original search strategy for both clinical and cost effectiveness studies from the sign-off date of the original assessment report and will be undertaken either by the Institute or by an external group commissioned by the NHS HTA Programme on the Institute’s behalf.
- h) Consultees will be asked:
- To indicate what new evidence they consider should be taken into account; and
  - To provide any new data they have which is not otherwise in the public domain.
- i) For three year maintenance reviews, consultees’ replies will be considered at a meeting of the guidance executive with the chairman of the Appraisal Committee in attendance.
- j) For three year and one year full reviews, the replies from consultees will be sent to the team preparing the updated assessment report.

k) The standard timeline for maintenance reviews is set out below:

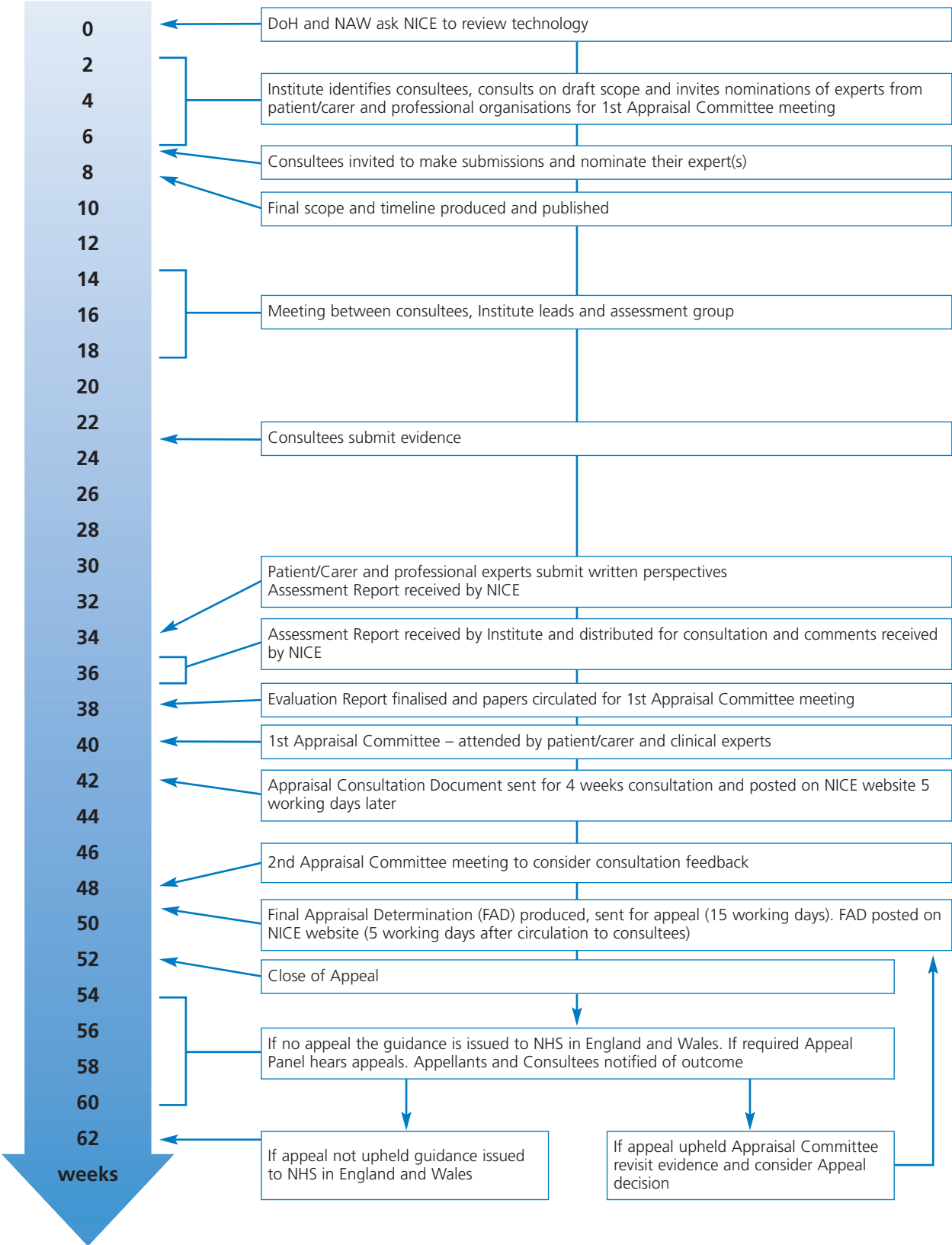
Review and updating technology appraisal guidance		Weeks (approx) since process commenced
<b>Step 1</b>	Identification and notification of consultees. Invitation to consultees to identify new evidence	1
<b>Step 2</b>	Response received from consultees	8
<b>Step 3</b>	Updated assessment report received	14
<b>Step 4</b>	Updated assessment report reviewed by guidance executive	18
<b>Step 5</b>	If there is to be no revision and the topic is referred to the 'static guidance list' consultees are informed and a notice posted on the Institute's website. If the guidance is to be updated, a new guidance document is posted on the Institute's website	19

l) The standard timeline for full reviews is set out below:

Review and updating technology appraisal guidance		Weeks (approx) since process commenced
<b>Step 1</b>	Identification and notification of Consultees. Invitation to consultees to identify new evidence	1
<b>Step 2</b>	Response received from consultees	8
<b>Step 3</b>	Updated assessment report received	14
<b>Step 4</b>	Updated assessment report reviewed by guidance executive	18
<b>Step 5</b>	Updated assessment report received by Appraisal Committee and the process follows the original appraisal timeline from Step 15	24

# Appendix A:

## Appraisal process diagrammatic timeline



## The Technology Appraisals Process Series

1. **Guide to the Technology Appraisal Process**
2. Guidance for Appellants
3. Guidance for Patient/Carer Groups
4. Guidance for Healthcare Professional Groups
5. Guidance for Manufacturers and Sponsors



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