

Guide to the technology appraisal and highly specialised technologies appeal process

Process and methods

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Contents

Foreword	4
Introduction	5
Background	5
The purpose of this document	5
1 Grounds of appeal	6
2 The Appeal Panel	7
3 Role of the Vice Chair of NICE	8
4 Making an appeal	9
4.1 Who can appeal?	9
4.2 How to lodge an appeal?	9
4.3 What is the scope of an appeal?	9
4.4 The grounds of appeal	9
4.5 What must the appeal letter contain?	11
4.6 Patient access schemes and flexible pricing in the technology appraisal programme.....	13
4.7 Can new data be submitted to the Appeal Panel?	13
5 Scrutiny of appeal points	15
5.1 Initial scrutiny of the appeal	15
5.2 What happens after initial scrutiny?	16
5.3 Final scrutiny of the appeal.....	17
6 Conduct of an appeal.....	18
6.1 Will there be a hearing?	18
6.2 Dealing with conflicts of interest	18
7 The oral appeal process.....	19
7.1 What is the timescale for an appeal?	19
7.2 Who may attend the oral appeal?.....	19
7.3 How is the oral appeal conducted?	20
7.4 Confidential submissions	21

8 The written appeal process	23
8.1 What is the timescale for an appeal?	23
8.2 How is the written appeal process conducted?	23
8.3 Who may attend the appeal?	24
9 Rejected appeals	26
10 Cancelled appeals	27
11 After the appeal	28
11.1 What is the timescale for the appeal decision?	28
11.2 Outcome of an appeal	28
11.3 What happens after the appeal decision is published?	29
Acknowledgements	31

Foreword

This document concerns the appeal process for the technology appraisal and highly specialised technologies programmes and provides an overview for organisations wishing to lodge an appeal.

Organisations invited to contribute to NICE technology appraisals and highly specialised technologies evaluation (consultees and commentators) should read this guide in conjunction with the documents listed below. All documents are available on NICE's website (www.nice.org.uk).

- Guide to the processes of technology appraisal
- Guide to the methods of technology appraisal
- Highly specialised technology interim process and methods guide

Introduction

Background

NICE is the National Institute for Health and Care Excellence. We provide guidance and standards to drive and enable improvements to health and social care. Further details about NICE and our programmes of work are [available](#).

The purpose of this document

This document sets out the process that NICE follows for appeals against final draft guidance in the technology appraisal and highly specialised technologies programmes. It provides guidance for those who wish to make an appeal or who are considering doing so.

NICE does not issue technology appraisal or HST final guidance to the NHS until after the appeal period or, if an appeal is lodged, until after the resolution of the appeal.

1 Grounds of appeal

The grounds of appeal are:

- Ground 1: In making the assessment that preceded the recommendation, NICE has:
 - a) failed to act fairly
 - or
 - b) exceeded its powers
- Ground 2: The recommendation is unreasonable in the light of the evidence submitted to NICE.

The Appeal Panel can only consider appeals that fall within one or more of the two strictly limited grounds. Either or both parts of ground 1 can be appealed. Appeals on any other grounds will not be considered.

2 The Appeal Panel

The Appeal Panel is drawn from a group of individuals approved by the Secretary of State for Health. Each Appeal Panel consists of 5 members. The Appeal Panel is chaired by an external member who is engaged in the provision of healthcare in the health services (health service representative); or someone who has experience in representing patients or carers or who is a patient or carer (patient representative). In addition to the chair of the panel, 1 non-executive director of NICE, 1 health service representative, 1 representative of the life sciences industry, and 1 patient representative will join the Appeal Panel.

3 Role of the Vice Chair of NICE

The Vice Chair of NICE is responsible for determining the arguability and validity of each of the appeal points lodged and will decide if an appeal (oral or written) will be held. In doing so, he or she may take legal advice.

In the absence of the Vice Chair, or where the Vice Chair is conflicted, the Chair of the Board will nominate an alternative Non-Executive Director to act as the Vice Chair in respect of appeals.

4 Making an appeal

4.1 *Who can appeal?*

Only consultees involved in a technology appraisal or a highly specialised technology can appeal against final recommendations. A consultee is referred to as an appellant once an appeal has been lodged.

4.2 *How to lodge an appeal?*

A consultee may appeal to NICE within 15 working days from the day the final draft guidance is issued to consultees and commentators. This is the appeal period. The letter from NICE that accompanies the final draft guidance states this deadline for appeal.

Consultees must lodge appeals in writing with the [appeal project manager](#) within the appeal period.

4.3 *What is the scope of an appeal?*

Generally the Appeal Panel will not rehear evidence or be persuaded by repetition of points previously made by the appellant and considered by the advisory committee unless it can be shown that 1 or more of the 2 grounds of appeal referred to in [section 1](#) are also valid.

An appeal may relate only to the final draft guidance for technology appraisals and HSTs, or the way in which the guidance process was conducted. An appeal cannot be lodged against other documents produced during the process (for example, the preliminary draft guidance, overview or scope).

Requests for corrections of minor factual or typographical errors are not normally considered at an appeal and will be looked at separately. If factual errors are submitted at the same time as an appeal is lodged, the Vice Chair of NICE, who initially considers the appeal, will be informed. For full details of correction of factual errors, see NICE's technology appraisal process guides.

4.4 *The grounds of appeal*

Ground 1 (a) – NICE has failed to act fairly

NICE is committed to following a fair process throughout the technology appraisal and HST processes. An appellant who believes that they have not been treated fairly by NICE or the advisory

committee because the published process has not been followed may appeal on this ground. This ground relates only to the fairness of the process followed and not to the content of the final draft guidance. It should be noted that the final draft guidance with which an appellant does not agree is not unfair for that reason. For example, although it would be unfair to exclude a relevant data set from the appraisal or HST process, it would not be unfair if the committee considered the relevant data set and reached a view with which the appellant did not agree.

This ground of appeal does not cover unfairness in the colloquial sense, for instance that it is 'unfair' to patients not to provide a treatment.

Unsubstantiated allegations of general unfairness, for example the alleged inability to understand a conclusion, will not be accepted as a valid appeal point. Details and evidence must be provided in every case. For example, if it is claimed that an appellant cannot understand the reasons for a conclusion, and so could not respond to a consultation, the appellant must first set out the range of possible reasons that they considered may have applied, then explain why they are unable to distinguish which was the correct reason, and finally indicate why that has affected their ability to participate fairly in the consultation.

NICE requires appellants to explain what steps they took to resolve any unfairness promptly at the time it arose, for example if the same issue was present in both the consultation draft of the guidance and in the final version and the point was not raised by the appellant at the earlier consultation stage. The Appeal Panel may interpret the absence of any such steps, without sufficient reason, as evidence that there was in fact no such unfairness.

Ground 1 (b) – NICE has exceeded its powers

NICE is a public body. It undertakes its work in accordance with public law, the statutory instruments under which it was established and the directions and guidance issued by the Secretary of State for Health. An appellant may appeal on the ground that NICE has acted outside its remit or has acted unlawfully.

Ground 2 – The recommendation is unreasonable in light of the evidence submitted to NICE

NICE will not accept an appeal simply because a consultee disagrees with the views or conclusions in the final draft guidance. However, a consultee may appeal if they consider that the recommendations in the final draft guidance cannot reasonably be justified from the evidence presented to the committee. This ground means that the guidance is obviously and unarguably wrong, illogical, or so absurd that a reasonable advisory committee could not have reached such

conclusions. The Appeal Panel will not make new judgements about the technology, but will review the advisory committee's decisions to see if they can reasonably be justified, based on the evidence that was available to the advisory committee. It should be noted that it is possible that 2 different committees could reach different conclusions based on the same evidence without acting unreasonably.

4.5 *What must the appeal letter contain?*

The appeal letter is the appellant's first opportunity to present the points they wish to appeal on. It is important that the appeal letter is submitted correctly, is presented clearly and contains the necessary information, as explained below. If the letter received is not appropriate (for example, the letter does not have sufficient supporting information or the relevance of the appeal points is unclear), there is a possibility that the appeal will be dismissed as 'not valid' because it does not fall within 1 or more of the grounds of appeal. The appeal letter requirements are stated in this section.

The appeal letter must contain an introductory statement clearly indicating the final draft guidance that is to be appealed and on which of the permitted grounds the appeal is being made. For complex appeals, or if a notice of appeal is longer than 5 A4 pages, appellants are asked to produce an executive summary of the appeal. This should be no longer than 1 page of A4.

The appeal letter must clearly and succinctly set out the appellant's points of appeal in detail. Appeal points must be made in order of the ground to which they relate, that is, all appeal points made under ground 1 must be made first, followed by all points made under ground 2. Appeal letters must be sufficiently comprehensive that the Appeal Panel can understand all points being raised.

Each point must be headed with the appeal ground to which it relates, and a 1-sentence description of the appeal point. For example:

Ground 1 (a): the change from a positive to negative recommendation following an ACD without further consultation is unfair

Appellants who wish to appeal under ground 1 must refer to the relevant NICE process document (including the specific paragraph number) that has allegedly been contravened. If arguments are for a final draft guidance being procedurally unfair, the arguments should be clearly outlined in the appeal letter.

Each appeal point must be numbered so that the first appeal point under ground 1(a) is numbered 1(a).1 with subsequent ground 1 points numbered 1(a).2, 1(a).3, and so on. The same numbering will apply for ground 1(b) and ground 2 points, for example: 1(b).1, 2.1 and so on. It is not necessary to number individual paragraphs in the appeal letter, but if the appellant considers that this aids clarity, they should simply number every paragraph in the appeal letter sequentially, and use the numbered headings described above for appeal points to break up the text.

The Appeal Panel only considers the exact grounds and arguments as set out in the appeal letter, and appellants should prepare their appeal letters accordingly. The grounds for appeal are quite distinct and are set out in [section 1](#). Appellants are therefore advised to consider carefully which ground of appeal any given complaint relates to. In particular, it is unhelpful to submit complaints that are essentially about the substance of guidance (that is, that the conclusion is unreasonable in light of the evidence) under ground 1(a). If the context for different appeal points overlaps, it is not necessary to repeat the same points under more than 1 appeal point, but appellants must set out the argument they wish to make under each ground in detail. They must not refer the Appeal Panel to earlier text without clearly indicating how that text relates to the current appeal point. For instance, it is not acceptable to state under ground 2: '*The appellant repeats the points made under point 1(a).1 above*'. But it is acceptable to state: '*The appellant argues that the points set out in 1(a).1 above also demonstrate that the guidance cannot reasonably be justified in the light of the evidence submitted in that...!*'

Appeals will not be considered unless the grounds for appeal are clearly identified, fall within 1 or more of the grounds set out in [section 1](#), and are arguable.

If the appeal letter contains commercial-in-confidence or academic-in-confidence information, the appellant will be responsible for ensuring that this information is clearly labelled and a second version of the appeal letter is submitted with the commercial-in-confidence or academic-in-confidence information redacted.

The letter must conclude with a final statement indicating whether the appellant wishes to be heard at an oral or a written appeal, should one take place. The Vice Chair of NICE will make this decision at their discretion; however, the appellant's preference will be taken into account.

In summary the appeal letter must include the following information:

- the ground(s) of appeal
- the aspect(s) of the final draft guidance or technology appraisal/HST process being appealed against

- the reasons why the aspect(s) of the final draft guidance or technology appraisal/HST process being appealed against fall within the specified ground(s) of appeal, in enough detail to demonstrate an arguable case
- the concluding statement indicating whether the appellant wishes to be heard at an oral or written appeal.

Only the original appeal letter submitted by an appellant for scrutiny will be considered. Revised versions of the appeal letter submitted after the appeal period and during the scrutiny stage will not be accepted.

The Vice Chair of NICE will respond to each appeal letter to indicate their preliminary view of the arguability and validity of each of the points made by the appellant. This response is known as an initial scrutiny letter, which is set out in section 5.1.

4.6 Patient access schemes and flexible pricing in the technology appraisal programme

Appeals following the rapid review of guidance after the submission of a new patient access scheme will only be accepted on points relating to the new patient access scheme. The Appeal Panel will not consider points previously raised unless they are directly concerned with the impact of the patient access scheme on clinical or cost effectiveness.

Appeals will be accepted only on points relating to the flexible pricing scheme proposal. The appeal will not consider points previously raised unless they are directly concerned with the impact of the flexible pricing proposal on clinical or cost effectiveness

4.7 Can new data be submitted to the Appeal Panel?

All data that consultees consider relevant to the guidance topic should be submitted to the advisory committee as part of the technology appraisal or HST process as described in the NICE process guides. New evidence or information that was not presented to the Committee, or re-analysis of existing evidence or information, must not be presented in the appeal letter or at the hearing, and will not be considered by the Appeal Panel.

An appeal is not an opportunity to reopen arguments and issues that the advisory committee has decided on. It is not possible to appeal against the final draft guidance because a consultee does not agree with it.

Generally the Appeal Panel will not rehear evidence or be persuaded by repetition of points previously made by the appellant and considered by the advisory committee unless it can be shown that 1 or more of the 2 grounds of appeal in section 1 is also valid.

5 Scrutiny of appeal points

5.1 *Initial scrutiny of the appeal*

NICE will acknowledge receipt of appeals within 2 working days. The Vice Chair of NICE will usually write to the appellant within 5 working days from the end of the appeal period with their initial views.

The Vice Chair of NICE will respond to each appeal letter to indicate their preliminary view of the arguability and validity of each of the points made by the appellant. In doing so they may take legal advice. This response is known as the initial scrutiny letter.

The letter will usually say whether the Vice Chair of NICE considers that the appeal should be held orally or in writing. In exceptional circumstances, where the validity of the appeal points are uncertain at initial scrutiny, the Vice Chair of NICE may defer deciding whether to proceed with an oral hearing or proposing that there should be a written appeal, until the appeal points are confirmed at final scrutiny. A written appeal process will only be adopted following consultation with appellant(s). If the notice of appeal does not present an arguable case under 1 or more of the grounds of appeal, the Vice Chair of NICE will give reasons for this and may request further information or clarification in the initial scrutiny letter. Appeals are only referred to an Appeal Panel if, after giving the appellant an opportunity to elaborate or clarify the grounds of appeal, the Vice Chair of NICE is satisfied that the appeal falls into one or more of the grounds and is arguable. The Vice Chair of NICE has the discretion to allow the appeal to go ahead on one or more grounds presented in any appeal letter but not others.

In determining the prospects of success of appeal points, the Vice Chair of NICE has regard to and is guided by past decisions of the Appeal Panel, but is not strictly bound by them. The Vice Chair gives greater weight to past decisions on legal or quasi-legal issues, and less weight to decisions on factual issues. For example, a finding that guidance should consider any significant groups of patients with disabilities who may be unable to take a treatment being recommended is likely to be given weight in future appeals. This is a finding on a legal issue. A finding that some specific aspect of guidance was or was not reasonably justified is unlikely to be given much weight in a future appeal. This is only a finding about the facts of 1 appraisal or highly specialised technology topic.

The Vice Chair of NICE may suggest reallocating grounds of appeal if the issues raised seem weak under the nominated ground, and may be stronger under a different ground.

Appellants are given 10 working days to respond to the initial scrutiny letter. Responses to this letter must not contain new points of appeal. Responses must deal only with requested clarifications, or arguments or comments about the Vice Chair of NICE's concern that an appeal point raised has no reasonable prospect of success, is unsupported by evidence, or is outside the scope for an appeal. Existing appeal points may be elaborated and further evidence in support of existing appeal points may be given. Responses received after the deadline may not be considered, and a final decision may be taken without their being taken into account. There may be occasions when further clarification is needed and more than 1 scrutiny letter may be sent.

The appellant must not submit a revised appeal letter in response to comments in the initial scrutiny letter unless invited to do so. For example, the appellant must not move and renumber appeal points to clarify what appeal points were being made if the original letter was insufficiently clear. The response to the initial scrutiny letter must only address the points raised by the Vice Chair of NICE.

If, exceptionally, the appellant is invited to submit a revised appeal letter, it must not contain new grounds of appeal. The numbering of the original letter should be preserved as far as possible or clearly indicate when an appeal point has changed number (for example, "2.1 [formerly 1(a).3]", if an appeal point changes from ground 1(a) to ground 2) or held to have no reasonable prospect of success (for example, 2.3 [not now used]).

5.2 *What happens after initial scrutiny?*

If the initial scrutiny letter indicates that there are valid appeal points, NICE informs the appellant(s) of the date of the appeal, who will be on the Appeal Panel, and in the case of an oral appeal, who will attend from NICE and its advisory committee and external advisors, as soon as possible. In the case of an oral appeal, the appellant is asked to provide the names and job titles of the representatives who will be representing their organisation at the appeal. It may be necessary to limit the number of representatives attending the appeal.

In the case of a written appeal, NICE confirms with the appellant(s) that the appeal will proceed as a written appeal, the date of the appeal, and who will be on the Appeal Panel.

NICE informs consultees and commentators that an appeal has been received, whether the appeal will be held orally or be on the papers, the name of the appellant(s) organisation, and the date of the appeal hearing. NICE publishes a notice on its website announcing that an appeal will take place at least 2 working days after consultees and commentators are informed of the date of the appeal.

5.3 *Final scrutiny of the appeal*

The Vice Chair of NICE writes to the appellant with the final decision on the admissibility of the appeal points raised within 5 working days of considering the appellant's response to the initial scrutiny letter. This is known as the final scrutiny letter.

The final scrutiny letter is the Vice Chair of NICE's final word and a further response cannot be submitted by the appellant. That letter will outline all of the appeal points that will be considered at the appeal and may also make specific directions for the conduct of an appeal, if necessary.

6 Conduct of an appeal

6.1 *Will there be a hearing?*

The decision to hold an oral or written appeal will be made following discussion with the appellant(s). Appeals may be conducted using a written process if this is fair. This is more likely for appeal points that are discrete and/or where few points are in dispute.

6.2 *Dealing with conflicts of interest*

None of the members of the Appeal Panel will have had any previous involvement in the technology appraisal or highly specialised technology being appealed against. Before being appointed to the Appeal Panel, members must declare conflicts of interest in accordance with NICE's conflicts of interest policy. NICE will ensure that no member of an Appeal Panel has any interest that may give rise to bias. Once appointed, the Appeal Panel acts impartially and independently of any party involved with the technology appraisal or HST topic, including the advisory committee. If an appellant believes that a member of the Appeal Panel has an interest that means that he or she may favour or disfavour the submissions of any appellant, they should inform the Chair of the Appeal Panel within 10 working days of receiving the letter listing the relevant Appeal Panel members. In these circumstances, if NICE considers it necessary, it may change the membership of the panel.

7 The oral appeal process

7.1 *What is the timescale for an appeal?*

Assuming that the appeal points are valid, the Appeal Panel will aim to hold an oral appeal within 8 weeks of an appeal being lodged.

7.2 *Who may attend the oral appeal?*

Oral appeals are open to consultees, commentators, members of the public and the press. Holding appeals in public is part of NICE's commitment to openness and transparency. It enables stakeholders and the public to better understand the way NICE makes its decisions.

To promote public attendance, NICE will publish a notice on its website announcing that an appeal will be heard, and opens the registration to attend the appeal at least 20 working days before the hearing. At this point, consultees, commentators, members of the public and press may register on the NICE website to attend the appeal as a public observer. Up to 25 places will be available, depending on the size of the venue. Once registration has closed, NICE will contact all the applicants. The successful applicants will receive an invitation to the appeal and documents related to the technology appraisal or highly specialised technology under discussion. Requests to attend are granted on a first-come, first-served basis, although priority is given to members of the public who are not employed by the appellant(s). To allow wide public access, NICE reserves the right to limit the number of representatives per organisation. Public observers are not allowed to participate in the discussions, record the appeal proceedings (video or audio), or take photographs in the premises in which the appeal is held. The Appeal Panel Chair may exclude any person from the appeal if he or she considers that person is disrupting proceedings.

Each appellant is allowed up to 5 representatives at the hearing, including legal representation if they wish. This number may be reduced to 3 representatives if there are more than 3 appellants. If appellants intend to make similar statements, the Appeal Panel will encourage them to be jointly represented, particularly if they have legal representation.

The Appeal Panel may have its own legal adviser present to advise on any procedural or legal issues that may arise.

All 5 members of the Appeal Panel must be present for the appeal. However, if a member is unable to attend or has to stand down at short notice, the Chair of the Appeal Panel will consult with the appellant(s) and NICE representatives. If all parties agree, the appeal will continue with only 4

members of the Appeal Panel, provided that there is still at least 1 representative of the life sciences industry, 1 health service representative, and 1 patient representative, and that one of the health service or patient representatives is the panel chair. This agreement to proceed will be noted in the Appeal Panel decision.

7.3 *How is the oral appeal conducted?*

On the morning of the appeal, the appeal letter(s), the scrutiny letters and responses to these letters are placed on the NICE website. Any confidential information and personal data are removed before publication on the website.

At the appeal, each appellant is allowed to make a brief 5-minute introductory statement. The amount of time given to each appellant is determined by the nature of the introductory statement they wish to make and the need for the Appeal Panel to manage the appeal efficiently and fairly. Appellants' introductory statements should be relevant to the grounds of appeal, avoid repetition and be as clear and concise as possible. Appellants should not expect to be allowed to make an introductory statement in connection with every appeal point.

The order in which appellants present appeal points is at the discretion of the Appeal Panel Chair. The Appeal Panel Chair may stop appellants from making introductory statements that are irrelevant, or that repeat something already said by another appellant. Statements are made in the presence of the other appellant(s), the public and the press unless there are issues of confidentiality. Appellants are treated impartially and will each be given a fair opportunity to make their statement. Visual aids such as Microsoft PowerPoint presentations are not accepted.

The Chair of the advisory committee or a representative of NICE is also invited to make an introductory statement of similar length.

The Appeal Panel will then consider and hear each appellant's appeal points and appellants are given the opportunity to argue individual points during the appeal.

Hearings are conducted in an inquisitorial rather than an adversarial style. This means that members of the Appeal Panel may ask appellants questions on any relevant issue. All questions must be made through the Appeal Panel Chair; appellants and representatives for the advisory committee and NICE may not question each other directly.

Points may be dealt with by way of questions from the Appeal Panel or, if the Appeal Panel is confident it has understood the arguments on each side, may not be specifically raised in oral

argument at all. The representatives for the advisory committee and NICE may be asked at any time to comment on the appellants' statements. Any such comments are made in the presence of the appellant and the appellant is given an opportunity to respond.

Each appellant and the representatives for the advisory committee and NICE are invited to make a brief concluding statement before the appeal ends.

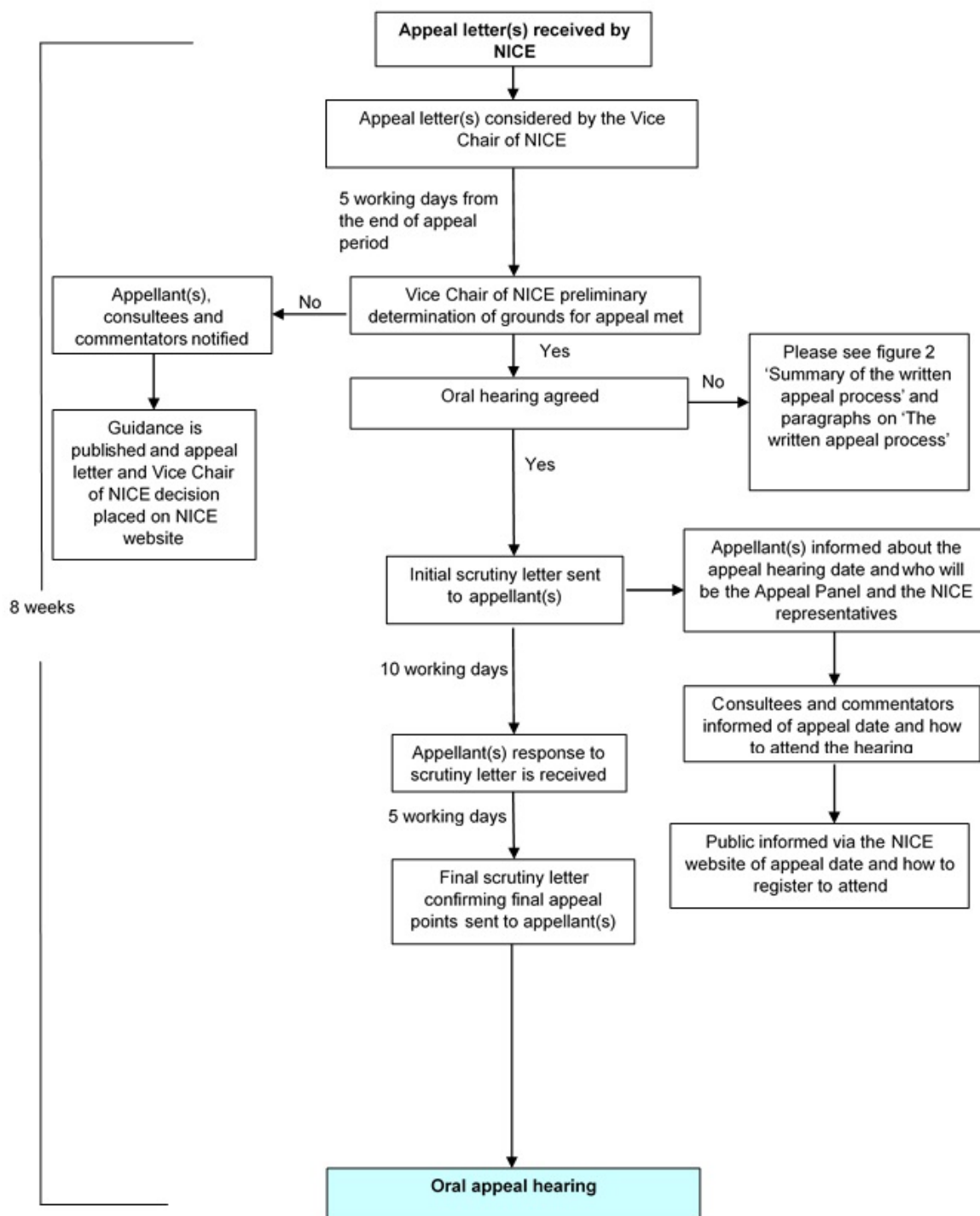
7.4 *Confidential submissions*

If an appellant wishes to make statements that involve disclosing confidential information, the Appeal Panel will allow them to be heard in private (that is, in the absence of the other appellants, the public and the press) if they fall within the conditions set out below.

An appellant who intends to make confidential submissions should inform the appeals project manager 15 working days before the appeal date. The Appeal Panel will be sensitive to the need to protect confidential and commercially sensitive information, but will balance this against the fact that a private hearing would deny the other appellants and the public of the opportunity to listen (and in the case of any other appellants, to respond) and would reduce the transparency of the process. Appellants should not rely on confidential information in their appeal letters and statements if their appeal could be supported equally strongly by information in the public domain. The Appeal Panel will only allow a statement to be made in private if it is satisfied that the disclosure of confidential information is necessary for an effective oral appeal. In addition, a private appeal will only be granted for specific submissions for which that test is satisfied; any other submissions will be heard in public.

Where part of an appeal hearing is held in private, the appellant(s) submitting the confidential information will be given the opportunity to review the appeal decision prior to publication to identify any information that should remain confidential. If other appellants are involved in the appeal, and the appellant making the confidential submission agrees that the other appellants can remain during the private discussion, the unredacted version of the appeal decision will be circulated to the other appellants in confidence and for information purposes prior to publication. The redacted version of the appeal decision will be published.

Figure 1 Summary of the oral appeal process



8 The written appeal process

8.1 *What is the timescale for an appeal?*

Assuming that the appeal is valid, the Appeal Panel will aim to hold a written appeal within 10 weeks of an appeal being lodged.

8.2 *How is the written appeal process conducted?*

All communication for written appeals is done through an exchange of letters. The Vice Chair of NICE scrutinises the appeal letter and composes the initial scrutiny letter, requesting clarification on the appeal points, if necessary, and proposing that the appeal proceeds as a written appeal usually within 5 working days of receiving the notice of appeal. The appellant has the opportunity to respond to the initial scrutiny letter to clarify and confirm the grounds to be considered at the appeal and respond to the written appeal proposal within 10 working days.

In exceptional circumstances, where the validity of the appeal points are uncertain at initial scrutiny, the Vice Chair of NICE may defer deciding whether to proceed with an oral hearing or proposing that there should be a written appeal, until the appeal points are confirmed at final scrutiny. A written appeal process will only be adopted following consultation with appellant(s).

Once the grounds for appeal have been determined and the written appeal agreed, the correspondence is forwarded to the Chair of the advisory committee and the NICE Centre for Health Technology Evaluation Director (Centre Director), who have the opportunity to respond in writing to the appeal letter(s), within 10 working days, with respect to the grounds agreed in the scrutiny letter. This response is sent to the appellant(s), who is given the opportunity to respond in writing to the comments made by the advisory committee Chair and the Centre Director. The appellant(s) also has 10 working days to respond.

All correspondence, along with the technology appraisal or highly specialised technology documents, is then provided to the Appeal Panel. The Appeal Panel meet to consider each appellant's appeal points and the submissions received.

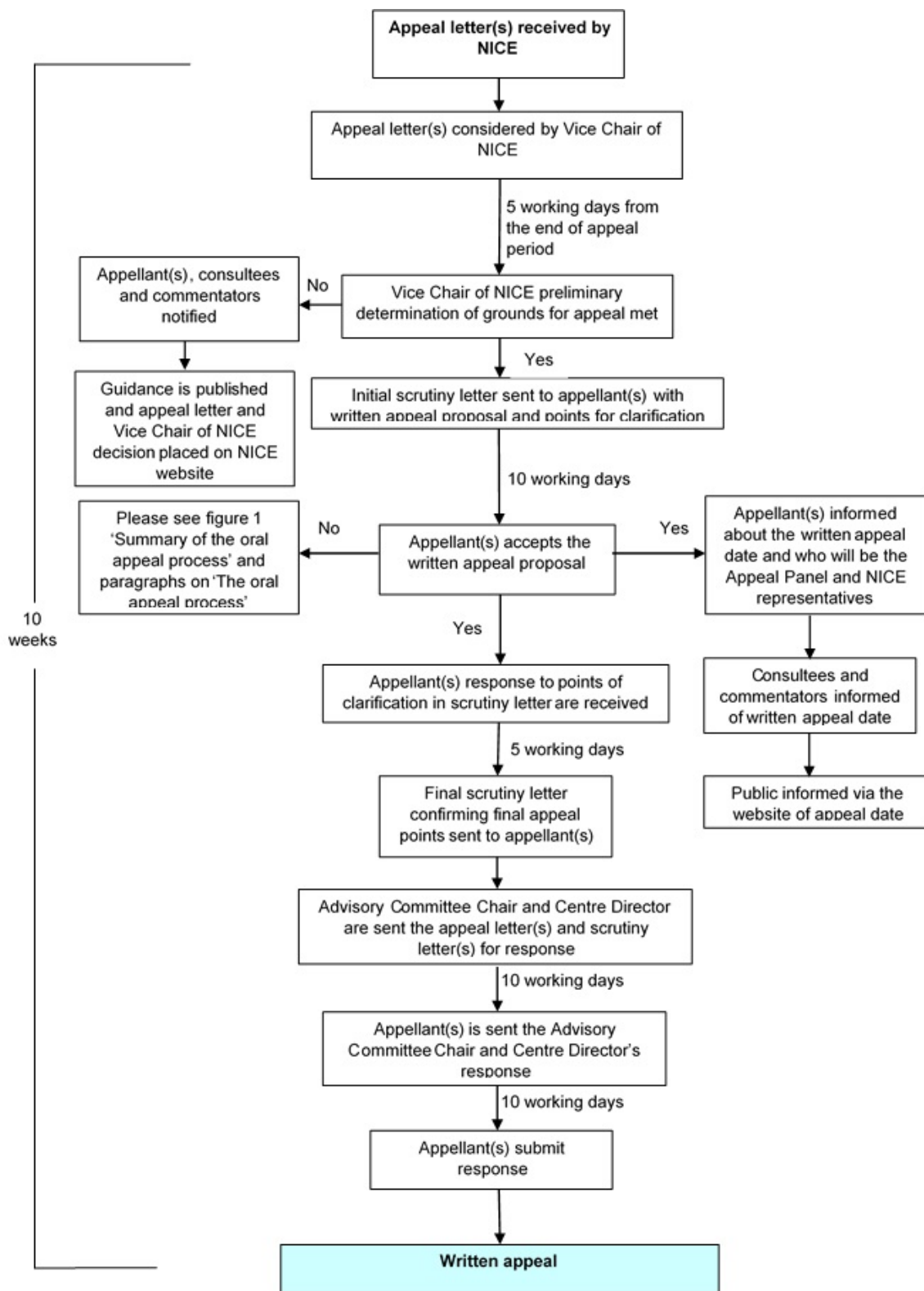
On the morning of the appeal, the appeal letter, the scrutiny letters and responses to these letters are placed on the NICE website. Any confidential information and personal data are removed before publication on the website.

All 5 members of the Appeal Panel must be present for the appeal. However, if a member is unable to attend or has to stand down at short notice, the Chair of the Appeal Panel will consult with the appellant(s) and NICE representatives. If all parties agree, the appeal will continue with only 4 members of the Appeal Panel, provided that there is still at least 1 representative of the life sciences industry, 1 health service representative, and 1 patient representative, and that one of the health service or patient representatives is the panel chair. This agreement to proceed will be noted in the Appeal Panel decision.

8.3 *Who may attend the appeal?*

The Appeal Panel convenes to discuss the appeal lodged, and the advisory committee Chair's and appellant(s) response. This meeting may be in person or via teleconference. The Appeal Panel may take legal advice if necessary. No appellants, advisory committee members, NICE staff, press or public will be in attendance at this meeting.

Figure 2 Summary of the written appeal process



9 Rejected appeals

If all grounds of appeal have been rejected following scrutiny, an oral or written appeal will not be held. The appellant(s), and consultees and commentators will be informed of the rejected appeal, and the newly anticipated guidance publication date. NICE will publish a notice on its website announcing that an appeal had been received but was rejected during the scrutiny stage at least 2 working days after consultees and commentators are informed. At the same time, the appeal letter(s), scrutiny letters and responses to these letters will be placed on the NICE website.

10 Cancelled appeals

Once an appeal is received there may be occasions when NICE wishes to withdraw the final draft guidance, or the appellant(s) withdraws their appeal resulting in the appeal being cancelled. If an appeal is cancelled after the notice of an appeal has been issued, NICE will publish a notice on its website announcing that the appeal has been cancelled, along with the appeal letter(s), scrutiny letters and responses to these letters, at least 2 working days after consultees and commentators are informed.

11 After the appeal

11.1 *What is the timescale for the appeal decision?*

In both the oral and written appeal processes, the Appeal Panel will aim to send its decision in writing to NICE within 15 working days of the appeal. There may be circumstances in which more time is needed. The appeal decision is then considered by the Guidance Executive. The Guidance Executive consists of the NICE Senior Management Team and is chaired by the NICE Chief Executive. Figure 3 summarises the appeal process from the release of the appeal decision to its publication as well as the publication of the guidance.

11.2 *Outcome of an appeal*

Appeal upheld and final draft guidance returned to the advisory committee

If 1 or more of the appeal points are upheld and it is necessary for the final draft guidance to be returned to the advisory committee, the Guidance Executive will aim to consider the appeal decision within 15 working days of receipt. The Guidance Executive will decide how to act on the decision of the Appeal Panel. The appeal decision is normally published within 10 working days of its consideration by the Guidance Executive. Consultees (including appellants) and commentators are informed of the appeal decision and details of when the final draft guidance will be reconsidered by the advisory committee, 2 working days before publication of the appeal decision.

The technology will be returned to the relevant programme and work will start on reviewing the guidance as advised by the Appeal Panel and agreed by the NICE Guidance Executive.

The advisory committee will meet to consider the Appeal Panel's decision for review. The advisory committee will then produce revised final draft guidance. When the final draft guidance is produced, it will be distributed to consultees and commentators. Consultees will then have a further opportunity to appeal or to identify any factual errors.

If an appellant from the first appeal lodges another appeal, the appeal letter must not raise the same points presented in the first appeal or those points presented by another appellant at the first appeal hearing. The Appeal Panel will have already determined the outcome on these points.

If an appellant who did not participate in the first appeal hearing lodges an appeal, the appeal will need to satisfy the Vice Chair of NICE that one or more of the grounds has been met and has a

reasonable prospect of success. The appeal process will follow its usual process and continue as either an oral or written appeal.

Only points that directly relate to the aspects of the revised final draft guidance associated with the appeal decision will be considered.

Appeal Panel requests changes to the final draft guidance but no further consideration by the Committee

If the Appeal Panel asks the Guidance Executive to approve changes to the final draft guidance that do not require further consideration by the Committee, the Guidance Executive will aim to consider the appeal decision within 15 working days of receipt of the appeal decision. After the Guidance Executive meeting, editorial changes to final guidance are made if required and the final guidance is normally published on NICE's website within 15 working days. 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 beforehand.

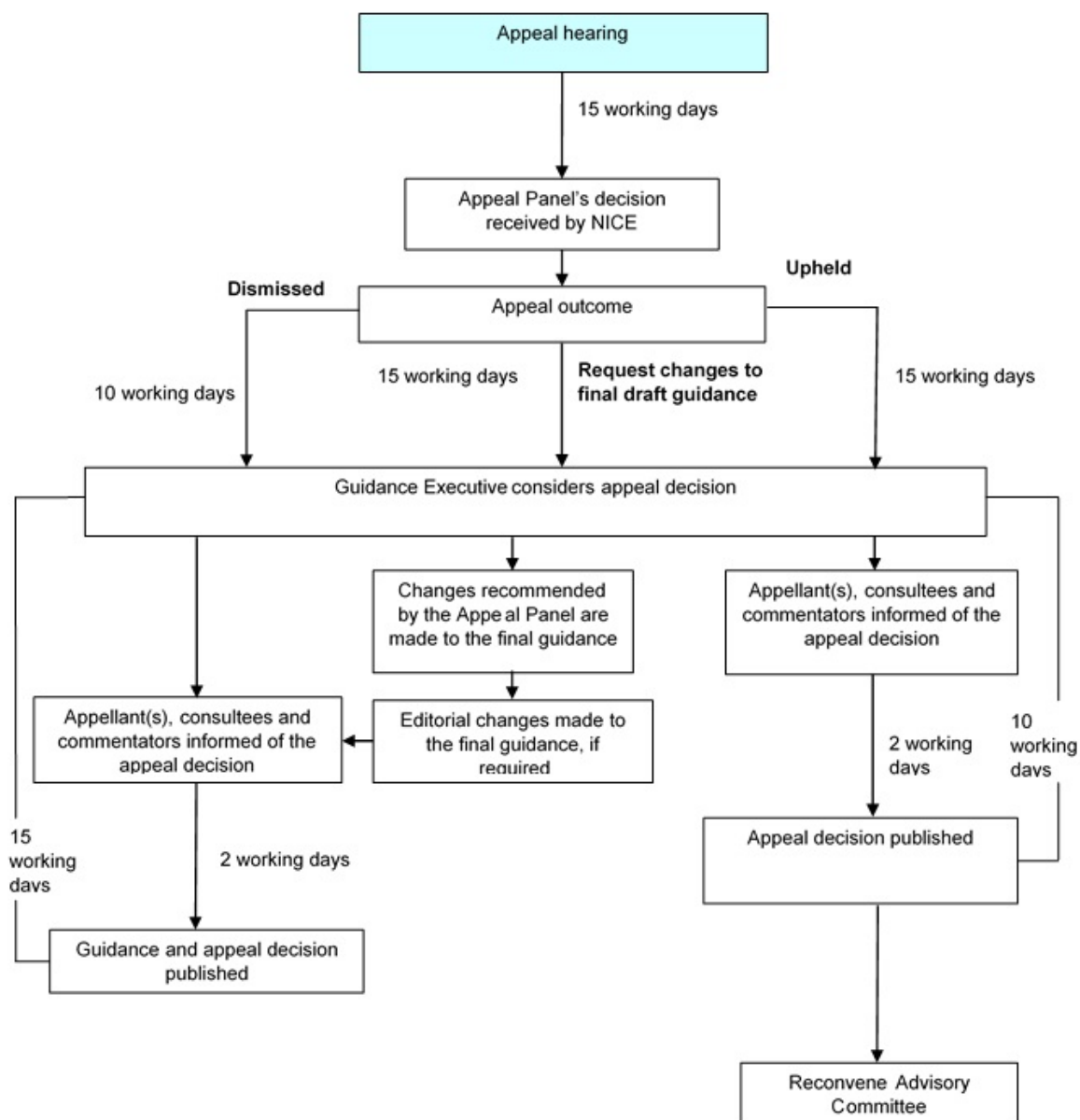
Appeal dismissed

If the appeal is dismissed and the Appeal Panel has not requested changes to the final draft guidance, the Guidance Executive will aim to consider the appeal decision within 10 working days of receipt of the appeal decision. After the Guidance Executive meeting, the final guidance is normally published on NICE's website within 15 working days. 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 beforehand.

11.3 What happens after the appeal decision is published?

There is no possibility of further appeal against the decision of the Appeal Panel. However, this decision and NICE's decision to issue the final guidance may be challenged by applying to the High Court for permission to apply for a judicial review. Any such application must be made promptly and within 3 months of publishing the final guidance.

Figure 3 Summary of process for publishing the appeal decision and guidance



Acknowledgements

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