

Guide to the technology appraisal and highly specialised technologies appeal process

Process and methods

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1 Introduction

This process guide applies to appeals against any final draft guidance issued to stakeholders on or after 1 June 2023.

For appeals against final draft guidance issued to stakeholders before 1 June 2023, use the [previous guide to the technology appraisal and highly specialised technologies appeal process](#).

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

Organisations invited to contribute to NICE technology appraisals and highly specialised technologies evaluation (consultees and commentators) should read this guide alongside the below documents on NICE's website before lodging an appeal:

- Evaluation started before 1 February 2022:
 - [Guide to the processes of technology appraisal](#)
 - [Guide to the methods of technology appraisal](#)
 - [Highly specialised technologies interim process and methods guide](#)
- Evaluation started after 1 February 2022:
 - [NICE health technology evaluations: the manual](#).

2 Who can lodge an appeal and on what grounds?

Only consultees involved in a technology appraisal or a highly specialised technologies evaluation can lodge an appeal. Consultee organisations include:

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

The ability to become a consultee ends when the final draft guidance is issued to the stakeholders, whether this is after consultation or without consultation. A consultee is referred to as an appellant once an appeal has been lodged. Stakeholders taking part in the evaluation but that are not consultees, including organisations designated as commentators, are unable to lodge an appeal.

Appeals can only proceed if they fall within one or more of the following grounds. Either or both parts of ground 1 can be appealed. Appeals on any other grounds will not be considered.

- 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.

See [section 4.3](#) for more information.

3 Who considers the appeal?

3.1 The lead non-executive director for appeals

NICE's chairman will appoint one of [NICE's non-executive directors](#) to oversee the appeals process. This non-executive director is responsible for determining the initial validity of each of the appeal points lodged and will decide if an appeal (oral or written) will be held. This is known as the scrutiny process and is outlined further in [section 5](#).

In the temporary absence of the appointed non-executive director, or when they have a conflict of interest with the topic, NICE's chairman will either do the scrutiny process themselves or nominate an alternative non-executive director.

3.2 The appeal panel

Appeals accepted during the scrutiny process are heard by an appeal panel. The appeal panel is drawn from a group of individuals appointed through an open recruitment process and approved by the Secretary of State for Health and Social Care.

Before being appointed, appeal panel members must declare conflicts of interest in accordance with [NICE's policy on declaring and managing interests for advisory committees](#). NICE will ensure that no member of an appeal panel has any interest that may affect the independence of their decision. The appeal panel acts impartially and independently of any party involved with the technology appraisal or highly specialised technologies evaluation, including the committee. None of the panel will have been involved in developing the guidance that is being appealed.

Each appeal panel consists of 5 members, 4 of whom are independent of NICE:

- appeal panel chair, who is:
 - engaged in the provision of healthcare in the health services (health service representative) or
 - a patient, carer or member of organisation that represents patients or carers (lay representative)

- 1 non-executive director of NICE (who was not involved in the scrutiny process)
- 1 health service representative
- 1 representative of the life sciences industry
- 1 lay representative.

4 Making an appeal

4.1 How to lodge an appeal?

A consultee may appeal to NICE within the appeal period. The appeal period starts when the final draft guidance is issued to stakeholders and ends 15 working days later at 5pm. The letter from NICE that accompanies the final draft guidance states this deadline for appeal. Appeals must be submitted in writing to appeals@nice.org.uk. See [section 12](#) for accessibility and adjustments.

4.2 What is the scope of an appeal?

An appeal is not a rehearing of the evaluation. The appeal panel will only consider arguments about valid grounds of appeal as listed in [section 2](#). It will not rehear evidence or consider points previously made by the appellant that do not fall within a valid ground of appeal.

An appeal can only relate to final draft guidance for a technology appraisal or highly specialised technologies evaluation, or the way that the evaluation was done. An appeal cannot be lodged against other documents produced during the process (for example, the draft guidance or scope), although the content of those documents may be relevant and referred to in an appeal. This is because an appeal must be brought against a 'recommendation', and only final draft guidance can be considered a recommendation.

NICE also considers the following as 'recommendations' for the purpose of the appeal process:

- all parts of final draft guidance that explain the recommendations
- the evidence considered
- the committee's reasoning or wording in the final draft guidance that otherwise could influence the use of a product within the NHS.

Any other part of the final draft guidance may not be the subject of an appeal.

Requests for corrections of minor factual or typographical errors in final draft guidance are not normally considered at an appeal but will be looked at separately by the NICE team responsible for the guidance. If factual errors are submitted at the same time as an appeal is lodged, the lead non-executive director for appeals, who initially considers the appeal, will be informed and receive a copy of the factual error submissions for information. The NICE team responsible for the guidance will usually consider such requests for amendments after the appeal decision.

4.3 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 highly specialised technologies process. An appellant who believes that an evaluation was not fair 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 if an appellant does not agree with final draft guidance this does not make it unfair. For example, although it is unfair to exclude relevant data from the technology appraisal and highly specialised technologies evaluation process, it is not unfair to consider the relevant data but then reach a view with which the appellant did not agree.

This ground of appeal does not cover an argument that it is 'unfair' in a general sense, for example, that it is 'unfair' to patients not to recommend a treatment.

Unspecific allegations of unfairness, for example, an alleged inability to understand a conclusion, will not be accepted as a valid appeal point. Details and evidence must be provided in every case.

NICE requires appellants to explain what steps they took to promptly resolve any unfairness when they first became aware of it. The appeal panel may interpret the absence of any such steps, without sufficient reason, as evidence that there was in fact no such unfairness, or potentially as a reason not to refer guidance back to the committee or to request changes to guidance.

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 and Social Care. An appellant may appeal on the ground that NICE has acted outside its remit or has acted unlawfully. This ground of appeal would also include allegations that either the process used to generate guidance or the guidance itself are contrary to equality legislation.

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

Draft guidance is produced after a formal evaluation process that includes structured evidence gathering, consultation, expert input and consideration by a broad-based committee. The appeal process cannot replicate those steps. Therefore, the properly exercised and reasonable judgement of a committee must be respected and 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 'does not add up'. The appeal panel will not make its own judgements about the technology, but it will review the committee's decisions to see if they can reasonably be justified, based on the evidence that was available to the committee.

4.4 Appeals against recommendations revised because of commercial arrangements

NICE may review published guidance recommendations either through a rapid review after submission of a new patient access scheme or a review after submission of a commercial access agreement.

Appeals against the reviewed recommendations are limited to appeal points that relate to consideration of the new patient access scheme or commercial access proposal. This is because there would have been an unrestricted opportunity to appeal the guidance before it was originally published.

4.5 Second appeals

Revised guidance produced after a successful appeal may itself be the subject of an appeal. In such cases, appeal points that were rejected at the first appeal, and which relate to elements of the guidance that have not been changed, may not be raised again at the second appeal.

4.6 What must the appeal letter contain?

The appeal letter is the appellant's first opportunity to present the points they wish to lodge an appeal on. It must be submitted by 5pm of the deadline for receipt of appeals and requests for corrections. It is important that the appeal letter is submitted correctly, is presented clearly and contains the necessary information (see appeal letter requirements). If the submitted letter is not appropriate (for example, it does not have enough 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 or appears unarguable. The appeal letter requirements are stated in this section and [an appeal letter template is available on the NICE technology appraisal and highly specialised technologies appeal webpage](#).

Appeal letter requirements

The appeal letter must contain an introductory statement clearly specifying 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 an appeal letter is longer than 5 A4 pages, appellants should produce an executive summary of the appeal. The executive summary should be no longer than 1 A4 page.

The appeal letter must clearly and concisely 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(a) must be made first, followed by all points made under ground 1(b) and then all appeal points made under ground 2. Appeal letters must provide enough information for the appeal panel to 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).1: the change from a positive to negative recommendation following draft guidance without further consultation is unfair'.

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(a) 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, 1(b).2, 2.1 and so on.

It is not necessary to number individual paragraphs in the appeal letter. If the appellant considers that this aids clarity, they should simply number every paragraph in the appeal letter sequentially, and use the numbered headings for the 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 of appeal are quite distinct (see [section 4.3](#)). So, appellants should consider carefully which ground of appeal any given concern 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), which is concerned with process.

If the context for different appeal points overlaps (for example, if an alleged unfairness is also said to have produced a recommendation that cannot reasonably be justified) it is acceptable to cross refer. But appellants must set out the argument they wish to make under each ground in detail. They should specify how earlier 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 of appeal are clearly identified, fall within 1 or more of the grounds set out in [section 4.3](#), and are arguable.

If the appeal letter contains commercial-in-confidence information ([in-confidence material](#) which cannot be shared in public), the appellant will be responsible for clearly labelling this information and for submitting a second version of the appeal with this information redacted.

Appeal letters and other information supplied as part of the appeals process will be published on the NICE website. To help ensure content is accessible to everyone including users with impairments to vision, hearing, mobility, thinking and understanding, appeal

letters (and the responses to scrutiny) should be submitted as Microsoft Word documents.

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 lead non-executive director for appeals will make this decision at their discretion but 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 or highly specialised technologies evaluation process, being appealed against
- the reasons why the aspect(s) of the final draft guidance, or technology appraisal or highly specialised technologies evaluation 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 only be accepted in exceptional circumstances and when these relate to factual corrections.

The lead non-executive director for appeals will respond to each appeal letter to indicate their preliminary view of the 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](#).

4.7 Can new data be submitted to the appeal panel?

All data that consultees consider relevant to the guidance topic should have been submitted to the committee as part of the technology appraisal or highly specialised technologies evaluation process (as described in the relevant NICE process guide that applied when the evaluation started, see [section 1](#)). 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. Stakeholders who consider that new data casts doubt on a recommendation should seek a review of the guidance, rather than appeal it.

The appeal panel will have access to the key material reviewed by the committee.

The appeal panel cannot accept late or ad hoc submissions, because this affects preparations for the appeal. If in exceptional circumstances appellants or representatives of NICE or the committee feel there is unsubmitted written material they wish to rely on during the appeal hearing they must inform the NICE appeal team as soon as possible about what the material is, why it is desirable to submit it, and when it will be available. The appeal panel chair will then decide if the information can be provided, and if so, the appeals team will provide a deadline for submission. The material must then be submitted to the NICE appeals team by the given deadline.

5 Scrutiny of appeal points

5.1 Initial scrutiny of the appeal

NICE will aim to acknowledge receipt of appeal letters within 2 working days. The lead non-executive director for appeals will usually write to the appellant within 5 working days from the end of the appeal period with their initial views on the appeal.

The lead non-executive director for appeals will respond to each appeal letter to indicate their preliminary view on the validity of each of the appellant's points. In doing so they may take legal advice. This response is known as the initial scrutiny letter.

To determine the validity of an appeal point, the lead non-executive director considers whether it is:

- within one of the permitted grounds of appeal, and
- arguable.

The reason for this step is to ensure the appeal process remains within its proper bounds, and to enable an appeal panel to use its time most effectively.

When deciding if a point is arguable, the lead non-executive director will consider factors such as whether the:

- appeal point appears to be directly contradicted by the evaluation documentation
- argument presented is logical
- matter complained of is so minor that it could not cast doubt on the recommendation
- matter complained of was fully corrected during the evaluation.

They will also consider whether the matter complained of has been previously considered and rejected by an appeal panel. NICE does not consider that past decisions of appeal panels are strictly binding on future appeals, but it does aspire to broad consistency of approach. If the lead non-executive director considers that past appeal decisions show a settled position on an issue, they may decide an appeal point is unarguable if it relies on a

position that is contrary to and cannot be factually distinguished from that settled position.

The lead non-executive director may suggest or require that a point is considered under a different ground of appeal to that suggested by the appellant. For example, an appellant may say that the committee 'has ignored' some evidence and that is unfair. If the lead non-executive director considers that the evaluation documentation shows the committee did consider the evidence, they may either dismiss the appeal point as unarguable or request that it be considered instead under ground 2 (for example, that the committee's treatment of the evidence led to an unreasonable recommendation).

If the lead non-executive director for appeals is minded to reject 1 or more grounds of appeal they will give reasons for this in the initial scrutiny letter and will invite further information or clarification.

If an appeal is to proceed, the scrutiny letter will usually say whether the lead non-executive director for appeals considers that the appeal should be held orally or in writing. In exceptional circumstances, the lead non-executive director for appeals 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 after consultation with the appellant(s).

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 lead non-executive director for appeals' initial view that an appeal point is not valid. Responses received after the deadline will not be considered.

The appellant's response to the initial scrutiny letter will usually be the last opportunity to elaborate or provide clarification to their appeal points, unless they are specifically invited to submit material by the lead non-executive director for appeals. Any uninvited material submitted after the response to the initial scrutiny letter will be rejected.

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 and who will be on the appeal panel as soon as possible. In the case of an oral appeal, NICE also informs the appellant(s) who will attend from NICE, the committee and external advisers. 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 (see [section 8.2](#)). In the case of a written appeal, NICE informs the appellant(s) that it will proceed as a written appeal, the date of the appeal and who will be on the appeal panel.

NICE informs stakeholders that an appeal has been received, whether the appeal will be oral or written, the name of the appellant(s) organisation, and the date of the appeal hearing. At least 2 working days after stakeholders are informed of the date of the appeal, NICE publishes a notice on its website announcing that an appeal will be held.

5.3 Final scrutiny of the validity of the appeal points

Within 5 working days of receiving an appellant's response to the initial scrutiny letter, the lead non-executive director for appeals will write to the appellant with their final decision on the validity of the appeal points raised. This is known as the final scrutiny letter. A further response cannot be submitted by the appellant. The letter outlines all appeal points that will be considered at the appeal and may also make specific directions for the conduct of an appeal.

Exceptionally, scrutiny letters may suggest that one or more appeal points could be further explored in writing before the appeal hearing or written appeal. Typically, this will be when a legal point has been raised and it will be unhelpful for the appeal panel's preparation for that point to be detailed for the first time in the hearing itself. In that case, the lead non-executive director for appeals will provide directions for how the point should be dealt with, usually by preparing written arguments in advance.

The final scrutiny letter may also contain advice or suggestions intended to support the conduct of the appeal. For example, drawing attention to a past decision when it appears likely that the appeal panel may have this in mind, or suggesting a grouping of appeal points. Any such advice will always be subject to the appeal panel chair's right to conduct the hearing as they think best.

If there is more than one appellant, each appellant will be sent a copy of the other appellants' appeal letters at this stage. If the appeal letter or responses to scrutiny contain confidential information, the appellant must ensure they have provided a version with this information redacted. When possible, appellants should coordinate when preparing their

appeal presentations to avoid duplication, although NICE appreciates there may be valid reasons why this is not always appropriate.

A decision that an appeal point is not valid may be challenged by way of judicial review. NICE's position is that:

- it is appropriate and necessary for all appellants to wait for the outcome of the whole appeal before beginning any such challenge, and
- unless all appeal points from all appellants have been rejected as invalid, the time to bring such a challenge should not be considered to start running until:
 - publication of final guidance (if an appeal has been wholly unsuccessful); or
 - the final appeal panel decision is published (if an appeal has been successful).

This is because NICE's final position on the recommendations cannot be known until the appeal is complete.

6 Rejected appeals

If the lead non-executive director for appeals rejects all appeal points during scrutiny, a letter will be issued to the appellant(s) to confirm an appeal will not be held. The appellant(s) and stakeholders will be informed of the rejected appeal and the new publication date of the final guidance. At least 2 working days after the stakeholders are informed, NICE will publish a notice on its website announcing that an appeal had been received but was rejected during the scrutiny stage. At the same time, the appeal letter(s), scrutiny letters and responses to these letters will be published on the NICE website.

7 Conduct of an appeal

7.1 Will there be a hearing?

The lead non-executive director for appeals' decision on holding an oral or written appeal will take account of the appellant(s) views in the original appeal submission. A written process is more likely to be suitable when there are only a small number of appeal points and appellants.

7.2 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 technologies evaluation being appealed. If an appellant believes that a member of the appeal panel has an interest that may bias them for or against the submissions of any appellant, they should inform the appeal panel chair within 10 working days of receiving the letter listing the relevant appeal panel members. In these circumstances, NICE may decide to change the membership of the panel if it considers this necessary in line with [NICE's policy on declaring and managing interests](#).

8 The oral appeal process

8.1 What is the timescale for an appeal?

If the lead non-executive director for appeals has decided that an oral appeal should be held, the appeal panel will aim to hold an oral appeal within 8 weeks of an appeal being lodged.

8.2 Who may attend the oral appeal?

Oral appeals are primarily held virtually and are open for observation by members of the public, stakeholders and the press. This supports NICE's commitment to openness and transparency. It enables stakeholders and the public to observe and better understand the way NICE makes its decisions.

A notice on the NICE website announces that an appeal will be heard. Registration opens for members of the public and staff to observe the appeal at least 15 working days before the hearing. The closing date for registration is usually 5 working days before the meeting and late registrations may not always be accepted. Once registration has closed, NICE will contact all registrants with the joining links, joining instructions, and weblinks to the frequently asked questions document and project documents for the technology appraisal or highly specialised technologies evaluation under discussion.

On the morning of the appeal, the appeal letter(s), scrutiny letters and appellant(s) responses to these letters are sent to the registrants along with a list of those taking part in the hearing and the anticipated order in which the appeal points will be heard. The appeal letter(s), scrutiny letters and responses to these letters are also published on the NICE website after confidential information and personal data have been removed.

Public observers are not allowed to take part in the discussions or record the appeal proceedings. The appeal panel chair may exclude anyone from the appeal if they consider that person is disrupting proceedings.

Each appellant is allowed up to 5 representatives at the hearing, including legal representation. This number may be reduced to 3 representatives if there are more than

3 appellants. Subject to the discretion of the appeal panel chair, an appeal will proceed in the absence of some or all of an appellant's representatives.

The committee and NICE (taken together) are allowed up to 5 representatives in total at the hearing. This may include a representative of the external assessment group or relevant commissioning organisations invited to attend committee meetings by NICE, or both.

The appeal panel will have its own legal adviser present to advise on any procedural or legal issues that may arise. When an appeal point under ground 1(b) raises an issue as to the interpretation of the law, any advice on that issue will be given in public (or circulated in writing beforehand).

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 NICE appeals team will invite another member of the appeal panel (of the same category) to attend. They will ensure there are no conflicts of interest with the evaluation being appealed. If it is not possible to replace the member at short notice, the appeal panel chair 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 lay representative, and that one of the health service or lay representatives is the panel chair. This agreement to proceed will be noted in the appeal panel decision.

8.3 How is the oral appeal done?

At the start of the appeal hearing, the appeal panel chair welcomes the participants and provides an oral briefing outlining the arrangements for the hearing. The appeal panel and representatives of the committee and NICE introduce themselves and confirm they do not have any undeclared interests or any conflicts of interest. The appellants introduce themselves, but they are not required to declare any interests. [NICE's policy on declaring and managing interests](#) does not apply to those representing the appellants. This is because the appellants will have a clear interest in the technology that is the subject of the appeal, often as the manufacturer, or bodies advocating the technology.

The appeal panel chair then invites each appellant (not each representative) to make a brief 5-minute introductory statement. 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 (see [section 8.4](#)). 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 committee chair or a representative of NICE is also invited to make an introductory statement of similar length.

The appeal panel then considers and hears each appellant's appeal points. It is not possible for an appellant to comment on another appellant's appeal point unless they had a similar appeal point accepted during scrutiny.

Hearings are done in an inquisitorial rather than an adversarial style. This means that all questions must be made through the appeal panel chair; appellants and representatives for the committee and NICE may not question each other directly. Members of the appeal panel may ask appellants and the representatives for the committee and NICE questions on any relevant issue.

Points may be dealt with by questions from the appeal panel. If the appeal panel is confident it understands the arguments in the appeal submission and the position of NICE or the committee, the appeal point may not be specifically discussed. The appeal panel chair will endeavour to ensure that the appeal panel uses the hearing time strategically, so that the greatest time is devoted to the points most in need of exploration in the hearing. If a point is not taken in the hearing or taken only briefly this will not be an indication that the appeal panel has prejudged it.

The representatives for the 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.

A representative from each appellant and a representative from NICE or the committee are invited to make a brief concluding statement before the appeal hearing ends.

When there are multiple appellants and some choose not to attend an oral hearing, the appeal panel will consider the written appeal letters of those not attending. They may ask questions of the representatives for the committee arising out of those letters before determining the appeal points raised by the non-attending appellant(s).

After the hearing the appeal panel will meet in private to discuss and agree their decision on each appeal point. The appeal decision will summarise the issues discussed at the hearing, the panel's decision on each appeal point and their rationale.

8.4 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 in this section.

An appellant who intends to make confidential submissions (in a private hearing) should inform the appeals team 15 working days before the appeal date. The appellant should indicate if they agree for other appellants (but not the public) to remain during any confidential submissions. The appeal panel will be sensitive to the need to protect confidential and commercially sensitive information. But it will balance this against the fact that confidential submissions would deny the other appellants and the public 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 confidential submissions if it is satisfied that the disclosure of confidential information is necessary for an effective oral appeal. In addition, permission to make confidential submissions will only be granted for specific submissions for which that test is satisfied; any other submissions will be heard in public.

When 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 before publication to identify any confidential information and request that it should remain confidential. NICE will then assess the request and consider what should be redacted from the publicly released decision. 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 hearing, the unredacted version of the appeal decision will be circulated

to the other appellants in confidence and for information purposes before publication. The redacted version of the appeal decision will be published.

9 The written appeal process

9.1 What is the timescale for an appeal?

If the lead non-executive director for appeals has agreed to proceed with a written appeal, the appeal panel will aim to meet within 10 weeks of an appeal being lodged.

9.2 How is the written appeal process done?

All communication for written appeals is done through an exchange of letters by email.

The lead non-executive director for appeals scrutinises the appeal letter and composes the initial scrutiny letter, usually within 5 working days of receiving the notice of appeal, requesting clarification on the appeal points, if necessary, and proposing that the appeal proceeds as a written appeal. The appellant has 10 working days to respond to the initial scrutiny letter and respond to the proposal that it will be a written appeal.

In exceptional circumstances, when the validity of the appeal points are uncertain at initial scrutiny, the lead non-executive director for appeals may wait to decide whether to proceed with an oral hearing or propose a written appeal, until the appeal points are confirmed at final scrutiny.

A written appeal process will only be adopted after consultation with appellant(s), however, the final decision rests with the lead non-executive director for appeals.

Once the grounds of appeal have been determined and the written appeal confirmed, the correspondence is forwarded to the committee chair and NICE's director for medicines evaluation, who have the opportunity to respond in writing to each appellant, within 10 working days, with respect to the grounds agreed in the scrutiny letter(s). This response is sent to the appellant, who is given the opportunity to respond in writing to the comments made by the committee chair and NICE's director for medicines evaluation. The appellant(s) also has 10 working days to respond. If there are multiple appellants, the comments made by the committee chair and NICE's director for medicines evaluation, along with any response to those comments, are shared with the other appellants.

All correspondence, along with the relevant documents from the evaluation, are then provided to the appeal panel. The appeal panel then meet to consider each appellant's appeal points and the submissions received.

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

As set out in [section 8.2](#), 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 NICE appeals team will invite another member of the appeal panel (of the same category) to attend. They will ensure there are no conflicts of interest with the evaluation being appealed. If it is not possible to replace the member at short notice, the appeal panel chair 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 lay representative, and that one of the health service or lay representatives is the panel chair. This agreement to proceed will be noted in the appeal panel decision.

9.3 Who may attend the appeal?

The appeal panel meets to discuss the appeal points accepted at the scrutiny stage, the committee chair's and NICE team's response, and the appellant's response to this. This meeting may be held in person or virtually. The appeal panel may take legal advice if necessary. No appellants, committee members, NICE staff (other than the appeals team), press or public will attend this meeting.

During the meeting, the appeal panel will discuss and agree their decision on each appeal point. The appeal decision will summarise the issues discussed at the hearing, the panel's decision on each appeal point and their rationale.

10 Cancelled appeals

Once an appeal is received there may be occasions when NICE wishes to withdraw the final draft guidance resulting in the appeal being cancelled. Similarly, an appellant may decide to withdraw their appeal, which would mean the appeal is cancelled if there are no other appellants. In both cases, the decision to withdraw must be submitted in writing to the lead non-executive director for appeals. The lead non-executive director for appeals will acknowledge the letter and the NICE appeals team will inform the other parties involved in the appeal.

If an appeal is cancelled after the notice of an appeal has been published on the NICE website, NICE will publish a notice on its website announcing that the appeal has been cancelled, along with the appeal letter(s), scrutiny letters, responses to these letters and letter explaining the cancellation and the response, at least 2 working days after the stakeholders are informed. For oral appeals and when registration to attend has opened, NICE will also inform members of the public and stakeholders registered to observe the hearing of the cancelled appeal after the stakeholders 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 but there may be circumstances in which more time is needed (such as when there are many appeal points).

The appeal decision will state whether the appeal is dismissed or upheld and explain on what grounds.

11.2 Outcome of an appeal

There are 3 possible outcomes of an appeal.

1: Appeal upheld and final draft guidance returned to the committee

If 1 or more of the appeal points are upheld the guidance executive will aim to review the appeal decision within 15 working days of receipt.

The appeal decision is then normally published on NICE's website within 10 working days of the guidance executive meeting. The appeals team send the appeal decision to stakeholders 2 working days before publication of the appeal decision.

After this, the NICE team responsible for the guidance will inform stakeholders of the next steps and details of when the final draft guidance will be reconsidered by the committee.

The final draft guidance will be returned to the relevant technology appraisal or highly specialised technologies programme and the committee will usually meet to consider the issues raised in the appeal panel's decision (or this may be done in writing). The committee will then produce revised final draft guidance.

When the revised final draft guidance is produced, it will be distributed to stakeholders. Consultees will then have a further opportunity to appeal or identify any factual errors.

As set out in [section 4.5](#), revised guidance produced after a successful appeal may itself be the subject of an appeal. In such cases, appeal points that were rejected at the first appeal, and which relate to elements of the guidance that have not been changed, may not be raised again at the second appeal.

2: Appeal panel requests changes to final draft guidance but no further consideration by the committee is required

The appeal panel may uphold at least 1 appeal point but only request minor changes to the guidance that do not require consideration by the committee. There may also be occasions when an appeal is dismissed but the appeal panel recommends minor clarifications to the final draft guidance.

In these circumstances, the guidance executive will aim to review the appeal decision within 15 working days of receiving the appeal decision. After the guidance executive meeting, the recommended minor changes will be made to the final draft guidance. The final guidance and appeal decision are then normally published on NICE's website within 10 further working days.

Stakeholders 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.

3: Appeal dismissed, no changes required to final draft guidance

If the appeal is dismissed and the appeal panel has not requested changes to the final draft guidance, the guidance executive will aim to review the appeal decision within 10 working days of receiving the appeal decision. After the guidance executive meeting, the final guidance and appeal decision are normally published on NICE's website within 10 further working days. Stakeholders 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 publication.

11.3 What happens after the appeal decision is published?

There is no possibility of further appeal against the appeal panel's decision. However, the panel's decision and any decision by NICE to issue the final guidance may be challenged

by applying to the High Court for permission to apply for a judicial review. Any application against the final guidance must be made promptly and within 3 months of NICE publishing the final guidance. Any application against the appeal decision must be made promptly and within 3 months of publication of the appeal decision.

12 Accessibility and adjustments

NICE wishes to ensure that the appeal process is fair and accessible to all appellants. If an appellant or their representative needs any reasonable adjustments to the appeal hearing or appeal process so they can participate effectively, this should be raised with the appeals team at the earliest opportunity. Possible reasons for an adjustment would include any difficulties in participating created by any of the protected characteristics listed in the Equality Act 2010. However, pressure of work or conflicting professional commitments cannot be accepted as a reason for an adjustment.

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