# Changes to appeal period for technology appraisal and highly specialised technologies appeals

# Background

1. Consultees can appeal against a technology appraisal (TA) or highly specialised technologies (HST) recommendation on the grounds that:

(a) in making the assessment that preceded the recommendation, NICE

(i) failed to act fairly, or

(ii) exceeded its powers; or

(b) the recommendation is unreasonable in the light of the evidence submitted to NICE.

1. The arrangements for the appeal process are set out in the [Guide to the technology appraisal and highly specialised technologies appeal process [PMG41]](https://www.nice.org.uk/process/pmg41). Consultees have 15 working days from receiving the final draft guidance to submit an appeal (this is known as the appeal period).
2. Between 20 January 2025 and 16 February 2025 NICE ran a 4-week public consultation on proposed changes to the appeal process so that a consultee who intends to submit an appeal, or is considering submitting an appeal, against TA or HST guidance that recommends a technology must notify NICE within the first 5 working days of the appeal period. The consultee would then have until the end of the 15 working days appeal period to submit the appeal.
3. Notifying NICE of an intention to appeal would not commit a consultee to submit an appeal. However, a consultee would be unable to submit an appeal if they had not notified NICE of an intention to appeal within the initial 5 working days deadline.
4. The consultation proposed that the changes would apply when the final draft guidance recommends the technology can be used, including during a managed access period. It would also apply when the guidance states a technology can be used and NICE has agreed to vary the funding requirement.
5. During the current 15 working days appeal period there is a separate opportunity for stakeholders to highlight any factual errors in the final draft guidance. To enable guidance that recommends a technology to publish 2 weeks faster than currently it is necessary to maintain alignment between the appeals and factual accuracy processes. The consultation also therefore proposed that stakeholders would in future have 5 working days to highlight factual errors in final draft guidance that recommends a technology can be used, including during a managed access period and where NICE has agreed to vary the funding requirement.
6. The consultation proposed that the appeal (and factual accuracy check) arrangements would remain unchanged when the final draft guidance recommends the technology should not be used or more research is needed. So, a consultee would still have the full 15 working days appeal period to consider whether to submit an appeal and to do so (and also 15 working days to highlight factual inaccuracies). There would be no requirement to notify NICE of an intention to appeal in the first 5 working days.

## Rationale for the changes

1. Appeals are an important part of the TA/HST guidance development process but are relatively infrequent. Most TA/HST guidance does not receive an appeal. The consultation paper noted that between 1 March 2019 and 31 March 2024 NICE published 416 pieces of TA and HST guidance (including terminations) and received appeals on 30 final draft guidance documents. Where appeals are received, these usually relate to guidance that does not recommend the technology (23 of the 30 appeals in this period).
2. NICE’s core purpose is to help practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer. By making this change, NICE will be able to publish guidance that enables access to new treatments 2 weeks faster than currently (if no notifications of an intention to appeal are received).
3. The proposals help NICE enable access to new technologies more quickly, while maintaining the current arrangements for challenging NICE’s guidance that does not recommend a technology.

# Consultation feedback

## Response rate

1. Eleven organisations responded to the consultation:

* 4 patient groups: 1 supported the proposals and 3 opposed them
* 2 professional bodies: both supported the proposals
* 2 life sciences companies: 1 supported the proposals and 1 opposed them
* 2 industry bodies: 1 supported the proposals and 1 opposed them
* 1 market access consultancy: which supported the proposal.

1. Overall therefore, a small majority (6 of the 11) organisational responses were in favour of the proposals.
2. Five individuals responded: 1 supported the change, 2 were neutral and 2 were against.

## Feedback themes

1. The organisations in favour of the proposals cited the acceleration of patient access to the recommended technologies.
2. The main concern raised by those against the proposals was the reduced timescale for deciding whether to appeal and provide factual accuracy comments.
3. It was suggested that the different timelines for making an appeal and/or highlighting factual inaccuracies depending on the type of recommendation may be confusing. Feedback highlighted there was some uncertainty about the types of recommendations to which the new arrangements would apply. It was also suggested that NICE should reconsider the types of recommendation the new process applies to.
4. Respondents commented on the future communication of these changes and the need to be very clear about the new process and ensuring it is as simple as possible.

# NICE’s response

1. NICE’s guidance executive (GE) carefully considered the feedback and issues raised. Having reflected on the benefits and risks of the proposals, it was agreed to proceed with the changes as it was felt they strike an appropriate balance between enabling access to new technologies while maintaining the existing arrangements for challenging guidance that does not recommend a technology. In taking this decision, GE were mindful of the overall majority of responding organisations in favour of the proposals and the low number of responses in the context of the extensive publication of the consultation.
2. GE agreed the following mitigating actions having reflected on the stakeholder feedback:

* We will ensure the communication to stakeholders that accompanies each piece of final draft guidance clearly states the timeframe for submitting factual accuracy comments and an appeal for that topic.
* The process for notifying NICE of an intention to appeal will be straightforward (a short email to the appeals team), and as noted above, clearly explained in the communication that accompanies each piece of final draft guidance.

1. It was also agreed to monitor the revised process for 12 months and consider whether to amend the process and/or revert to the previous appeal process if it appears the overall impact of the change is negative.
2. As a further mitigation to the shortened timescale, the technology appraisal programme have confirmed that factual inaccuracies can continue to be remedied after the guidance has published if needed.
3. The [Guide to the technology appraisal and highly specialised technologies appeal process [PMG41]](https://www.nice.org.uk/process/pmg41) has been updated to reflect these new arrangements and was published on 1 April 2025. In response to the consultation feedback the process guide clearly states the appeal arrangement for each type of recommendation used in NICE’s TA and HST guidance.
4. As proposed in the consultation, the revised process will apply to appeals against any final draft guidance issued to stakeholders 2 months after the amended guide is published. As the new guide published on 1 April 2025 these new arrangements will apply to appeals against any final draft guidance issued to stakeholders on or after 1 June 2025.
5. An equality and health inequality assessment was produced for the consultation. This acknowledged that some stakeholder groups may find it challenging to indicate within 5 working days whether they intend to appeal. The mitigations were to retain the existing arrangements for negative final draft guidance and to state that notifying NICE of an intention to appeal is not a binding commitment to submit an appeal. In addition, it was noted that this potential downside is offset by the positive equality impact of NICE being able to publish guidance that enables access to new treatments 2 weeks earlier than present.
6. As noted above, these issues featured in the consultation feedback. No new equality issues were identified.