

**National Institute for Health and Care Excellence (NICE)  
and NHS England**

**Proposals for changes to the arrangements for evaluating  
and funding drugs and other health technologies  
appraised through NICE's technology appraisal and highly  
specialised technologies programmes**

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# **National Institute for Health and Care Excellence (NICE) and NHS England**

## **Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's technology appraisal and highly specialised technologies programmes**

### **Why are NICE and NHS England proposing to make changes?**

1. NICE and NHS England intend to work together more closely to better manage access to new drugs and medical technologies (devices and diagnostics) by simplifying and speeding up some appraisals, and by making the arrangements for funding others more clear. The proposed changes will benefit patients by providing access to the most effective and cost-effective new treatments more quickly and will help the life sciences industry by increasing the opportunities for companies to help manage the introduction of their new technologies into the NHS.
2. The NHS is committed to providing timely access to new treatments, but introducing new technologies in a way that is both good for UK business and, at the same time, optimises the financial sustainability of the NHS can be challenging. This consultation sets out a number of ways in which NICE and NHS England can provide an environment that encourages the life sciences industry and the NHS to work together in the best interests of patients. By facilitating collaboration and providing opportunities for early dialogue between innovators and the NHS, and by speeding up appraisal and adoption processes, NICE and NHS England can enable the development of arrangements that deliver the right outcomes for both patients and the life sciences industry.
3. The proposals set out in this document provide:
  - Quicker access for patients to the most cost-effective new treatments.
  - More flexibility in the adoption of cost-effective, high budget impact technologies into the NHS.
  - Greater clarity for patients and companies about the point at which treatments for very rare conditions that are appraised by NICE will automatically qualify for funding from routine commissioning budgets.

## What are the consultation proposals?

### 4. NICE and NHS England propose to:

- Introduce a 'fast track' NICE technology appraisal process for the most promising new technologies, which fall below an incremental cost-effectiveness ratio of £10,000 per QALY (quality adjusted life year), to get these treatments to patients more quickly.
- Operate a 'budget impact threshold' of £20 million, set by NHS England, to signal the need for a dialogue with companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. This would apply to a small number of technologies that, once determined as cost effective by NICE, would have a significant impact on the NHS budget.
- Vary the timescale for the funding requirement when the budget impact threshold is reached or exceeded, and there is therefore a compelling case that the introduction of the new technology would risk disruption to the funding of other services.
- Automatically fund, from routine commissioning budgets, treatments for very rare conditions (highly specialised technologies) up to £100,000 per QALY (5 times greater than the lower end of NICE's standard threshold range), and provide the opportunity for treatments above this range to be considered through NHS England's process for prioritising other highly specialised technologies.

## Why is this a joint consultation between NICE and NHS England?

5. NICE appraises the clinical and cost effectiveness of new health technologies. In doing so, it takes account of the fact the NHS has fixed resources available to it. NHS England manages the budgets that enable care to be provided and has a statutory responsibility to ensure that its functions are exercised effectively, efficiently and economically within the funds provided to it by the Department of Health.
6. The importance of taking account of the financial impact when managing the introduction of new drugs and other technologies was highlighted by the Public Accounts Committee which recommended that *'The Department of Health and NHS England should, in collaboration with NICE, ensure affordability is considered when making decisions that have an impact on specialised services. For example, building in consideration of how the cost of implementing NICE recommendations can be kept affordable within available commissioning*

*budgets, and by using national bargaining power to get best prices for high-cost drugs*.<sup>1</sup>

7. The independent Accelerated Access Review has also identified the general issue of affordability, as well as emphasising the importance of developing a collaborative framework through which transformative technologies can be moved quickly through development, evaluation and adoption.
8. NHS England and NICE have worked together to develop the best approach to implementing these proposals and this consultation sets out how both organisations propose to develop and coordinate their processes. Some of the proposals in this consultation relate to NICE's processes and methods and others to the way in which NHS England manages its budgets. In some cases, the changes that NICE is proposing to make are a consequence of the approach that NHS England wants to take. In others, the changes are being proposed by NICE. In all cases, the proposals have been agreed by both organisations, subject to the outcome of consultation.

## **The changes in more detail**

### ***NHS England budget impact threshold***

9. NHS England, as the budget holder, is responsible for allocating funding for new technologies. Some new technologies that meet the NICE cost-effectiveness threshold also have a high budget impact. In order to balance value and affordability, NHS England believes that special arrangements should be put in place to manage the budget impact of the new treatment in order to avoid compromising access to other forms of care. NHS England proposes that these special arrangements would be triggered when a technology being appraised by NICE, through its technology appraisal and highly specialised technologies programmes, is estimated to exceed a 'budget impact threshold'.
10. It is important to note that budget impact and the application of a budget impact threshold will not influence NICE's consideration of the clinical and cost effectiveness of a technology. It will be used to inform the arrangements, described below, which NHS England will seek to put in place to help manage the impact of technologies, recommended by NICE, which have a very high budget impact.
11. Having considered the frequency and magnitude of high budget impact NICE-recommended technologies, NHS England proposes to set the threshold at £20 million per annum. NICE will assess the potential budget impact by estimating the net annual cost to the NHS. The threshold would be regarded as having been triggered if it is projected to be reached or exceeded in any of the first 3 financial years of its use in the NHS. NICE will take advice from the manufacturer and clinical experts in making this estimate. It should be noted that the budget impact threshold is not necessarily the maximum amount that the NHS would commit to funding a new technology in any one financial year.

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<sup>1</sup> Committee of Public Accounts' 10th report of the 2016-17 session

12. It is anticipated that only a small number of new technologies recommended by NICE would exceed this budget impact threshold. An analysis of positive technology appraisals published between June 2015 and June 2016 reveals that around 80% of new technologies recommended by NICE fell below the proposed budget impact threshold.
13. For those technologies that receive a positive NICE recommendation, but are above the budget impact threshold, NICE would signal the need for a commercial agreement between the company and NHS England. When agreement is reached and this brings the budget impact below the threshold, the standard 90-day funding requirement would apply.
14. When it is not possible to fully address the budget impact challenge, NHS England may ask NICE to vary the standard funding requirement and make a case for NICE to allow a longer period of phased introduction. The nature of NHS England's request to NICE to vary the funding requirement would reflect any commercial agreement that NHS England and the company have been able to reach. Patient access schemes would remain the main route to ensuring a product is considered cost effective during the NICE appraisal process.
15. Technologies recommended by NICE that fall below the proposed budget impact would be unaffected by these arrangements.

### ***Varying the timescale for the funding requirement***

16. NICE would consider requests from NHS England to vary the funding requirement when the budget impact threshold is expected to be exceeded in any of the first 3 years of the use of a technology in the NHS. The length of any variation and potential phasing of implementation of NICE guidance would necessarily depend on the individual circumstances for each technology and any commercial arrangements NHS England and the company are able to agree.
17. Under current [regulations](#) NICE can consider extending the standard 3-month period of deferred funding (the funding requirement) if it considers that one or more of the criteria it is allowed to apply is satisfied. One of these criteria indicates that NICE may vary the funding requirement if it considers that: *'the health technology cannot be appropriately administered until other appropriate health services resources, including staff are in place'*. This applies in both the technology appraisal and highly specialised technologies programmes.
18. NICE considers that 'resources', as referred to in this criterion, includes the availability of funds and that application of the criterion in this way is consistent with its duty to have regard to the broad balance between the benefits and costs of the provision of health services or of social care in England. By doing this, NICE can help to ensure that the necessary resources can be made available for the introduction of new technologies with large, in-year budget impact or with large and enduring budget impacts over time, without causing disruption to other services.

## **NICE fast track process**

19. NICE needs to ensure that the weight and complexity of its appraisals are in proportion to the technical challenges and the risks posed by the evidence that it considers. In line with this, NICE proposes to introduce a 'fast track' appraisal process for the appraisal of health technologies for which a confident judgement about value for money can be made at an early stage. The fast track route would be a variant of the standard technology appraisal process.
20. The aim would be to make available, more quickly, those technologies that NICE can be confident would fall below £10,000 per QALY, and whose budget impact is below the threshold set by NHS England. This cost per QALY level has been selected because technologies with incremental cost-effectiveness ratios at or below £10,000 per QALY can, with a reasonable degree of certainty, be predicted at an early stage in their evaluation as potentially cost effective. Between 2007 and 2014, around 15% of NICE's technology appraisals fell at or below £10,000 per QALY in the final guidance. The introduction of a fast track process would enable them to be routed through a lighter touch appraisal process, speeding up access for patients.
21. The proposed £10,000 cost per QALY level for the fast track process would not change the current standard NICE cost-effectiveness threshold range of £20,000 to £30,000 per QALY. Treatments with incremental cost-effectiveness ratios of between £10,000 and £30,000 per QALY could still be recommended, subject to the application of NICE's published methods.
22. The criteria for application for a technology to be appraised through a fast track process would be:
  - The availability of strong evidence (with a low degree of decision uncertainty) that products would be cost effective at or below £10,000 per QALY.
  - An estimate that the budget impact of the technology would fall under the proposed budget impact threshold for the full patient population relevant to the appraisal.
23. Technologies would be identified through the standard topic selection and referral processes. Companies would be invited to indicate that they would like their product to follow a fast track appraisal. Once referred and when an evidence submission is received, entry into the fast track process would be considered by NICE following an analysis of the company's submission, supported by an external review. If, following this analysis, the selection criteria cannot be satisfied with sufficient confidence, the topic would be re-routed to the standard technology appraisal process.
24. In the case of a newly licensed technology, NICE would undertake a fast track appraisal to enable draft guidance to be issued, in the case of new drugs, immediately after the European Medicines Agency issues the Committee on Human Medicinal Products' opinion. Final guidance, on new drugs, would be published immediately following the publication of the marketing authorisation.

The process for other types of technologies would follow a similar course, taking account of the regulatory processes that apply to individual products.

25. Fast tracked technologies that fall below the proposed £10,000 cost per QALY level and the proposed budget impact threshold would be provided with access to NHS funding within 30 days of the publication of final NICE guidance.
26. The fast track route would involve companies and NICE using less resource. NICE estimates that it would be able to make a 25% saving in process time compared with standard appraisals, with final guidance issued up to 3 months earlier than normal. Companies would need to invest less time in engaging with NICE.
27. The essential elements in the fast track appraisal route are set out below, and presented in the flow diagram in appendix 1:
  - standard topic selection and scoping processes
  - a request from the company to use the fast track route
  - ministerial referral of the topic onto NICE's work programme
  - an evidence submission by the company that holds, or has filed for, the marketing authorisation, or medical technologies equivalent
  - an initial evidence review by NICE, supported by an external review
  - a final decision by NICE that the topic is suitable for the fast track process, following a review of the applicability of the selection criteria
  - the production of a technical briefing by the NICE technical team, supported by an external review
  - consideration by an appraisal committee
  - the publication of a final appraisal determination
  - the opportunity for an appeal
  - a funding requirement when NICE has published guidance.
28. Unlike the standard NICE technology appraisal process, the fast track route would not need the following process elements, which would therefore facilitate a more rapid process:
  - A second appraisal committee meeting (because failure to demonstrate clinical and cost effectiveness at the committee meeting would mean that the technology would be re-routed through the standard appraisal process).
  - Consultation on draft recommendations (because NICE does not normally consult on positive draft recommendations).
  - Attendance of clinical experts, patient experts, commissioning experts, the evidence review group (ERG) and the company (because the basis of the fast track process is built on a clear and convincing case for the clinical and cost effectiveness of the technology).
29. Normally, the elapsed time from the invitation to make an evidence submission in the fast track process to the publication of final guidance would be expected to be 32 weeks. The standard process takes 43 weeks.

30. The NICE technology appraisal process already has a number of variants designed to respond to the particular characteristics of the technologies when, for example, appraising cancer drugs, and those medicines recommended through the early access to medicines scheme.
31. Because a number of arrangements proposed for the fast track appraisal would also apply to an 'abbreviated' technology appraisal process, on which NICE has recently consulted, it is proposed that the abbreviated process should be absorbed into the fast track process. This will mean that topics can be considered for the fast track process irrespective of whether NICE guidance has been published for the key comparator.
32. These proposed process changes are supplemental to NICE's current guide to the processes of technology appraisal.

### ***Linking NICE and NHS England processes for evaluating highly specialised technologies***

33. NICE evaluates a small number of (mainly) drugs for very rare conditions each year through its highly specialised technologies programme. NHS England considers many others through its own specialised commissioning prioritisation process. It is therefore important that the 2 processes are properly linked.
34. To help achieve this, it is proposed that the funding requirement for NICE guidance will be applied to technologies it recommends, up to £100,000 per QALY, which is 5 times greater than the lower end of NICE's standard threshold range and would typically allow for a significant additional cost over the standard care comparator. This would provide greater clarity for patients and companies about the point at which highly specialised technologies would receive automatic funding from routine commissioning budgets.
35. Technologies with a QALY value above £100,000 per QALY would not be subject to the funding requirement but would be provided with a further opportunity to be considered for use in the NHS through the NHS England process for prioritising other highly specialised technologies.
36. NICE and NHS England believe that these arrangements would lead to greater equity and consistency in the prioritisation of funding for highly specialised services across the whole range of NHS England's responsibilities for specialised care.
37. NICE would undertake an assessment of the budget impact of the technology as described elsewhere in this consultation. This assessment would be made before the first meeting of the highly specialised technologies committee. The budget impact assessment would not be presented to the committee since it only has a bearing on a consideration of whether a dialogue is needed between NHS England and the company or whether the funding requirement should be deferred. This would be a change to the current interim methods, which require the committee to take account of budget impact in its consideration of the evidence.

38. When the budget impact appears likely to exceed the budget impact threshold, the company would be asked to engage with NHS England, facilitated by NICE through its 'safe harbour' service which provides an opportunity for confidential discussions on matters relating to a current or future evaluation undertaken by NICE. The purpose of this engagement would be to provide an opportunity for the company to propose ways to manage the budget impact of the adoption of the technology, through a commercial agreement with NHS England.
39. Technologies that fall below £100,000 per QALY and the budget impact threshold, with or without a patient access scheme or a commercial agreement, would continue to proceed on the standard highly specialised technologies evaluation timeline.
40. When a product is determined to be below £100,000 per QALY but the NHS England budget threshold is estimated to be exceeded despite the earlier opportunity to reach a commercial agreement, the process would be paused at this point for a maximum of 12 weeks to provide for a second opportunity for a commercial agreement to be reached.
41. In the event that a product is determined to be below £100,000 per QALY, and has exceeded the budget impact threshold, but for which a commercial agreement has not been reached, NICE would nevertheless publish its final draft guidance and NHS England would be able to ask NICE for a variation to the funding requirement.
42. Technologies above £100,000 per QALY would not be funded through the funding requirement but would then be considered by NHS England for funding through its annual specialised commissioning prioritisation process.
43. These proposed process changes are supplemental to NICE's current interim process and methods of the highly specialised technology programme.

### ***Proposed changes to NICE's standard technology appraisals***

44. In NICE's standard technology appraisal process, an assessment would be made of the budget impact of the technology as described elsewhere in this consultation. This assessment would be made before the first meeting of the appraisal committee. The budget impact assessment would not be presented to the committee since it only has a bearing on a consideration of whether a dialogue is needed between NHS England and the company or whether the funding requirement should be deferred.
45. When the budget impact appears likely to exceed the budget impact threshold, NICE would ask the company to engage with NHS England, facilitated by NICE through its 'safe harbour' service, which provides an opportunity for confidential discussions on matters relating to a current or future evaluation undertaken by NICE. The purpose of this engagement would be to provide an opportunity for the company to propose ways to manage the budget impact of the adoption of the technology, through a commercial access agreement with NHS England.

46. Products that fall below the standard NICE threshold range and the budget impact threshold, with or without a patient access scheme or a commercial access agreement, would continue to proceed on the standard appraisal timeline.
47. Where a product is determined to be clinically and cost effective at the appraisal committee meeting, but the NHS England budget threshold is estimated to be exceeded despite the earlier opportunity to reach a commercial access agreement, the appraisal process would be paused at this point for a maximum of 12 weeks to provide for a second opportunity for a commercial access agreement to be reached.
48. In the event that a product is determined by the appraisal committee to be clinically and cost effective, but a commercial access agreement has not been reached, NICE would nevertheless publish its final draft guidance and NHS England would be able to apply to NICE for a variation to the funding requirement.
49. These proposed process changes are supplemental to NICE's current guide to the processes of technology appraisal.

## **Implementation**

50. NICE will introduce the fast track process option routinely for technology appraisal topics referred from 1 April 2017.
51. For technology appraisal topics referred before 1 April 2017, and when the company evidence submission deadline is set for later than 1 April 2017, companies can approach NICE to discuss access to the fast track process.
52. The arrangements for the consideration and application of the budget impact threshold will apply from 1 April 2017.
53. The use of the cost per QALY level for the funding requirement for highly specialised technologies evaluations will apply to topics that have their first committee meeting after 1 April 2017.

## **Consultation questions**

### ***NHS England budget impact threshold***

- 1 Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost-effective new technologies?
- 2 Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?
- 3 Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?

### ***Varying the timescale for the funding requirement***

- 4 Do you agree that NICE should consider varying the funding requirement for technologies it recommends, for a defined period, in circumstances where NHS England makes a case for doing so, on the grounds that the budget impact of the adoption of a new technology would compromise the allocation of funds across its other statutory responsibilities?

### ***NICE fast track process***

- 5 Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?
- 6 Do you agree that NICE should 'fast track' new health technologies with a maximum incremental cost-effectiveness ratio of £10,000 per QALY and whose costs are estimated to fall below the budget impact threshold?
- 7 Do you agree that NHS England should commit to accelerating funding for technologies approved under the fast track process from 90 days to 30 days?
- 8 Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?

### ***Linking NICE and NHS England processes for evaluating highly specialised technologies***

- 9 Do you agree that NICE and NHS England should use a cost per QALY below which the funding requirement is applied for highly specialised technologies?
- 10 Do you agree that £100,000 per QALY is the right maximum up to which the funding requirement would be applied? If not, what cost per QALY do you suggest, and why?

- 11 Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation process?
- 12 Do you agree the proposed new arrangements mean that NICE would not need to take budget impact into account in its highly specialised technologies evaluations?

***Other***

- 13 Do you consider that any proposals in this consultation would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation?

**Appendix 1: Comparison of indicative timelines for a standard appraisal and the fast track process**

