

NICE and NHS England consultation on changes to the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programmes

NHS England and NICE recently consulted publicly on proposals to change the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal (TA) and highly specialised technologies (HST) programme.

In light of this consultation, the Board is invited to consider and comment on the recommendations for making changes to the arrangements.

NHS England's Specialised Services Commissioning Committee considered the response to consultation at its meeting on Wednesday 22 February. The recommendations in this paper are consistent with the position adopted by NHS England.

NOTE: The response to proposals relating to the Highly Specialised Technologies programme is the subject of a separate paper.

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Purpose of this paper

1. For the Board to consider the comments received in consultation on the joint proposals of NICE and NHSE for changes to the TA programme;
2. For the Board to consider and approve amendments made to the original proposals;
3. For the Board to consider and approve plans for implementation and next steps;
4. For the Board to note that proposals relating to the HST programme will be considered in a separate paper, in due course.

Background

The proposals

5. NICE and NHS England held a public consultation on proposals to change the arrangements for evaluating and funding drugs and other health technologies assessed through NICE's technology appraisal and highly specialised technologies programme, that would seek to provide:
 - rapid access for patients to the most cost-effective new treatments;
 - more flexibility in the adoption of technologies into the NHS which are cost effective but high in budget impact; and
 - greater clarity for patients and companies about the point at which treatments for very rare conditions appraised by NICE will automatically be routinely commissioned.

The consultation

6. In October 2016, NICE published a joint consultation with NHS England containing proposals to change aspects of the NICE Technology Appraisal and Highly Specialised Technologies programmes.
7. In summary, the proposals covered:
 - **Introduction of 'budget impact threshold' of £20m.** For those technologies that pass the NICE value assessment (applying NICE's published methods) and where the budget impact is below the threshold set, there would be no need to conduct a commercial negotiation. Should the budget impact exceed the set threshold in any of the first three years, a commercial negotiation would be triggered. Should this negotiation fail

to conclude or not fully resolve the budget impact issues, NHS England would be able to apply to NICE to vary the funding requirement in order to phase introduction of the product over a longer period to help manage its impact on the NHS.

- **Linking NICE and NHSE processes for evaluating highly specialised technologies.** We consulted on introducing quality adjusted life years (QALY) as a measure of value in the HST programme, and on the application of a 'limit' of £100k per QALY below which the legal funding directive would apply (either immediately if there are no budget impact concerns or phased in over a period of time if the budget impact threshold of £20 million is triggered). For those technologies for which the cost per QALY calculation exceeds £100,000, there would be an opportunity to be considered for funding through NHS England's Clinical Priorities Advisory Group (CPAG) relative prioritisation process. This opportunity for a second consideration recognises the special position of very small groups of patients for whom new treatments are exceptionally expensive.
- **Introduction of a new 'Fast Track Appraisal'.** The consultation set out a proposal that appraisals in which we can be confident that a reliable judgement about value for money can be made at an early stage in the appraisal, would be able to enter a new Fast Track Appraisal, which would have lighter touch methods and a shorter process. In addition, where a positive recommendation is made, a shorter period of deferred funding - 30 days instead of 90 days, would be applied. The consultation proposed to use a cost per QALY level of £10,000 as one of the criteria for routing into fast track, as at that level it could, with a high degree of certainty, be predicted at an early stage in the evaluation that a technology would be cost effective. The budget impact threshold would still apply to products qualifying for the Fast Track Appraisal process.

8. The public consultation, which closed on 13 January 2017, having received 150 responses. In addition, four webinars for stakeholders (350 people registered to attend in total) and two face-to-face events in London and Manchester (63 attendees in total) were held, along with a number of individual meetings with key stakeholder groups.

9. The consultation report at Appendix A includes details of the number of responses by stakeholder type and responses to each consultation question. The published consultation document is included for reference at Appendix B.

10. NICE's response to the comments on the proposals specific to the Highly Specialised Technologies programme will be the subject of a separate paper, in due course.

Budget impact

Questions asked in consultation

11. The following questions were included in consultation:

- Question 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?
- Question 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?
- Question 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?
- Question 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?

Summary of comments received

12. Much of the discussion at the events and webinars focused on the proposal in the consultation to introduce a net Budget Impact Threshold. As shown in the consultation analysis (see Appendix A), respondents had mixed views on the proposal.

13. There was a strong challenge from large pharmaceutical companies and industry representative bodies that the proposal was not needed at all. They felt that questions of affordability, whilst of valid concern, are addressed already through the Pharmaceutical Price Regulatory Scheme (PPRS). Indeed many, including academics and patient groups, questioned why the PPRS, which reduces the amount of money the NHS pays for new drugs, had not been referenced in the consultation document. Some smaller biotech firms, some patient groups and academics did, however, support the principle of introducing an affordability test for those products which have a high net budget impact.

14. A number of respondents warned about the potentially disproportionate impact on first to market products, and that the proposal looks to be at odds with the ambition for England to remain an attractive launch market for innovative products; as set out in the Accelerated Access Review (AAR) and expected to be an important element of the Life Sciences Strategy.
15. There was also concern from many respondents about the proposed level of the net budget impact threshold. Pharmaceutical companies who disagreed with the principle also disagreed with the proposal to set the threshold at £20 million level, in any of the first three years of NHS use. Some respondents (for example the Association of the British Pharmaceutical Industry (ABPI) felt that £20 million was too low, and that only very high budget impact products should trigger a commercial discussion. They therefore suggested raising the threshold to £100 million, considered over the first two years of introduction. The ABPI also suggested that, if implemented, the proposal should be reviewed after one year to consider what impact it has had. There were other respondents who said that they felt unable to comment on the proposed level of the net budget impact threshold, as they did not feel there was sufficient exploration of the rationale or economic modelling in the consultation document.
16. Some of the challenges revealed a misunderstanding about how the budget impact threshold would work, which may relate to the language used to describe the proposal. Some consultees had interpreted the 'threshold' as an absolute expenditure limit meaning that NHS England would only ever routinely commission those products that have a net budget impact of £20m or less in any one year. Some respondents also interpreted the commercial discussion for products over £20 million as having the sole purpose of bringing the price down, so that the product would 'get under' the £20m threshold. Although the consultation document made it clear that £20 million was not "necessarily the maximum amount that the NHS would commit to funding a new technology in any one financial year", some respondents did interpret it that way.
17. Another key area of concern was in relation to the impact of this proposal on patients' access to new treatments, both in general and in terms of potential inequity for some patient groups; for example, those with rare/ultra-rare diseases, those with significant unmet need, those receiving curative treatments such as gene therapy that require a short term investment but deliver longer term benefits. Respondents wanted to know if there would be exceptions to the potential delay to the process and the funding, or example, treatments that fulfil the end-of-life criteria. Other potential exceptions suggested included treatments for populations with an unmet need, treatments recommended with managed access agreements, including those

recommended for use in the cancer drugs fund, treatments considered ‘transformational’ and fast-track products. Some stakeholders also suggested that there should be an upper limit to the variation of the funding timeframe (for example 200 days) and also to consider a shorter period than 3 years over which to assess the net budget impact.

18. A further concern was that the proposal may be at odds with the commitments in the NHS Constitution that patients have “the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you”. Some also suggested that the proposal threatens the independence of NICE.

19. Most stakeholders including companies supported the principle of discussing commercial arrangements with NHS England during the NICE appraisal. However, others felt that this discussion would come too late to be of value. One company noted that an arbitrary net budget impact threshold would not allow companies enough flexibility in commercial negotiations. Stakeholders nevertheless accepted that commercial discussions were important and should happen anyway, regardless of whether the budget impact proposal is implemented.

20. Stakeholders noted the difficulty in accurately estimating net budget impact. It was suggested that the uptake of high budget new medicines should be closely monitored after launch, with commercial agreements potentially being based on actual rather than predicted uptake, or that a commercial discussion should only need to be undertaken when the actual uptake of the technology reaches an agreed threshold. There was also the question of how net budget impact should be assessed for a technology with multiple indications.

21. NHS England can, if it chooses to, conduct commercial discussions at a national level on behalf of CCGs. Further detail of the governance for this arrangement will be worked up prior to implementation. NICE will accept a request for variation to the timescale for the funding requirement from NHSE on behalf of CCGs. No specific arrangements have been made for technologies that are, in rare circumstances commissioned by local authorities.

Response, including amendments to the proposals

22. Consultees raised a range of relevant and reasonable concerns about the proposals, challenging both the need for and the nature of the threshold. However, other than suggesting that the PPRS should negate the need for phased funding or that threshold should be set at a much higher level, no practical alternative, which addressed NHS England’s assessment of the acuity of its financial position was put forward. The financial effect of the

PPRS rebate mechanism has already been taken into account in NHS budgeting and so is not available as a solution to significant in year surges in the demand for resources to fund new treatments. A higher threshold and especially one set as high as £100 million would materially fail to provide NHS England with the tools it needs to pursue the orderly management of its budgets.

23. The consultation document did not contain any information about how NHS England would frame its requests for a variation to the funding requirement, or how NICE would consider its requests. Consultees were concerned about this and so we have provided more detail in this response.

24. In light of the responses received we propose:

- To alter the terminology used for the consideration of net budget impact to **'budget impact test'** in order to clarify to stakeholders and the public that it is not a funding maximum;
- To **confirm £20m, in any of the first 3 years, as the budget impact test**, on the basis that no alternative solutions, which would provide NHS England with the facility we consider it urgently needs to manage significant in year demands on its budget, have been put forward;
- To **review the impact of the proposals** three years after its introduction.

25. NICE has developed a procedural statement to support the proposed arrangements. This statement is set out at Appendix C. The procedural statement sets out the information that NHS England will be asked to provide when it applies for a variation to the funding requirement, in cases where the budget impact test has been triggered. It also sets out what NICE's Guidance Executive will take into account when considering the request. These considerations are set out below, for ease of reference:

Information required from NHS England

26. For products where the budget impact test is engaged, NICE Guidance Executive will consider applications to vary the funding requirement, normally for up to a maximum of 3 years. In exceptional circumstances, a longer period may be considered.

27. Regardless of the duration of the variation requested, all applications will need to contain proposals for a phased allocation of funding.

28. When submitting a request for a variation, NHS England will be asked to provide the following information:

- The duration of the proposed variation;
- The relevant provisions of any commercial agreement reached with the company;
- In the case of a technology funded from the national specialised commissioning budgets, the amount and phasing of funding that will be made available and how it is intended that this should be applied to eligible patients;
- In the case of technologies funded by clinical commissioning groups, what direction NHS England intends to give about the phasing of funding during the deferred funding period;
- An assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed as a result of the funding variation;
- The measures proposed to ensure that the alternative timescale for the funding requirement is not exceeded.

NICE's consideration of the request

29. NICE's Guidance Executive will consider a request from NHS England to vary the timescale for the funding requirement, taking the following into account the extent to which:

- The budget impact test been met;
- All reasonable opportunities for commercial discussions been pursued;
- The request in proportionate to the magnitude of the budget impact;
- The request has taken account of the severity and acuity of the condition to which the guidance relates;
- A commissioning policy been developed for managing appropriate access to the technology during the funding variation period.

30. NHS England will be expected to submit any application for variation to the funding requirement, in time for it to be considered by NICE's Guidance Executive, at the earliest opportunity, and no later than when it receives the outcome of the meeting at which the final recommendations are agreed.

31. Where NICE agrees to a variation of the timescale for the funding requirement, it is required to seek comments from the consultees to the appraisal.

32. The assessment of net budget impact will be undertaken by the NICE Resource and Impact (RI) team at NICE. The RI team have recently completed a targeted consultation exercise with key stakeholders who have been invited to comment on their process and methods statements. The RI process and methods statement is included in Appendix D.
33. Applications to vary the funding requirement are specific to each topic. However, in the case of treatments with indications for which a funding variation is already in place, NICE will take into account the total budget for all relevant technologies, when considering an application for a funding variation for the second (and subsequent) technologies.
34. NICE and NHS England intend to put in place the arrangements for managing the budget impact test from 1 April 2017, for topics for which a first evidence submission is received after this date.

Decision

35. The Board is asked to:

- Approve the proposals for the budget impact test and for managing requests for variations to the funding requirement, as amended;
- Approve the process and methods statement for varying the duration of the funding requirement, as set out at Appendix C and D;
- Approve the implementation plan for consideration of varying the timescale for the funding requirement, as set out in paragraph 34;
- Note the proposal to review the application of the budget impact test after three years.

Fast track appraisal

Questions asked in consultation

36. The following questions were included in consultation:

- Question 5: Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?
- Question 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?
- Question 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?
- Question 8: Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?

Summary of comments received

37. The Fast Track Appraisal (FTA) proposal was originally developed in order to find a way to provide faster access to those treatments which are highly cost-effective. The £10,000/QALY level was chosen to reflect the situation where a product could be deemed highly cost effective and where the risk of decision-error was minimal; i.e. the risk that a technology is over the £30,000/QALY upper limit.

38. Respondents broadly supported the concept of FTA, recognising that there was merit in speeding up the appraisal approach and implementation of treatments that are particularly cost-effective.

39. Some respondents expressed concern that net budget impact, as defined in the proposals, should not be used as an entry criterion for the FTA, as it would filter out products that may be extremely cost-effective but could have a high budget impact.

Response, including amendments to the proposals

40. Respondents broadly supported the FTA proposal, recognising that there was merit in speeding up the appraisal approach and implementation of treatments

that are particularly cost-effective. They identified and offered varying views on the materiality of the risks associated with the proposals, which had been identified in the consultation document. No substantive additional risks were put forward and no alternative options, beyond in the case of some responses, the need for the proposal in the first place.

41. Since publishing the consultation document, it has become clear that expanding the fast track approach to cover more appraisals could help address an emerging challenge. This is that the NICE technology appraisal programme is facing a significant increase in the number of treatments it will need to consider, beyond the level at which the current process will be able to accommodate. This increase, of around 30%, rising to as much as 50% is due to the increasing numbers of products being assessed by the regulators, with some products requiring multiple licences, with some cancer products aiming for in excess of 20 indications for a single drug. This capacity challenge could, in part, be addressed through a less intensive appraisal process of the kind described in the fast track option.
42. Such a broadening of the scope of the proposed 'fast track' appraisal fits with the ambitions set out in the Accelerated Access Review and is also likely to be consistent with the emerging Life Sciences Strategy.
43. Nevertheless, in the short term, we intend to **introduce the FTA process** as proposed in consultation for products with a base case cost effectiveness of £10,000/QALY. A proposal to extend the fast track concept to a wider group of treatments will be brought to the Board in due course.
44. The new process will require a commitment from companies to ensure that the evidence underpinning their value proposition meets NICE's expectations at the start of their engagement. Companies will have the opportunity to engage in commercial conversations before and, in exceptional circumstances, during NICE's process, with NHS England. It is essential that system wide arrangements are in place to ensure commercial discussions can take place, on time, at pace, and with the necessary flexibilities in place, brokered by NICE. NICE will need to establish a team to support these commercial conversations.
45. The introduction of a fast track process will require judgements to be made about the evidence to be made earlier in the process. Decision makers will have to rely on much of the scrutiny having been applied before they meet, and so will be asked to accept that the scrutiny applied provides the basis on which to make a decision. NICE, and those working in the evidence review groups, will have to apply the experience and skills required to do this at an

earlier stage in the process, and will need to build enough senior capacity to deal with this.

46. The consultation document referred to the fast track process potentially applying to medical technologies and diagnostics that meet the eligibility criteria. The relevant industry bodies and a number of medtech and diagnostics companies responded with comments. The exploration of a broader scope for fast track appraisals, and the longer term development of the new technology appraisal process, will explicitly address non-pharmaceutical technologies. This is consistent with the report of the Accelerated Access Review, which recommended that there should be a single set of clear national and local routes to get medical technologies, diagnostics, pharmaceuticals and digital products to patients.
47. As proposed in consultation, the fast track process will subsume the previous proposal for an 'abbreviated technology appraisal' (ATA). In drafting the process statement for the fast track process, comments received in consultation on the ATA process have been incorporated. The methods proposed for ATA have been set out as a 'cost comparison' addendum to the guide to the methods of technology appraisal (see Appendix F).
48. Consultees argued that excluding technologies, with a net budget impact of more £20 million, risked extending unnecessarily the time it will take to evaluate otherwise important new treatments. NICE and NHS England agree with this and so now propose to remove this restriction to entry into the fast track process.
49. NHS England has committed to ensuring that funding is available within 30 days from NICE having published guidance for products that go through FTA at £10,000 per QALY or less. NHS England is already making the same commitment for products that have gone through the Early Access to Medicines Scheme (EAMS).
50. A procedural statement to support the FTA process has been developed and is set out at Appendix E.
51. The consultation proposed that the fast track proposals would be introduced for topics referred to NICE from 1 April 2017. Considering the need to capture more topics than originally planned we propose to change this to topics with a first evidence submission from 1 April 2017.

Decision

52. The Board is asked to:

- Approve the introduction of fast track appraisals, as proposed in consultation, from 1 April 2017;
- Approve the process, as set out at Appendix E;
- Approve the removal of the budget impact test as a criterion for entry into the fast track process;
- Approve the methods for cost comparison as set out in Appendix F;
- Note that a proposal to extend the fast track concept to a wider group of topics will be brought to the Board in due course;
- Approve the implementation plan, as amended as set out in paragraph 51.

National Institute for Health and Care Excellence

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List of Appendices

Appendix A – Consultation analysis

Appendix B – Consultation on 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; analysis of responses to the consultation.

Appendix C – Budget impact and varying the time for statutory funding; procedural statement

Appendix D – Resource and Impact process statement

Appendix E – New fast track appraisals; process statement

Appendix F – Cost comparison; methods statement