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 and highly specialised technologies 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 at that meeting.

This paper only addresses the proposals relating to the highly specialised technologies programme. The response to the other two proposals put forward in consultation are the subject of a separate paper.

A revised statement of the methods and processes for the evaluation of highly specialised technologies, incorporating the changes set out in this document, will be submitted to the Board at its meeting in April.

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March 2017

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 HST 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.

Background

The proposals

4. 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

5. 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 evaluation programmes.

6. 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.

7. The public consultation, which closed on 13 January 2017, 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.

8. The consultation report, which has already made available to the Board, includes details of the number of responses by stakeholder type and responses to each consultation question.

Highly specialised technologies

Questions asked in consultation

9. The following questions were included in consultation:

    - Question 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?

    - Question 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?

    - Question 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 (CPAG) process?

    - Question 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?

Summary of comments received

10. Respondents raised concerns about the proposal for a cost per QALY limit for automatic funding (though not necessarily any funding) of NICE guidance, developed through the highly specialised technologies programme, as well as the proposed level of £100,000 per QALY. Consultees also expressed broader concerns about linking the process to NHS England's CPAG process.

11. Many of the respondents appear to have interpreted the level at which automatic funding would be applied as a 'threshold' for value. Indeed, a number of respondents asked whether NICE would still 'recommend' a highly specialised technology when the cost per QALY exceeds the level for automatic funding. Some respondents felt that it was not appropriate to use QALYs to determine whether or not a highly specialised technology should be funded.

12. Some respondents felt strongly that the £100,000/QALY level is too low, with no or very few HSTs likely to be able to reach this level for automatic funding. Even taking account of the possibility of funding through the NHS England CPAG process, respondents considered that the prospects for access to

treatment would be so remote that patients with very rare conditions would be significantly disadvantaged.

13. Another strong message from consultation was concern about the NHS England relative prioritisation process (CPAG). Respondents argued that the CPAG process is not well understood and that the methodology is such that it will be very hard for HST products to move successfully through it. There was also concern that going through CPAG after HST would add too much time into the process and further delay access for patients.

Response, including amendments to the proposals

14. Despite the opposition to the proposal, NICE and NHS England remain of the view that it is essential to develop an objective, systematic, transparent and repeatable approach, to evaluating HSTs, which explicitly recognises the financial constraints under which NHS England's specialised commissioning budgets are operating.

15. NICE and NHS England take the view that using QALYs as a measure of value for highly specialised technologies has merit. Indeed, we consider that expressing health benefits by modelling quality of life and length of life, over a time horizon that is long enough to capture the benefits of a new technology, is a necessary and an important enhancement to the evaluation of these treatments.

16. It is worth noting that most of the highly specialised technology evaluations we have undertaken reveal QALY gain that is an order of magnitude greater than those seen in standard technology appraisals, where the average QALY gain is less than 1. Exposing this explicitly reveals the magnitude of the incremental therapeutic benefit of these treatments and will form the basis of a new approach to their evaluation, which recognises that the NHS has long regarded patients with very rare conditions, and the treatments designed for them, as requiring special consideration.

17. Few consultees considered that migrating topics that NICE is unable to recommend into the CPAG process has merit. Accordingly, this proposal has been withdrawn.

A modified approach

18. NICE and NHS England have reflected on the consultation responses and consider that a modified approach to the application of the £100,000 QALY limit for automatic application of the funding directive should be put in place This will involve the introduction of a QALY weighting, which will progressively advantage treatments that offer greater QALY gains. The £100,000 per QALY

maximum for automatic funding (subject to the budget impact test) would be retained, but the HST Evaluation Committee would have discretion to apply the QALY weight in defined circumstances. By using incremental QALY gain, we can illustrate, quantitatively, what actually matters to patients (incremental therapeutic benefit) with a corresponding measure that everyone can understand (additional QALYs). And by making it clear that higher incremental cost effectiveness ratios (£s per QALY) are only acceptable when associated with higher QALY gains, we both provide a more explicit framework for decision-making than we have had so far, and we send a clear signal that what matters most, and what will attract the highest premium, is therapeutic benefit.

19. This revised approach takes account of our current methodology for evaluating HSTs. This describes the special features of treatments for very rare conditions. The methodology also describes a range of factors the HST Evaluation Committee needs to take into account during decision making. It is clear that, in reaching its previous decisions, the factor on which the HST Committee placed most weight is the extent to which technologies demonstrate significant therapeutic improvement. This is described in our current HST methods as 'overall magnitude of health benefits to patients and, when relevant, carers'.

20. For the HST QALY modifier to be applied, there would need to be compelling evidence that the treatment offers significant QALY gains over established NHS practice. The HST Evaluation Committee will consider the size of the QALY gain in relation to the additional weight that would need to be assigned to the QALY benefits for the cost-effectiveness of the technology to fall within HST £100,000 QALY limit. Depending on the number of QALYs gained over the lifetime of patients, when comparing the new technology with its relevant comparator(s), the committee will apply a weight of between 1 and 3, using equal increments, for a range between 10 and 30 QALYs gained.

21. The weighting would be applied in the following way:

Table 1 - Weighting of QALYs in HST

Incremental QALYs gained (per patient, using lifetime horizon)	Weight versus 100k/QALY
Less than or equal to 10	1
11 – 29	Between 1 and 3 (using equal increments)
Greater than or equal to 30	3

22. The proportion of technologies that will attract a weighting will depend the magnitude of the incremental benefit they offer. It is not possible to predict how many will do so, with any certainty. However, it is likely that 3 of the HST topics so far evaluated would have attracted some weighting under the new arrangements. Having attracted a weighting, the cost to the NHS will be the critical determinant in whether NICE is able to issue a positive recommendation.

23. All positive HST guidance will be issued with a description of the special arrangements required for managed access; defining selected populations, starting and stopping rules, requirements for evidence collection, and patient consent.

24. The changes set out above have been incorporated in the process and methods statement for the Highly Specialised Technologies programme.

25. NICE and NHS England will review the revised arrangements and if necessary, make proposals for amendments, after 3 years.

26. Although we indicated in the consultation proposals that we could implement the proposal for all topics that have their first committee meeting after 1 April 2017, in light of the changes proposed, we now intend to put these arrangements for topics that are initiated after 1 April 2017.

Decision

27. The Board is asked to approve:

- The proposals laid out in the consultation, as amended;
- The introduction of a QALY weight;
- The implementation plan, as amended.

National Institute for Health and Care Excellence

March 2017