NICE National Institute for Health and Care Excellence

NHS England

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE 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

Comments proforma

Name:	**Alex Davison**	
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Organisation:	**Asthma UK**	
Have you or your organisation received any payments, grants or other funding from the pharmaceutical industry in the last three years?	Yes	
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Consultation Question	**Response to consultation questions** **Please do not paste other tables into this table, as your comments could get lost – type directly into this table.**	
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?	No	Asthma UK recognises the need for NHS England to manage their budget to meet the increasing financial pressures. However, the introduction of a budget impact threshold risks causing routine delays in the introduction of new urgently needed treatments to meet unmet needs. As a result, Asthma UK does not support this proposal. A budget impact threshold poses a significant risk to patient cohorts for which there is unmet need, for example those with severe eosinophilic asthma, a condition that affects around 125,000 people in the UK. People with severe eosinophilic asthma do not respond to standard treatments currently available on the NHS. Instead, their only treatment option is oral cortical steroids (OCSs). Long term use of oral cortical steroids has serious side effects including Diabetes,

		Osteoporosis. There are currently several new monoclonal anti-body treatments for severe eosinophilic asthma in the pipeline. These include Mepolizumab which was recently recommended by NICE but is not yet available and will not comprehensively meet all unmet need. Currently the price of this treatment is confidential. However, if the costs of their implementation were to fall above the budget impact threshold, a patient cohort of up to 125,000 who currently do not have access to an effective treatment for severe eosinophilic asthma would be kept waiting for an indeterminate period of time. In effect, a budget impact threshold risks perpetuating unmet need in patient cohorts who currently do not have access to life-changing treatments. Furthermore, the introduction of a budget impact threshold would create another barrier to the introduction of innovative new treatments into the UK market. This risks making England a less attractive market for the most innovative technologies. This is at odds with the vision set out in the Accelerated Access Review, now part of the government's Industrial Strategy, to make the UK "the best place in the world to design, develop and deploy innovations".
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?	NO	The introduction of a £20 million threshold would pose a significant risk to patient cohorts with unmet needs, such as people with severe asthma. In the case of monoclonal anti-bodies, such as Mepolizumab, if the price of the treatment was £13,000 per year per person, the treatment could only be given to 1500 people before the threshold was exceeded (£13,000 per year per patient is an estimate, the funding of Mepolizumab is being negotiated and is therefore confidential). Given that the severe eosinophilic asthma population is estimated to be around 125,000, such treatments are very likely to fall above the threshold. As a result, if these proposals are implemented, there is a significant risk that a large patient cohort who currently do not have access to effective treatments will face an indeterminate wait for life changing medicines. In addition, the £20 million threshold would delay the introduction of new low cost treatments for large patient populations. If a population was large enough, for example all people with asthma, a very cheap treatment would still push it over the threshold. In short, the threshold has the potential to delay access to treatments to a large number of patient cohorts. The consultation document implies that, if these proposals are implemented,

		approximately 20% of new technologies will face a longer wait for approval. The document refers to an "analysis of positive technology appraisals published between June 2015 and June 2016". As this was not shared alongside the consultation document there is no way to assess whether this figure is accurate. Regardless, this is a significant proportion of new technologies and a significant number of patients who will be waiting for treatments The consultation document does not provide any information on how the £20 million figure was reached. In addition, the consultation document is not accompanied by an impact assessment. NICE and NHSE should make it clear how they arrived at the £20 million figure and how the budget impact will be calculated.
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?	NO	It is essential that NHS England, NICE and other regulators, patients and pharmaceutical companies should work together to ensure new technologies become available. This measure encourages dialogue far too late in the process. Discussion should begin far earlier in the drug development process to ensure that any new treatment achieves outcomes that meet patient need as well as payer and clinical expectations.
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?	NO	This measure will create yet another barrier to the adoption of new technologies. It will make the process less transparent and has the potential to cause regular and significant delays in the availability of new treatments. This measure risks some technologies being delayed for significant periods of time while others are only delayed for a short period without clear and transparent explanation as to why. Patients will receive treatment or be kept waiting for treatments as a result of factors beyond their control. This is will be a significant inequality. Furthermore, NHS England and NICE have not set out a process through which decisions, on which technologies will have their funding requirement varied and for how long, will be reached. The absence of a set process combined with the fact that discussions over funding requirements are, as a rule, confidential means that any process will still lack transparency. This risks jeopardising the objectivity of the NICE appraisal process which is internationally highly regarded.

		An opaque process will lead to a lack of understanding of why certain technology appraisals are being implemented faster than others. As a consequence, the process risks becoming highly politicised as some drugs are not made available for reasons the public do not fully understand. This risks jeopardising the objectivity of the NICE appraisal process which is internationally regarded. NHS England and NICE should look for ways to counter financial pressures which do not risk delaying access to innovative new treatments, such as engaging stakeholders earlier on in the appraisal process to identify unmet needs further upstream.
5. Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?	No	The fast track process and the criteria have not been explained in sufficient detail in the consultation document for Asthma UK to support such a measure. The document does not outline how such a process will be resourced. If new resources are not made available, there is a significant risk that it will take capacity away from the regular appraisal process. This will lead to faster access to the most cost effective treatments at the expense of other, potentially more innovative, medicines. In addition, a faster process must not detract from the quality of the evaluation. The proposed fast track framework does not include an evidence review group report. If the fast track process was implemented in its current form, there is a risk that evidence would not be scrutinised to the same extent as the regular appraisal process. A lack of scrutiny increases the risk of unforeseen costs becoming apparent after the appraisal process once NHSE has a statutory obligation to fund a fast tracked treatment. The prioritisation of technologies for the fast track process should be based on innovation and the impact of a technology on the patient cohort, not the lowest quality adjusted life year.
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?	No	The decision to fast track a medicine should not be based only on a QALY. This is simplistic. Such a decision should also be based on innovation and its impact on the patient cohort.

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?	No view	
8. Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?	No view	
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?	No view	
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?	No view	
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?	No view	
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?	No view	
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?	No	There is a significant risk that the budget impact threshold as laid out in the proposals would restrict treatment to some groups rather than others due to criteria which is not in their control. For example, large patient populations such as all people with asthma or diabetes could have delays in access to new treatments which are relatively cheap simply due to the number of people who could benefit from them. In addition, people who currently have no treatment options available to them, such as people with severe asthma, and are waiting for new treatments would face further delays in accessing treatments. This will lead to some patient cohorts facing significant delays in accessing new treatments for reasons that are beyond their control.

Section number primarily related to your comment (please enter only one)	**Other section numbers**	**General comments** **Please insert each new comment in a new row.**

Indicate **'general'** if your comment relates to the whole document	**related to your comment**	

To submit your comments, please email this form to: TAandHSTconsultation2016@nice.org.uk

Closing date: Friday 13 January 2017

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