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:	**Phillip Anderson**	
Role:	**Policy Manager**	
Organisation:	**Prostate Cancer UK**	
Have you or your organisation received any payments, grants or other funding from the pharmaceutical industry in the last three years?	**Yes**	
E-Mail address:	**phillip.anderson@prostatecanceruk.org**	
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	Overall view We recognise that NHS England must find ways to achieve sustainability at a time when it faces large financial deficits and increased demand for its services. We also understand that it has to balance the breadth of demands on its finite resources and we agree that Industry has a role to play in making its new treatments and technologies affordable to the NHS. However a budget impact threshold has the potential to throw the brakes on the most effective new treatments and technologies just before they get to patients. We are very concerned that delays to clinically effective treatments getting to patients could be catastrophic in terms of both progression-free and overall survival. In particular, patients with terminal and end-of-life conditions cannot afford to wait longer for medicines to be introduced and are often relying on the next breakthrough treatment to become available so they can have another

		option of treatment. **End-of-life treatments must be exempt from the budget impact threshold and the impact on patients of any proposed delay to the normal funding requirement must be set out as part of a public consultation on this delay.** The threshold also risks undermining the proposals in the Accelerated Access Review and reforms to the Cancer Drugs Fund, which both have set out a vision for effective new drugs to be accelerated through licensing and appraisal. If we allow financial pressures to stifle innovation in this way, the NHS may no longer be able to maintain its status as a world-leading base for clinical research, because new treatments can no longer be trialled against the best comparators. The PPRS is the process through which the Department of Health attempts to ensure a sustainable drugs bill by negotiating a global rebate on spending that provides certainty for both Industry and NHS England. Changing horses in midstream by adding a new way of managing affordability in the middle of a PPRS period has the potential to undermine the ability of the next renegotiation to make treatments affordable to the NHS and accessible to patients, because this is less likely to be seen as providing the budgetary certainty that is one of its main attributes. The industrial strategy green paper should consider the impact all the recent proposals aimed at reducing the drugs bill: this consultation plus the recent reforms to the Cancer Drugs Fund and the Medical Supplies (Costs) Bill. It should set out how this influences its approach to fostering research from medical research charities and the life sciences industry that can have crucial benefits for men with prostate cancer. <u>Mitigations if the proposal is taken forward in spite of the above</u> If the proposals are taken forward in spite of the risks we have outlined, there are a number of key checks and balances that must be brought into the policy to avoid a grave risk of unintended consequences, especially unacceptable clinical impacts on patients, some of whom could see significant progression of illness or even death during a period of delay that could have otherwise been prevented or slowed. There must be a clear limit on the potential variation to funding requirements, a shorter scope over which impact will be considered, and several

		key exemptions where the threshold will not apply. It is unacceptable to put in place an open-ended "blank-cheque" for NHS England to request a very lengthy delay if the impact threshold is breached. **NICE and NHS England must commit to a "backstop" whereby the funding requirement for any approved treatment is fully implemented within 200 days** (compared to the current 90-day requirement). This timeframe would allow NHS England scope to negotiate a delay or temporary discount, while providing certainty to patients that they will not have to wait years to gain access to an approved treatment. **The threshold should only apply to financial impact within the current financial year and the one after**. Looking at the first three years is unreasonable as it would be completely unacceptable to delay a drug (even partially) by three years if it has been approved by NICE. Moreover the NHS should have time to plan for fully fulfilling the funding requirement of a treatment NICE has deemed cost-effective if its main impact falls two or three years later. We also feel that there are several key categories of treatments and technologies where a budget threshold is not appropriate. In order of priority, any budget impact threshold should **not** apply where: ○ **End-of-life criteria** were applied in the treatment appraisal: by definition any delay will very likely mean that some patients who would have benefited from a new treatment or technology will die before it becomes available, losing the opportunity of additional months of life. This is completely unacceptable and the higher accepted cost per QALY of £50,000 for end of life medicines in fact makes these medicines more likely to be halted by the budget impact threshold proposals. ○ A treatment that has **previously been approved** is being reviewed: any treatment that is already in the system should by definition be factored into NHS budgets and it would be unacceptable to take a cost-effective treatment away from patients when they have already been receiving it.

		○ A treatment that **meets an unmet need**: it would not be acceptable to delay a treatment that provides hope to patient who do not currently have any other options. ○ A treatment receives **conditional approval** in its appraisal: conditional approval will deliver a real-world evaluation of new treatments and technologies to provide NICE with greater certainty of clinical benefit. To achieve this, these treatments will be made available to patients through managed access agreements that are likely to be more affordable than the NICE ICER, should the treatment or technology be approved. It would be unacceptable to deny future patients this treatment or technology, if at approval it falls within the budget threshold. It could also lead to a waste of resources if the potential for a non-discounted drug to be delayed via the budget threshold process is not considered at the point of conditional approval. ○ A treatment receives the "**transformational" designation** set out in the Accelerated Access Review final report (if these proposals are taken forward): applying the threshold to these treatments could prevent effective treatments and technologies that are accelerated through the appraisal system getting to patients. This would undermine the ambitions of the AAR ○ A treatment that is in the **Early Access Medicines Scheme** as the most innovative cancer treatments would potentially be disproportionately penalised. ○ Treatments that are within the **'fast-track' process** outlined in this consultation (if it is to be implemented). Cancer treatments with an ICER under £10,000/QALY should improve cost-effectiveness in the system so should not be delayed.
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	If the budget impact threshold is going to be implemented, NICE and NHS England must provide much more robust analysis as assurance that this is an appropriate level. Currently the analysis is based simply on the level where 20% of treatments were captured in one year (June 2015 – June 2016). The analysis should instead be based on five years of treatment appraisal impact estimates,

		cross-checked against their actual usage, and should include a clear statistical demonstration that the threshold is pitched at a level where it applies only to treatments that have an exceptionally high impact on budgets. A good approach would be setting the threshold at three standard deviations above the (inflation-adjusted) mean budget impact over the five-year period. This is a common definition of an outlier. Our own analysis of the June 2015 – June 2016 data indicates that there are a large number of treatments in the £16-19m impact range, which indicates that the threshold is pitched around the mean, rather than capturing only exceptionally expensive treatments. This analysis has also indicated that there is a consistent pattern where treatment usage is lower than that predicted by NICE. It is not clear whether this is due to conservative estimation of impact or more worryingly to poor commissioning and prescribing practices. This ambiguity underlines the importance of further investment in monitoring and data collection to ensure that as innovative technology is offered consistently throughout the NHS to all patients for whom it is appropriate.
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?	Yes	Better horizon scanning and earlier commercial negotiations will be essential elements of any sustainable system going forward. This also makes it more likely that industry will work to make their prices affordable and maximises the chances of flexible pricing models being developed. The NHS England Strategic Commercial Unit recommended by the Accelerated Access Review would be an ideal vehicle for horizon scanning and for NHS England to engage at an early stage in commercial negotiation. It will be very important for NICE and NHS England to engage early enough to gather views of clinicians, patients, and representative groups on efficiencies potentially released by new technologies at an early stage, so that both the budget impact estimate and commercial negotiations can be based on an accurate picture of the overall net cost of a technology. We would also like to see NHS England plan their budgets in response to horizon-scanning of new medicines, as they make their way coming down the research pipeline. This should include engaging with Industry as early as possible to understand predicted price banding of a new technology, with involvement at

		the scoping stage of a NICE appraisal. Medical research charities could help with this horizon-scanning process, possibly via the Association of Medical Research Charities.
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	As set out above, we are not supportive of the budget impact threshold. The interpretation of the relevant regulations set out in the consultation appears legally questionable and certainly contrary to the spirit, if not the letter, of the NHS Constitution, which guarantees patients access to treatments approved by NICE. The regulations stipulate that a funding requirement can be varied if "*the health technology cannot be appropriately administered until other appropriate health services resources, including staff are in place*". This seems to clearly envisage an exceptional scenario where administration is especially complicated, not a scenario where a treatment is merely expensive. If these proposals are taken forward in spite of this, **NICE must apply the same rigor to consideration of a funding requirement variation as it does to a treatment appraisal.** This must include: • Full public consultation on a variation (not simply those directly involved in the appraisal) • Publication of a "clinical impact assessment" that sets out the expected impact on patients of a proposed delay • Publication of a statutory equalities assessment for the proposed delay • Publication of other options considered and resource implications of these To avoid adding further delays to the process, as much of this material as possible should be prepared during the negotiating window so that a consultation on any delay approved by NICE can begin shortly after the negotiating window closes. In addition, any variation in the funding requirement should be accompanied by an interim arrangement whereby there is a clear option for clinicians to make an individual funding request using the "critical clinical urgency" criteria, where they believe that the delay envisaged by NICE would cause significant harm to their

		patient. If the proposals are taken forward, this must be used as an opportunity for NHS England to undertake more consistent and faster consideration of in-year service developments, particularly if coupled with more comprehensive horizon-scanning as discussed above.
5. Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?	Partially	As set out above, we think that treatments that meet the criteria of £10,000/QALY incremental cost-effectiveness ratio should not be within the scope of the budget impact threshold. Any treatment that achieves this level of cost-effectiveness should by definition help with the efficiency challenges in the NHS so should not be delayed.
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?	Yes	We are supportive of a faster and simpler process for very cost-effective medicines, whilst recognising that not many new medicines will fall into this category, so this new route will be of limited benefit to most patients.
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?	Yes	We welcome faster access for patients to new treatments.
8. Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?	Yes	Yes, it would be simpler to have one shorter process for very cost effective medicines. We understand from the consultation events that "integrate" is a more accurate description of the intention than "absorb" and it makes sense to align two schemes with similar objectives and scope.
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	It would be very helpful to confirm that the definition of a "highly-specialised technology" does not include a technology that applies to a small sub-set of patients within a common disease. Given the likely increasing prominence of stratified medicine in the coming years, this clarification will be particularly important in defining the scope of these proposals. Highly specialised technology is specifically defined as technology that addresses "rare and very rare conditions" in *The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013*. There does not seem to be a formal legal definition of "rare and very rare conditions", but given this definition

		we do not see that under any reasonable interpretation it could be taken to include small sub-sets of patients in common diseases. We understand from colleagues that there are a number of problems with applying the QALY methodology to HSTs, however if the above is correct then this is not relevant to prostate cancer and so it is not for us to comment further on this section.
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?	Yes/No/Partially (delete as appropriate)	Not applicable
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?	Yes/No/Partially (delete as appropriate)	Not applicable
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?	Yes/No/Partially (delete as appropriate)	Not applicable
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?	Yes	We are very concerned about how the budget impact threshold and the associated potential delays would impact on patients with terminal and end of life conditions. These patients cannot afford to wait longer for medicines to be introduced and are often relying on the next breakthrough treatment to become available so they can have another option of treatment. The higher accepted cost per QALY of £50,000 for end of life medicines, would in fact make these medicines more likely to be halted by the budget impact threshold proposals. **Treatments that meet end-of-life criteria absolutely must be excluded from the scope of the budget impact threshold.**

Section number primarily related to your comment (please enter only one) Indicate **'general'** if your comment relates to the whole document	**Other section numbers related to your**	**General comments** **Please insert each new comment in a new row.**

	comment	

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Closing date: Friday 13 January 2017

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