NHS England NICE National Institute for Health and Care Excellence

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

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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	1.1 The question implies that '..the sustainable introduction of cost effective new technologies' remains an objective that NHSE is currently unable to meet. 1.2 There are, however, already special arrangements in place that involve not just the estimation of budgets and their likely impact on resources (for example: UK PharmaScan and NICE's resource planner, but also special arrangements that cap overall expenditure on branded medicines (the Pharmaceutical Price Regulation Scheme (PPRS)). We are surprised and disappointed that there is no reference to these arrangements anywhere in the consultation document. 1.3 Efforts should be made to ensure that these existing mechanisms are working as effectively as possible before introducing further arrangements

		into what is already a complex pathway for the adoption of new, cost-effective, medicines. 1.4 On UK PharmaScan, strengthening existing wording that commits companies to provide data to this body, such as wording similar to, or more proscriptive than, that found in Section 43 of the 'Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund)' (see here) could further encourage companies to provide submissions that will aid the NHS to plan ahead. 1.5 On the PPRS, the 2014 scheme is a global level scheme which addresses affordability of branded medicine spend via allowable growth rates and PPRS payments, with the exception of those medicines that are not covered by the PPRS but which are covered by the Statutory Scheme for Branded Medicines, with minor exceptions including branded generics. 1.5.1 Legislative reform of pricing regulation (the Health Services Medical Supplies (Costs) Bill currently going through Parliament) is underway with the aim of aligning the Statutory Scheme with the PPRS (plus price regulation of generics). 1.5.2 We support Simon Stevens 'leaky around the boundaries' comments (response to Q 79 see here) about the Scheme to the Public Accounts Committee (PAC) hearing as part of their inquiry into specialised services and the provisions of the Bill that seeks to address the problem he referred to. The DH should also work on how such 'leaks' can be addressed as part of a future PPRS. 1.6 A key problem with the current PPRS is that it sits uneasily with a mix of levels of commissioning from local to central – dependent upon the product – yet a company's PPRS payments are made at a national level to the Department of Health (DH). Over time more information has become available on payments including amounts allocated to NHSE and the devolved nations (see here and here). However distribution of these

		allocations within the NHS remains completely opaque (with the exception of Scotland). There is no assurance that these monies support access to new medicines. This needs to be addressed in the future. 1.7 Running alongside these mechanisms, is the increasing use by NHSE of its monopsony position to secure further discounts through procurement (which can be in addition to those secured through the presence of a NICE cost effectiveness threshold – i.e. companies pricing to the threshold – and Patient Access Schemes (PAS)). There are also ad hoc NHSE efforts to reduce price; companies were, for example, asked to provide their 'best and final' prices for specialised services for which investment was being considered during 2016 following the PrEP judgment. 1.7.1 Further use of NHSE's monopsony position may well be likely given the recommendations made in a number of recent reports including: Lord Carter's final report in February 2016 'Operational productivity and performance in English NHS acute hospitals: Unwarranted variations' (Recommendation 3 (h) p.35), the Accelerated Access Review (AAR): 'Final Report Review of innovative medicines and medical technologies' (section 2.5 p.32), the AAR commissioned PWC report 'AAR Review Proposition 2: Getting ahead of the curve & Recommendations for accelerated access pathways and a flexible pricing and reimbursement framework' (Exhibit 12 p.48) and the PAC (Recommendation 5: 'using national bargaining power to get the best prices for high cost drugs'). 1.8 However, it seems even after allowing for these special arrangements, including proposals for their reform, and the array of other recommendations and initiatives noted above; NHSE still considers there is a need for an additional evaluation stage to be introduced to secure the sustainability referred to in this question. There is certainly no indication that NHSE plan to review their own role and performance in the operation of existing arrangements.

		1.9 Just as we stated in our response to NHSE's consultation in 2015 on investing in specialised services, we accept that NHSE must work within the broader policy framework and politics of the day; these, in large part, determine the affordability envelope within which NHSE must work. It is against this backdrop that NHSE has made these proposals. 1.10 At the same time, there is a conflict with NHSE's stated intentions (made as part of the investing in specialised services consultation) to first invest in those treatments given a positive recommendation from NICE appraisals, followed by NHS Constitution requirements. The proposals amount to a 'work around' of funding requirements and potential NHS Constitution requirements. 1.11 NHSE has proposed they should adopt a budget impact threshold and set a specific threshold value, breaches of which might act as a precursor to the 'need for a commercial agreement' (section 13). If no agreement was possible or if an agreement was not able to 'fully address the budget impact challenge' (section 14), then NHSE would be granted an option to seek not only a variation of the standard 3 month (or 90 day) funding requirement but also a 'period of phased introduction' (section 14) of the new technology for those patients eligible for the new technology. 1.12 We are also skeptical of NHSE's capability given the PAC recommendation 4 which revealed NHSE lacks 'information - on costs, access and outcomes necessary to assess how to improve its services' and in particular notes 'there are no consistent national data for' some services which include 'high cost drugs' because 'local commissioning teams collect data differently'. The conclusion was that 'NHS England cannot make strategic decisions about where and how services are delivered to achieve better value for money.'

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	2.1 NHSE provide no clear underpinning logic or rationale for the selection of £20million. 2.1.1 £20million appears to have been selected based on an analysis of positively appraised new technologies and their budget impacts between June 2015 and June 2016. This resulted in what is implied to be a manageable proportion (20%) breaching the budget impact threshold. This in no way links to an available budget for the NHS in the future, nor involves consideration of what may be displaced if high budget impact new medicines were to be adopted. No justification is also given for the selection of June 2015 to June 2016. 2.2 No justification is given as to why a period of 3 financial years after launch has been chosen. The consequence of this proposal is a greater chance of 'breaching' the £20million in year 3 because of the potential for carry over of patients from previous years into each subsequent year, subject to variation as to duration of treatment. 2.2.1 We also note that it is not clear if the percentage of new technologies that would have breached the threshold in the selected timeframe would have been higher had they been modelled over 3 years rather than a single year. 2.3 To be aligned with recommendations made by the Public Accounts Committee (PAC) report (Tenth Report of Session 2016–17) NHSE must ensure that a consistent process is put in place to ensure its decision-making is transparent and equitable (Recommendation 2). We are not convinced that this is met by the proposals made by NICE and NHSE; it is unclear why £20million was chosen and why 3 years was also chosen. 2.4 Although we do not agree with the proposals, we accept that they may be implemented. If so, we urge NHSE to reconsider their choice of budget impact threshold; an appropriate amount to use as a budget impact threshold should be based on both ensuring that all inefficiencies are removed as far as feasible from within the NHS (providing 'headroom for innovation' through de-commissioning and disinvestment as appropriate) and that the budget impact is in some way related to the additional funding

		available for spending on new medicines within the NHS, specifically funding for specialised services. 2.5 Horizon scanning would also provide further insights as to future budget impact. This should be used to provide reassurance that the £20million is proportionate and practically implementable in terms of the potential number of NHSE and company negotiations. This should also consider capacity at NHSE and NICE given there is scope for multiple types of engagement by the company with the DH, NICE and NHSE (i.e. via PAS proposals, advice on budget impacts, commercial access agreements etc). 2.6 This question asks respondents to suggest an alternative budget impact threshold if they disagree with £20 million and justify it; we note though that those outside of Government and its agencies would not have sufficient information at this time to select a preferred budget impact threshold. NHSE should also apply the same standards to itself that it asks of others; NHSE have not justified their choice.
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?	Partially	3.1 An agreement that provides an alternative to the 'price per pill' model may be a pragmatic response that enables both patient access, revenue for the company, and a contribution towards the management of budget impact for NHS commissioners. 3.2 Such pragmatism relies on a reasonable budget impact threshold being set. It also requires both NHSE and companies to be 'reasonable' in the resulting discussion to reach a commercial agreement. There is a very real risk that if both NHS commissioners and companies cannot behave in a reasonable manner that patients will 'pay the price for delay'. 3.2.1 NHS commissioners must not be perversely encouraged to focus on this meeting 'staying within budget' performance targets at the expense of incentivising fast access to cost effective new medicines. To do so would have uncertain short, medium and long-term impacts.

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	4.1 It's unclear to us that NICE retains the appropriate legal authority to do this. Much rests on the interpretation of the precise wording set out in the relevant legislation for when NICE can and might defer funding of a cost-effective new medicine within the defined 3 month (90 days) period. 4.1.1 We would interpret the word 'resources' in Regulation 7 section (5) (a) (iii) of the Statutory Instrument to mean, when taken with 5 (a) (i) & (ii), training, goods, materials, facilities and staff available, not funding. The more so because of the orthodox distinction between capital and operational expenditure being detectable in (ii) & (iii). In contrast section 8 of Regulation 7 is clearly dedicated to the provision of funding to enable compliance with the recommendation which reinforces our view. Our overview is that section 5 clearly refers to (and groups) expenditure items which section 8 sanctions funding for (whilst also indicating the agency responsible for their funding). 4.2 Our view is that, if adopted, the proposals would result in NICE being unable to ever decline a request. Our concern is that NHSE would in effect be able to thwart implementation of NICE technology appraisal guidelines whenever funding was a cause for concern. Their funding concerns would also not be open to scrutiny given that they would be based on confidential estimates of budget impact. 4.3 A related concern is that NHSE would in effect be able to determine the timetable for implementation for technology appraisal guidelines. NICE may also be unable to determine the appropriate time period for a deferral as set out in 7 (4) because NICE does not set out funding for the NHS, nor control its allocation over time. Again, NHSE would in effect be able to determine the timetable for implementation for technology appraisal guidelines. This would challenge NICE's reputation as a truly independent agency. 4.4 Companies may also change their behaviour in response to the proposals. Companies can and do - according to NICE's own statistics (see here) – choose not to provide a submission to NICE. Companies may

		enter into discussion with NHSE, and bypass NICE, in order to secure baseline funding. The impact on patients is unclear.
5. Do you consider that the criteria for the fast track process are appropriate? If not, what other criteria do you suggest?	Partially	5.1 Strong evidence of being below £10,000 per QALY with low decision uncertainty appears to be a sound principle. We caution about taking an approach that over emphasises the cost per QALY to determine decision-making and process. This applies generally, but also at relatively low cost per QALY estimates. Assumptions are made in using the QALY and in the associated modelling that do not always reflect the reality of clinical decision making. We have previously expressed our concerns about the tools underpinning QALYs. There are also broader concerns about how well such tools pick up what really matters to patients. Mistakenly adopting low cost per QALY technologies that may offer limited clinical effectiveness but are very cheap in relative terms has implications for resource use, just as they do for the adoption of high cost per QALY technologies. 5.1.1 The £10,000 cost per QALY is arbitrary, and should not lead to algorithmic process and decision-making. 5.2 We question the second criterion in light of our concerns for the budget impact threshold discussed earlier.
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?	Partially	6.1 A fast-track process may be attractive as it would minimise health benefits forgone during long decision-making processes. It may also improve the efficiency of NICE itself. 6.2 A fast-track process with a lower cost-per-QALY may also encourage companies to lower prices to achieve this lower threshold. However, there is value in scrutiny and NICE should ensure that sufficient scrutiny remains even as part of the fast-track. 6.3 NICE should review experience to reassure stakeholders that appropriate scrutiny is not compromised.
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	7. Patients should benefit from this.

8. Do you agree that NICE should absorb its proposed 'abbreviated' technology appraisal process into the proposed fast track process?	Don't know	8. NICE needs to clarify what 'absorb' means and set out a clear process chart to allow stakeholders to understand and compare each route for their relative pros and cons, including providing clarity as to when and how patient groups can provide input.
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	9.1 These are separate and discrete issues. 9.1.1 Setting a threshold should reflect political and economic decisions about funding for the NHS as well as opportunity costs. Commissioners in particular should know what they intend to stop funding in order to provide funding for new medicines. 9.1.2 NICE should be informed 'top down' and 'bottom up' and not arbitrarily pick a number to inform their Appraisal Committee on HSTs. NHS England is the commissioner of specialised services and should hold information on what they need to stop funding in order to provide funding for new medicines. They should be able to justify the choice of £100,000. 9.2 The timeline for funding is a separate issue to setting the threshold.
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	10.1 We do not understand how and why the £100,000 cost per QALY was chosen. NICE and NHSE must set out how they reached the estimate of £100,000 cost per QALY, otherwise we cannot meaningfully comment. 10.2 We also do not support the funding requirement being used as a negotiating tool by NHS England given that it means that delaying access to new medicines becomes a bargaining tool with the costs of delay borne by patients. The proposals potentially allow NHSE to use delay as a bargaining tool, and it will be patients who face the consequences. 10.2.1 Protracted negotiation can have profound consequences for patients, for example the media reported deaths of children and disability for those who survived Men B whilst the Government undertook a lengthy negotiation on the price of the Men B vaccination. 10.3 As difficult as it may be in practice, both NHSE and the company will need to commit to a time limited negotiation, where needed, to manage affordability.

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	11.1 This raises the prospect of even further delay, greater costs to patients in terms of health benefits forgone, and would also put these technologies into an opaque decision making process that does not even have the option for appeal. 11.2 We are also surprised by the appearance of this particular proposal in the consultation. There are already concerns about the design and operation of the current specialised commissioning prioritisation process systematically disadvantages highly specialised technologies. NHSE, in a letter from Noel Gordon to Lord Sharkey on 28 November 2016 acknowledges the need for further work; "[NHSE] will continue to engage with stakeholders on further work to ensure that treatments for rare conditions receive fair consideration, and we will consider whether, and if so how, a premium can be provided for rarer diseases."
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	12. HST Appraisal Committees currently have access to this information. Research should explore whether the proposal not to provide it to the HST Committee would be likely to change their recommendations? An understanding is needed of the potential impact of these proposals before making the change.
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?	Don't know	13. We don't know but we do note that these changes will likely have an impact on particular patient groups over others (not least those who have a rare condition). For example, for rare cancers where a higher unit price is more likely to apply reflecting the small size of the patient population on which a commercial pharmaceutical company is reliant to recoup R&D costs and secure profits there may be a higher chance of breaching the budget impact threshold of £20million than for new medicines for more common conditions even if the number of patients treated is relatively small.

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 comment**	**General comments** **Please insert each new comment in a new row.**

General		1. The proposals make it even more complex to understand the options for appraisal (e.g. ATA, FTA, 'standard'). NICE should clarify and provide guidance to support all stakeholders, particularly with respect to what 'absorb' ATA into the fast track route means.
General		2. There is an ambition described in the proposals to deliver the 'right outcomes' for the life sciences industry. The proposals are complex, raise the spectre of further delays to accessing even cost-effective medicines, with a focus on securing further discounts and not offering prices that reflect value. We question whether the proposals can be credible in their suggestion that they can deliver the right outcomes for the life sciences industry.
General		3. There is also the hope expressed that inking NICE and NHSE processes for HSTs will generate greater equity and consistency. This seems unlikely at best since all qualifying HSTs will not go through the NICE process which instead is arbitrarily limited to 3 a year by funding given to NICE (see here). We ask that NICE clarifies whether HSTs will remain limited to 3 a year or not?
General		4. We ask that NICE clarify if the £100,000 maximum cost per QALY threshold would apply to new medicines for ultra rare conditions?
General		5. We ask that NICE and NHSE plan a review within 3 years of the impact of their proposals taking particular care to include patients and their representative groups evidence and views into account
General		6. We ask that NICE clarify how it will be calculating budget impact, specifically will NICE be using the same approach as used in NICE resource impact assessments?
General		7. We ask that NICE and NHSE clarify how their proposals fit with recommendations made by the Accelerated Access Review (AAR), particularly whether their proposals provide any scope for outcomes based payments as one of the models considered as part of the AAR work.
General		8. It would have been helpful for NICE to have published the supplements to the relevant Guides referred to in sections 32, 43 and 49 as part of the consultation process. We consider this good practice and are disappointed that NICE has not done so for this consultation. We hope that this is not setting a new precedent.
General		9. To more fully understand the proposals, we also ask NHSE to publish operating procedures.

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

Closing date: Friday 13 January 2017

PLEASE NOTE: NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

Cancer52
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