

Charging for NICE technology appraisal and highly specialised technologies guidance: a document for consideration and comment by the life sciences industries' associations

Comments on this proposal

1. Industry trade associations are asked to send comments on NICE's intention to charge companies for the cost of undertaking technology appraisals and highly specialised technology appraisals to Jennifer Butt at jennifer.butt@nice.org.uk **by Friday 30 September 2016.**
2. NICE will take account of the comments received in the further development of its proposals, which will then be subject to Department of Health and HM Treasury approval.

Introduction

3. NICE intends to charge for its technology appraisal (TA) and highly specialised technologies (HST) guidance, from the 2017/18 financial year, subject to the necessary approvals and amendments to NICE's Governing Regulations¹
4. In scope are the NICE technology appraisal and highly specialised technologies recommendations, referred to in paragraphs 7 and 8 of the NICE Governing Regulations that require relevant 'health bodies' (NHS England, CCGs, local authorities) to provide funding within a given period. Charges would apply to guidance on all technologies that fit the definition used in the Regulations for 'health technology'² or for 'highly specialised health technology'³, and that are routed through the NICE technology appraisal or highly specialised technologies programme.
5. The introduction of charges will not have an effect on NICE's methods or processes. NICE will continue to develop its methods independently. Industry will continue to be given the opportunity to be involved and consulted, and the introduction of a direct payment relationship will not confer any more right to influence NICE's methods than currently exists.

¹ The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, SI 259

² 'Health technology' may include—(a) a medicinal product to which Directive 2001/83/EC applies;(c); (b) a medical device; (c) a diagnostic technique; (d) a surgical procedure or other therapeutic technique; (e) a therapeutic technology other than a medicinal product to which Directive 2001/83/EC applies, medical device, diagnostic technique or surgical procedure; (f) a system of care; or (g) a screening tool;

³ 'Highly specialised health technology' means a health technology intended for use in the provision of services for rare and very rare conditions provided for in regulations under section 3B(1)(d) of the 2006 Act(d)

6. Only costs incurred by NICE will be included in the charges.
7. These proposals will be reviewed in the light of the report of the Accelerated Access Review, which may contain recommendations for changes to the processes NICE uses for its technology evaluation programmes. The charges set out in this document are therefore subject to alteration.

Rationale for charging

8. The Cabinet Office triennial review, published in July 2015 recommended that NICE should consider the introduction of charges to industry for appraisals activity. This was reinforced, in the context of the Government spending review, in the Department of Health's priorities for NICE for 2015-16. Beyond the specific requirement for Government bodies to reduce their reliance on Grant-in-Aid funding, there are a number of reasons why we believe moving to cost recovery for NICE appraisals is appropriate.
9. There is no absolute requirement for the costs of appraisals to be met out of general taxation. Indeed, it is now the norm for public bodies in the health and care sectors to recover the costs of independent regulatory, inspection, licensing and compliance activities directly from the organisations subject to these regimes.
10. NICE currently funds all its appraisals activity through Grant-in-Aid funding received from the Department of Health. The resources that can be committed to appraisal activity is subject to rigid annual limits. This means that NICE cannot readily respond to additional demand and indeed within a now reducing fiscal envelope it will become even more difficult to respond to increased demand in the future.
11. The establishment of a direct financial relationship will bring with it an obligation for NICE's already high standards of responsiveness to be more explicitly set out as part of the contractual relationship between NICE and its payers.

The approach to charging

12. In line with Treasury's guidance *Managing Public Money*⁴, NICE proposes set charges based on a full cost recovery model. The key paragraphs in this context are:

6.3.5 The standard approach is that the same charge should apply to all users of a defined category of service, so recovering full costs for that category of service. Different charges may be set for objectively different categories of service costing different amounts to provide. (...)

6.3.6 However, different groups of customers should not be charged different amounts for a service costing the same, e.g. charging firms more than individuals. Similarly, cross subsidies are not standard practice, e.g. charging large businesses more than small ones where the cost of supply is the same.

13. The approach set out in this document seeks to balance the need to eliminate, as far as is possible, any significant cross subsidisation, with the desire to produce a practical and workable pricing regime.
14. The proposed charges are based on NICE's current costs according to current processes, but also include changes to processes which are known will occur by the time charging starts. Costs are also based on current service levels and current forms of engagement with industry.

What is covered by the charges?

15. The charges cover NICE's full costs of **producing, publishing and disseminating** TA and HST guidance.
16. TA and HST guidance consists of:
- Guidance
 - Tools and resources such as: resource impact tools; into practice guides; and, where appropriate, research recommendations, managed access arrangements, commercial access agreements
 - Information for the public
 - NICE Pathways

4

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454191/Managing_Public_Money_AA_v2_-jan15.pdf

17. The costs to be recovered consist of:

- **Direct costs:** These are the costs of all the staff who work on the production, publishing and dissemination of the guidance plus non pay costs elements that support the functioning of the (currently) five Committees, and the supplementary externally procured decision support and assessment activity not undertaken by the external assessment/evidence review groups.
- **Corporate overheads:** Appropriate apportionment of corporate costs including the board and corporate office, finance, HR, IT and accommodation costs.

18. The following are not included:

- Work undertaken by the external assessment/evidence review groups (also known as TAR teams)
- The non-appraisal cost of NICE's support to the Cancer Drugs Fund.

Scrutiny of cost recovery model

19. Before NICE can raise charges the proposals need HM Treasury approval. In order to obtain this the proposed cost recovery model will be subject to review by HM Treasury.
20. Once the cost recovery model is operational NICE will account for the activity within a ring fenced segment of its published accounts. This will be subject to annual external audit by the NAO.

Points at which charges will be raised

21. In steady state, charges will be raised when:

- The topic is referred by the DH Minister to NICE for an appraisal to be undertaken – 100% of the standard cost for the type of appraisal. (Note that fees will apply to appraisals which have been referred before charging starts but where the appraisal has not yet started.);
- NICE's Guidance Executive decides that published guidance needs to be updated – 100% of the standard cost for the type of appraisal;
- Additional services are provided – monthly in arrears (see charge list below for details).

22. Transitional arrangements, for topics already referred to NICE but not initiated before charging commences, will be notified once the charging arrangements are approved.

Charges to small companies

23. HM Treasury rules about full cost recovery (see paragraph 12) do not normally allow differential charges to be charged for the same service. NICE has considered whether a reduced charge for small companies⁵, offset by higher charges for medium and large companies, can be justified and has concluded that it cannot. To help small companies with their cash-flow, NICE will look into charging small companies in instalments rather than 100% in advance. These are the same arrangements as offered by MHRA⁶.

Appraisals of non-pharma products

24. Appraisals of non-pharma products (medical devices, diagnostics, digital and other non-drug technologies) referred for a TA or HST will be undertaken at the standard charge for that type of appraisal. Non-pharma products go through the same appraisal process in a TA or HST as do pharma products, and HM Treasury rules do not allow cross-subsidisation which could take into consideration the different funding structure of non-pharma companies.
25. NICE is sometimes asked to review a clinical procedure rather than a technology product, for example prophylactic removal of wisdom teeth. In these cases, because no manufacturer or other chargeable sponsor can be identified, the costs will continue to be borne through direct grant funding from the DH.

Reviews of charges

26. HM Treasury requires charges to be reviewed regularly. Since the charges are restricted to full cost recovery, this means that they will vary as NICE's costs vary. An appraisal which starts at a given charge will normally be completed at that charge.

⁵ The Companies Act 2006 defines a small company as one which meets at least two of the following three conditions: a turnover of no more than £6.5m; a balance sheet of no more than £3.26m; no more than 50 employees.

<http://www.legislation.gov.uk/ukpga/2006/46/part/15/chapter/1/crossheading/companies-subject-to-the-small-companies-regime>

⁶
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/474152/Payment_Easements_for_Small_Companies.pdf

Charge list (draft)

27. The following is a **DRAFT** list of the proposed charges:

Single Technology Appraisal (STA)	£142,000
Highly Specialised Technology (HST)	
Abbreviated Technology Appraisal (ATA)	£99,000
Rapid Review	
Multiple Technology Appraisal – standard	£210,000
Multiple Technology Appraisal – complex	

Notes

28. **Multiple technology appraisals**: A standard MTA evaluates up to three technologies and a complex MTA more than three. The charge will be divided by the number of technologies being appraised.
29. **Appeals**: Because appeals can be brought by individuals or organisations other than the company, they will not be charged.
30. **Refunds**: In the case of terminated appraisals (where the company ceases to participate in the appraisal) or suspended appraisals (where the product being appraised does not receive a licence) the charge will be refunded, less the costs of NICE's time taken to date. No other refunds will be offered.
31. **Cancer Drugs Fund**: Each appraisal of a cancer drug (before and after any period spent in the CDF) is charged at the standard charge for the type of appraisal it undergoes.
32. **Updates of existing guidance**: Updates which involve a new appraisal are charged to the company at the standard charge for the type of appraisal.
33. **Additional services**: NICE's involvement in developing a managed access arrangement (MAA) or a commercial access agreement (CAA) will be charged monthly in arrears according to NICE's standard day rates.
34. **Non-payment**: If a company does not pay the charge, NICE retains the right to terminate the appraisal or withdraw the existing guidance in the case of an update.
35. All charges are in pounds sterling, are invoiced in England, and exclude VAT where applicable.

Timetable for introducing charges

36. The proposed timetable, which is subject to ministerial approval, is set out below.

Comments invited from the Industry associations'	By end September 2016
NICE offers engagement opportunities to industry associations	During September 2016
Proposal to introduce charging is submitted to Treasury	By end November 2016
Amendment to NICE's regulations is laid before Parliament	By end January 2017
Parliament agrees amendment to NICE's regulations	By end April 2017
Amendment comes into effect and NICE starts charging	May 2017

Comments on this proposal

37. Industry trade associations are asked to send comments on this proposal to Jennifer Butt at jennifer.butt@nice.org.uk **by Friday 30 September 2016**.
38. Any requests for engagement with NICE, during the consultation period, should also be sent to Jennifer Butt.

National Institute for Health and Care Excellence

August 2016