

# Centre for Health Technology Evaluation

## Highly Specialised Technologies

### Charging Procedure

#### Introduction

1. In August 2018, the Department of Health and Social Care held a [consultation](#) on changing regulations to allow the National Institute for Health and Care Excellence (NICE) to charge for evaluating highly specialised technologies (HST).
2. The new regulations and charges come into effect on 1 April 2019. Those HST evaluations with a formal start date (invitation to participate) after 1 April will be subject to a charge.

#### Basis

3. In accordance with [UK Statutory Instrument 2018 No.1322](#), NICE must recover the cost of a HST evaluation from the company that expects to market the technology in England. Technologies are selected for evaluation in accordance with the [NICE topic selection process](#).
4. NICE will evaluate the technology in accordance with its [published HST evaluation process](#).
5. [Our timelines](#) show more information on charging for HST evaluations in the context of the guidance development process. NICE will charge for an HST evaluation by issuing an invoice for the amount due, in accordance with the pricing table set out below. The charge will be made to the company holding the marketing authorisation for the technology. NICE must receive the payment for the HST evaluation within 30 days of the invoice being received.
6. The relationship between NICE and the company is not contractual and is governed exclusively by NICE's published processes, including this charging process.
7. NICE expects companies to work proactively with its staff, evidence review groups and independent committees to ensure the evaluation follows the timelines set out in NICE's process documents. Companies are expected to use all opportunities available to them, to facilitate the evaluation, including commercial and managed access arrangements described in the [2019 Voluntary Scheme for Branded Medicines Pricing and Access](#).

## Pricing

| Product   | Charge<br>2019/20 |
|---|-------------------|
| <b>Highly Specialised Technologies Evaluation (HST)</b>   | £126,000          |
| <b>Multiple Technologies Evaluation (MTE) – Standard*</b><br>Charges are split between participating companies and the 75% discount applies to any participating small companies. | £188,000          |
| <b>Multiple Technologies Evaluation (MTE) – Complex**</b><br>Charges are split between participating companies and the 75% discount applies to any participating small companies. | £251,000          |

\*covers up to 3 technologies \*\* covers more than 3 technologies

8. NICE will request a unique reference number from the company approximately 3 months before the invitation to participate (ITP) is issued. The unique reference number identifies the HST Evaluation in the company's finance systems and enables payment for the full charge to NICE. The company is required to submit the unique reference number by the deadline that NICE provides. If the company issues a purchase order as the unique number, any terms and conditions attached to the purchase order will not apply and no contract will be created (see [UK Statutory Instrument 2018 No.1322](#) for the legal basis of this charge).
9. NICE reserves the right not to start the evaluation until this unique number has been received.
10. NICE reserves the right to pause the evaluation if payment is not received in full by the deadline for evidence submission.
11. Where an assessment requires substantially different resource to that of a standard assessment, alternative cost models may be explored by NICE using a methodology consistent with Managing Public Money.
12. The charge is exclusive of UK VAT which shall be payable by the company, where applicable, in addition to the charge. All invoices are subject to the relevant rate of VAT at the time of invoice, where applicable.
13. The company will be responsible for any applicable sales, value-added, use and similar taxes, together with all customs and import duties, and similar levies and impositions ("Taxes") payable with respect to its payment of the charge. Unless expressly specified otherwise in this procedure, all charges exclude Taxes. If the

company has tax-exempt status, then it must provide written evidence of this when asked by NICE.

14. If the company is required to withhold taxes which may be imposed on NICE for any payment under this procedure by virtue of the statutes, laws, codes or governmental regulations of a country, then the company will make these payments on behalf of NICE by deducting them from the payment then due to NICE and remitting such taxes to the proper authorities on a timely basis. In such cases, NICE will adjust the charges upwards or issue another invoice so that it receives the full amount of the charge as specified in the tables above. The company will provide NICE with official documentation or tax receipts on any withholdings supporting such taxes and related payments that NICE may need for its tax records, as soon as reasonably possible after payment to the applicable tax authority, and no later than when required by applicable law.

### **Small companies**

15. The definition of a small company for the purposes of this process is in section 382(3) (qualification of a company small) of the [Companies Act 2006](#).
16. The table below shows how much NICE will charge small companies for highly specialised technologies evaluations.

| <b>Product</b>  | <b>Charge 2019/20</b>               |
|---|-------------------------------------|
| <b>Highly Specialised Technologies Evaluations (HST)</b>  | £31,500                             |
| <b>Multiple Technologies Evaluation (MTE) – Standard*</b> | Refer to above table in paragraph 7 |
| <b>Multiple Technologies Evaluation (MTE) – Complex**</b> | Refer to above table in paragraph 7 |

\*covers up to 3 technologies. \*\* covers more than 3 technologies

17. Small companies have the option to pay the charge in 3 instalments:
  - an initial 40% (forty percent) of the charge on receiving the invoice from NICE
  - a further 50% (fifty percent) of the charge before the first committee meeting at which the technology is to be discussed
  - the final 10% (ten percent) of the charge before publication of the final evaluation document (FED).

18. Companies will declare whether they are a small company as part of their response to the charging notice.
19. If the company pays an initial instalment of the charge under paragraph 16, the company must provide written evidence to validate its status as a small company when asked by NICE. If NICE does not accept the evidence provided (at its sole discretion), the company must immediately pay the remaining balance of the charge in full.
20. Companies that declare themselves as small will be asked to confirm that they have not reached the limit on the amount of state aid that companies can receive (that is, €200,000 over a 3-year period, in line with the UK Government's [guidance on state aid](#)).

### **Late payment**

21. NICE has the right to claim interest, compensation, administrative fees and reasonable costs under the [Late Payment of Commercial Debts \(Interest\) Act 1998](#) and it is agreed that the term implied by that Act will apply after any judgment as well as before. If for any reason the Late Payment of Commercial Debts (Interest) Act 1998 does not apply, interest will be payable on overdue amounts at 8% over the Bank of England base rate together with compensation at the rate of £100 per invoice on amounts unpaid by the company on their due date and the costs of claiming these amounts in the event of late payment.

### **Refunds**

22. NICE will fully or partially refund the charge of the evaluation if, in the sole opinion of NICE, it is unable to complete the evaluation after it has started (for example, if the technology does not receive a marketing authorisation or the company withdraws an application from the relevant regulatory authority). NICE will refund the amount paid less any costs incurred during the evaluation process up to that point (including fair allowance for overheads and other similar costs).

**National Institute for Health and Care Excellence**  
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