

## **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

### **Technology Appraisal and Highly Specialised Technologies Programmes**

#### **Procedure for varying the funding requirement to take account of net budget impact**

## **1 Introduction**

- 1.1 This document describes the procedure involved in varying the funding requirement, when NHS England has made an application for NICE to do so, on the grounds that a technology has exceeded the budget impact test.
- 1.2 This document should be read with NICE's [Guide to the processes of technology appraisal](#).

## **2 Policy context**

- 2.1 The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, further described as [regulations](#), expect NICE to
  - 'recommend[.] that relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients' and
  - 'specify in a technology appraisal recommendation the period within which the recommendation [...] should be complied with', which 'must be a period that begins on the date the recommendation is published by NICE and ends on the date 3 months from that date'.
- 2.2 The Regulations state that 'if NICE considers it appropriate, NICE must specify a longer period', when:
  - 'the health technology cannot be appropriately administered until:
    - training is,

- certain health service infrastructure requirements including goods, materials or other facilities are, or
- other appropriate health services resources, including staff, are, in place; or
- the health technology is not yet available in England’.

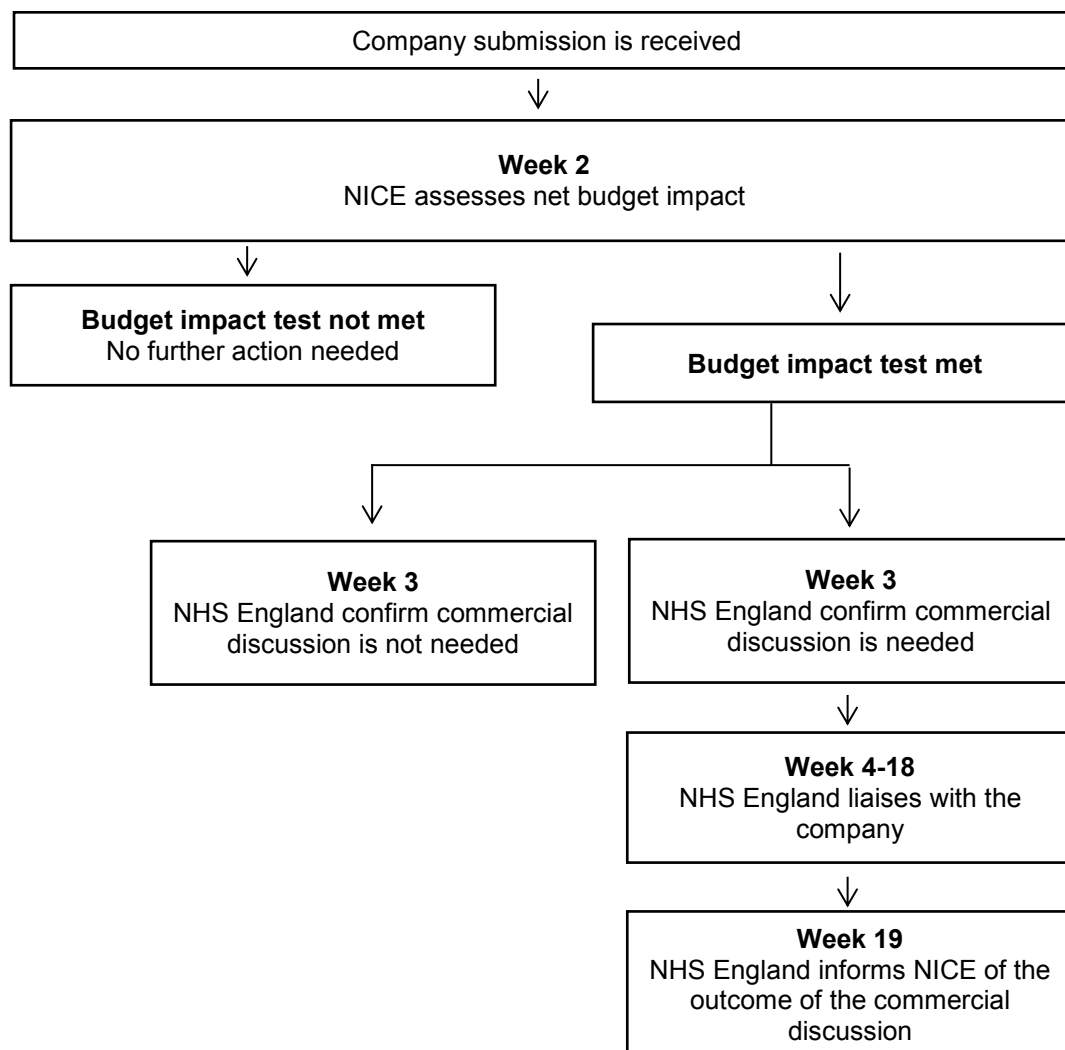
- 2.3 The regulations require NICE, when it is minded to specify a longer period, to consult with ‘such persons with an interest in the appraisal of a health technology ... ‘about the appropriate period that may be specified in a technology appraisal recommendation’, and that this consultation must include ‘the Secretary of State and the [Commissioning] Board [now referred to as NHS England]’.
- 2.4 NHS England has indicated that it may request consideration of a longer time to implement the statutory funding requirements for technologies funded through its specialised commissioning budgets, when the potential net budget impact is expected to exceed £20 million per year in any of the first 3 financial years of its use in the NHS. NHS England has indicated that it will also do this on behalf of clinical commissioning groups, for locally commissioned technologies that have been appraised by NICE.
- 2.5 NHS England will offer to engage in commercial discussions with companies whose technologies have been appraised by NICE and where the budget impact test has been engaged before requesting a variation to the funding requirement.
- 2.6 An agreement may not result in a budget impact of less than £20 million per year in each of the first 3 financial years of the product’s use in the NHS in England. In such cases, and when NHS England requests a variation to the funding requirement, NICE will take into account any relevant aspects of the agreement in responding to the variation request.

## **3 Process**

### ***Evidence submission***

- 3.1 After receiving the company submission, NICE will make an assessment of the potential budget impact of the technology by estimating the net annual cost to the NHS; using the methods described in this guide.
- 3.2 NICE will inform the company and NHS England of any topic that it has assessed which is likely to exceed the net budget impact, normally within 12 working days after receiving the company submission.
- 3.3 Within 5 working days after receiving the net budget impact estimate, NHS England must indicate to NICE whether it intends to pursue a commercial engagement with the company. This will allow NICE to plan in advance for potential changes to the timelines of a technology appraisal/highly specialised technologies evaluation.
- 3.4 The commercial engagement between the company and NHS England will be conducted in parallel with the appraisal or evaluation timescales. NHS England must provide a progress update to NICE at least 5 working days before the first appraisal or evaluation committee meeting. Any commercial agreements confirmed at this point will be to specifically manage the net budget impact of the technology, and will not be taken into account by the Appraisal or highly specialised technologies committee in determining the cost effectiveness of the technology.

**Figure 1 Steps in budget impact assessment (before the first appraisal or evaluation committee)**



### ***Application to vary the funding requirement***

3.5 NHS England can advise NICE that it may need to apply for a variation to the funding requirement directly after receiving the estimate of the net budget impact at the evidence submission stage, as described above, or at later stages in the technology appraisal or highly specialised technology evaluation, as described below.

3.6 When submitting a request for a variation, NHS England should provide:

- the duration of and the justification for the proposed variation;

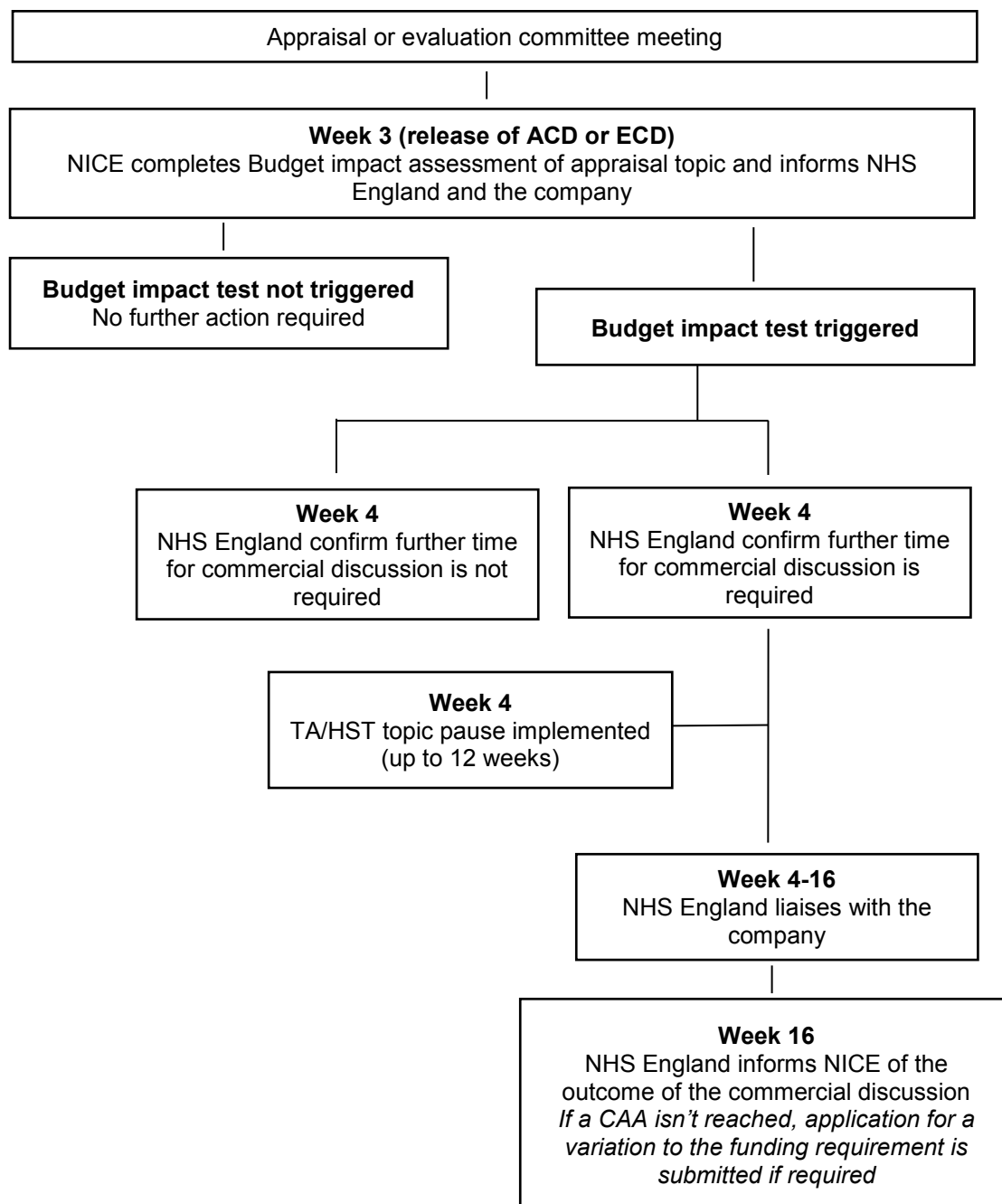
- the relevant provisions of any commercial agreement reached with the company;
- in the case of a technology funded from the national specialised commissioning budgets, the amount and phasing of funding that will be made available and how it is intended that this should be applied to patients eligible for treatment;
- in the case of technologies funded by clinical commissioning groups, what direction NHS England intends to give about the phasing of funding during the deferred funding period;
- an assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed because of the funding variation, taking into account NHS England's and NICE's responsibilities under equalities legislation;
- details of the interim commissioning policy that would be applied to phase in funding and to manage access to the technology during the extended funding variation period.

### ***First appraisal or evaluation committee meeting***

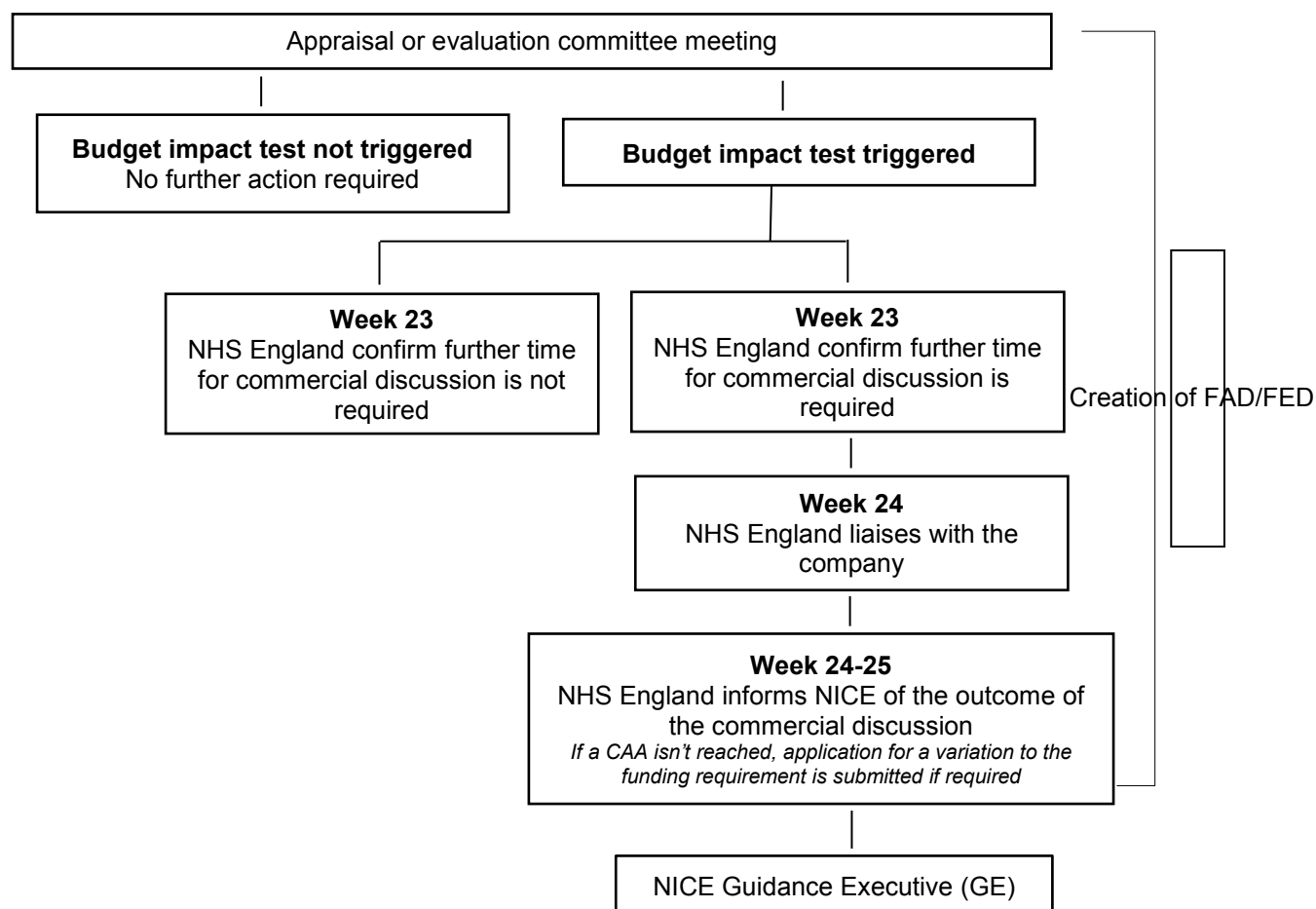
- 3.7 If the appraisal or highly specialised technologies committee recommends the technology as an option or makes a recommendation that optimises use of the technology, NICE will update its assessment of the budget impact of the technology (see the '[Assessing Resource and Impact](#)' process manual for further details).
- 3.8 NICE will inform the company and NHS England of the (new) estimate for budget impact, at the same time an appraisal consultation document (ACD), evaluation consultation document (ECD), final appraisal determination (FAD) or final evaluation determination (FED) is published.

- 3.9 If NHS England and the company intend to pursue a commercial agreement at this stage of the process, and they anticipate that it will need more time than the next phase of the NICE process provides for, NHS England must formally notify NICE within 5 working days of being informed of the potential impact of the committee's recommendations on the budget impact. NICE will suspend the appraisal/evaluation process for a maximum of 12 weeks, to allow for a second opportunity for commercial engagement and inform consultees and commentators. NICE will determine the date at which the appraisal/evaluation will re-start. The subsequent appraisal or highly specialised technologies committee meeting will be rescheduled in line with the time required for concluding the commercial engagement.
- 3.10 If NHS England intends to apply for a variation to the funding requirement at this point, it must submit an application at the earliest opportunity, and no later than the end of the period of suspension of NICE's process.
- 3.11 Where a FAD or FED is issued for appeal after the first appraisal committee meeting (straight to FAD or FED), NICE will not offer a formal pause in the process to allow the company and NHS England to re-enter into a commercial engagement period. NHS England and the company will be informed of the net budget impact in advance of release of the FAD or FED and will have an opportunity for commercial engagement in advance of the FAD or FED publication.

**Figure 2 Steps in budget impact assessment (after the first appraisal or evaluation committee) when a ACD or ECD is released**



**Figure 3 Steps in budget impact assessment (after the first appraisal or evaluation committee) when FAD or FED is released**



### ***Subsequent technology appraisal or highly specialised technologies committee meeting***

3.12 If the Appraisal or highly specialised technologies committee chooses to alter the draft recommendations, NICE will update its assessment of the budget impact of the technology, where appropriate (see the '[Assessing Resource and Impact](#)' process manual for further details). NICE will inform the company and NHS England of the updated budget impact, upon publication of the FAD or FED. No further pause will be offered for the company and NHS England to re-enter into a commercial engagement period.

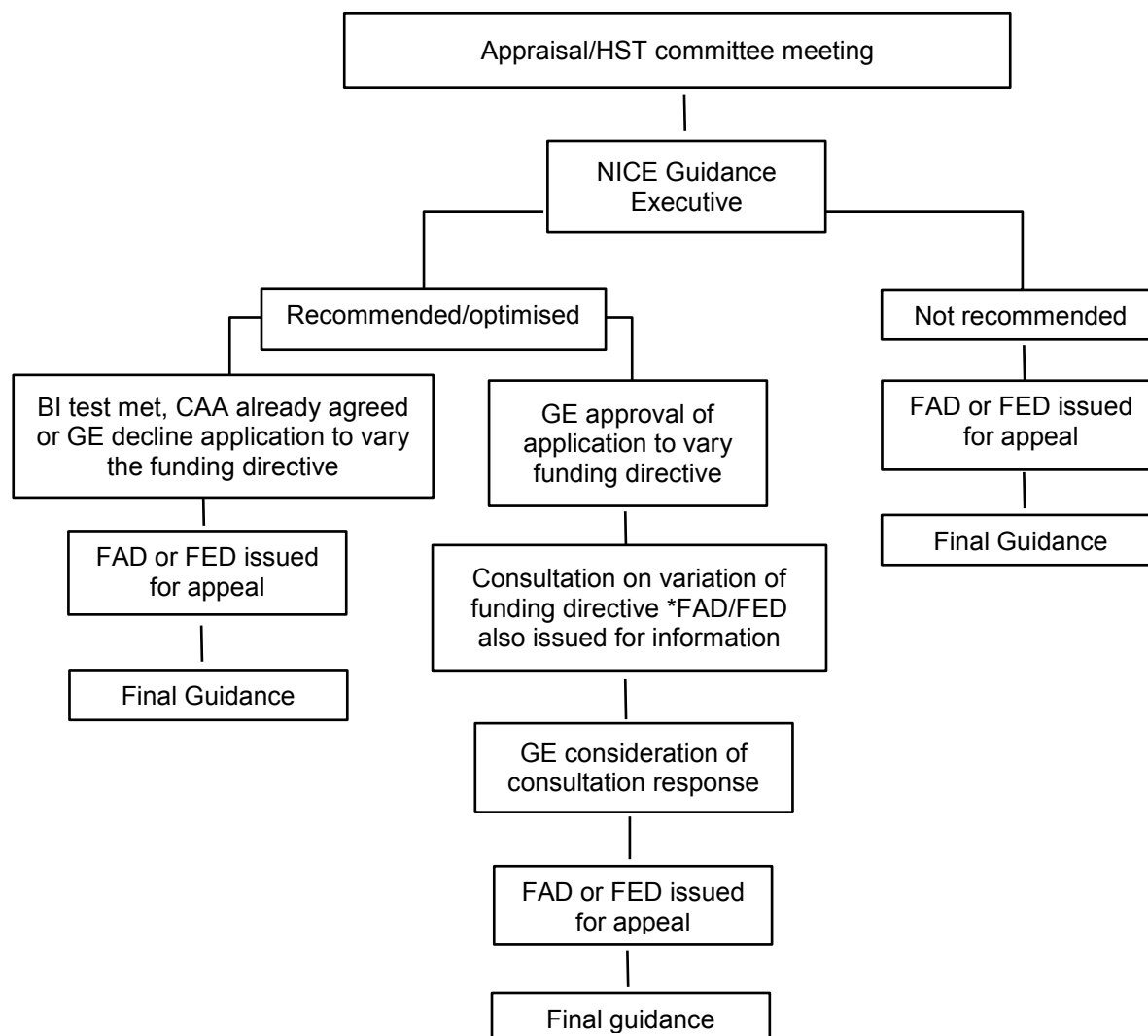
- 3.13 In the event that NHS England intends to apply for a variation to the funding requirement, it must submit an application at the earliest opportunity, and no later than the end of the period for consideration and lodging an appeal.

### ***Guidance Executive***

- 3.14 The NICE appraisal project team will present the application for a variation to the funding requirement to the NICE Guidance Executive at the earliest opportunity.
- 3.15 This can be at the stage of developing the ACD or ECD, to allow for consultation on GE's decision to take place at the same time as consultation on the recommendations, with the FAD or FED, or during the FAD or FED appeal period.
- 3.16 At each of these stages, GE will decide whether it is minded to vary the timescale for the funding requirement.
- 3.17 GE will consider a request from NHS England to vary the timescale for the funding requirement, taking into account whether:
- the budget impact test been met;
  - all reasonable opportunities for reaching a commercial agreement been pursued;
  - the request is in proportion with the magnitude of the budget impact;
  - the request takes account of the severity and acuity of the condition to which the guidance relates;
  - consideration has been given to NHS England's and NICE's duties under equalities legislation;
  - an interim commissioning policy been developed to provide phased funding for and access to the technology during the extended funding variation period.
- 3.18 Regardless of the duration of the variation requested, all applications will need to contain proposals for a phased allocation of funding.

- 3.19 For products for which the budget impact test is engaged, NICE Guidance Executive will consider applications to vary the funding requirement, normally for up to a maximum of 3 years. In exceptional circumstances, a longer period may be considered.
- 3.20 Applications to vary the funding requirement are specific to each topic. However, when considering technologies with indications for which a treatment has already been recommended and a funding variation is in place, NICE will take into account the combined budget impact for both technologies, when considering an application for a funding variation for the second (and subsequent) technologies.
- 3.21 When GE decides to vary the timescale for the funding requirement, this decision will be shared with consultees and commentators, including NHS England and the Secretary of State for Health, for a 3 week consultation period. The provisional decision will be placed on the NICE website 5 working days later; for information.
- 3.22 Comments received in consultation from consultees and commentators will be presented to the GE to reach a final decision on the timescale for the funding requirement. The decision and comments received will be published on the NICE website at the next appropriate step in the process.
- 3.23 The final guidance will make reference to the variation to the funding requirement (when appropriate).
- 3.24 In line with the regulations, consultees, including NHS England, can lodge an appeal against this decision.
- 3.25 As the decision to vary the timescale for the funding requirement is made by the GE, and not the TA or HST committee, a representative of Guidance Executive will attend the hearing on behalf of NICE.

**Figure 4 Steps in Guidance Executive assessment of application to vary the funding requirement**



## 4 Information Handling

- 4.1 Please see section 3.1.7 – 3.1.29 of the [Guide to the processes of technology appraisal](#) for more detail on information handling within an appraisal/HST evaluation.
- 4.2 If the budget impact analysis for an appraisal or evaluation includes confidential details of a simple patient access scheme for a comparator technology, NICE will not share these details with the company for the new technology being appraised or evaluated. This may limit the level of information that can be shared within the company making the new technology

being appraised. All information will be shared with NHS England, under a confidentiality agreement, through which it has access to the confidential details of all patient access schemes.

## 5 Tools and resources

- 5.1 The implementation of the budget impact assessment within the appraisal process will not affect the publication of the advice and tools to support the local implementation of NICE guidance. This includes costing tools or statements for most technology appraisals and additional tools, for selected technology appraisals.

## 6 Methods

- 6.1 This section provides an overview of the methods for the analysis that supports net budget impact calculations. It builds on the methods outlined in section 5.12 (Impact on the NHS) of NICE's [guide to the methods of technology appraisal, and 'assessing resource impact process manual: technology appraisals and highly specialised technologies'](#). This document should be read alongside both these guides.
- 6.2 The arrangements in this document do not change the consideration by the appraisal committee of the net budget impact of the adoption of a technology on NHS resources (see section 6.2.14 of the guide to the methods of technology appraisal). NICE will develop a procedural statement addressing the handling of commercial arrangements entered into by companies with NHS England to manage the budget impact in an ongoing technology appraisal or highly specialised technology evaluation, and in subsequent appraisals or evaluations where the technology is a comparator.
- 6.3 The budget impact assessment will estimate the total net budget impact of providing the technology to the NHS in England as a direct consequence of the guidance. It will therefore be specific to the licensed indication of the technology that is likely to be part of the final guidance; starting with the value proposition by the company, and taking into account, over the course of the appraisal/evaluation, the recommendations being developed by NICE.

6.4 NICE will estimate the potential net budget impact for each appraisal/evaluation in accordance with the 'assessing resource impact process manual'. Key approaches used in this manual are:

- A focus on the cost to the commissioner;
- sources for estimating future practice include previous uptake of similar technologies, and the NICE medicines and technologies programme;
- use of a national tariff (price) where possible;
- the cost of the technology appraised and comparator as used in the appraisal (incl. patient access schemes, or commercial access arrangements directed at the value of a technology);
- estimating costs and savings only as a direct consequence of implementing the guidance;
- ensuring that costs and savings relate to the same time period;
- based on accounting principles which may differ from health economic approaches

6.5 Companies are required to provide an estimate of the potential net budget impact, using the NICE evidence submission template for the technology appraisal and highly specialised technologies evaluation programmes.