

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

**Abbreviated technology appraisal (ATA): process and methods
addenda for consultation**

Process addendum

1 Introduction

- 1.1 This document provides an overview of the process of the NICE abbreviated technology appraisal (ATA) process. It builds on the general processes outlined in NICE's [guide to the processes of technology appraisal](#) (2014). This document should be read alongside the guide.
- 1.2 This document does not describe the methods used to develop guidance. Information on the methods of doing an ATA is in the accompanying methods addendum.
- 1.3 The aims of the ATA process are:
- To allow NICE to meet an expected increase in demand for technology appraisal guidance by providing a robust but less resource-intensive process for appraising technologies compared with the single technology appraisal (STA) and multiple technology appraisal (MTA) processes.
 - To appraise technologies that provide similar or greater health benefits compared with existing NICE-recommended technologies, at a similar or lower cost.
- 1.4 Technologies appraised through the ATA process are subject to the funding requirements outlined in the guide to the processes of technology appraisal (see section 1).

2 Selection of technologies

- 2.1 The topic selection process and prioritisation of technologies for the ATA process will, in general, follow the selection process outlined in NICE's guide to the processes of technology appraisal (see section 2).
- 2.2 Technologies can be appraised through the ATA process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with those that have been previously recommended in NICE guidance (normally technology appraisal guidance) for the same indication. NICE will select technologies for appraisal through ATA if the technology can be reasonably expected to meet these criteria, and if it is confident that the ATA process is an appropriate route to establish the clinical and cost effectiveness of the technology.

3 Developing the scope

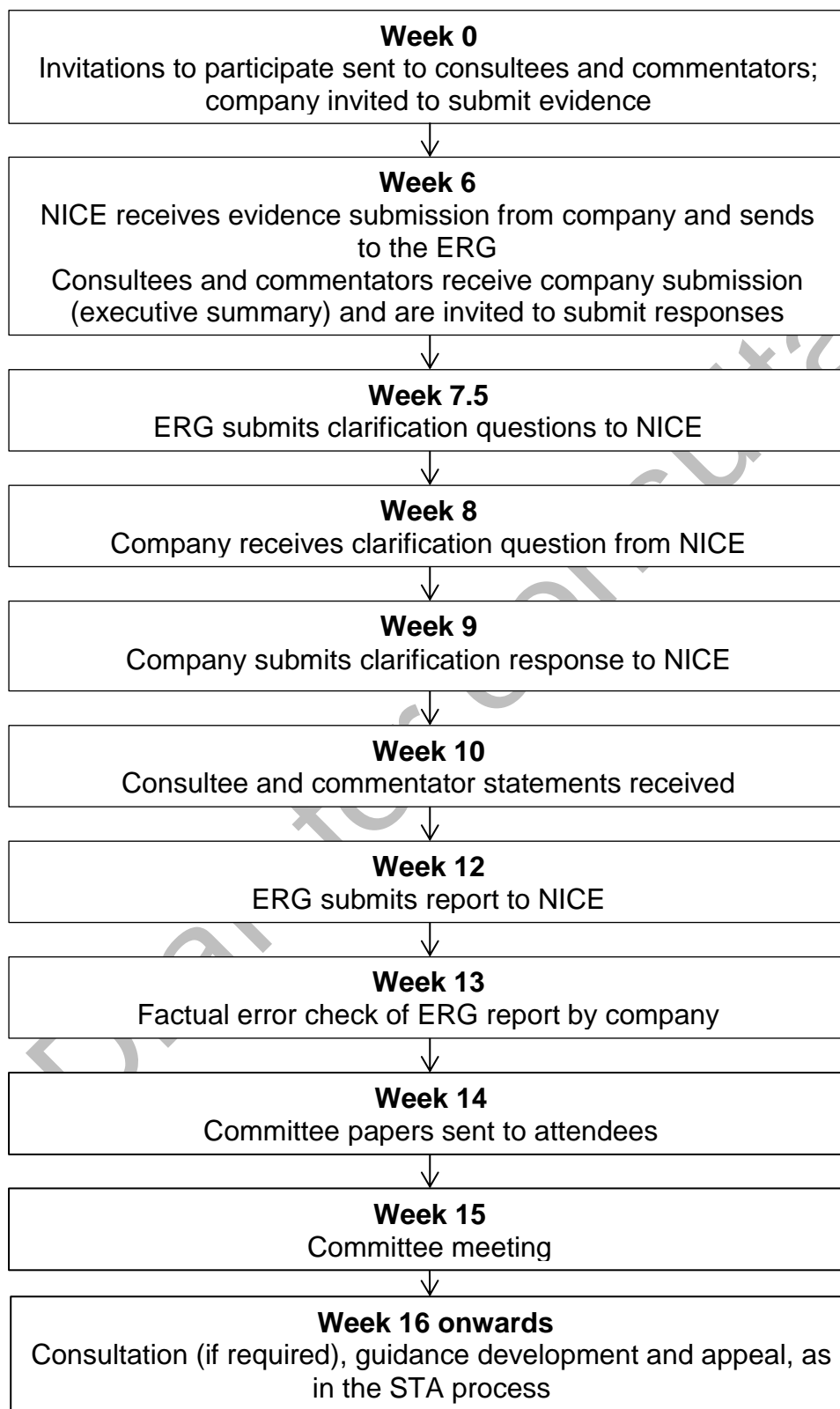
- 3.1 Technologies that are being considered for appraisal through the ATA process will, in general, follow the scoping process outlined in NICE's guide to the processes of technology appraisal (see section 2).
- 3.2 When an ATA is proposed, the company is invited to make a case as to whether it supports its technology following the ATA process. This case should take into account the clinical evidence and likely costs of the technology, including any relevant patient access schemes for the intervention and comparator(s).
- 3.3 Consultees and commentators are invited to comment during the scope consultation on whether the technology is suitable for the ATA process.

4 The appraisal process

- 4.1 The ATA process consists of 4 phases: evidence submission, evidence review, engagement with non-company consultees and commentators, and appraisal (figure 1). The evidence submission, review and appraisal phases follow the STA process as described in NICE's guide to the processes of technology appraisal (see section 3), except for the steps

detailed below. The ATA process includes the opportunity for appeal, consistent with the STA and MTA processes.

Figure 1 Overview of the ATA process



Evidence submission from the company

- 4.2 NICE invites the company to provide an evidence submission using a detailed ATA template. The deadline for receipt of the evidence submission is at least 6 weeks from invitation. After receiving this, NICE sends it to the evidence review group (ERG) for review.

Evidence review

- 4.3 The ERG prepares a report on the clinical and cost evidence in line with relevant sections of NICE's guide to the methods of technology appraisal. The deadline for receipt of the report is at least 6 weeks after the ERG receives the company submission.
- 4.4 The ERG must submit any requests for clarification within 1.5 weeks of receiving the company submission. NICE then sends the clarification requests to the company, and the company has 5 working days to respond.

Engagement with non-company consultees and commentators

- 4.5 NICE invites non-company consultees and commentators to comment on whether the technology under consideration provides similar health benefits at a similar cost to the comparator(s) specified in the scope. Companies that have comparator technologies are also invited at this stage to state whether there are any factual inaccuracies in the evidence presented on the comparator technologies (that is, their own technologies), or whether they know of any additional evidence for the comparator that has emerged since the publication of the NICE guidance on that technology. After the company's evidence submission is received, all non-company consultees and commentators will be sent the executive summary of the submission and a template in which to provide their comments. They will have at least 15 working days to provide their response to NICE.
- 4.6 Clinical experts, patient experts, non-company consultees and commentators will not normally be invited to take part in the appraisal

committee meeting discussion. In exceptional circumstances, the committee chair and NICE may agree to invite clinical or patient experts to the meeting to help address specific uncertainties.

Appraisal

Appraisal committee meeting to develop the recommendations

4.7 When the appraisal committee meets it may develop an appraisal consultation document (ACD) or a final appraisal determination (FAD). The committee will be able to make a range of recommendations:

- **Recommended as an option:** a FAD will be produced.
- **Not recommended**, or the **recommendation limits the use** of the technology more than the marketing authorisation or than published NICE recommendations for comparator technologies: an ACD will be produced, and a second appraisal committee meeting will be held.

4.8 In exceptional circumstances, the committee may identify such substantial uncertainties in the evidence that it is not able to recommend the technology without further information. If this happens, the committee will request additional information and analyses from the company and discuss these at a subsequent appraisal committee meeting.

5 Appeals

5.1 Guidance produced through the ATA process includes the option for appeal. The principles and processes for appeals will be the same as those for STAs and MTAs, as outlined in the guide to the processes of technology appraisal (see section 4).

6 Patient access schemes and flexible pricing

6.1 The principles and requirements for patient access schemes for ATAs will be the same as those for STAs and MTAs, as outlined in the guide to the processes of technology appraisal (see section 5).

7 Reviews

- 7.1 The review of guidance produced through the ATA process will, in general, follow the same principles and requirements for STAs as outlined in the guide to the processes of technology appraisal (see section 6). This includes the option for rapid review if a new patient access scheme is agreed within 16 weeks of guidance publication as outlined in the guide to the processes of technology appraisal (see section 5).
- 7.2 If guidance for a technology used as a comparator in an ATA is reviewed, the ATA guidance will be reviewed at the same time.

8 Tools and resources

- 8.1 NICE will not provide tools to support the local implementation of its ATA guidance. Therefore, resource impact tools or statements will not normally be published. This is because technologies appraised through the ATA process are not expected to cause substantial increases in resource use in the NHS.

Methods addendum

1 Introduction

- 1.1 This document provides an overview of the methods used in the National Institute for Health and Care Excellence (NICE) abbreviated technology appraisal (ATA) process. It shares and builds on the general methodological concepts outlined in NICE's guide to the methods of technology appraisal (2013) for the single technology appraisal (STA) and multiple technology appraisal (MTA) processes. This document should be read alongside the guide.
- 1.2 This document does not describe the processes used to develop guidance. Information on the process of doing an ATA is in the accompanying process addendum.

2 Clinical effectiveness and cost-comparison analysis

- 2.1 The methods for the appraisal of technologies suitable for ATA, in general, follow the existing NICE reference case (as described in NICE's guide to the methods of technology appraisal, section 5), except for the economic evaluation. The preferred form of economic evaluation is a cost-comparison analysis (see section 2.4–2.6); a cost-utility analysis is not required. Other aspects of the NICE reference case that apply solely to the cost-utility analysis (for example, modelling of quality-adjusted life years [QALYs] and discounting of health effects) are therefore not applicable to ATA and may be disregarded.
- 2.2 The guiding principles for the clinical evidence base, and the types of evidence considered relevant for the ATA programme, are outlined in NICE's guide to the methods of technology appraisal (see sections 3.2, 3.3 and 5.2). The evidence requirements of clinical effectiveness for the ATA process are the same as those defined for the STA and MTA processes, through the outcomes defined in the scope for the appraisal.

- 2.3 A systematic review of published, relevant evidence on the cost effectiveness of the technology is not needed. However, possible data sources used for parameters in the cost-comparison analysis (such as acquisition or monitoring costs) should be identified systematically to avoid selection bias in the choice of sources, taking into account any relevant considerations in recent published NICE guidance for the same indication.
- 2.4 In ATA, a cost-comparison analysis is the preferred form of economic evaluation. This is a simple analysis of the costs and resource use associated with the intervention compared with that of the comparators. The effects of the intervention and comparator on health outcomes are captured in the clinical-effectiveness evidence, and are not included in the cost-comparison analysis.
- 2.5 The cost-comparison analysis should capture the relevant cost differences between the intervention and comparator(s), over a time horizon that is long enough to reflect all important differences between the technologies being compared. As a minimum, this must include the acquisition costs of the technologies. If other relevant differences in costs or resource use are identified, these may also be included – for example, drug administration, monitoring and healthcare appointments. If there are relevant differences in health outcomes that affect resource use (for example, managing adverse events), these may be included in the cost-comparison analysis. However, it is noted that substantial differences between technologies in costs that directly relate to health outcomes (such as adverse events) are unlikely to be consistent with a conclusion that the intervention and comparator provide similar health benefits, and any such cost differences must be clearly justified. It is expected that a lifetime time horizon will not normally be necessary in the ATA process. Whenever possible and appropriate, cost data and data sources should be consistent with any corresponding data and sources that were considered appropriate in recent published NICE guidance for the same indication.

- 2.6 When a technology has a patient access scheme that has been agreed with the Department of Health or when there is a nationally available price reduction (for example, through contracts negotiated by the NHS Commercial Medicines Unit), these should be included in the base-case analysis to best reflect the prices relevant to the NHS.

Exploring uncertainty

- 2.7 Appropriate methods of exploring uncertainty will, in general, include the use of clinically relevant scenario analyses and univariate sensitivity analyses to identify parameters that may have a substantial impact on the cost-comparison results. A probabilistic analysis is not needed for the cost-comparison analysis.

Impact on the NHS

- 2.8 Technologies appraised through the ATA process are not expected to cause substantial increases in resource use in the NHS. Information on the net impact of the implementation of the health technology on the NHS (and personal and social services, when appropriate) is therefore not needed in an ATA.

3 Structured decision-making

Appraisal of the evidence

Structured decision-making: clinical effectiveness

- 3.1 The appraisal committee's judgements on clinical effectiveness in an ATA take account of the following factors:
- The nature and quality of the evidence derived from:
 - the company submission
 - the review of the company submission by the evidence review group
 - the views expressed by non-company consultees and commentators during the engagement phase including experience of the technology in clinical practice and patients' perspectives on the benefits and adverse outcomes associated with the technology.

- Evidence of whether the new technology provides similar or greater health benefits, compared with the comparator, taking into account all relevant outcomes (including both clinical-effectiveness outcomes and adverse effects), for example:
 - evidence that the clinical effectiveness of the intervention is the same or greater than the comparator
 - absence of evidence indicating that the intervention is less effective than the comparator
 - evidence of whether any apparent differences in effectiveness are clinically meaningful
 - evidence on the clinical or biological plausibility of similarities or differences in health benefits
 - whether there is sufficient certainty that the technology produces similar or significantly greater clinical benefits.
- Uncertainty generated by the evidence.
- Consideration of the evidence submitted for licensing and also that relating to effectiveness in clinical practice.
- The possible differential benefits or adverse outcomes in different groups of patients.
- The position of the technology in the overall pathway of care and the alternative treatments that are established in clinical practice.

Structured decision-making: cost-comparison analysis

3.2 In an ATA the appraisal committee will consider the cost-comparison analysis of the intervention relative to its comparators. The committee's judgements on the cost-comparison analysis are likely to be influenced by the following factors:

- The robustness and appropriateness of the approach to cost comparison. In particular, the committee considers carefully whether the analysis reflects the decision problem.
- The uncertainties around the assumptions on which the analysis is based and the results from relevant cost-comparison scenarios and univariate sensitivity analyses.

- The possible differential costs in different groups of patients.
- The committee's preferred analysis, taking into account all of the cost-comparison evidence submitted.
- The likelihood of decision error and its consequences.

Decision-making

3.3 The appraisal committee's main considerations when making its decisions are:

- Health benefits to patients: whether the technology provides similar or greater health benefits to patients, compared with technologies recommended by NICE for the same indication, measured by relevant outcomes.
- Cost to the NHS: whether the impact of the technology is likely to result in similar or reduced overall costs to the NHS compared with technologies recommended by NICE for the same indication.

3.4 The appraisal committee makes its recommendations based on the clinical and economic evidence, informed by contributions from the company, the evidence review group, patient and professional organisations, comparator companies and other consultees and commentators. The appraisal committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations. If there are any uncertainties the appraisal committee makes informed judgements and describes its uncertainties in the 'committee discussion' section of the guidance.

Table 1: Committee recommendations

Decision	Type of recommendation
Technology provides similar or greater benefits at a similar or lower cost than the comparator(s)	Recommended 'as an option'
Technology provides less health benefit at a similar or greater cost or Technology provides similar health benefits at a greater cost	Not recommended

- 3.5 Consultation takes place only if the appraisal committee does not recommend use of the technology, or the recommendation limits the use of the technology more than the marketing authorisation or more than published NICE recommendations for comparator technologies. This may happen if the technology provides similar health benefits at a similar or lower cost to the comparator only in a subgroup of the population.
- 3.6 In exceptional circumstances, the committee may identify such substantial uncertainties in the evidence that it is not able to recommend the technology without further information. If this happens, the committee will request additional information and analyses from the company.