

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Abbreviated technology appraisal (ATA): supporting document – proposal paper

#### Overview

1. The **aim** of the abbreviated technology appraisal (ATA) process is to provide a less resource-intensive process for appraising technologies that provide similar or greater health benefits compared with those already recommended in NICE guidance for the same indication, at a similar or lower cost – for example, new drugs within an established therapeutic class of treatments (such as a new TNF-alpha inhibitor or a new factor Xa-inhibiting oral anticoagulant). The process will help NICE to appraise new technologies efficiently, supporting patients and clinicians in accessing a broader range of treatment options. By adopting a practical and pragmatic approach, NICE can appraise technologies efficiently by avoiding unnecessary analysis and assessment.
2. The **ATA process** is an adaptation of the single technology appraisal (STA) process. It broadly follows the same steps as an STA, but with shortened timelines for the company submission and evidence review group (ERG) review. A summary of the differences between ATA and STA is given in appendix 2. Recommendations developed through ATA will be subject to appeal, and will carry a funding direction.
3. The **methods of ATA** are also adapted from STA, drawing on relevant aspects of the methods used in the medical technologies evaluation programme (MTEP). A summary of the differences between ATA and STA is given in appendix 2. The methods have been refined to focus on particular aspects of clinical effectiveness and to avoid unnecessary economic analyses.
4. ATA offers a number of **advantages** for NICE, ERGs, appraisal committees and companies, including: shorter evidence submissions, reduced time to critique and summarise the evidence for committee, shorter committee discussions, and shorter guidance documents. This will increase capacity in

NICE technical and project teams, appraisal committees, and ERGs, while minimising the burden on companies.

5. The **challenges** in introducing an ATA process include the need to balance a pragmatic and resource-saving process with academic rigour, selecting and scheduling topics for ATA based on incomplete information, and the small risk that the evidence collected for an ATA may be insufficient for decision-making in some cases. An additional risk is that companies may not be enthusiastic to follow this process, or that they consider that it benefits companies that develop second- or third-in-class technologies over more innovative products. The risks associated with introducing this process are summarised in appendix 1.

## Proposal for ATA

### *Selecting topics for appraisal through ATA*

6. Technologies may be eligible for appraisal through the ATA process if they meet the following criteria:
  - they are expected to provide similar or greater health benefits, compared with an established NICE-recommended treatment for the same indication
  - they are expected to have a similar or lower cost, compared with this comparator
  - they can be compared with 1 or more technologies already recommended in published NICE 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 NICE is confident that the ATA process is an appropriate route to establish the clinical and cost effectiveness of the technology.

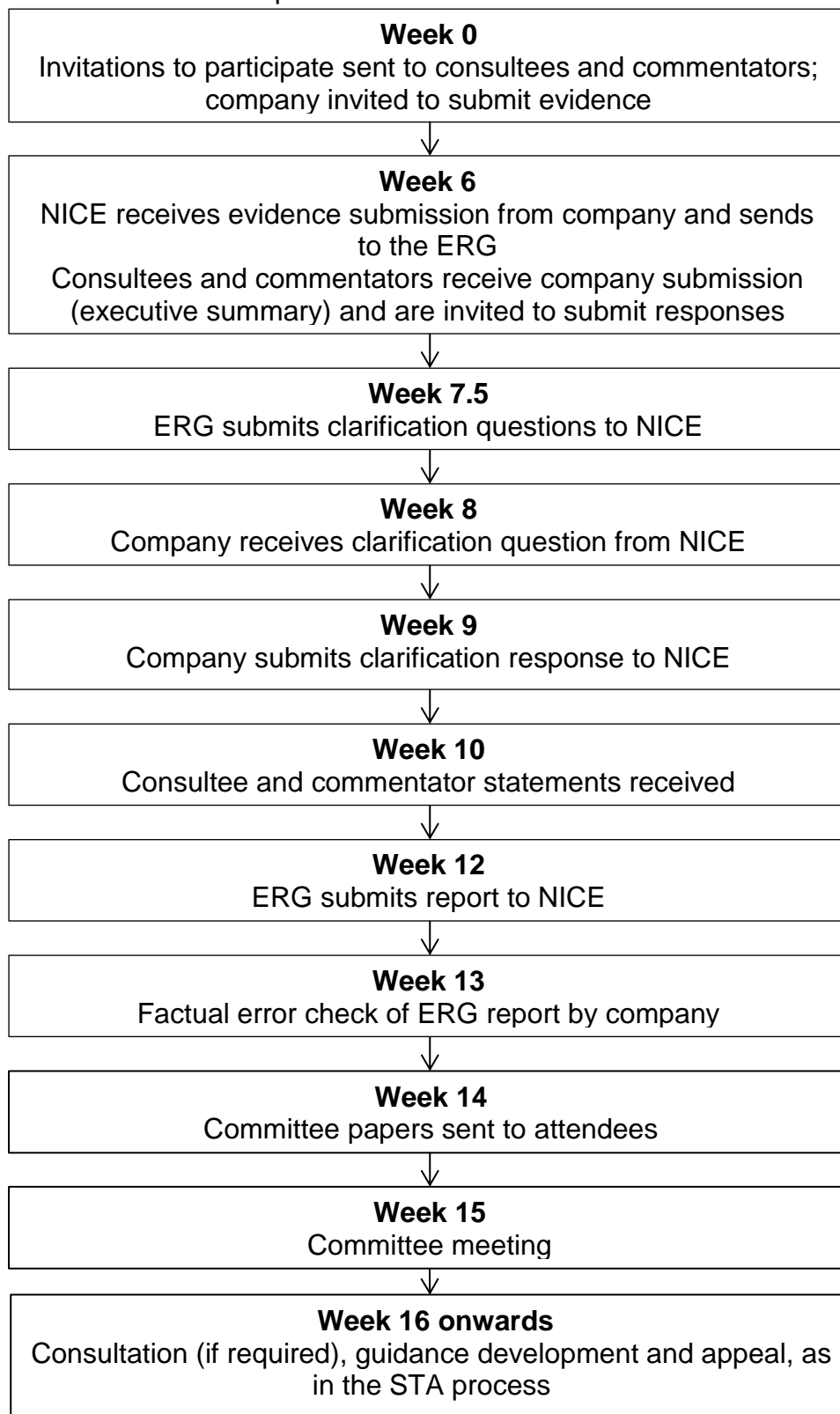
7. When possible, technologies will be identified for appraisal through the ATA process during the topic selection and scoping processes. The topic selection and scoping processes will, in general, be the same as the equivalent processes for STA – that is, topics will be identified from a variety of sources, after which NICE will develop a draft scope and seek the views of consultees and commentators through a scope consultation, before finalising the scope and seeking referral by the Department of Health. A decision on whether to

follow the ATA process will ideally be made after the scope consultation, by a group including representatives from NICE, the Department of Health, NHS England and the appraisal committees (the 'Decision Point 4' or 'DP4' meeting). This decision will take into account information from the company and key stakeholders, including any case made by the company as to whether it supports its technology following the ATA process. In addition, to maximise opportunities to follow the ATA process, the process includes the option to change to ATA at a later stage. If the company considers that its technology is suitable for the ATA process after the DP4 meeting, it can advise NICE before the start of the appraisal. NICE will consider whether the topic fulfils the ATA selection criteria and whether it is logistically possible to change process.

8. To allow maximum flexibility, it is proposed that referrals from the Department of Health will not specify which appraisal process will be used (that is, the topics will be referred for 'technology appraisal' and not specifically for ATA, STA or MTA), with the final decision on the type of appraisal resting with NICE. The wording of the remit for ATA topics will be the same as for STAs and MTAs.

*Appraisal process and methods*

Overview of the ATA process:



9. The ATA process will broadly follow the same steps as STA (including scoping, evidence submission, evidence review, appraisal, opportunity for appeal, and publication), modified for efficiency and to reflect the specific needs of ATA as follows:
- The analytical burden for companies and ERGs will be reduced compared with STA; the timelines for the company submission and the ERG critique are reduced from 8 weeks to 6 weeks each to allow for flexibility.
  - After the first appraisal committee meeting, a final appraisal determination (FAD) will be produced if the technology is recommended. An appraisal consultation document (ACD) will be produced only if the committee does not recommend the technology, or limits its use more than the marketing authorisation or than published NICE recommendations for the comparator.
  - Patient access schemes will only be considered when approved by the Department of Health by the company submission deadline, or as part of a rapid review of guidance produced through an ATA. It will not be possible to accept a patient access scheme during the ATA process.
  - NICE is not intending to provide tools to support the local implementation of ATA guidance, and no budget impact information will be requested in the submission.
  - An additional 'engagement' step is included in the ATA process, starting at the same time as the ERG review of the company submission. Consultees will be sent a redacted executive summary from the company submission and asked to provide their opinion on the clinical and resource similarities of the technology in clinical practice. Comparator companies will have the opportunity to comment on factual inaccuracies related to their own product.
10. The clinical evidence to be considered will be broadly similar to that in an STA, including a full systematic review to identify all relevant studies and, where necessary, indirect comparisons. Committees will make pragmatic decisions based on all available evidence, taking into account factors such as evidence supporting similarity, non-inferiority or equivalence in the key outcomes on which the clinical and cost-effectiveness of the comparator were based, absence of evidence for non-equivalence, how clinically meaningful any

apparent differences in specific outcomes may be, and clinical or biological plausibility (see section 3.1 of the methods guide for ATA).

11. The ATA approach to appraising the costs of investing in a technology will be through a cost-comparison analysis. This compares the costs and resource use associated with the intervention 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 estimated in an economic model (see section 3.1 of the methods guide for ATA). A key difference from the STA process is that quality-adjusted life years (QALYs) are not needed to assess the benefit of the technology. The appraisal committee will consider the results of the cost-comparison analysis in light of the clinical-effectiveness evidence, to establish whether the technology represents an appropriate use of NHS resources.
12. When recommending a technology that has been appraised through the ATA process, committees will be encouraged to recommend that, if 2 or more clinically similar treatments recommended by NICE are suitable, treatment should normally start with the lowest cost option.

## **Issues for information and discussion**

### *Benefits of ATA*

13. It is anticipated that ATA will provide advantages for NICE, ERGs, appraisal committees and companies. The key advantage of the ATA process for NICE is the opportunity to meet an expected increase in demand by offering another option for guidance development that requires fewer resources than an STA. It is expected that less time will be needed for the NICE technical team, project team and appraisal committee at each step. The estimated resource requirements per topic (compared with an STA) are summarised in table 1. The ATA process will also reduce the overall duration of appraisals, although this is not the main priority – the proposed timelines allow timely guidance to be produced while maximising efficiency and flexibility in scheduling.

**Table 1: Anticipated resource requirements per topic for ATA**

	Anticipated resources required compared with STA
NICE	
Technology appraisals technical team	75%
Technology appraisals project team	75%
Editors	50%
Implementation team	0 (no implementation tools required)
ERG	From discussions with NETSCC and ERGs: approximately 40–50%, to be confirmed
Committee	30–50%

14. It is acknowledged that the precise resource savings for companies, ERGs and NICE through the ATA process are currently uncertain. It is also difficult to predict how many topics will be eligible for ATA.

### *Risks*

15. It is anticipated that introducing the ATA process will be associated with limited risks, and that these risks can be effectively mitigated. The key risks associated with introducing an ATA process are summarised in appendix 1.
16. There remains a risk that some companies may be reluctant to follow the ATA process. In addition, some stakeholders may perceive that ATA is a less-intensive appraisal process and therefore unfairly advantages less-innovative products (such as second- or third-in-class technologies or small additions to the treatments for conditions which already have several effective options), rather than encouraging more novel treatments that target important areas of unmet need. However, it is important to note that technologies appraised through the ATA process will not gain an advantage in the timing of market access (because the guidance will be published within 6 months of the marketing authorisation, as in STA), and the decision-making process within ATA is no more or less rigorous than an STA. Consequently, although companies gain a small advantage in terms of analytical burden with an ATA, this is unlikely to outweigh the commercial advantages of being the first product to the market.

*Identifying suitable topics*

17. Identifying suitable topics will be crucial for the success of the ATA process. In particular, the key challenge will be that the information available at the topic selection and scoping stages is likely to be limited (for example, if clinical trials have not completed and pricing strategies are not yet known), and it is not practical to independently assess large amounts of information in detail before the appraisal starts.
- The ATA process is expected to need fewer resources than an STA, but if a topic were selected for the ATA process inappropriately, it may become delayed and need additional resources. This situation is not expected to happen frequently. The risks are reduced by the broad, flexible eligibility criteria defined in the process guide, and by exercising careful judgement on a case-by-case basis. In the early days of the ATA process, it may be appropriate to select topics cautiously (for example the first ATA topics could be limited to those in which there are 2 or more comparators that have been recommended in published technology appraisal guidance, or the intervention is in the same therapeutic class as its comparators). The broad eligibility criteria allow for this cautious approach, while enabling the process to be expanded to include more topics in the future if appropriate (without the need to amend the process).
  - Candidate topics will be identified by the NICE topic selection and technical teams, taking into account factors such as the characteristics of the technology, an initial review of completed and ongoing studies, existing NICE guidance and any input from the company and stakeholders during scope development and consultation. Where possible, in line with the STA and MTA processes, a decision on whether to follow the ATA process will be made at the DP4 meeting, taking into account feedback from the company and key stakeholders.
  - It will be crucial to consult with the company and stakeholders on the suitability of the ATA process for individual products. It is recommended that the company's agreement is obtained before the final decision is made, if possible (rather than enforcing the ATA process) to minimise the risk of non-submission, inappropriate submission or appeal. However, the final decision



rests with NICE. The decision will be communicated to companies, consultees and commentators (without reference to any specific commercially sensitive information).

- Topic selection for the ATA process will, as much as possible, take into account whether the technology is expected to have a similar or lower cost to at least 1 of its comparators. This may be challenging if the technology's price has not been agreed or if one or more comparators has a confidential patient access scheme. By including cost in the eligibility criteria, the risk of selecting inappropriate topics will be reduced – for example, by avoiding technologies that companies position as more effective than their comparators to justify a higher price. The company will be asked to include the expected resource impact on the NHS (if known) in its case for inclusion in the ATA process during the scope consultation. If the price of the technology is not known, and so the resource impact on the NHS cannot be estimated, NICE will seek assurance of the company's expected positioning of the technology. The decision whether to follow the ATA or STA process may then be made based on the balance of risk for NICE.
- In addition, the process is able to accommodate later requests to route topics to ATA, to maximise opportunities to benefit from this process. If a company with a product scheduled for an STA becomes aware that the technology is likely to have similar efficacy with a similar or lower cost to its comparators, it can make a request to follow the ATA process at any time before the start of the appraisal. NICE will then consider whether the technology meets the ATA criteria and whether it is possible for the appraisal to convert to the ATA process.
- The current proposal specifies that technologies will normally have at least 1 comparator that has been recommended in published technology appraisal guidance for the same indication. This minimises risks by increasing the likelihood that the treatment pathway will be well established and the key issues will have been discussed previously. It is likely, particularly in the early days of the process, that all ATA appraisals will have a comparator that is recommended in a NICE technology appraisal. However, the process is flexible enough that technologies with comparators recommended in other

guidance (NICE or other nationally recognised clinical guidelines) can be included in the future, if that guidance is sufficiently complete and robust.

- There is likely to be some uncertainty about the appropriateness of the ATA process when the comparator has an 'optimised' recommendation from NICE. It is proposed that if the company wishes to make a case only for the same recommendation as for the comparator, ATA would be suitable. Otherwise, an STA would be more appropriate. In cases when the company makes its case within the comparator recommendation, and the technology is recommended in that context, the guidance may proceed straight to FAD (without consultation). In all other cases, an optimised recommendation for the technology through the ATA process would lead to an ACD being prepared.

### *Process*

18. An additional engagement step has been included in the ATA process, at the same time as the ERG review, to ensure consultees and commentators other than the company and the ERG are provided with the opportunity to state their view on whether the technology provides similar or greater health benefits at similar or lower costs to the comparator. This step replaces consultee and commentator submissions at the time of the invitation to participate, and is focused primarily on the clinical similarity of the technology with the comparators.
- It is proposed that as part of this engagement step, companies that have comparator technologies will be invited 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. This is necessary to ensure the committee has an accurate and comprehensive picture of all views.
  - The ATA working group considered that early engagement (at the invitation to participate stage, as in the STA and MTA processes) would not be particularly helpful because the consultees and commentators may be limited in how much additional information they can provide for the committee without information about the case being made by the company. It considered that it

would be more appropriate for the engagement step to coincide with the  
ERG's review of the company submission.

19. With the agreement of the chairs of the appraisal committees, it is proposed that clinical experts, patient experts, non-company consultees and commentators will not normally be invited to take part in the appraisal committee meeting discussion. Although expert attendees could help the committee address specific uncertainties in some circumstances, this is not expected to be necessary for most topics. A substantial amount of time would be saved (for NICE, the committee and the experts) if experts were not invited routinely. It is acknowledged that there is a small risk that some uncertainties may be more difficult to address. However, this risk is minimised by actively seeking experts' views throughout the scoping and engagement processes and carefully tailoring the submission templates to capture the key information required.
20. The proposed ATA process is aligned to the STA process at the time of writing, including the nature of pre-meeting briefing documents, committee meeting preparation and guidance documents. If any changes to the STA process are agreed as part of the strategic review, these changes could be included in the ATA process and further efficiencies could be realised.

### *Methods*

21. The appraisal of clinical effectiveness aims to establish whether the technology provides similar or greater health benefits to the comparator. It is not possible or appropriate to establish a single, robust definition of clinical similarity, non-inferiority or equivalence that would apply to all topics. Rather, a list of factors that could be considered is identified in the methods addendum. This list is not exhaustive and committees will have the flexibility to take into account these factors and others depending on the specifics of the appraisal topic (see section 3.1 of the methods guide for ATA for more details). This approach strikes a balance between a complete and rigorous appraisal of the evidence and a pragmatic, practical and resource-saving process.
22. Similarly, the proposed cost-comparison analysis is a balance between efficiency and completeness. Although a full cost–utility analysis might provide

the most robust evaluation of cost effectiveness, for technologies that are clinically similar to existing treatments it is sufficient to compare costs only. This is expected to substantially reduce the analytical burden for companies, NICE, ERGs and committees. The analysis will capture only relevant differences in resource requirements and costs – as a minimum, the acquisition costs, with other costs such as drug administration, healthcare appointments and treatment of adverse events considered only if relevant. 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 new drug and the comparator provide similar health benefits. Uncertainty will be explored through univariate sensitivity analyses and scenario analyses, and probabilistic sensitivity analyses will not be done. See sections 2.4–2.7 and 3.2 of the methods guide for ATA for more details.

23. The cost-comparison analysis will include the acquisition cost of the technologies, with other costs (such as drug administration or monitoring) included only if there are relevant, meaningful differences. In this way, committees will have the flexibility to consider aspects beyond the acquisition cost if appropriate. For example, if the new technology has a higher acquisition cost but less frequent administration than the comparator, the committee can consider if any additional purchasing cost is offset by savings elsewhere. It will be important to ensure that, if relevant, costs relating to health outcomes (such as for managing adverse events) are included in the analysis.

### *Implementing ATA*

24. The processes and methods of ATA are undergoing a consultation with key stakeholders. This consultation will last 12 weeks and includes selected organisations representing industry, professional groups and patient groups, as well as NHS England and the Department of Health. After this consultation completes, the final processes and methods will be presented to the NICE Board, and the ATA process will be implemented for appropriate topics.

## Appendix 1: Risk assessment

Risk	Mitigation
Selection of the ATA process for individual topics may be based on limited information – inappropriately selected topics may be delayed and require additional resources.	<p>The proposal defines broad, flexible selection criteria. The decision to follow the ATA process will be made on a case-by-case basis, using as much information as possible and taking into account information from companies and key stakeholders (including any case made by the company and, if known, the price of the technology).</p> <p>In addition, the process is able to accommodate requests to route topics to ATA at several stages, to maximise flexibility.</p>
Companies may not be enthusiastic to follow the process in some cases.	<p>There will be a consultation with key stakeholders to maximise engagement with the process and identify any concerns. For individual topics, careful negotiation with the company during the topic selection and scoping stages will maximise the likelihood that the company understands the most appropriate appraisal process for its product.</p>
Stakeholders may perceive that ATA is a less-intensive appraisal process and therefore unfairly advantages less-innovative products.	<p>Technologies appraised through the ATA process will not gain an advantage in the timing of market access (because the guidance will be published within 6 months of the marketing authorisation, as in STA), and the decision-making process within ATA is no more or less rigorous than an STA. Consequently, the benefits of the ATA process for some technologies are unlikely to outweigh the commercial advantages of being the first product to the market.</p>
Clinical experts, patient experts, non-company consultees and commentators will not normally be invited to take part in the appraisal committee meeting discussion – some uncertainties may therefore be more difficult to address.	<p>Experts' views will be actively sought throughout the scoping and engagement processes, and the submission templates will be carefully tailored to capture the key information required.</p>

## Appendix 2: Comparison of ATA and STA

