NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Fast track appraisal

Addendum to the Guide to the processes of technology appraisal

1 Introduction

1.1 This document provides an overview of the NICE fast track appraisal (FTA) process. It builds on the processes outlined in NICE's guide to the processes of technology appraisal for the single technology appraisal (STA) and multiple technology appraisal (MTA) processes. This document should be read alongside the guide. The aims of the FTA process are to provide equally robust but less resource-intensive processes for appraising technologies than the STA and MTA processes.

1.2 Technologies appraised through the FTA process are subject to the funding requirements outlined in NICE's guide to the processes of technology appraisal. Clinical commissioning groups, NHS England and local authorities (with respect to their public health functions) must comply with the recommendations in the appraisal within the specified timeframe. NHS England and commissioners have committed to providing funding for the highly cost-effective technologies recommended in FTA guidance within 30 days of its date of publication.

2 Selection of technologies

2.1 The topic selection process and prioritisation of all technologies for health technology appraisal follows the selection process outlined in NICE's guide to the processes of technology appraisal. The decision about selecting the technology for a particular process is described in section 3 of this document.

2.2 All health technologies that are referred to NICE as technology appraisals, such as pharmaceuticals or medical devices, are candidates forthe FTA process as long as they fulfil the criteria (see section 3).

3 Selecting products for the FTA process

3.1 A technology will be appraised through the FTA process if:

- the company's base-case incremental cost-effectiveness ratio (ICER) is less than £10,000 per quality-adjusted life year (QALY) gained.
- it is likely that the most plausible ICER is less than £20,000 per QALY gained, and it is highly unlikely that it is greater than £30,000 per QALY gained.

3.2 Topics will be appraised through the FTA process, considering the criteria outlined in section 3.1, if:

- NICE is satisfied that the proposed route is appropriate
- there is sufficient information to make recommendations through a FTA and
- the uncertainties in the evidence and consequences of decision error are manageable.

3.3 Topics will not be appraised through the FTA process if NICE considers that the uncertainty is too large for an appropriate recommendation to be made. If NICE considers that the topic is unsuitable for FTA, for example, there is a very high degree of uncertainty in the cost-effectiveness estimates, then the topic will be appraised through the STA process.

3.4 Companies that wish their technology to be appraised through the FTA process are encouraged to engage with NICE during the scoping stage and up to the submission.

3.5 The scheduling of any FTA will initially follow the timing of a standard STA until NICE confirms that the technology being appraised is suitable for FTA.

3.6 The final decision about the routing of the technology is the responsibility of NICE, informed by stakeholder input during scoping. It is based on a review of the evidence by NICE supported by an external review group, and is normally taken 3 to 4 weeks after the company submission is received.

4 Developing the scope

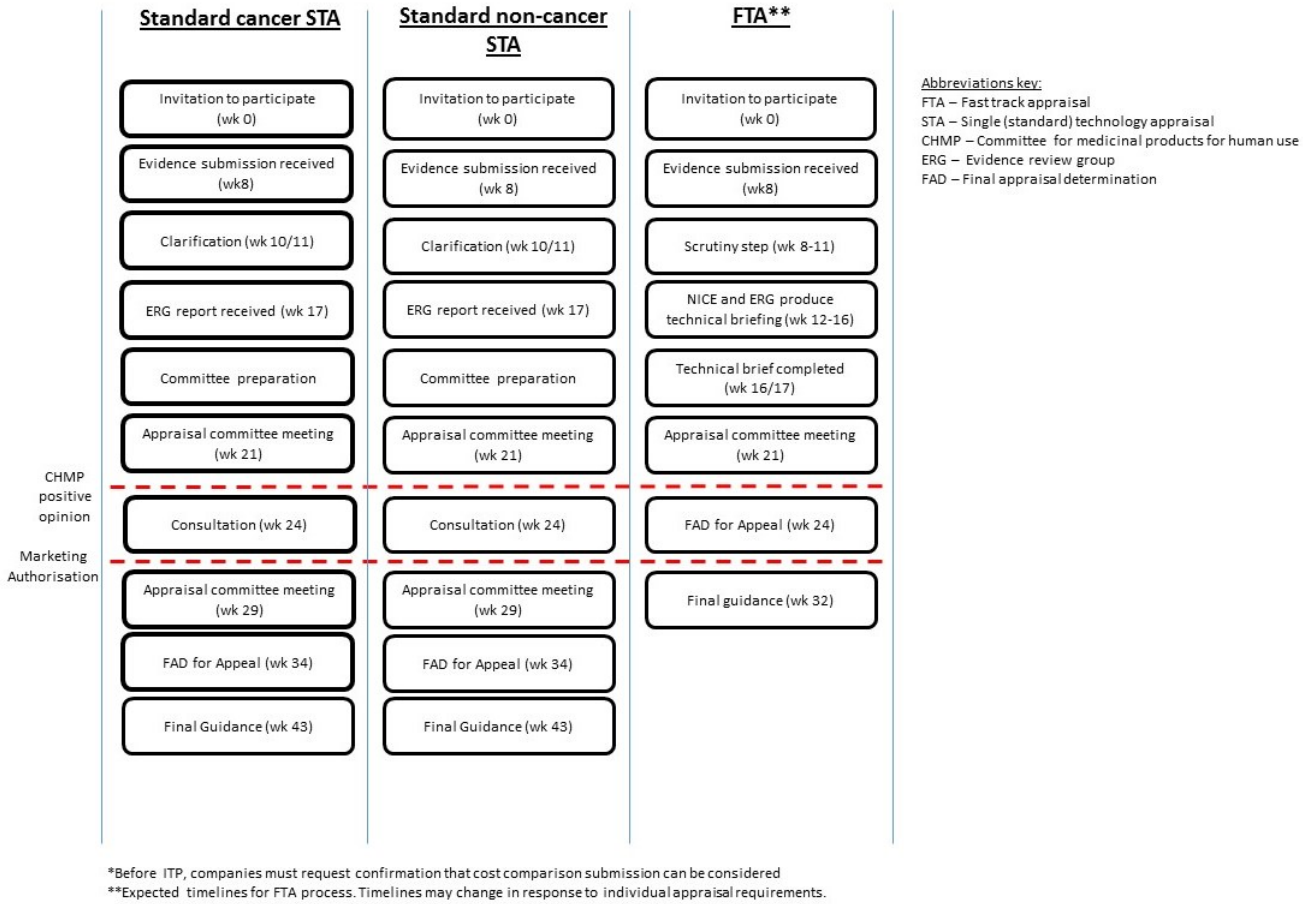
4.1 Technologies that are being considered for the FTA process will follow the scoping process outlined in NICE's guide to the processes of technology appraisal.

4.2 Consultees and commentators are invited to comment on whether the technology is suitable for the FTA process during the scope consultation.

5 The appraisal process

5.1 The FTA process follow the procedural steps of the STA process as described in section 3 of NICE's guide to the processes of technology appraisal which consists of 3 phases: evidence submission, evidence review and appraisal (see figure 1).

Figure 1 Overview of the STA and FTA processes



*Before ITP, companies must request confirmation that cost comparison submission can be considered
**Expected timelines for FTA process. Timelines may change in response to individual appraisal requirements.

Evidence submission from the company

5.2 NICE invites the company to provide an evidence submission. The company will have at least 8 weeks, from the formal invitation to participate, to prepare the evidence submission. For an FTA, the evidence must be submitted in the STA template except for a case of 'cost-comparison', where the cost-comparison template should be used.

External participation in FTA

5.3 Clinical, patient and commissioning organisations are invited to submit their views on the technology and nominate experts. Clinical, patient and commissioning experts are nominated and selected during the appraisal process and are asked to provide a personal statement as described in section 3.6 of NICE's guide to the processes of technology appraisal.

5.4 Selected experts will not be invited to take part in the appraisal committee meeting. In exceptional circumstances, the committee chair and NICE may agree to invite clinical, patient or commissioning experts to the meeting to help address specific uncertainties that cannot be resolved through written testimony.

Evidence review, confirming the process and developing the technical briefing

5.5 When a company evidence submission for the FTA process is received, supported by the evidence review group, NICE will confirm whether the selection criteria [see section 3 above] are met, and that the appraisal can proceed as a FTA.

5.6 If the selection criteria are not met, the appraisal will proceed according to the STA process. When a company has made a case for the FTA process based on 'cost-comparison', the company will asked to make a submission using the full STA template and the topic will be rescheduled into the work programme at the earliest opportunity.

5.7 If a topic is not selected for the FTA process, NICE will inform the company, and provide the rationale for this decision. If a company does not agree with the rationale provided, the company must contact NICE within 2 working days of receiving the routing decision stating reasons for its objections. The Centre Director will then review the routing decision rationale and the company's counter argument and make a final decision on the appropriate route for the appraisal

5.8 When NICE confirms that the appraisal can proceed as a FTA, NICE and the evidence review group will produce a joint, technical briefing summarising the evidence. The joint briefing will replace the evidence review group report and pre-meeting briefing in the standard STA process.

5.9 The joint briefing will include:

- the case made by the company;

- a commentary of the evidence received,
- a commentary on the testimony from experts;
- the technical judgements of the evidence made by NICE and the ERG;
- the application of NICE's structured decision making framework;
- the scope of potential recommendations.

5.10 Companies will be provided with an opportunity to consider the briefing before the appraisal committee meets.

Appraisal

Appraisal committee meeting to develop the recommendations

5.11 NICE aims to hold the appraisal committee meeting around the time when the Committee for Medicinal Products for Human Use of the European Medicines Agency meets. Occasionally therefore, it can be that the appraisal committee meeting is held before the technology gains a Marketing Authorisation.

5.12 After the meeting a final appraisal determination will be developed. The committee can come to one of the following recommendations:

- **Recommended for routine commissioning**
- **Not recommended for routine commissioning**
- **Not recommended for routine commissioning, but recommended for inclusion in the Cancer Drugs Fund or in some other form of managed access arrangement**

5.13 In exceptional circumstances, the committee may find it is unable to develop recommendations for the technology without further scrutiny, or further submission of evidence. If this is the case, guidance will still be produced, indicating that the committee is '**unable to make a recommendation**'.

5.14 When a company wishes to resubmit as a consequence of 'unable to make a recommendation' guidance, the topic will be rescheduled into the

committee work programme although it will not always be possible to prioritise the topic for immediate review.

6 Appeals

6.1 The FTA process includes the opportunity for appeal against the final draft recommendations. The principles and processes for appeals are the same as those for STAs and MTAs, as outlined in section 4 of the guide to the processes of technology appraisal.

7 Patient access schemes and flexible pricing

7.1 The principles and requirements for patient access schemes for the FTA process are broadly similar to those for STAs and MTAs, as outlined in section 5 of the guide to the processes of technology appraisal.

7.2 The exception is that a patient access scheme proposals must be included in the company evidence submission. The initiation of the patient access scheme process will not be accepted at later points in the FTA process. Modifications to access schemes presented in the company evidence submission will be considered.

8 Reviews

8.1 The review of guidance produced through the FTA processes follows the same principles and requirements for STAs and MTAs, as outlined in section 6 of the guide to the processes of technology appraisal.

9 Tools and resources

9.1 NICE will assess the potential budget impact of technologies appraised through the FTA. See budget impact addendum.