# Assessment of the NICE fast-track appraisal (FTA) process

Audrey Brown[1], Alistair Curry[2], Stephen Ralston[2], David Cork[1]
[1]SIRIUS Market Access, Newcastle upon Tyne, United Kingdom
[2]SIRIUS Market Access, London, United Kingdom. email: info@siriusmarketaccess.com

PHP279

## Introduction

NICE introduced the fast-track appraisal (FTA) process in April 2017 to provide an equally robust but less resource-intensive appraisal process compared with the standard single technology appraisal (STA) process.

The aim of FTA is to make highly cost-effective new technologies accessible to patients nearly five months quicker than through the STA process. This is achieved by making the appraisal process more rapid and by providing funding within 30 days of guidance publication compared with 90 days for the STA process.

The criteria for appraisal through the FTA process are[1]:

- The base-case incremental cost-effectiveness ratio (ICER) is less than £10,000/ QALY gained.
- It is likely that the most plausible ICER is less than £20,000/ QALY gained, and it is highly unlikely to be greater than £30,000/ QALY gained.

Or:

- A cost-comparison can be performed to show that the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies already recommended for the same indication.

## Objectives and methods

- The objective of this study is to describe the FTA process and review the outcomes and time taken to publication of FTA guidance.
- NICE technology appraisal guidance was searched from 1st April 2017 to 18th September 2018 to identify FTAs. Identified FTAs were reviewed to assess the key drivers associated with the decision-making process.

## Results

### The FTA process

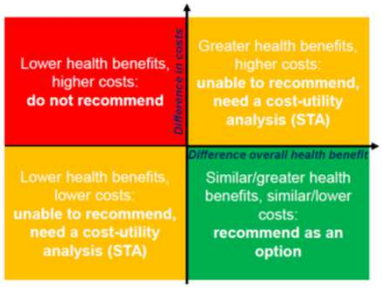
- The FTA process follows the same procedure (evidence submission, evidence review, and appraisal) as the standard STA.
- For FTA, a technical briefing is produced by NICE and the evidence review group (ERG) in place of the ERG report in the STA.
- FTA guidance publication is intended 24 weeks after evidence submission instead of 35 weeks for STAs (**Figure 1**).[1]

**Figure 1: Overview of the STA and FTA processes**

| Standard STA | FTA |
|---|---|
| Invitation to participate (wk 0) | Invitation to participate (wk 0) |
| Evidence submission received (wk 8) | Evidence submission received (wk 8) |
| Clarification (wk 10/ 11) | Scrutiny step (wk 8-11) |
| ERG report received (wk 17) | NICE and ERG produce technical briefing (wk 12-16) |
| Committee preparation | Technical brief completed (wk 16/ 17) |
| Appraisal committee meeting (wk 21) | Appraisal committee meeting (wk 21) |
| Consultation (wk 24) | FAD for appeal (wk 24) |
| Appraisal committee meeting (wk 29) | Final guidance (wk 32) |
| FAD for approval (wk 34) | NHS funding implementation (wk 36) |
| Final guidance (wk 43) | |
| NHS funding implementation (wk 55) | |

- A successful cost-comparison must show that the technology has greater or similar health benefits and similar or lower costs compared with other comparators recommended by NICE for the same indication (**Figure 2**).[2]

**Figure 2: Possible recommendations for cost-comparison analysis**




### FTA outcomes

- Final FTA guidance was identified for three technologies (**Table 1**).[3,4,5]
- In all three appraisals a cost-comparison analysis was performed.
- Clinical effectiveness was shown through analysis of phase III RCT data and indirect treatment comparison with NICE-recommended comparators.
- Key drivers of cost-effectiveness were identified from TA guidance of comparators. The key drivers were used to inform the cost-comparison analysis.

**Table 1: FTA outcomes**

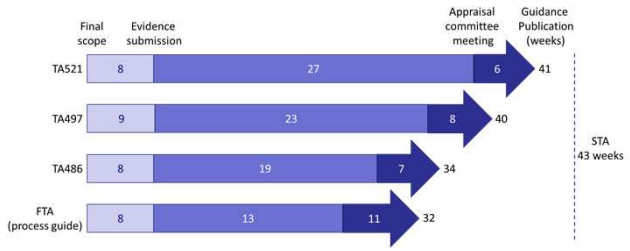
| Drug | Aflibercept (TA486) | Golimumab (TA497) | Guselkumab (TA521) |
|---|---|---|---|
| Indication | Myopic choroidal neovascularisation | Non-radiographic axial spondyloarthritis | Moderate to severe plaque psoriasis |
| Clinical effectiveness evidence | Indirect treatment comparison vs. standard of care | Phase III RCT and NMA | Phase III RCT and NMA |
| Criteria for cost-comparison met? | ✓ | ✓ | ✓ |
| Decision | Recommended with PAS | Recommended | Recommended with PAS |
| Time from evidence submission to publication | 26 weeks | 31 weeks | 33 weeks |

Abbreviations: NMA, network meta-analysis; PAS, patient access scheme; RCT, randomised controlled trial

In all three appraisals:

- Comparison of the efficacy and safety data showed that the overall health benefits of the technologies being appraised were greater than or similar to the appropriate NICE-recommended comparators.
- Cost-comparison model results were driven by drug acquisition costs alone. Administration and monitoring costs and costs associated with adverse event treatment were not included as it was assumed that these would be similar across all comparators.
- Time from evidence submission to guidance publication was slightly longer than the intended timelines. Time from evidence submission to appraisal committee meeting is the factor likely to have the biggest effect on the overall timeline. The time taken for each appraisal was 19 weeks (TA486), 23 weeks (TA497), and 27 weeks (TA521) as shown in **Figure 3**.

**Figure 3: Timeline for the FTA process**




## Conclusion

- The first three treatments to undergo NICE FTA were recommended within 33 weeks of evidence submission, slightly longer than the FTA process timetable but more rapid than would have been likely through the standard STA process.
- Up to September 2018, all drugs have been considered under cost-comparison rather than cost-effectiveness criteria.
- Technologies that offer exceptional value for money have not yet been evaluated through the FTA process therefore how these will be assessed is unknown.
- The NICE FTA process should be considered by manufacturers of technologies that offer exceptional value for money or that have similar/ lower costs and similar/ greater benefits launching in indications with NICE-recommended comparators.

**References**

1. NICE (2017) Fast track appraisal process guide addendum; 2. NICE (2017) Cost comparison addendum; 3. NICE (2017) TA486; 4. NICE (2018) TA497; 5. NICE (2018) TA521.

**Abbreviations**

FAD, final appraisal document; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year; TA, technology appraisal.