

PMG19 Addendum A - Final amendments to the NICE technology appraisal processes and methods guides to support the proposed new Cancer Drugs Fund arrangements

Technology Appraisal Processes - CDF

This document sets out the proposed changes to the [Guide to the Processes of Technology Appraisal](#) necessary to support the joint NHS England and NICE proposals for the management of the Cancer Drugs Fund from April 2016.

Only relevant sections of the Guide are shown. Therefore the sections below need to be read in conjunction with the [Guide to the Processes of Technology Appraisal](#).

New text proposed to be inserted into the guide is shown below in *italics*.

2. Selection of technologies

2.3 **Prioritisation**

2.3.3 *All new cancer drugs and significant new licensed indications for cancer drugs will be referred to NICE for appraisal.*

The Appraisal Process for Cancer Drugs

In order to be able to publish guidance on cancer drugs within 90 days of the marketing authorisation, NICE will hold the first Appraisal Committee meeting for a cancer drug before the CHMP opinion is published, ideally at or about the 180 day point in the regulatory process. Because the drug will not, at this stage, have received a regulatory opinion, this Appraisal Committee meeting will be held in private, in order to preserve the confidentiality of the data submitted by the company. Patient, clinical and commissioning experts, and company representatives will be invited to participate in the meeting under normal confidentiality arrangements.

After this Appraisal Committee meeting, an Appraisal Consultation Document (ACD) with a preliminary recommendation, or a Final Appraisal Determination (FAD) will be developed. As soon as the CHMP opinion has been published, NICE will establish whether the CHMP opinion is the same as, or similar to, the indication provided in the company submission. If it is, the ACD and the committee papers will be sent to consultees, commentators, the clinical

experts, NHS commissioning experts and patient experts for consultation (or consideration of appeal where a FAD is produced). In cases where the CHMP opinion is substantially different from the indication provided in the company submission, a further Appraisal Committee discussion may be necessary. An ACD or FAD is confidential until NICE publishes it on its website, normally 5 working days after it has been sent to consultees.

Where an ACD has been produced, the subsequent Appraisal Committee meeting will be held in public shortly after the publication of the Marketing Authorisation.

Consultation on the Appraisal Consultation Document (ACD) (if produced)

3.7.26 When a cancer drug is recommended for use within the Cancer Drugs Fund (CDF), the Appraisal Committee will state the conditions for its use in the Appraisal Consultation Document (ACD) and will identify the nature of the clinical uncertainty which should be addressed through data collection. Details of data collection, including the protocol and the analysis plan, will be set out in a 'managed access agreement'.

3.7.27 The data collection arrangements will be developed, during the consultation period, by the company, NHS England, and NICE with input from clinicians and patients, and on advice from NHS England's Chemotherapy Clinical Reference Group and NICE's Observational Data Unit (ODU). It will be completed before the final guidance is published. Funding for data collection and analysis will be provided by the company holding the marketing authorisation for the product.

5 Patient access schemes, flexible pricing and commercial access arrangements

5.2 In the context of the Cancer Drugs Fund, companies agree 'commercial access arrangements' with NHS England. Such arrangements will be considered in the NICE technology appraisal.

Definitions

5.5 A commercial access arrangement is a proposal from a company to NHS England to manage the cost of a drug to the NHS. Commercial access agreements support the inclusion of cancer drugs in the CDF and facilitate patient access to a medicine through the CDF where NICE technology appraisal, on the current evidence base, is unlikely to support a recommendation for routine use.

- 5.6 NICE can only consider patient access schemes (see figure 5) and flexible pricing proposals (see figure 6) after these have been formally approved by the Department of Health.

Commercial access arrangements

- 5.31 *When the Appraisal Committee decides to recommend a technology for use within the CDF, the company will be invited to propose a commercial access arrangement, or amend an arrangement that has already been proposed.*
- 5.32 *In order for a cancer drug to be recommended for use through the Fund, it must display plausible potential for satisfying the criteria for routine use, taking into account the application of the End of Life criteria where appropriate.*
- 5.33 *Companies should work with NICE and ask for advice about the assumptions used in the consideration of clinical and cost effectiveness by the Appraisal Committee, which must form the basis of their proposal for a commercial access arrangement.*

6 Reviews

Updating technology appraisals after inclusion in the Cancer Drugs Fund

- 6.22 *NICE will normally review its guidance for a cancer drug funded through the CDF within 24 months of publishing it. The aim of the CDF guidance review is to decide whether or not the cancer drug can be recommended for routine use. The drug (or indication) may not remain in the CDF once the guidance review has been completed*
- 6.23 *Progress with data collection will be reviewed regularly. An annual report, provided by the company or the organisation collecting the data, will be submitted to NICE to check whether the data collection is on track, and to establish whether any additional action is needed. This will be coordinated through the NICE Observational Data Unit. Guidance may be considered for review before the published review time when there is significant new evidence that either supports the original case for clinical and cost effectiveness, or when the evidence points to the likelihood that the original recommendations are not valid. The steps involved are shown in table 8, 9 and figure a.*

- 6.24 *The published guidance will be withdrawn, and the drug removed from the CDF, if the company stops data collection for reasons other than an early guidance review.*
- 6.25 *Review of guidance for cancer drugs funded by the CDF will be scheduled into the technology appraisal work programme to coincide with the end of the data collection period determined at the point of entry of the drug into the fund. This will normally not be longer than 24 months. If NICE considers it reasonable to review the published guidance earlier than at the designated data collection period, the decision to do so will be subject to consultation.*
- 6.26 *The guidance review will be undertaken through a shortened technology appraisal process, which will normally take a maximum of 6 months. The company will have 4 weeks to submit the new evidence from data collection, and the ERG will have 4 weeks to critique the new evidence (see table 8).*
- 6.27 *The CDF guidance review will take into account the data that have become available since the original appraisal, together with any change to the patient access scheme or commercial access arrangement proposed by the company. No changes to the scope of the appraisal will be considered.*
- 6.28 *Companies must provide an evidence submission to support the CDF guidance review. The managed access agreement signed at the time of the original appraisal will include this obligation.*
- 6.29 *After the first committee meeting for the guidance review, a Final Appraisal Determination (FAD) will be produced if its recommendations are consistent with the original conditions for use in the Cancer Drugs Fund. In all other circumstances, an ACD will be produced.*

Table 8 Expected timelines for the Cancer Drugs Fund guidance review - shortened technology appraisal process

		Weeks (approx.)
Step 1	<i>NICE invites organisations to participate in the guidance review as consultees or commentators</i>	0

Step 2	NICE receives evidence submission from company holding the marketing authorisation	4
Step 3	NICE requests clarification from the company on the evidence submission	5
Step 4	NICE invites selected clinical experts, NHS commissioning experts and patient experts to attend the Appraisal Committee meeting	7
Step 5	NICE sends the ERG report to the company for fact checking	8
Step 6	NICE compiles a review summary report and sends it to the Appraisal Committee	10

**Timelines may change in response to individual appraisal requirements.*

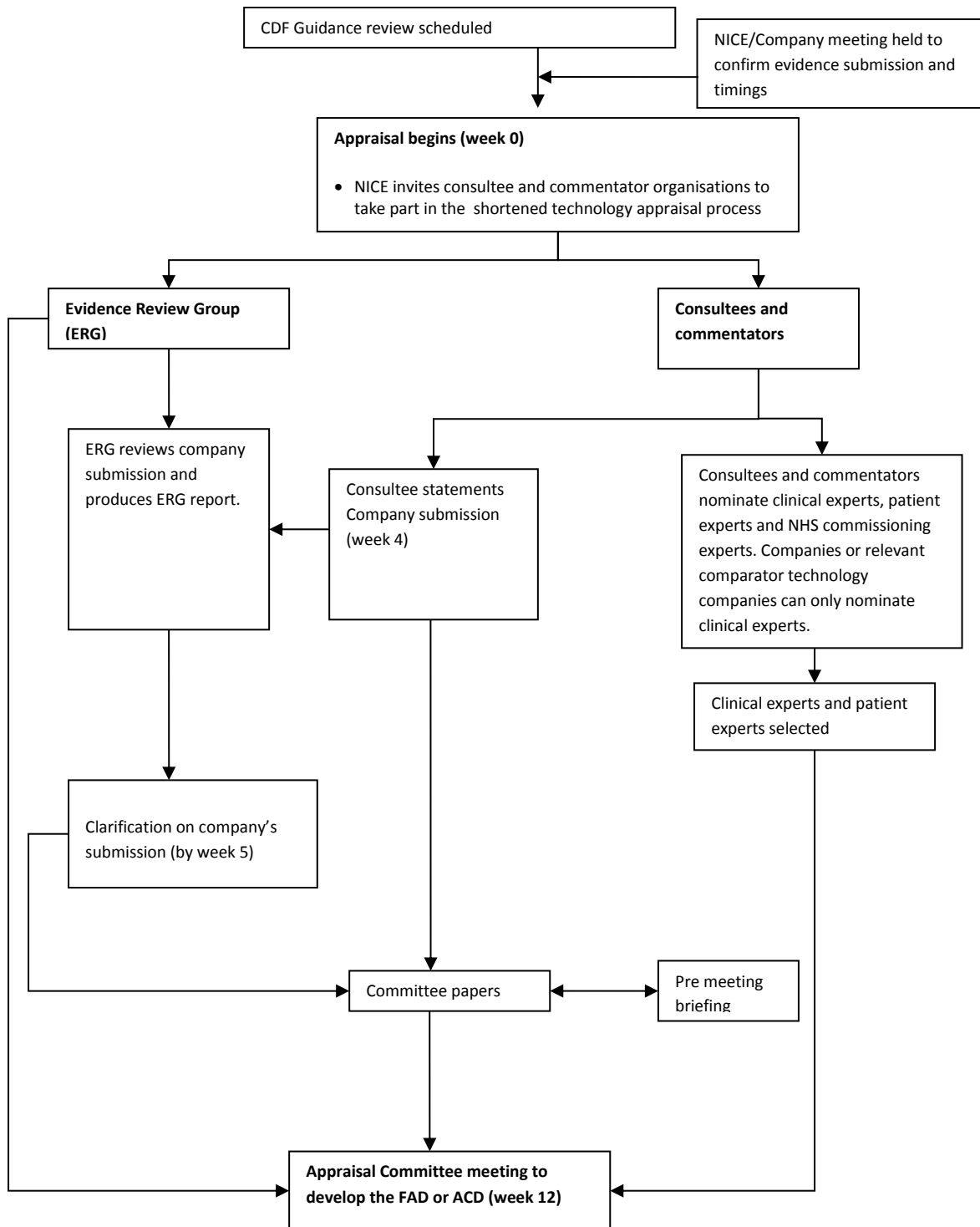
Table 9 Expected timelines for the Cancer Drugs Fund guidance review using the shortened appraisal process if an ACD is produced*

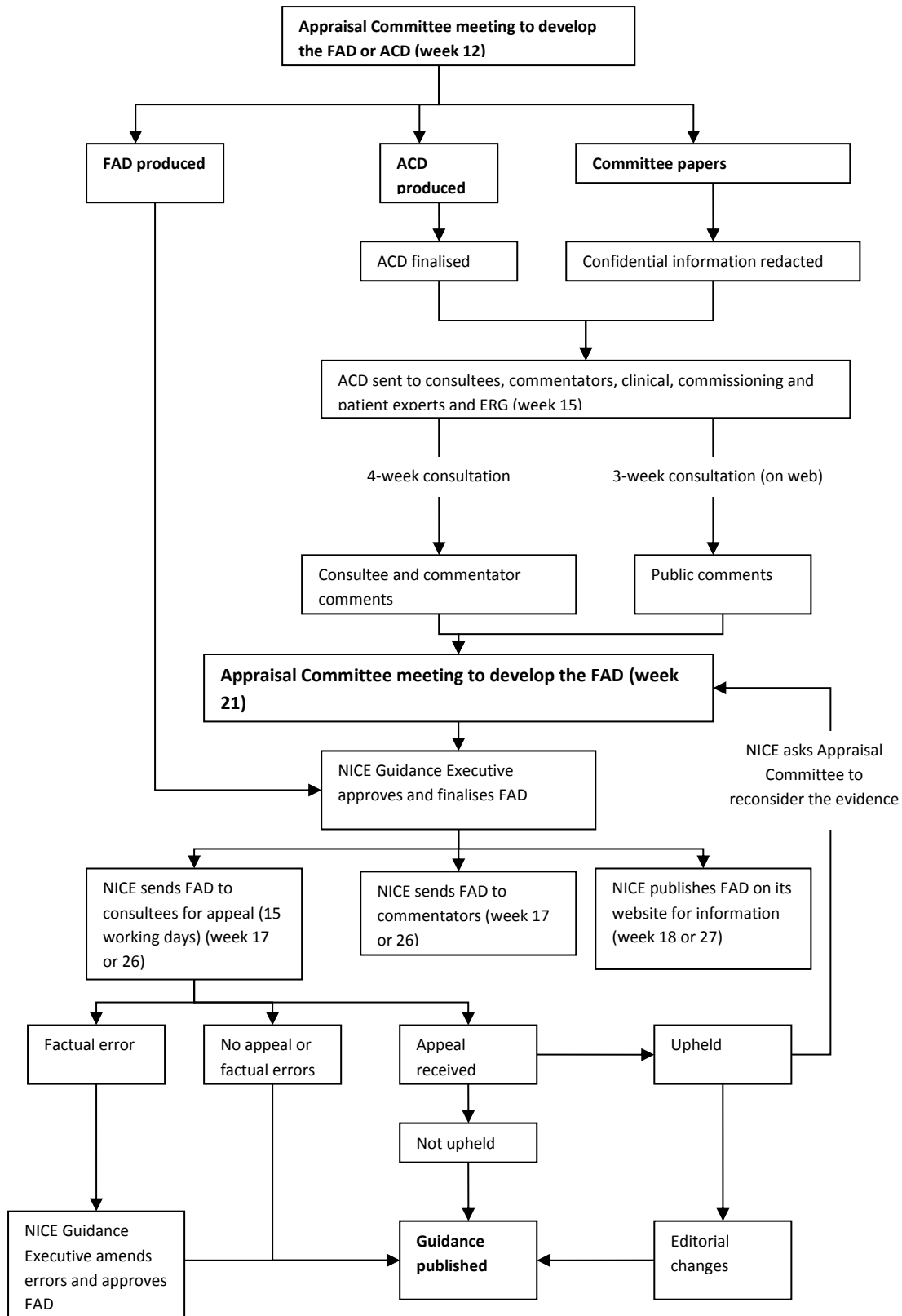
		Weeks
Step 7	Appraisal Committee meeting	12
Step 8	The ACD is produced. NICE distributes the ACD and publishes it on the website 5 working days later	15
Step 9	Fixed 4-week consultation period on the ACD	15-19
Step 10	Appraisal Committee meeting to consider comments on the ACD from consultees and commentators, and comments received through the consultation on the NICE website. Appraisal Committee agrees the content of the FAD	20/21
Step 11	The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later	26
<i>*Timelines may change in response to individual appraisal requirements.</i>		

Table 10 Expected timelines for the Cancer Drugs Fund guidance review using the shortened appraisal process if an ACD is not produced*

		Weeks
Step 7	<i>Appraisal Committee meeting to develop a FAD</i>	12
Step 8	<i>The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later</i>	17
<i>*Timelines may change in response to individual appraisal requirements.</i>		

Figure a Summary of the Cancer Drugs Fund guidance review using the shortened technology appraisal process





Technology Appraisal Methods

This document shows all proposed changes to the [Guide to the Methods of Technology Appraisal 2013](#).

Only relevant sections of the Guide are shown. Therefore the sections below need to be read in conjunction with the [Guide to the Methods of Technology Appraisal](#)

New text proposed to be inserted into the guide is shown below in *italics*.

The text ~~scored out~~ is proposed to be deleted from the current Guide.

6 The appraisal of the evidence and structured decision-making

Structured decision-making: clinical effectiveness and health-related factors

6.2.10 In the case of a 'life-extending treatment at the end of life', the Appraisal Committee will satisfy itself that all of the following criteria have been met:

- the treatment is indicated for patients with a short life expectancy, normally less than 24 months and
- there is sufficient evidence to indicate that the treatment has the prospect of offering an extension to life, **normally** of a mean value of at least an additional 3 months, compared with current NHS treatment.

~~and~~

~~the technology is licensed or otherwise indicated, for small patient populations normally not exceeding a cumulative total of 7000 for all licensed indications in England.~~

In addition, the Appraisal Committees will need to be satisfied that:

- the estimates of the extension to life are *sufficiently* robust and can be shown or reasonably inferred from either progression-free survival or overall survival (taking account of trials in which crossover has occurred and been accounted for in the effectiveness review) and
- the assumptions used in the reference case economic modelling are plausible, objective and robust.

6.2.11 When the conditions described in section 6.2.10 are met, the Appraisal Committee will consider:

- the impact of giving greater weight to QALYs achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age and
- the magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost effectiveness of the technology to fall within the normal range of maximum acceptable ICERs, with a maximum weight of 1.7.

6.2.12 Treatments recommended following the application of the 'end-of-life' criteria listed in section 6.2.10 will not necessarily be regarded or accepted as standard comparators for future appraisals of new treatments introduced for the same condition. Second and subsequent extensions to the marketing authorisations for the same product will be considered on their individual merits.

6.5 *Making recommendations for use through the Cancer Drugs Fund*

6.5.1 *When the evidence for the clinical and cost effectiveness of a drug has been assessed, including, when appropriate, the factors described in 6.2.10–17, the Appraisal Committee will decide whether the drug can be recommended for routine use.*

6.5.2 *The Appraisal Committee will determine whether the estimates of the extension to life are sufficiently robust.*

6.5.3 *If the Appraisal Committee concludes that estimates of the extension to life are not sufficiently robust, such that the uncertainty in the clinical and cost effectiveness data is too great to recommend the drug for routine use, the Committee can consider a recommendation for use within the Cancer Drugs Fund if the following criteria are met:*

- *The incremental cost-effectiveness ratios (ICERs) presented have the plausible potential for satisfying the criteria for routine use, taking into account the application of the End of Life criteria where appropriate. (see sections 5.8.10 and 6.3.2–5 of the guide to the methods of technology appraisal).*

- *It is possible that the clinical uncertainty can be addressed through collection of outcome data from patients treated in the NHS.*
- *It is possible that the data collected (including from research already underway) will be able to inform a subsequent update of the guidance. This will normally happen within 24 months.*

6.5.4 *The arrangements for data collection will be part of the managed access arrangement to be drawn up between the company, NHS England, and NICE with input from clinicians and patients, and with advice from NHS England's Chemotherapy Clinical Reference Group and NICE's Observational Data Unit (see the [guide to the processes of technology appraisal](#) section 3.7.27) before final guidance is published.*