



NICE National Institute for
Health and Care Excellence

**CONSULTATION ON PROPOSALS FOR
A NEW CANCER DRUGS FUND (CDF)
OPERATING MODEL FROM 1ST APRIL
2016**

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Contact Details for further information	Clinical and Scientific Policy and Strategy Team NHS England, Medical Directorate 5W06 Quarry House Quarry Hill LS2 7UE 0113 825 1125 england.futurecdfconsultation@nhs.net

Document Status

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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HOW CAN I MAKE MY VIEWS KNOWN?

NHS England and NICE are opening a public consultation for twelve weeks from 19th November 2015 until midnight on 11th February 2016. This is in line with Cabinet Office guidance on consultations. Comments must be received by midnight on 11th February 2016 to be considered.

You can respond to this consultation in one of the following ways:

- Complete the online consultation at www.engage.england.nhs.uk
- Download and print a copy of the consultation response form at www.engage.england.nhs.uk Send your responses to Clinical and Scientific Policy and Strategy Team, NHS England, 5W06, Quarry House, Leeds, LS2 7UE
- Alternatively, you may request a copy of the consultation response form to be posted to you. Please contact: england.futureCDFconsultation@nhs.net

This summary document can also be requested in alternative formats, such as easy read, large print and audio. Please contact: england.futureCDFconsultation@nhs.net

Any general queries relating to the consultation should be sent to: england.futureCDFconsultation@nhs.net

We would like to hear from anyone with an interest in the subject matter of the consultation. We are committed to involving patients, and potential future patients, in the planning and consideration of the future sustainability of the CDF, and we are particularly keen to hear from as many patients, carers and patient representatives as possible to inform decisions on proposals concerning the fund.

Responses will be public documents and all, or any part, of a response may be put in the public domain. If you wish to refer to any confidential information in your response, it must be included in a separate document which is very clearly marked as confidential on each page. NHS England and NICE are subject to the Freedom of Information Act. While they would seek to respect the confidentiality of any information provided to them, respondents should be aware that they may be obliged to release even confidential information under that Act. Please try not to include sensitive personal data in a response unless you feel this is absolutely essential to the point you are making.

Any comments that relate to services or issues outside of the scope of this consultation will be noted and passed on accordingly.

POST-CONSULTATION

Following this consultation, NHS England and NICE will review all relevant feedback received. Due to the likely volume of responses, feedback is likely to be presented in the form of a report capturing all material issues. The report will be published on the NHS England and NICE websites.

Due to the likely number of responses to this consultation, NHS England and NICE will not be able to provide individual replies to any submissions.

QUESTIONS

There are a total of 24 questions to answer. These are included at **Appendix C**.

There are 14 consultation questions, and a further 10 questions regarding information about you or your organisation.

Please tick one box only per question (Questions 15 – 24)

If you require more space than provided for your comments, please continue on a separate sheet, clearly referencing the question number.

INTRODUCTION AND CONTEXT

1. The Cancer Drugs Fund (CDF or Fund) was developed by the Government to improve access to treatment for patients. Since its inception in 2010, it has provided access to treatment for more than 72,000 patients whose individual circumstances suggest that they will benefit from drugs that have not been adopted for routine use in the NHS. This includes drugs which have not been recommended by the National Institute for Health and Care Excellence (NICE), those used for rare cancers not selected for NICE appraisal, or those which are being used for unlicensed indications.
2. NHS England is committed to ensuring quick and effective access for patients to newer and better drugs. The proposals in this consultation are aimed at delivering this through a new clinical assessment framework. We need to ensure that the right patients gain access to better drugs, within a process which is fully aligned with the evolving health and care system and which can rise to the challenge faced by all advanced economies in dealing in an affordable way with the increasing pace of biomedical discovery of new, targeted and often expensive drugs.
3. The CDF was originally intended to be a bridge to a new approach to the adoption of new drugs into the NHS, using 'value based pricing'. As circumstances changed and alternative methodologies were explored, this approach was not, in the end, adopted. One of the barriers to the routine commissioning of some cancer drugs is the uncertainty about their clinical benefit, and therefore their cost effectiveness, at the time they are licensed. Under the current arrangements, although the CDF provides the means for temporary funding to be made available, there is no process through which the NHS can resolve some or all of that uncertainty through a systematic approach to collecting relevant data. Resolving uncertainty is essential to enable a clear decision to be taken about whether to make a new drug available routinely or to restrict its use to individual patient requests.
4. The budget for the CDF was initially set at £200m; however, this has been increased twice, most recently to £340m for 2015/16. The budget for 2015/16 will not be affected by the arrangements proposed in this consultation. The CDF has increased access to cancer drugs; however, as the Independent Cancer Taskforce's report ("*Achieving World Class Cancer Outcomes: A Strategy for England 2015-2020*") noted, the current arrangements are not designed to reduce uncertainty about the benefits of new treatments or to make a decision about their long term use. As a result, the NHS in England is currently allocating an increasing share of the cancer budget to treatments of uncertain value, and the impact of this is being felt in other cancer services and in other parts of the NHS.
5. The CDF was considered by the Independent Cancer Taskforce, which was chaired by the chief executive of Cancer Research UK and drew on expertise from clinicians and patient groups. The Taskforce made the following recommendations on the CDF, which we propose to accept:

"Section 5.3.3.1 Access to innovative drugs

The Cancer Drugs Fund has helped more than 72,000 cancer patients in England access the drugs their doctors think they need in the absence of NICE approval. It has enabled pull through of innovative drugs into routine NHS use. However, because it has also enabled some pharmaceutical companies to bypass NICE cost-effectiveness assessments, it is widely acknowledged that it is no longer sustainable or desirable for the Cancer Drugs Fund to continue in its current form. In its place a solution is needed that ensures patients have routine access to a greater range of cancer drugs, including earlier access to innovative drugs, while ensuring that cost-effectiveness is maintained. A process is under way to find such a solution and it is anticipated that this will be agreed by summer 2015. Part of the solution will continue to be a national fund to make new cancer treatments available prior to NICE assessment or which are subject to a conditional approval.”

And:

“Recommendation 31: NHS England should work with NICE, the Government, the pharmaceutical industry and cancer charities to define a sustainable solution for access to new cancer drugs. This updated process should enable NHS England to confirm clinical utility, whilst managing within a defined budget, and should be aligned with NICE appraisal processes. The new process should be published for consultation in summer 2015, with a view to implementation from April 2016. The solution should set out reforms to NICE processes to make them more flexible for cancer drugs.”

6. The arrangements for the current CDF are due to end in March 2016. In light of this, and the increasing budgetary pressure on the CDF, the NHS England Board requested that proposals be developed for a new CDF operating model, to be introduced from April 2016 following a public consultation. The proposals set out in this consultation document are consistent with the recommendations in the Independent Cancer Taskforce report.
7. These proposals will provide access to medicines while data is collected to inform a decision on whether to adopt the drugs for routine commissioning. It provides the means for selected cancer drugs with apparent clinical promise but uncertain value to move into and out of the CDF, which will become a transitional fund to facilitate patient access with tightly focussed research and a fixed cost for the NHS, aimed at securing the best outcomes for patients.
8. It should be noted that an independent review of access to innovative treatments (the Accelerated Access Review or AAR) is currently underway. The aim of this review is to identify options for speeding up access to transformative innovative drugs, devices and diagnostics for NHS patients. The review is considering the long term landscape for innovation adoption. The proposals for the new CDF are consistent with the emerging conclusions of the AAR.

WHY ARE WE CONSULTING?

9. Arrangements for the current Fund are due to end on 31st March 2016. Consulting now allows sufficient time for responses to be analysed, and for the new CDF to be operational from 1st April 2016, with a target to complete the full transition by the end of March 2017.

AN OVERVIEW OF THE PROPOSED NEW CDF PROCESS

10. The proposal is that the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria. It would be used to enable access to those drugs which appear promising but where NICE indicates that there is insufficient evidence to support a recommendation for routine commissioning. These drugs would be given a conditional recommendation by NICE and their use enabled by the CDF for a pre-determined period whilst further evidence is collected. At the end of this period the drug would go through a short NICE appraisal, using this additional evidence. It would attract either a NICE positive recommendation, at which point it would move out of the CDF into routine commissioning, or a NICE negative recommendation, at which point it would move out of the CDF and become available only on the basis of individual patient funding requests. This approach will enable the money in the CDF to be more effectively managed, as well as providing a new pathway for innovative drugs to be assessed and made available to patients.

11. The key features of the proposed new model are as follows:

- NICE will appraise all cancer drugs that are expected to receive a Marketing Authorisation
- NICE will normally issue draft guidance prior to Marketing Authorisation
- NICE will normally publish their final guidance within 90 days of Marketing Authorisation
- NICE will make a recommendation falling into one of 3 categories:
 - Recommended for routine use
 - Not recommended for routine use
 - Recommended for use within the Cancer Drugs Fund
- At the point of Marketing Authorisation, all drugs with a draft recommendation for routine use, or a draft recommendation for conditional use within the CDF will receive interim funding from the CDF budget
- An additional option would be to provide interim funding for drugs or indications that NICE has not been able to produce an interim recommendation for at the time of Market Authorisation. This would have consequences for continuity of care and the use of funds in the CDF, should NICE issue negative draft guidance.

12. A summary of key decision making points in the proposed process is included at **Appendix A**.

13. NHS England will retain overall legal responsibility for, and governance of, the CDF, given it is responsible for the NHS budget and commissioning the use of cancer drugs. The impetus for this consultation is the need to ensure the CDF budget is used effectively and that those drugs that have demonstrated their clinical and cost

effectiveness become available through routine commissioning. NICE has the technical expertise and capacity to undertake the assessment of the benefit to be gained from these drugs, and to advise on when more data is necessary to reach a definitive view on their clinical and cost effectiveness. NHS England will therefore ask NICE to identify those drugs which are appropriate for time-limited funding under the CDF. The recommendations of the NICE Appraisal Committees for drugs they consider suitable for entry into the Cancer Drugs Fund will be received by a joint committee of NHS England and NICE (the Cancer Drugs Fund Investment Group), which will be responsible and accountable for confirming that an acceptable commercial access arrangement (the financial arrangements which determine the cost of the drug to the NHS, agreed between the company and NHS England) and data collection arrangements, which together form the managed access agreement, are in place before accepting the drugs into the Fund.

BENEFITS OF THE NEW ARRANGEMENTS

14. Patients will benefit from access to treatments for which there are insufficient data to support routine use but which nevertheless may represent a significant improvement on the treatment they are currently receiving.
15. The NHS will benefit from a careful process which will select only those drugs for which there is reason to believe that additional data collected, either through the CDF or from clinical studies already underway, will provide the basis for a clear decision as to whether a drug is clinically and cost effective and thus whether to move it into routine commissioning or not. Given the increasing overspend under the current arrangements, mechanisms are described in this consultation to contain the cost of the new CDF arrangements in line with the 2014 Pharmaceutical Price Regulation Scheme between the Government and the Association of the British Pharmaceutical Industry.
16. Pharmaceutical companies will benefit from a transparent and contestable process, managed by NICE, which will make clear the basis on which their products will be selected for use in the NHS, including the circumstances in which they may be eligible for time limited access to funding through the CDF.

THE NEW CDF PROCESS – PROPOSALS FOR CONSULTATION

Topic Selection and Appraisal Timescales

17. The Cancer Reform Strategy, published in 2007, stated that *'in future the default position for all new cancer drugs and significant new licensed indications will be that they will be referred to NICE, providing that NICE agrees that there is a sufficient patient population and an evidence base on which to carry out an appraisal and that there is not a more appropriate alternative mechanism for appraisal'*. Since then NICE has appraised virtually all new cancer drugs, excluding a small number (three to four each year), usually because of small population size.

18. From April 2016, it is proposed that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal. Extending NICE's remit across all cancer drugs will make the scheduling of drugs for appraisal quicker and more efficient. It is also proposed that all cancer drugs will receive draft guidance from NICE before marketing authorisation, and final guidance within 90 days of marketing authorisation being granted (subject to appeals).
19. Cancer drugs that go through the normal European Medicines Agency licensing process will be scheduled into the NICE work programme such that final guidance can normally be produced within 90 days of marketing authorisation. In order to achieve this, the first Appraisal Committee meeting will be held before an opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has been published. The NICE Appraisal Committee will meet in private at this stage, as no public regulatory decision will have been made. An Appraisal Consultation Document (ACD) or Final Appraisal Determination (FAD) will only be released when the CHMP has published a positive opinion. Where a second Committee meeting is needed (when an ACD has been issued), it will be held when the product has received its Marketing Authorisation.
20. For NICE to publish guidance within 90 days of marketing authorisation, companies must provide their best estimate for the date of the expected CHMP opinion to *UK PharmaScan* and to the NICE Topic Selection and scheduling teams. Companies will be invited to submit evidence for clinical and cost effectiveness of their products to NICE at the same time as they submit to the European Medicines Agency. Evidence submissions will have to include all evidence the company intends to submit to NICE, including any patient access scheme.
21. NICE will, in each case, provide the company a date by which they will be required to provide their evidence submission to NICE in order for a draft recommendation to be available at the point of marketing authorisation. If companies do not provide their evidence submission by this date, it will not normally be possible to ensure a draft recommendation is available at the point of marketing authorisation which, in turn, may impact on the provision of interim funding (see paragraphs 35 - 38) and the ability to issue a final decision within 90 days of marketing authorisation.

Appraisal of Drugs for entry into to the CDF

22. The NICE technology appraisal process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs.
23. The outcome of a NICE appraisal for a cancer drug will be a recommendation falling into one of the following three categories:
 - **Recommended for routine use** and funded from the baseline commissioning budget (a drug which thus demonstrates both clinical and cost effectiveness)

- **Not recommended for routine use** and thus there is no baseline funding (a drug which thus does not demonstrate both clinical and cost effectiveness)
- **Recommended for use within the Cancer Drugs Fund** for evaluation within a pre-determined period of time and on the basis of an estimated number of patients required to be treated in England in order to gain further evidence to address the uncertainty in the key outcomes which determine whether a drug is clinically and cost effective.

24. All access to the CDF will use the same pricing control mechanism.

25. *Recommended for routine use* would require the incremental cost effectiveness ratio to fall within the standard NICE range (£20,000 to £30,000 per QALY gained), taking into account the application of the End of Life criteria where appropriate.

26. *Recommended for use within the Cancer Drugs Fund* would require the drug to display plausible potential for satisfying the criteria for routine use, taking into account the application of the End of Life criteria where appropriate. Entry into the CDF would be subject to the company agreeing to fund the collection of a pre-determined data set, during a period normally lasting no longer than 24 months, and a commercial access arrangement which is affordable within the available CDF budget.

27. *Not recommended for routine use* would indicate that the drug is unable to satisfy either of the first two conditions.

End of Life Criteria

28. As is currently the case, it is proposed that the appraisal of certain cancer drugs will be modified by the application of the 'End of Life' criteria, which recognise the particular features of drugs designed to extend life, at the end of life. The current End of Life criteria are as follows:

- 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 offers an extension to life, **normally** 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.

Proposed changes to NICE's End of Life criteria

29. In order to allow for uncertainty in the clinical benefit of cancer drugs with incremental cost effective ratios in excess of NICE's standard range (£20,000 to £30,000 per QALY gained) to be explored in the context of recommendation for use within the Cancer Drugs

Fund, NICE proposes to make the following changes to the End of life criteria (see **Appendix B, Technology Appraisal Methods, section 6** for further details):

- Removing the restriction of the cumulative patient population from the current End of Life criteria to recognise that it has been rarely engaged; and
- Amendments to emphasise the discretion that exists for NICE Appraisal Committees to interpret the uncertainty criteria when considering a drug for inclusion in the Cancer Drugs Fund.

Determining Recommendations for use within the Cancer Drugs Fund

30. When the evidence for the clinical and cost effectiveness of a drug has been assessed, including, where appropriate, the application of the End of Life criteria, the NICE Appraisal Committee will decide whether the drug can be recommended for routine use or not.

31. If the NICE Appraisal Committee cannot recommend a drug for routine use, it will consider whether the drug is eligible for recommendation for use within the Cancer Drugs Fund. The Appraisal Committee will apply its usual technology appraisal methods and process, subject to the amendments set out in **Appendix B**. To inform this decision, the Committee will take into account the following factors:

- Whether the incremental cost effectiveness ratio considered has the potential to lie within the thresholds specified in the NICE technology appraisal methods; and
- The extent and nature of the uncertainty in the clinical effectiveness of the drug; and
- The likelihood that the timeframe for data collection (including research already underway) will be able to inform a subsequent NICE appraisal, normally within 24 months.

32. Drugs whose potential range of cost per QALY does not include £30,000, taking into account any QALY weight applied in line with the End of Life criteria where appropriate, will not be accepted into the CDF.

33. The duration for which each drug is to remain in the CDF will be determined at the point at which it enters the Fund. This will depend on the arrangements agreed for the data collection exercise and will normally be for a period up to 24 months. An interim review of the data collected will, where appropriate, be conducted, which may accelerate earlier transition of a drug through the Fund, where sufficient data has been collected before the predetermined end date. At the end of the data collection period, NICE will undertake a review of its original recommendation and will issue either a 'recommended' or 'not recommended' for routine use decision. This review will be undertaken through a short technology appraisal process which will normally take either 17 weeks, if the Appraisal Committee recommends that the drug should move into routine commissioning, in which case there will be no public consultation, or 26 weeks, if it does not and public consultation is therefore required. (See Figure a, Appendix B). The review will take into account only those data which have become available since the original appraisal,

together with any change to the commercial access arrangement proposed by the company.

34. The data collection specification, process and funding, forming the managed access agreement, will need to be clearly identified before a drug enters the fund, and the protocols and resources will need to be in place to manage it. The company will be required to agree to these arrangements before its drug can enter the CDF.

Interim Funding

35. It is proposed that all drugs that receive a draft recommendation for routine use from NICE will receive interim funding (out of the CDF budget) from the point of marketing authorisation. Normally within 90 days of marketing authorisation, final NICE guidance will then determine whether funding moves into baseline commissioning (recommended for routine use), stops altogether except for individual funding requests (not recommended), or is funded for use within the CDF.
36. Furthermore, it is proposed that all drugs that receive a draft recommendation for conditional use within the CDF from NICE will also receive interim funding from the point of marketing authorisation. Normally within 90 days of marketing authorisation, final NICE guidance will then determine whether funding moves into baseline commissioning, stops altogether except for individual funding requests (not recommended), or is funded for use within the CDF.
37. Drugs that are not recommended in draft NICE guidance will not receive interim funding.
38. A variant of this approach could be to provide interim funding for any new cancer drug or indication where the manufacturer has submitted the necessary information to NICE on a timely and comprehensive basis (including in accordance with paragraphs 20 and 21) but where NICE has not been able to make an interim decision at the point of marketing authorisation. This interim funding might continue until such time as NICE is able to issue draft guidance at which time the arrangements in paragraphs 35, 36 and 37 would apply, with draft recommendations for 'routine use' or 'conditional use' enabling the continuation of CDF funding until final appraisal, and draft 'not recommended' drugs or indications ceasing to be funded by the CDF. The disadvantage of this approach would be the potential provision of interim funding for drugs that subsequently receive a draft 'not recommended for routine use' decision from NICE. In such circumstances, these drugs might only receive interim funding for a very short period of time if the interim appraisal decision was 'not recommended for routine use'. Furthermore, widening the provision of interim funding in this way would also reduce the amount of funding available, from the fixed CDF budget, for more clinically and cost effective drugs. It would also be necessary for manufacturers to agree that they would continue to fund patients in receipt of their drug initially funded under this variant option if at the time of subsequent interim assessment it is not recommended.

Funding after Exit from the Fund

39. If and when NICE determine that a drug should not be recommended for routine commissioning, that drug will cease to receive funding from the CDF, with the company expected to pay for the drug for those patients who had previously received it. The exception to this will be for those drugs that remain in the CDF as at 31st March 2016. Should one of these drugs receive a 'not recommended' decision at first appraisal, then funding for existing patients will continue to be met from the CDF budget.

Off-Label Cancer Drugs

40. It is recognised that the potential provision of off-label drugs is an important issue for certain rare cancers, and we wish to invite views, through this consultation, on how this can be addressed.

COSTS OF OPERATING THE NEW PROCESS

Investment Control Arrangements

41. Companies will be asked to propose a commercial access arrangement when their drug is identified by the NICE Appraisal Committee as a candidate for the CDF. The cost of the drug in the commercial access arrangement may not exceed what would otherwise have been necessary for NICE to have recommended the drug for routine commissioning. Acceptance of the company's proposal will be conditional on these costs being acceptable to NHS England, in the context of the investment control arrangements set out below.

42. To ensure the financial sustainability of the CDF, investment control mechanisms will be put in place to enable it to operate within a fixed budget. These measures will ensure that companies are encouraged to develop the most competitive commercial access arrangements and that there is an incentive for companies to generate and publish the required data as quickly as possible. The measures are aimed at ensuring that the NHS can secure maximum benefit for patients from its expenditure on these drugs while more data is obtained on their effectiveness.

43. As a general principle, the allocation of funds from the CDF to an individual drug/indication will be influenced by the number of patients in the UK necessary to collect the data required by the NICE Appraisal Committee and the cost effective price of the drug implied by the NICE appraisal. These factors will be taken into account in agreeing the commercial access arrangement.

44. A range of budget control measures, which could be applied singly or in combination, depending on the circumstances, has been considered. In the light of this evaluation, the proposal is to introduce a prospective contingency provision and a cost cap for the total cost of each drug.

Prospective Contingency Provision

45. During the year, the amount paid out by the CDF to all companies will be set at a consistent level below 100% of the sums which would otherwise be due under the commercial access arrangements. The remainder will be retained until the end of the year as a contingency. At the end of the year:

- if the CDF has stayed within the budget (net of the contingency), the retained contingency will be released to companies (the sums being paid in proportion to the payments already made during the year);
- if the CDF expenditure has exceeded the net budget, the retained contingency will be retained to the extent necessary to balance the budget and any remaining amount will again be paid to manufacturers proportionately;
- if the amount by which the net budget is exceeded is more than the retained contingency, the whole contingency will be used to balance the budget as far as possible and an across the board reduction in the price paid for each CDF product will also be used to bring the total expenditure within budget.

Capping the cost of the drug aligned to prospective maximum patient numbers needed for data collection

46. The application of the CDF budget needs to be closely associated with the number of patients in England required to generate the data needed for NICE to review clinical and cost effectiveness. NICE will provide advice on the likely numbers of patients required for the data collection exercise, and the maximum cost borne by the NHS in each financial year the drug is in the CDF will be closely linked to this requirement. Access to the drug by eligible patients will not be restricted to the number of patients considered necessary for data collection, but any costs for treatment over and above this number will be paid for by the company.
47. Other ways of managing the CDF budget that were considered included a ‘queuing’ approach, in which a new drug would not be approved to enter the CDF if projected expenditure on it would result in the Fund exceeding its annual budget, and options for placing global caps on total expenditure on any one drug/indication or with any individual supplier. However, it was concluded that these alternative approaches would not be as effective as the options selected in achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget.

CDF Investment Group

48. A CDF Investment Group (a joint committee of NHS England and NICE) will be established, consisting of staff from NHS England and NICE. The Group will be responsible and accountable for ensuring that the CDF is managed within its budgetary limits. It will receive and make decisions on recommendations from the NICE Appraisal Committees for drugs to enter the Fund, determine the managed access agreement in each case and monitor the use of the CDF. To achieve this, both NICE and NHS England will establish new operational teams and mechanisms. The main day to day liaison at the operational level will be via these teams, with strategic level liaison between NHS England and NICE occurring through the CDF Investment Group.

CONSULTATION AND TRANSITION ARRANGEMENTS

49. This consultation will take place for a 12 week period, beginning on 19th November 2015. The results of this consultation will be received by both NHS England and NICE Boards. Both NHS England and NICE will agree a decision on the shape of the new operating model, having taken into account the consultation responses, and the new CDF will become operational from 1st April 2016 with a target to complete the full transition by the end of March 2017.
50. Transition arrangements are not included in the current consultation, as the nature of the arrangements required will depend on the substantive decisions to be taken about the new CDF framework following consideration of responses to this consultation.
51. Once the consultation on the new CDF arrangements has started, and without prejudging the outcome of that consultation, NHS England and NICE will have provisional discussions with companies about the implications of the new framework including existing individual commercial access arrangements or need for data collection, for those products remaining in the CDF in November 2015. The process of appraising drugs currently in the CDF in line with the new CDF criteria will be completed during the course of 2016/17.
52. All patients receiving treatment funded through the CDF on 31st March 2016 will continue to receive treatment until the point that they and their consultant agree that it is appropriate to stop.

APPENDIX A – SUMMARY OF KEY DECISION POINTS

Initial appraisal at grant of Marketing Authorisation		
Outcome	Effect for new patients	Effect for any patients already receiving the drug
Draft recommendation for routine commissioning	Drug immediately available to patients at the point of Marketing Authorisation (receiving interim funding from CDF budget)	Drug continues to be available
Draft recommendation for use within the CDF	Drug immediately available to patients at the point of Marketing Authorisation (receiving interim funding from CDF budget)	Drug continues to be available
Draft "not recommended" guidance	Drug only available if an individual funding request is made and succeeds	Patients may continue their course of treatment until they/their clinician agree it is appropriate to stop. Funding from original source.
Guidance within 90 days of grant of Marketing Authorisation		
Outcome	Effect for new patients	Effect for any patients already receiving the drug
Recommended for routine commissioning	Drug immediately available to patients, (funded from the CDF budget for 90 days before moving to baseline commissioning budget)	Drug continues to be available
Recommendation for use within the CDF	Drug immediately available to patients (funded from CDF budget)	Drug continues to be available
Not recommended	Drug only available if an individual funding request is made and succeeds	Patients may continue their NHS funded course of treatment until they/their clinician agree it is appropriate to stop. Funding to be provided by the company.

Final decision after CDF funded evaluation period		
Outcome	Effect for new patients	Effect for any patients already receiving the drug
Recommended for routine commissioning	Drug immediately available to patients (funded from the CDF budget for 90 days before moving to baseline commissioning budget)	Drug continues to be available
Not recommended	Drug only available if an individual funding request is made and succeeds	Patients may continue their NHS funded course of treatment until they/their clinician agree it is appropriate to stop. Funding to be provided by the company.

APPENDIX B - Proposed amendments to the NICE technology appraisal processes and methods guides to support the proposed new Cancer Drugs Fund arrangements

Technology Appraisal Processes

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	<i>NICE receives evidence submission from company</i>	4

holding the marketing authorisation

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

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

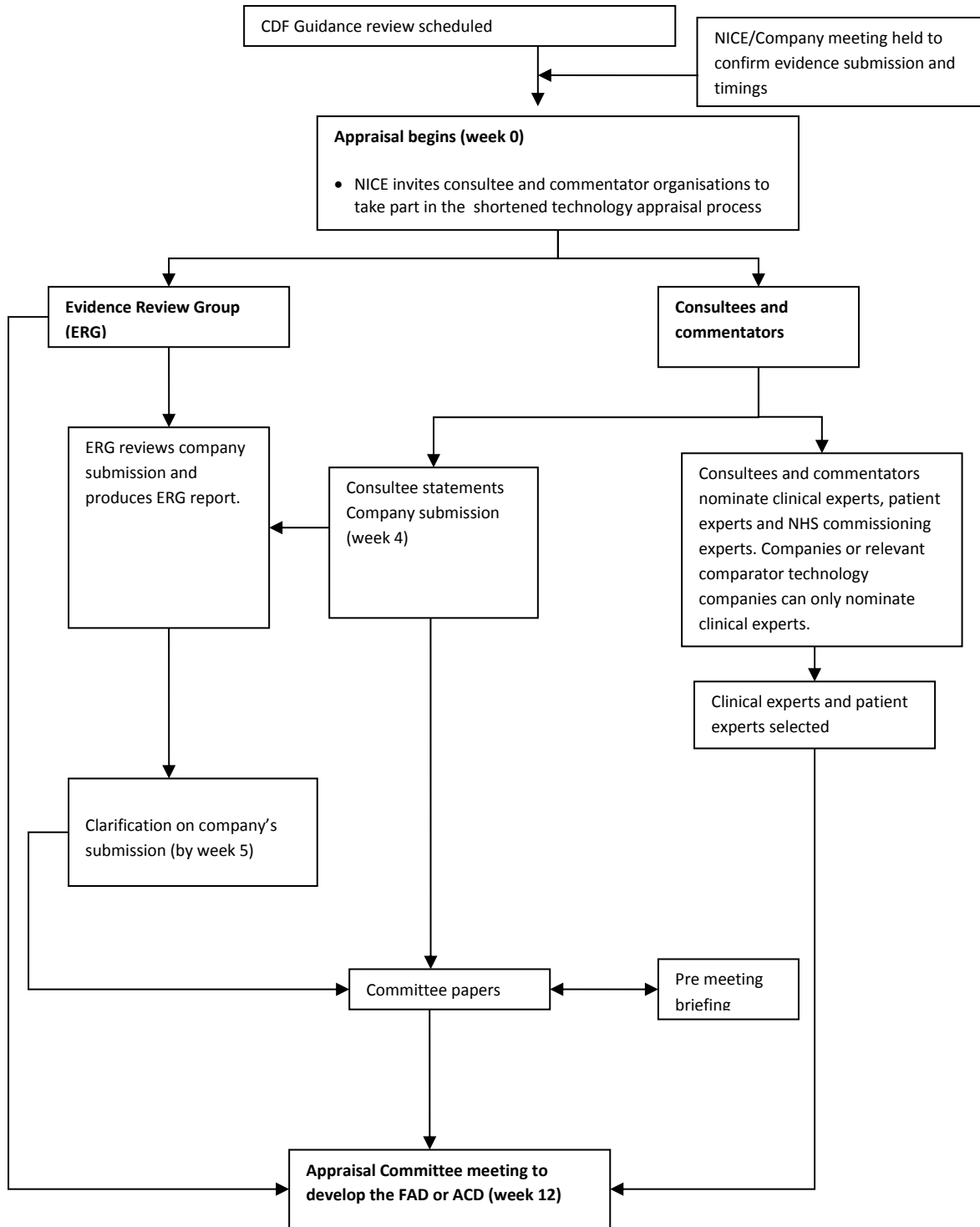
Table 9 Expected timelines for the Cancer Drugs Fund guidance review using the shortened appraisal process if an ACD is produced*

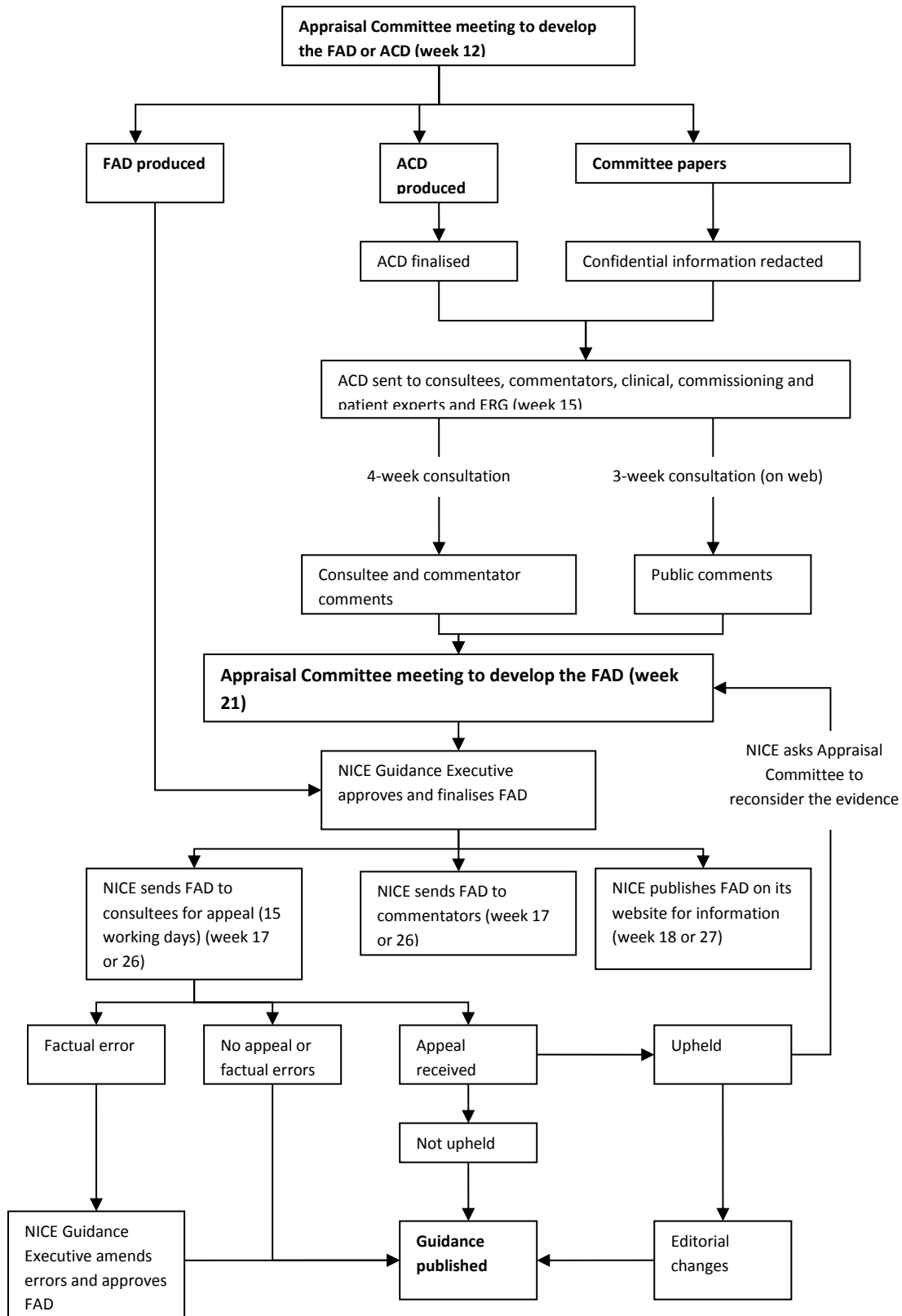
		Weeks
Step 7	<i>Appraisal Committee meeting</i>	12
Step 8	<i>The ACD is produced. NICE distributes the ACD and publishes it on the website 5 working days later</i>	15
Step 9	<i>Fixed 4-week consultation period on the ACD</i>	15-19
Step 10	<i>Appraisal Committee meeting to consider comments on the ACD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

APPENDIX C

CONSULTATION QUESTIONS:

IMPORTANT NOTE: *In line with standard requirements regarding transparency of payments by the pharmaceutical industry, all respondents should complete question 18, disclosing any payments, grants or other funding received by their recipient or their organisation from the pharmaceutical industry in the last three years, and specifying the source of funding and sums involved in each of the last three years.*

1. Do you agree with the proposal that the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria?

- Agree
 Disagree
 Unsure

Please provide comments to support your response:

2. Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

- Agree
 Disagree
 Unsure

Please provide comments to support your response:

3. Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?

- Agree

- Disagree
- Unsure

Please provide comments to support your response:

4. Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee's evaluation would be a set of recommendations falling into one of the following three categories:

- i. Recommended for routine use;
- ii. Recommended for use within the Cancer Drugs Fund;
- iii. Not recommended.

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

5. Do you agree with the proposal that “*patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation*” be removed from the criteria for the higher cost effectiveness threshold to apply?

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

6. Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

7. Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

8. Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

9. What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?

10. Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?

11. Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in this consultation document?

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

12. Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

13. Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?

14. Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?

- Agree
- Disagree
- Unsure

Please provide comments to support your response:

QUESTIONS ABOUT YOU:

15. Are you responding:

- as a patient *
- as a carer *
- as a member of the public *
- as a health or social care professional**
- on behalf of an organisation ***

* If you are responding as a patient, carer or a member of the public, please proceed directly to Question 18

** If you are responding as a health or social care professional, please go to the next question.

*** If you are responding on behalf of an organisation, please only complete Questions 17 and 18.

16. Please indicate if you are a:

- Paramedic
- Radiographer
- Other Allied Health Professional
- Doctor
- Nurse/Health Visitor
- Pharmacist
- Other Health and Social Care Professional

If you selected 'Other Health & Social Care Professional', please specify.

17. If you are responding as a health or social care professional, or on behalf of an organisation, please indicate your primary area of work or the nature of the organisation you represent:

- NHS Acute
- NHS Community
- Social Care
- Private Health
- Third Sector
- Regulatory Body
- Professional Body
- Education
- Trade Union
- Local Authority
- Independent Contractor to NHS
- Pharmaceutical Company
- Other Supplier
- Other

If you selected 'Other', please give details:

18. 'Sunshine' provision/conflict of interest disclosures: have you or your organisation received any payments, grants or other funding from the pharmaceutical industry in the last three years?

- Yes
- No

If yes, please specify the source of funding and sums involved in each of the last three years:

DEMOGRAPHIC QUESTIONS: EQUALITY MONITORING

19. How old are you?

- Under 18
- 18 – 24
- 25 – 34
- 35 – 54
- Over 55
- Prefer not to say

20. What gender do you identify yourself as?

- Male
- Female
- Neither
- Prefer not to say

21. Do you consider yourself as a person with a disability?

- Yes
- No
- Prefer not to say

22. What is your ethnic group?

- British
- Irish
- White and Black Caribbean
- White and Black African
- White and Asian
- Indian
- Pakistani
- Bangladeshi
- Caribbean
- African

- Chinese
 - Other
 - Do not wish to disclose
- If you selected 'Other', please specify

23. What is your religion or belief?

- None
 - Christian
 - Buddhist
 - Hindu
 - Jewish
 - Muslim
 - Sikh
 - Other
 - Prefer not to say
- If you selected 'Other', please specify

24. Which of the following best describes your sexual orientation?

Only answer this question if you are aged 16 years or over.

- Heterosexual / Straight
- Lesbian / Gay Woman
- Gay Man
- Bisexual
- Prefer not to say