

**Appraisal and Funding of Cancer Drugs
from July 2016 (including the new
Cancer Drugs Fund)**

**A new deal for patients, taxpayers and
industry**



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Directorate		
Medical	Operations and Information	Specialised Commissioning
Nursing	Trans. & Corp. Ops.	Commissioning Strategy
Finance		
Publications Gateway Reference:		05261
Document Purpose	Other (see Description)	
Document Name	Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund) - A new deal for patients, taxpayers and industry	
Author	NHS England Cancer Drugs Fund Team	
Publication Date	08 July 2016	
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, CSU Managing Directors, Foundation Trust CEs, Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, All NHS England Employees, Directors of Finance, Communications Leads, NHS Trust CEs, Patients; Patient Groups; Charities; Industry	
Additional Circulation List		
Description	This document provides guidance for the NHS and other interested stakeholders on how cancer drugs will be appraised and funded from 29 July 2016, including the operation of the Cancer Drugs Fund (CDF).	
Cross Reference		
Superseded Docs (if applicable)	NHS England Standard Operating Procedures: The Cancer Drugs Fund 2014-15	
Action Required	N/A	
Timing / Deadlines (if applicable)	Implementation from 29 July 2016	
Contact Details for further information	NHS England Cancer Drugs Fund Team Skipton House 80 London Road London SE1 6LH england.cdfteam@nhs.net	
Document Status		
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Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund)

A new deal for patients, taxpayers and industry

Version number: 1.0

First published: 8th July 2016

Prepared by: NHS England Cancer Drugs Fund Team

This document provides guidance for the NHS and other interested stakeholders on how cancer drugs will be appraised and funded from 29th July 2016, including the operation of the Cancer Drugs Fund (CDF).

This document replaces the previous guidance *NHS England Standard Operating Procedures: The Cancer Drugs Fund 2014-15*.

Although operational management of the new CDF and financial responsibility for the fixed CDF budget rests with NHS England, the new approach described within this document will require close partnership working with the National Institute for Health and Care Excellence (NICE) as well as other Department of Health Arms-Length Bodies, including Public Health England (PHE). Although the approach to funding for and access to cancer drugs set out in this document only applies to patients eligible for NHS services in England, the broader approach to appraising licensed cancer drugs is relevant to the UK Devolved Administrations. Operational management of the CDF is the responsibility of NHS England.

This guidance will be kept under review and updated as appropriate.

Contents

Introduction..... 5

Executive Summary..... 6

Chapter 1: NICE Appraisal of Cancer Drugs 11

Chapter 2: Interim Funding for Licensed Cancer Drug Indications 14

Chapter 3: The Cancer Drugs Fund 16

Chapter 4: Financial Control..... 24

Chapter 5: Off-label Cancer Drug Indication Management..... 29

Chapter 6: Transition 31

Chapter 7: Administration 33

Contact Details 35

Appendix One - Interim Funding Agreement 36

Appendix Two – Managed Access Agreement.....41

Appendix Three – Data Sharing Specification.....42

Introduction

1. The Cancer Drugs Fund (CDF) was established by the Government in April 2011 as a temporary solution to support clinicians and their patients gain access to cancer drugs not routinely available on the NHS. The Fund was originally due to end in 2014, having acted as a bridge to a new system of Value Based Pricing. However, proposals for Value Based Pricing were not pursued and the CDF was extended further to the end of March 2016.
2. The fund has benefitted over 95,000 patients since its inception, but the lack of clear criteria for how and when drugs should exit the fund has placed it under unsustainable financial pressure. The annual budget for the CDF was increased from £200m in 2011/12 to £340m in 2015/16. Despite this, the CDF has exceeded its allocated budget each year since 2013/14. Furthermore, even though two reprioritisation exercises were undertaken the final outturn position for 2015/16 was £466m - an overspend of £126m (37%).
3. Both the independent Cancer Taskforce and the National Audit Office agree that the CDF is not sustainable in its current form. On the basis of their reports, the Public Accounts Committee recommended the need for urgent change.
4. NHS England and NICE launched a full public consultation on proposals for reforming the CDF at the end of 2015. Subsequently, on 26th February 2016 the NHS England Board approved plans to establish the CDF as a new managed access scheme with clear entry and exit criteria.
5. This document sets out in detail the new framework for appraising, evaluating and funding all cancer drugs, including the operation of the new Cancer Drugs Fund. It is the product of partnership working between NHS England, the National Institute for Health and Care Excellence, Public Health England, and the Department of Health and has been informed by further engagement with patient groups and industry.
6. The new framework and operating model will 'go live' from 29th July 2016.

Executive Summary

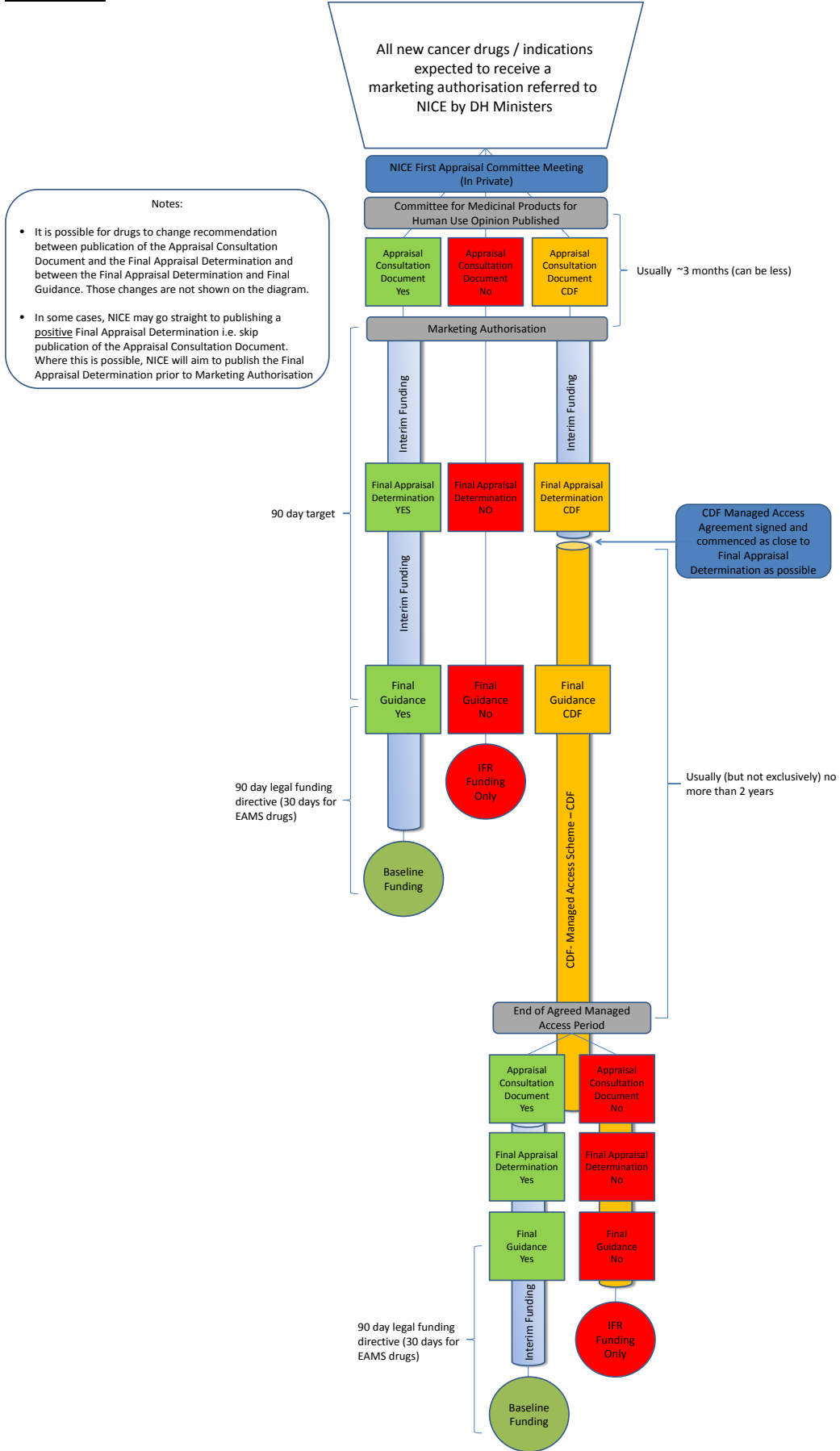
7. The changes being introduced to the way in which cancer drugs are appraised and funded, as described in this document, are designed to achieve three key objectives:
 - Firstly, to provide patients with faster access to the most promising new cancer treatments
 - Secondly, to drive stronger value for money for taxpayers in drugs expenditure
 - Thirdly, to offer those pharmaceutical companies that are willing to price their products responsibly, a new fast-track route to NHS funding for the best and most promising drugs via an accelerated NICE appraisal process and a new CDF managed access scheme.
8. A summary of the key features of the new approach is set out below, with **Figure 1** providing an overview of the new process for licensed cancer drugs.

Start of the Process - NICE Appraisal (Chapter 1)

9. **Chapter 1 describes the start of the process and the new role that NICE will play in appraising cancer drugs and the adapted processes it will follow.**
10. From now on, all new systemic anti-cancer therapy drug indications expected to receive a marketing authorisation will be appraised by NICE following Ministerial referral.
11. A modified appraisal process for cancer drugs was introduced on 1st April 2016 and now allows NICE to make one of three recommendations:
 - Recommended for routine commissioning- 'yes'
 - Not recommended for routine commissioning- 'no'
 - Recommended for use within the CDF (new)
12. The new recommendation available to NICE - '*recommended for use within the CDF*' – can be used when NICE considers there to be plausible potential for a drug to satisfy the criteria for routine commissioning, but where there is significant remaining clinical uncertainty.
13. The NICE appraisal process will also start much earlier with the aim of publishing draft guidance prior to a drug receiving its marketing authorisation and then final guidance within 90 days of marketing authorisation wherever possible.

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Figure 1



Early Access - Provision of Interim Funding (Chapter 2)

14. **Chapter 2 sets out how the new framework will provide earlier access to new drugs for patients through the provision of interim funding arrangements.**
15. In order to ensure patients can benefit from new cancer drugs as quickly as possible, pharmaceutical companies will now have the option of accessing interim funding from the point of marketing authorisation for those drugs that have received either a draft recommendation for routine commissioning - 'yes' - or a draft recommendation for use within the CDF. Any pharmaceutical company wishing to take advantage of the new interim funding arrangements will have to agree to the expenditure control mechanism described in Chapter 4. If a pharmaceutical company does not wish to accept interim funding, the drug in question cannot be made routinely available to patients at that point in time. If a pharmaceutical company does wish to accept interim funding, the drug in question will be made immediately available to patients.
16. For those drugs/indications that receive a positive draft recommendation for routine commissioning, interim reimbursement will be set at 100% of the price that generated that recommendation. This interim funding will be met out of the fixed CDF budget and be subject to the expenditure control mechanism described in chapter 4. Subject to NICE's Final Guidance remaining positive, funding will then switch permanently to baseline commissioning budgets 90 days after positive NICE Final Guidance is issued (or 30 days in the case of drugs with an Early Access to Medicines Scheme [EAMS] designation), at which point the drug will no longer be subject to the expenditure control mechanism.
17. For those drug/indications that receive a recommendation for use within the CDF, interim funding will also be available to pharmaceutical companies, again met out of the fixed CDF budget and subject to the same expenditure control mechanism. Reimbursement during this period will be at the price that is subsequently agreed as part of the CDF Managed Access Agreement. However, because this price will not be known at the point of marketing authorisation, the price submitted to NICE for the appraisal will be temporarily used, with the pharmaceutical company then repaying to the CDF budget the difference once the Managed Access Agreement price has been set.
18. Where NICE issue optimised draft recommendations (e.g. where the draft recommendations differ for different subgroups of the licensed indication under review), interim funding will be available for those patients within the optimised recommendation only.
19. Acceptance of all interim funding will be optional, and the pharmaceutical company's decision whether to accept will not prejudice the outcome of the NICE Final Guidance.

Resolving Uncertainty - The Cancer Drugs Fund (Chapter 3)

20. **Chapter 3 explains how the CDF will operate as a new managed access fund for resolving uncertainty.** For those drugs that receive a recommendation for use within the CDF, a Managed Access Agreement will need to be agreed between the pharmaceutical company and NHS England.
21. The purpose of the 'managed access' period will be to resolve significant remaining clinical uncertainty after consideration by NICE, with the CDF Managed Access Agreement consisting of two key components - a data collection arrangement and a CDF Commercial Agreement.
22. The data collection arrangement will set out the data that need to be collected in order to resolve the key areas of uncertainty. This will need to be considered on a case by case basis and will be jointly agreed between NHS England, NICE, Public Health England and the pharmaceutical company, with input from patients and clinicians.
23. The CDF Commercial Agreement will determine the level of reimbursement during the managed access period. This will be a confidential agreement between NHS England and the pharmaceutical company, with input from NICE, and will be considered on a case by case basis. However, the level of reimbursement should reflect the decision uncertainty, and the pharmaceutical company will need to present an offer that brings the range of potentially plausible cost effectiveness estimates as determined by NICE to below the relevant cost effectiveness threshold (i.e. £20k-£30k per QALY or up to £50k per QALY for end of life care drugs / indications).
24. The entire eligible patient population, as determined by the NICE guidance, will be covered by the CDF Managed Access Agreement.
25. At the end of the managed access period, NICE will re-appraise the drug with a view to deciding whether or not the drug can be recommended for routine commissioning.

Financial Control (Chapter 4)

26. **Chapter 4 sets out how the overall CDF budget will not overspend in future years.** The CDF budget is fixed at £340m and will need to cover the following costs: any interim funding being provided; CDF Managed Access Agreements; existing CDF drug indications pending NICE appraisal or re-consideration; existing Individual Funding Request commitments; any off-label indication commitments agreed as part of the clinical policy development process; and, CDF administration. The Association of the British Pharmaceutical Industry has previously agreed with the Department of Health that only CDF expenditure up to £320m in 2016/17, £300m in 2017/18 and £280m in 2018/19 will count towards the agreed voluntary Pharmaceutical Price Regulation Scheme (PPRS) rebate scheme.

27. Therefore, in order to ensure that the CDF does not overspend and does not have to close to potential new entrants, a proportional rebate will be applied to all pharmaceutical companies receiving any funding from the CDF budget in the event of an overspend. Agreement to this mechanism will be a condition for all pharmaceutical companies receiving funding from the CDF budget.
28. A joint NHS England / NICE CDF Investment Group will be responsible for managing the overall budget, including determining if and when the rebate mechanism needs to be applied. It will also approve CDF Managed Access Agreements.

Off-Label Cancer Drugs (Chapter 5)

29. **Chapter 5 outlines the process that will be followed for considering off-label cancer drug indications.** Off-label indications will have similar opportunities for gaining access to CDF funding to licensed drugs, if deemed clinically promising. The process for consideration of off-label indications will be integrated with NHS England's specialised commissioning clinical policy development process, with NICE in time providing all the necessary underpinning evidence reviews.
30. Applications for clinical policy proposals will be made by clinicians with the endorsement of NHS England's Chemotherapy Clinical Reference Group. Once received and endorsed, NHS England will add the proposal to the clinical policy development work programme. A clinical evidence review will be commissioned and a policy proposal drafted. NHS England will consider the proposal and will make one of three recommendations:
 - Progress as a routine commissioning proposal for consideration in the annual prioritisation round;
 - Progress as a not routinely commissioned proposal for consideration as an in year decision;
 - Progress within the CDF for further data evaluation to inform a commissioning position.

Transition (Chapter 6)

31. **Chapter 6 confirms arrangements for the transition between the old and new CDF operating models.** All drugs on the previous CDF as of 31 March 2016 will be reconsidered or appraised by NICE over the course of the next 18 months. Until NICE is able to provide a commissioning recommendation, these drugs will continue to receive funding from the CDF budget at current commercial terms. However continuation of funding will be subject to the expenditure control mechanism set out in chapter 4. For off-label indications, NHS England is in the process of commissioning clinical evidence reviews to inform their consideration.

Chapter 1: NICE Appraisal of Cancer Drugs

32. All new cancer drugs and significant new licensed indications will now be appraised by NICE subject to referral by Ministers. This began on 1st April 2016.
33. These appraisals will follow the standard process described in the NICE [Guide to the processes of technology appraisal](#) with amendments relating to the Cancer Drugs Fund described in an [addendum](#). These NICE guidance documents should be read in conjunction with this guidance. This chapter describes the recommendations NICE can make in relation to cancer drugs, the appraisal timetable and the key performance indicators NICE will be required to meet.

NICE Recommendations - 'yes', 'no', 'use within the CDF'

34. A modified appraisal process for cancer drugs was introduced on 1st April 2016 and now allows NICE to make one of three recommendations:
- Recommended for routine commissioning - 'yes'
 - Not recommended for routine commissioning - 'no'
 - Recommended for use within the CDF (new)
35. The new recommendation available to NICE - '*recommended for use within the CDF*'- will be used where there is plausible potential for a drug to satisfy the criteria for routine commissioning, but where there is currently too much uncertainty surrounding the clinical data and consequently the cost effectiveness estimates to make such a recommendation. Regulation 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 does not apply at this point.
36. A cancer drug/indication can be identified for entry into the CDF at several time points during a technology appraisal:
- Firstly, when the pharmaceutical company sends its evidence submission to NICE for a technology appraisal and includes a proposal for data collection in this submission;
 - Secondly, at the assessment phase, at which time the evidence review group or the NICE team may identify that a drug could be a CDF candidate;
 - Thirdly, at the appraisal committee meeting, when the committee identifies that a drug is a CDF candidate.
37. The appraisal process will take into account the application of the End of Life (EOL) criteria where appropriate. Changes to the criteria mean that, in the case of a 'life-extending treatment at the end of life', the Technology Appraisal

Committee will satisfy itself that the following two key criteria have been met (for full details see the NICE [addendum](#)):

- the treatment is indicated for patients with a short life expectancy, normally less than 24 months;
 - 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 three months, compared with current NHS treatment.
38. If a scheduled Technology Appraisal is terminated by NICE on account of a lack of an evidence submission from a pharmaceutical company, no funding can be made available from the CDF budget for that indication. If NICE is unable to complete an appraisal due to a lack of the submission of requested information by the pharmaceutical company there can also be no funding from the CDF budget for that indication.

Appraisal Timetable

39. All cancer drugs referred to NICE for appraisal from 1st April 2016 onwards are subject to an accelerated appraisal timetable with the aim of publishing:
- draft guidance prior to a drug indication receiving its marketing authorisation; and,
 - final guidance within 90 days of a drug indication receiving its marketing authorisation
40. In order to be able to publish guidance on cancer drugs within 90 days of marketing authorisation, NICE will hold the first Appraisal Committee meeting for a cancer drug before the Committee for Medicinal Products for Human Use (CHMP) opinion is published. Because the drug will not, at this stage, have received a regulatory opinion, this Appraisal Committee meeting will be held in private. Patient, clinical and commissioning experts, and company representatives will be invited to participate in the meeting under normal confidentiality arrangements.
41. After this Appraisal Committee meeting, an Appraisal Consultation Document with a preliminary recommendation, or in some circumstances a Final Appraisal Determination, will be developed.

Key Performance Indicators

42. A Memorandum of Understanding (MoU) has been agreed between NHS England and NICE to underpin the additional resource that NHS England has made available to support NICE in its expanded role around appraising all licensed cancer drugs. This MoU includes a number of Key Performance Indicators, including that 90% of new cancer technology appraisals referred to

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NICE after 1 April 2016, and for which the following conditions apply, will have guidance published within 90 days of marketing authorisation or launch:

- The product has been identified and referred early enough to allow for guidance publication to be timely; and
 - The technology appraisal follows standard NICE process (i.e. a maximum of 2 Committee meetings, normally no more than 2-3 months apart), and
 - No changes to the regulatory schedule are received after the company has been invited by NICE to make an evidence submission; and
 - No changes to the regulatory schedule are communicated, where the dates are brought forward without opportunity for NICE to react (that is notification less than 35 weeks before the CHMP meeting date); and
 - No requests for further submission of evidence are made after the initial submission of evidence, including for a PAS or CDF Commercial Agreement; and
 - No appeal is received; and
 - No other factors out of NICE's control are in play (for example 'purdah').
43. Pharmaceutical companies must share with NICE exact timelines for regulatory submission and immediately make NICE aware of any changes. In particular, NICE is interested in the 'intended submission date of Marketing Authorisation Application' included in the [pre-submission request form](#) of the European Medicines Agency, or the equivalent if another regulatory process is used.

Chapter 2: Interim Funding for Licensed Cancer Drug Indications

44. A key objective of the new approach is to provide patients with access to the most promising cancer drugs at the earliest opportunity. Currently, any drug that receives a routine commissioning recommendation from NICE receives funding 90 days after the publication of NICE's Final Guidance, in line with the legal funding requirement. However, under the new arrangements, interim funding (provided from the overall CDF budget) will be available from the point of marketing authorisation for any drug in receipt of a draft recommendation for routine commissioning or a draft recommendation for use within the CDF.
45. From 29th July 2016 interim funding is available for eligible drugs subject to pharmaceutical companies having signed an interim funding agreement. A template or framework interim funding agreement is included at **Appendix One**. The terms of the contract will be non-negotiable.
46. A single national list of approved drugs will exist, with approved criteria for funding the use of such drugs and indications through the CDF. This will be published on the NHS England dedicated CDF website www.england.nhs.uk/ourwork/cdf/ and regularly updated. This will inform clinicians, commissioners and the public what drug indications are available for access. In addition, NHS England Commissioning Hubs will receive notification via a communication circular and clinicians will receive the same information via a letter that will be sent to NHS Trusts. CDF drug use notification systems will be updated accordingly.

Interim Funding- Routine Commissioning Recommendation

47. For those drugs that receive a draft recommendation for routine commissioning, interim funding will be available from the point of marketing authorisation, or from release of the Appraisal Consultation Document, or Final Appraisal Determination (where no consultation on draft recommendation has been considered necessary), whichever is later. The intention is to publish draft guidance prior to marketing authorisation (as described in paragraphs 39-41 of chapter 1) and where NICE do decide to go straight to issuing a Final Appraisal Determination they will also aim to do this prior to marketing authorisation.
48. Reimbursement during this interim funding period will be at 100% of the price that generated the positive routine commissioning recommendation but will be subject, as required, to the expenditure control mechanisms set out in Chapter 4.
49. In order to receive interim funding, a pharmaceutical company must have signed an interim funding agreement confirming that they accept the expenditure control mechanism set out in Chapter 4. This offer of interim funding is optional, and the decision taken will not prejudice the outcome of the NICE Final Guidance. If a pharmaceutical company does not accept

interim funding, funding for the product will not be made available by the NHS to patients at that point in time. If the pharmaceutical company does accept interim funding, the product will be made available immediately.

50. Interim funding will end 90 days after positive Final Guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme [EAMS] designation), at which point funding will switch to baseline commissioning budgets. At this point, the drug will no longer be subject to the CDF expenditure control mechanism (however, the funding for the previous use of that drug in the relevant interim period will still be).
51. In the highly unlikely event that the NICE recommendation for a drug / indication changes from a 'routine commissioning' draft recommendation to a 'not routinely commissioned' recommendation between the Appraisal Consultation Document and Final Appraisal Document stage, interim funding will remain in place until NICE Final Guidance is published. If the NICE Final Guidance confirms the 'not routinely commissioned' recommendation, then funding will cease for any new patients with the pharmaceutical company continuing to meet the costs of any existing patients.
52. If, for any reason, Final Guidance is not published, the drug/indication will be deemed not to have been recommended for routine commissioning 12 months after the commencement of any Interim Funding Agreement. At this point, interim funding will cease for new patients, although the CDF budget will continue to meet the drug costs of patients already receiving the drug in question.

Interim Funding - CDF Recommendation

53. For those drug/indications that receive a recommendation for use within the CDF, interim funding will also be available to pharmaceutical companies. Again, this will be met out of the fixed CDF budget, be subject to the same expenditure control mechanism set out in Chapter 4 and will be optional. Reimbursement during this period will be at the price that is subsequently agreed as part of the CDF Managed Access Agreement. However, because this price will not be known at the point of marketing authorisation, the price submitted to NICE for the appraisal will be temporarily used, with the pharmaceutical company then repaying to the CDF budget the difference once the Managed Access Agreement price has been set and the Managed Access Agreement agreed.
54. If no CDF Managed Access Agreement can subsequently be agreed then normally all interim funding that may have been provided will need to be repaid by the pharmaceutical company, with the company also picking up the continued drug costs for any patients who had already started treatment. It is, however, recognised that exceptional circumstance may arise, beyond the control of the company or NHS England, which may prevent a Managed Access Agreement from being finalised and which may justify a sharing of any costs incurred between the company and NHS England.

Chapter 3: The Cancer Drugs Fund

55. From 29th July 2016, the Cancer Drugs Fund will be operational as a managed access scheme allowing entry of drugs of clinical promise, but where there is uncertainty as to their cost effectiveness. The CDF will allow the opportunity to resolve that uncertainty whilst at the same time benefitting patients. This Chapter describes the entry requirements, including arrangements for agreeing a CDF Managed Access Agreement, what happens during the managed access period and how drugs will exit the fund.

Entry to the Cancer Drugs Fund – Managed Access Agreement

56. A drug/indication is eligible for funding from the CDF when NICE considers there to be plausible potential for the drug/indication to satisfy the criteria for routine commissioning, but where there is significant remaining clinical uncertainty.
57. Drugs can be identified as potential candidates for the CDF at three different points in the appraisal process:
- Firstly, when the company sends its evidence submission to NICE for a technology appraisal and includes a proposal for data collection in this submission.
 - Secondly, during the assessment phase, at which time the evidence review group or the NICE team may identify that a drug could be a CDF candidate.
 - Thirdly, at the first appraisal committee meeting, when the committee identifies that a drug is a CDF candidate.
58. Final acceptance into the CDF will depend on the pharmaceutical company accepting the requirements of the CDF, as recorded in a CDF Managed Access Agreement which will contain a data collection arrangement and a CDF Commercial Agreement. The Managed Access Agreement will also require agreement to the expenditure control mechanism described in chapter 4. (A Template Managed Access Agreement is included at **Appendix Two**)
59. For any drug that receives a CDF recommendation at the Appraisal Consultation Document stage, the aim should be to launch the Managed Access Agreement at the point of or as close as possible to the Final Appraisal Determination being published. Of course, this assumes that the pharmaceutical company is satisfied with the CDF recommendation and does not intend to appeal the decision. If a CDF recommendation is made after the first consultation (or at a later stage in the appraisal process) then the aim will be to have a Managed Access Agreement in place at the point that Final Guidance is published.

Data Collection Arrangement

60. When considering whether a drug is a suitable candidate for the CDF, the NICE Technology Appraisal Committee will define and describe the specific area(s) of clinical uncertainty. Data collection will vary from drug to drug depending on the issues of uncertainty identified by NICE for licensed indications. NICE will seek advice from NHS England and Public Health England in this matter given the increasing complexity of treatment pathways in cancer, competing clinical trials and the nature of the data which requires collection.
61. The Appraisal Committee will receive advice from the company, NHS England and Public Health England on the nature of the data already being collected through existing studies or routine population-based datasets. Depending on the nature of the data collection question and required analyses, NICE, the Appraisal Committee and NHS England will identify the most appropriate framework for data collection. For further details, see the Data Collection Specification, which is available online and included at **Appendix Three**.
62. The exact length of time that is required for appropriate data collection for each drug/indication will be informed by advice from the appraisal committee and following discussion between NICE, NHS England and the pharmaceutical company. This will then be included in the Managed Access Agreement which will be approved by the CDF Investment Group. This is dependent on the type of data and the numbers of patients required to address the specific uncertainty. The timeframe should be as short as possible, normally up to two years, but will be considered on a case by case basis.

CDF Commercial Agreement

63. The CDF Commercial Agreement will form part of the overall Managed Access Agreement and is a proposal from a pharmaceutical company to NHS England to manage the cost of a drug to the NHS in a sustainable and financially sound way. CDF Commercial Agreements will be considered on a case by case basis so as to support the inclusion of cancer drugs in the CDF and facilitate patient access, where the NICE technology appraisal, on the current evidence base, has been unable to support a recommendation for routine commissioning.
64. It is recommended that the pharmaceutical company propose the commercial agreement terms as they state their interest in entering the CDF through the CDF Commercial Agreement template, which will be available online and is included at **Annex A of the template Managed Access Agreement at Appendix Two**. The template enables applicants to provide the information the CDF Investment Group will need to assess the feasibility of implementing the proposed CDF Commercial Agreement.
65. In circumstances where the pharmaceutical company is proactively seeking a CDF recommendation, the template for the CDF Commercial Agreement must be submitted by email to the CDF mailbox no later than the point at which the

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company provides its evidence submission to NICE. Where the NICE Appraisal Committee recommends a drug for inclusion in the CDF, without the company having sought such a recommendation, the earliest the template can be submitted is after receipt of the Appraisal Consultation Document by the company. In this circumstance, and if the company is minded to accept the CDF recommendation, the template should be submitted no later than one week after the Appraisal Consultation Document is published by NICE (that is two weeks after receipt of the confidential Appraisal Consultation Document by the company). Where during the assessment phase, the NICE team identifies a product as potentially eligible for the CDF, and if the company is minded to take this forward, it should immediately submit the template. More information on how to submit the template is available in the template itself.

66. The CDF Commercial Agreement will determine the level of reimbursement during the managed access period. This will be a confidential agreement between NHS England and the pharmaceutical company, with input from NICE, and will be considered on a case by case basis. However, the level of reimbursement should reflect the decision uncertainty, and the pharmaceutical company will need to present an offer that brings the range of potentially plausible cost effectiveness estimates as determined by NICE to below the relevant cost effectiveness threshold i.e. £20k-£30k per QALY or up to £50k per QALY for end of life care drugs / indications.
67. The entire eligible patient population, as determined by the NICE guidance, will be covered by the Managed Access Agreement.
68. The CDF Commercial Agreement proposed by the company will either be accepted or rejected by the CDF Investment Group. Companies will be permitted to resubmit a revised CDF Commercial Agreement. Neither the CDF Investment Group nor NHS England shall owe any duty to any third party in respect of agreeing or rejecting a CDF Commercial Agreement.
69. If the company does not propose an acceptable CDF Commercial Agreement, the drug will not enter the CDF or be available to patients. In that situation, NICE Guidance will be issued and the drug will not be commissioned routinely or through the CDF. The topic could return to NICE for further consideration, if the pharmaceutical company offers a new price.
70. Between the submission of the CDF Commercial Agreement template by the pharmaceutical company and the second NICE Technology Appraisal Committee meeting, there will be room for discussion about the CDF Commercial Agreement between the company and the NHS England CDF team.
71. Any CDF Commercial Agreement should be operationally manageable for the NHS without unduly complex monitoring, disproportionate additional costs and bureaucracy, and it must be possible to apply the CDF expenditure control mechanism fairly. Any burden for the NHS should be proportionate to the benefits of the scheme for the NHS and patients.

72. It is anticipated that the majority of CDF Commercial Agreements will be managed centrally. However, where the provisions of the agreement are such that NHS providers need to pay a reduced price directly, they must be allowed to know the agreed price of the drug. Confidentiality agreements will be considered in these cases.
73. The CDF Investment Group will approve the final Managed Access Agreement (which includes both the CDF Commercial Agreement and Data Collection Arrangement). A communication will be sent to the company upon CDF Investment Group sign off.

During the CDF Managed Access Period

74. Whilst the drug is in the CDF, data will be collected as per the Managed Access Agreement. A regular review of the data will be conducted to ensure that progress is being made to resolve the uncertainty.
75. A number of systems within the NHS will support this process: electronic prescribing of chemotherapy; the Systemic Anti-Cancer Therapy dataset; and, the CDF notification system.

Chemotherapy E-prescribing

76. A key requirement of NHS England's service specification for all chemotherapy providers is that electronic prescribing systems are in place in all chemotherapy services. Chemotherapy e-prescribing systems support the safe, effective and efficient delivery of chemotherapy. They have been shown to significantly reduce errors associated with the prescription, supply and administration of medicines, and to reduce drug wastage and associated costs. In addition, e-prescribing reinforces the use of standard, evidence based chemotherapy regimens. The use of e-prescribing also supports completion of SACT data returns.
77. The 2016/17 NHS Standard Contract includes national quality requirements within Schedule 4 which requires full implementation of an effective e-prescribing system for chemotherapy across all relevant clinical teams within the Provider. Full implementation as described under the published *NHS England Specialised Commissioning Service Specifications B15/S/a and b (Cancer: Chemotherapy Adult and Children)* is required by 31 March 2017 for adult services and 30 September 2017 for paediatric services. This covers all systemic anti-cancer therapy. Quality development plans will be agreed with local commissioners to ensure this target is met. For adult services, plans needed to be agreed by June 2016 and for paediatric services plans need to be complete by September 2016.
78. Clinicians and Trusts wishing to access any drugs in the CDF (whether they be for licensed cancer indications given conditional approval by NICE, or for off-label use given conditional approval by NHS England, or those drugs signalled for approval by NICE and therefore given access to CDF interim

funding at marketing authorisation, or those drugs which are CDF transition drugs) must have by 2017 (see paragraph 77) an e-prescribing system in operation which is used for all prescriptions of cancer drugs in the Trusts concerned, whether the drugs be for haematological or solid tumour use and whether the drugs are given by intravenous, oral, subcutaneous or intrathecal routes. Trusts must collect and submit the full required data set for each new CDF drug.

79. From April 2017 (for adults) and September 2017 (for paediatrics), restrictions will be placed on Trusts' ability to access and be reimbursed for CDF drugs if they fail to comply with e-prescribing requirements.

Systemic Anti-Cancer Therapy (SACT) Data

80. SACT dataset is a mandated dataset as part of the Health and Social Care Information Standards. This is listed as a Schedule 6 national information requirement within the NHS Standard Contract.
81. The SACT dataset team is based within Public Health England and is responsible for providing timely, good quality intelligence to NHS England on the use of anti-systemic cancer therapies and impact of changes in therapies available on clinical practice. Monitoring of all systemic anti-cancer therapy activity will inform and underpin financial and service planning, policy development and prioritisation as part of NHS England's specialised commissioning work for cancer.
82. Any hospital trust administering chemotherapy will be required to be fully compliant with the mandated collection of the SACT dataset for all patients receiving chemotherapy treatment. This covers all administration routes – intravenous, oral, subcutaneous, and intrathecal medication.
83. Public Health England data sources including SACT dataset form the main observational data collection system for the CDF. Other data sources, such as ongoing clinical trials may accompany the SACT data to inform the issues of uncertainty identified by the technology appraisal committee, or the SACT data outcome collection could be the sole source of outcome data.
84. The existing infrastructure allows data collection to begin in a timely fashion and progress to be easily monitored.

Notification of the use of all drugs funded by the CDF budget

85. Each CDF regional team will process notifications to access all drugs funded by the CDF from providers located within their region. The following information broadly outlines the processes for notifications to the CDF from 29th July 2016.
86. A single national list of approved drugs / indications will exist with approved criteria for funding the use of all such drugs / indications through the CDF

OFFICIAL

budget. This will be published on the NHS England dedicated CDF website www.england.nhs.uk/ourwork/cdf/ and regularly updated. This will inform clinicians, commissioners and the public what drug indications are included and available for access. In addition, NHS England Commissioning Hubs will receive notification via a communication circular and clinicians will receive the same information via a letter that will be sent to Trusts. CDF drug use notification systems will be altered and updated accordingly.

87. This list will incorporate the following groups of drugs: drugs for interim funding as a consequence of a provisional/final recommendation by NICE until funding continues via baseline commissioning; new drugs entering the CDF for further evaluation as a consequence of a NICE recommendation for use within the CDF; new off label drugs entering CDF evaluation as a consequence of recommendation by NHS England; and, drugs transitioning from the old CDF to the new CDF via the NICE appraisal process if for licensed indications or via the NHS England process if off-label.
88. An online submission will be required to request funding for drug/indications on the CDF List. Requests may come from individual clinicians or, where agreed by the Trust, Trusts may nominate an individual to co-ordinate requests from that organisation. If a Trust decides to take this route this should not delay the submission process. Clinicians and Trust co-ordinators will be required to register using a valid NHS.net email address. Notifications will not be accepted nor correspondence undertaken via other email networks.
89. Standardised online submission forms for licensed indications will be developed as required using the clinical criteria supplied by NICE and NHS England and will be used to match the request against relevant clinical criteria. If the request meets the agreed criteria, approval of funding will be confirmed online.
90. Standardised online submission forms for off-label indications will be developed as required using the clinical criteria supplied by NHS England and will be used to match the request against relevant clinical criteria. If the request meets the agreed criteria, approval of funding will be confirmed online.
91. The standard timeline for the response to notification of the use of a CDF drug on the CDF List is two working days. In practice, online submission systems will facilitate an immediate response. Online submission systems will allow Trust nominated administrators to access the details of responses to notifications for patients to be treated in their organisation.
92. A requirement for funding will be for clinicians or Trust co-ordinators to submit all required treatment data, both clinical (via SACT dataset) and financial (including via the financial minimum dataset). Clinicians or Trust co-ordinators notifying the CDF of use of drugs on the national CDF List will be required to provide all necessary clinical outcome data on treatment. Payment of Trust invoices will be contingent on the full SACT and financial minimum dataset database record applicable to the drug being completed and this information being made available in a timely way.

93. Treatment should be started within one month of receiving confirmation of CDF funding, although it is expected that in the vast majority of successful notifications, treatment will commence very shortly after approval has been obtained. CDF funding of treatment started more than one month after notification/confirmation will need to be re-submitted, as the patient's condition may have changed. Trusts will be treating patients at their own financial risk without a resubmission.
94. Trusts commencing treatments prior to successful notification to the CDF do so at their own financial risk. Invoices sent to the CDF for cycles of treatment administered prior to gaining of funding (or more than two days after the notification for funding in urgent situations) will not be paid. Invoices will only be paid for cycles of treatment administered to a patient after approval of funding (or within two days of successful notification for funding in urgent situations). The financial responsibility for treating patients prior to confirmation of funding rests with the provider Trust.
95. Requesters will get an automated response for requests which do not meet the access criteria. This will advise them of the further options available.
96. Trusts should ensure the implementation of access to CDF drugs as efficiently as possible to prevent delay to patients accessing treatment while minimising any avoidable risks associated with implementation. If a Trust decides that they are unable to implement a CDF treatment for a cohort of patients that they would normally treat, they should notify their regional specialised commissioning team within 30 days of the date of granting of access to CDF funding.
97. All the above arrangements apply to drugs funded from the CDF budget i.e. for all groups of drugs as set out in paragraph 78.

Quarterly Activity Reporting

98. Quarterly activity reporting in relation to numbers of notifications to the CDF will be signed off by the CDF Investment Group and published on the NHS England website. This will include all patients funded through the CDF managed access scheme for new drugs/indications as well as for drugs/indications transitioning from the previous CDF and those granted interim funding arrangements. Other reporting will be considered by the CDF Investment Group.

Exiting the Cancer Drugs Fund

99. A drug will begin the process of exiting the CDF at the point agreed during the Data Collection Arrangement, when sufficient data is available to answer the original uncertainty. NICE will schedule the re-appraisal of the drug and this will take account of data available since the original appraisal and any newly proposed price by the company. The NICE recommendation will either be a

OFFICIAL

positive recommendation for routine commissioning or a negative routine commissioning recommendation. In the latter case funding for the drug would only be available via Individual Funding Request if the patient is considered clinically exceptional.

100. If, when re-appraised, a CDF drug is recommended for routine commissioning at Appraisal Consultation Document stage then it will become eligible to receive interim funding, subject to the expenditure control mechanism, from the CDF budget at 100% of the price that generated that recommendation before switching to baseline commissioning 90 days after Final Guidance is issued.
101. If at Final Guidance after review NICE does not recommend the drug for routine commissioning, no further routine funding will be available for patients to be prescribed the drug. Any patients who have been prescribed the drug during the time in which the drug was in the Fund will continue to receive the drug at the pharmaceutical company's cost until the prescribing physician deems it appropriate to discontinue treatment.
102. Drugs that are recommended for routine commissioning will move to baseline commissioning 90 days after the publication of the NICE Final Guidance (30 days for drugs with an EAMS designation).

Chapter 4: Financial Control

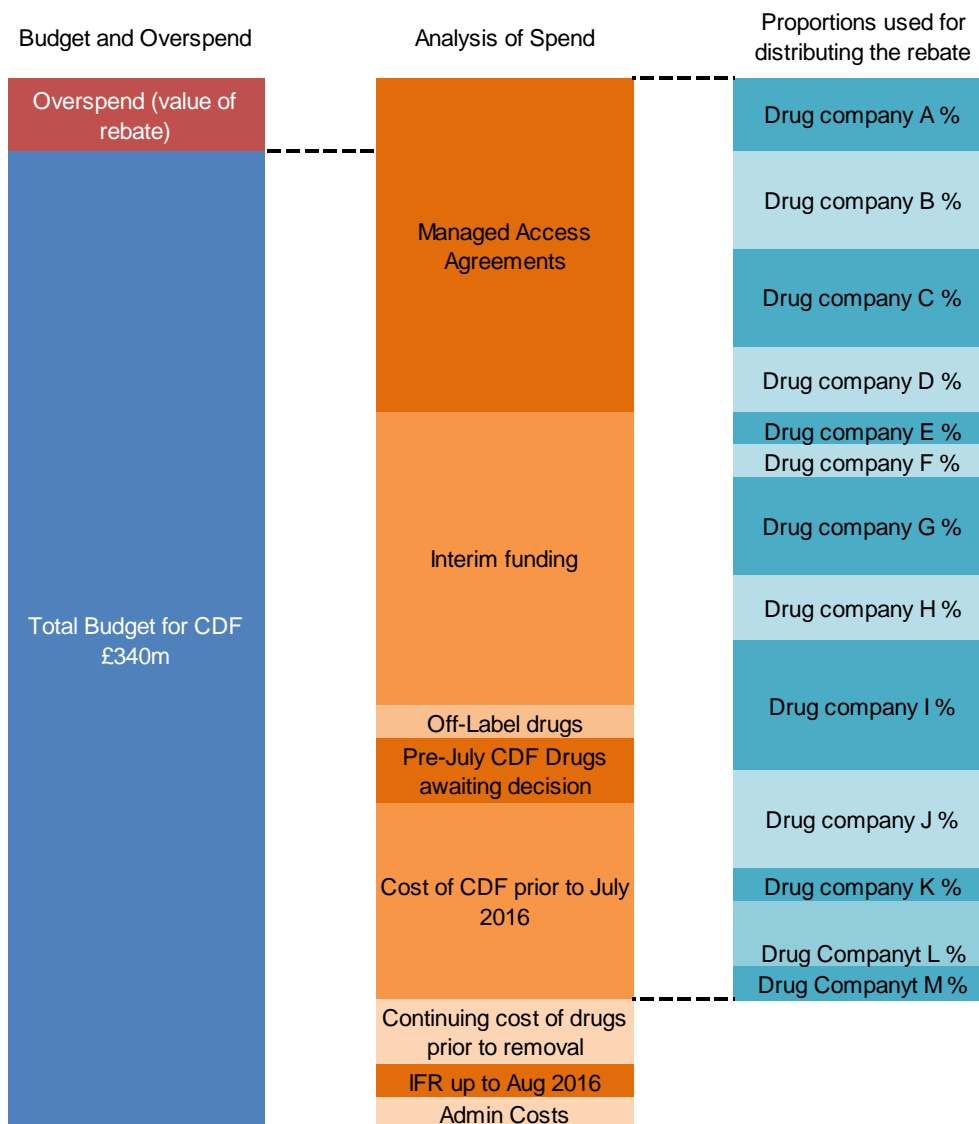
103. The CDF budget is a fixed amount agreed annually by the NHS England Board. The budget for 2016/17 has been set at £340m. Financial modelling and forecasting will be subject to independent verification.
104. The budget is required to cover the cost of:
- Drugs/indications in receipt of interim funding;
 - CDF Managed Access Agreements;
 - Off-label drug/indications approved for funding from the CDF;
 - The administrative cost of the CDF (capped at 2% of the fixed £340m budget in 2016/17).
105. In addition, during transition it will also need to cover the cost of:
- Individual Funding Requests approved for cancer drugs up to 31 July 2016
 - Existing CDF drugs/indications awaiting reconsideration or appraisal by NICE;
 - Drugs/indications removed from the CDF due to previous reprioritisation exercises or due to NICE/NHS England decisions in so far as they relate to patients who commenced treatment prior to their removal and who remain on treatment.
 - The CDF in the period from 1 April 2016 to 28th July 2016.
106. The CDF Investment Group will ensure the overall CDF expenditure remains within the fixed budget through the application, if required, of the expenditure control mechanism.

Expenditure Control Mechanism

107. The joint NHS England/NICE CDF Investment Group has responsibility for ensuring that the budget is not overspent. In the event that the fund is overcommitted at the end of a financial year the pharmaceutical companies that have had drugs funded through the CDF budget will be required to pay a rebate to NHS England.
108. The CDF is a reimbursement fund; NHS trusts are reimbursed for claims made of the cost of drug/indications that they have incurred. The cost of reimbursements may vary from the amounts paid to pharmaceutical companies for drugs purchased because of VAT and wastage charges, as appropriate.
109. NHS England operates to a financial year that ends on 31 March. Claims for reimbursement from trusts are up to two months in arrears, so the final spending for the year will be based upon actual claims made for up to eleven months of the year and an estimate for the final weeks based on a projection of cost and activity.

110. Pharmaceutical companies will be notified of the expected cost of any rebate required in March of each year. The calculation required to arrive at this amount will be partially based upon a projection of the cost of the final months. Early in the following year an adjustment to the rebate will be issued, to take account of variations between the actual and forecast activity and spending in the final months. This could be either a further rebate or a credit.
111. The total rebate will be distributed between the companies that have provided drugs funded by the CDF through Managed Access Agreements, interim funding, off-label drugs and transition drugs. The proportions will be a pro-rata calculation of the spending on each company's drugs as claimed by the trusts. This is illustrated by the diagram below:

Diagram Showing Methodology for the Calculation of the Retrospective Rebate



Size of the blocks is for illustrative purposes only and does not represent a forecast.

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112. NHS England recognises that pharmaceutical companies will need regular intelligence on their possible exposure should a rebate be required. However, a full disclosure of the cost of the fund and each company's possible rebate contribution would be commercially sensitive information. On a quarterly basis, commencing in 2017/18 the CDF Investment Group will provide an indication of the current CDF expenditure showing interim funding, new CDF drugs, and transitional CDF drugs. At the end of each calendar year, following the December meeting of the CDF Investment Group, pharmaceutical companies will be notified as to whether, based on latest available information, a rebate may be required for the current financial year. Each company will be notified of their likely share of a possible rebate. Such estimates will be non-binding on the part of NHS England.
113. NHS England is also aware that pharmaceutical companies will want assurance that the calculation of the rebate is done in a way that is fair and accurate. The calculation of the rebate will be reviewed by independent consultants appointed by NHS England and a statement confirming that the calculation has been independently verified will be issued with any request for a rebate.
114. Each CDF Managed Access Agreement and Interim Funding Agreement will include standard terms describing the expenditure control mechanism and committing the pharmaceutical company to contributing to any rebate that may be required. There will be no appeal against the rebate and no upper limit to the amount that may be recovered.
115. Any dispute concerning the expenditure control mechanism should be formally raised by the pharmaceutical company with the CDF Investment Group.
116. The CDF budget will only fund licensed pharmaceutical products for the active treatment of cancer. This definition can include licensed radiopharmaceutical treatments. The use in the CDF need not necessarily be in the licensed indication (i.e. it can be off-label). The CDF will not fund drugs used in the supportive care of cancer patients and in cancer patients receiving systemic therapy. The CDF therefore only reimburses for the cost of the active new cancer drug.
117. The CDF budget will not fund drugs which are reimbursed via the tariff system e.g. hormone treatments for the treatment of breast cancer and prostate cancer. The CDF budget will, therefore, only fund cancer drugs which are funded through specialised commissioning.
118. The CDF budget will not fund radiotherapy treatments or medical devices.

Minimum Dataset

119. The drug Minimum Dataset (MDS) used for high cost drugs will incorporate CDF data requirements as the source of data for authorising reimbursement and monitoring drug expenditure.

120. The dataset, with cross-reference to data from the online CDF notification system, will be the primary source of information for reporting actual expenditure and information against the CDF budget. The database will give sufficient information to create reports of activity and expenditure. It will be the primary source of data for invoice validation.
121. Trusts should collect information for the MDS for prescriptions issued from July 2016.

Trust Reimbursement

122. Trusts will be reimbursed for the cost of drugs prescribed to patients that have been approved for treatment through the CDF budget. Trusts will only be reimbursed for:
 - the cost of the drug at the point of prescription
 - any VAT payable
123. Delivery costs and on-costs for dispensing or handling will not be reimbursed through the CDF budget. Depending on the contractual arrangements in place with an individual trust, these costs may potentially be reimbursed by the relevant local NHS England Commissioning Hub.
124. The cost of prescribing a drug will be eligible for reimbursement if:
 - the drug/indication has been approved for funding from the CDF budget; and
 - the patient has been approved as suitable following a submission through the online CDF notification system.
125. To receive reimbursement the trust should:
 - submit a monthly invoice for the cost of the prescription to the appropriate Regional CDF Team of NHS England. Invoices for CDF reimbursement should be distinct from other charges to NHS England;
 - submit (to the Commissioning Support Unit (CSU) providing an informatics service to the NHS England regional hub) a monthly batch of MDSs for the patient's prescription that is consistent with the invoice. The form of the MDS will be the same as that used for the drug MDS. (See CSU contact details in Contact Details section).
126. The invoice and the MDS should be consistent. Invoices and MDSs should be issued according to the rules that apply to other commissioning in the standard contract; invoices should normally be issued within one month of the treatment with a "refresh" of the MDS allowed the following month unless alternate arrangements are in place on an exceptional basis.
127. The Regional Team will clear the invoice for payment following a number of validation checks. Payment in respect of a prescription may be withheld if:

OFFICIAL

- the patient has not been authorised for treatment as a CDF patient;
 - the drug/indication has not been authorised for reimbursement by the CDF, or if authorisation has ended prior to the treatment date;
 - the trust has failed to complete mandatory fields on the MDS;
 - the invoice or the MDS has been submitted after the allowed time;
 - the costs charged are incorrect.
128. In addition payment could be withheld if the trust is not compliant with the requirement to introduce e-prescribing by April 2017 or if the full SACT record applicable to the drug is not completed or made available in a timely way, or if the MDS submissions consistently fail to be accurate, timely or complete.
129. NHS England will undertake routine checks on the value of treatments made in claims. The cost of a treatment cycle for a specific drug/indication will vary from patient to patient and from trust to trust. Reasons for the variation include:
- the weight of the patient;
 - the level of wastage;
 - the trust's treatment of VAT.
130. If it is found that a trust is consistently claiming more than the prices agreed for drugs, the inconsistency will be investigated and remedial interventions initiated as appropriate.

Chapter 5: Off-label Cancer Drug Indication Management

131. NICE, under their current terms of operations agreed with the Department of Health, is only allowed to appraise a drug within its marketing authorisation. Therefore, NHS England will be responsible for overseeing a process for considering the commissioning of cancer drugs for off-label indication use.

The Process

132. The established process will broadly mirror the NICE process in terms of generating a recommended 'yes', 'no' or a CDF recommendation and will also align with the specialised commissioning clinical policy development and annual prioritisation process through the Clinical Priorities Advisory Group (CPAG) and Specialised Commissioning Oversight Group (SCOG). This will ensure that off-label cancer drugs/indications have similar access to CDF funding for the purposes of resolving uncertainty as licensed drugs/indications will.
133. However, unlike drugs that receive a positive NICE appraisal for routine commissioning and attract a statutory funding requirement, there can be no baseline funding guarantees for off-label cancer drug indications receiving a positive routine commissioning recommendation, whether this is at the outset or following a period within the CDF for further data collection and evaluation. Therefore the CDF budget will act as a bridge for interim funding of those indications that are recommended for routine commissioning until annual prioritisation decisions are made.
134. All submissions for an off-label cancer drug clinical policy proposition will be considered through the specialised commissioning clinical policy development process and will need to be made by a clinician, with the endorsement of NHS England's Chemotherapy Clinical Reference Group. A Preliminary Commissioning Policy Proposition will be submitted to the specialised commissioning Clinical Effectiveness Team.
135. Once received and endorsed, NHS England will then determine if the proposal is added to its policy development work programme. If so, a clinical evidence review will be commissioned and a policy proposal drafted. NHS England will consider the proposal and will make one of three recommendations:
- progress as a routine commissioning proposal for consideration in the annual prioritisation round;
 - progress as a not routinely commissioned proposal for consideration as an in year decision;
 - progress within the CDF for further data evaluation to inform a definitive commissioning position.

136. For further information contact CET@nhs.net regarding the clinical policy proposal submission, methods guide and policy programme details.

Reimbursement

137. The rate of reimbursement for an off label drug will be set at the then current rate of reimbursement for that drug in the NHS. This could be at list price, at a price agreed via a patient access scheme or a CDF Commercial Agreement, whichever is the lowest.

Chapter 6: Transition

138. The 2015-16 CDF was closed in the autumn of 2015 both to potential new entries and to further removal of drug indications at the time that NHS England stated its intent to change the future CDF as outlined in this SOP. At that time, there were 48 indications in the CDF which comprised 4 types of drug indications:
- Licensed drug indications which had previously been appraised by NICE and received final guidance with negative recommendations;
 - Licensed drug indications which were within the NICE technology appraisal process but had not received final guidance;
 - Licensed drug indications which had not been referred to NICE for appraisal;
 - Off-label drug indications.
139. As NHS England intends to make final commissioning decisions for all of these drug indications, it has made arrangements described in the paragraphs below in order to effect transition of all of the 48 autumn 2015 CDF drug indications into final consideration of whether they should be routinely commissioned or not.

Drug Indication Groupings

140. All CDF drugs/indications which had previous negative NICE recommendations in final guidance have been planned into the NICE work programme for a rapid reconsideration. Unless new indications are also being considered at the same time, it is expected that final guidance on these re-appraisals will be issued before the end of the 2016/17 financial year. These drug indications will remain in the CDF until such final guidance is issued. Drugs receiving a positive NICE recommendation will be funded by routine baseline commissioning budgets within 90 days of NICE final guidance. Drugs receiving negative NICE final guidance will be given two months' notice of their removal from the CDF. No new patients will be funded from this point although the CDF budget will continue to meet the drug costs of patients already receiving the drug in question.
141. All CDF drugs/indications for which the NICE appraisal process is ongoing or has recently been completed will remain in the CDF until such final guidance is issued. Drugs receiving a positive NICE recommendation will be funded from routine baseline commissioning budgets within 90 days of NICE final guidance. Drugs receiving a negative NICE final guidance will be given two months' notice of their removal from the CDF. No new patients will be funded from this point although the CDF budget will continue to meet the drug costs of patients already receiving the drug in question.
142. All CDF drugs/indications which have not previously been considered by NICE, and for which Ministerial referral has been sought, will be scheduled for NICE appraisal before 31 December 2017. These drug indications will remain in the CDF until final guidance is issued. Drugs receiving a positive NICE

OFFICIAL

recommendation will be funded from routine baseline commissioning budgets within 90 days of NICE Final Guidance. Drugs receiving negative NICE Final Guidance will be given two months' notice of their removal from the CDF. No new patients will be funded from this point although the CDF budget will continue to meet the drug costs of patients already receiving the drug in question.

143. All CDF off-label drugs/indications, will be entered into the NHS England assessment and prioritisation process for off-label drug indications described in chapter 5 of this document.
144. For all the licensed indications in the above categories, pharmaceutical companies which market these cancer drugs will have to agree by 29th July 2016 for expenditure on their drugs to be subject to the CDF expenditure control mechanism (as outlined in this document). All such pharmaceutical companies with drugs still in the CDF on 29th July 2016 will be contacted to confirm acceptance of this requirement. Any pharmaceutical company marketing a licensed drug indication which fails to agree to this mechanism will have a 2 month notice period served on the removal of CDF funding for their drug indication(s).
145. NHS England notes that there are a small number of licensed cancer drug indications for relatively rare cancers and/or small patient numbers which were not able to be assessed before the 2015-16 CDF was closed to new considerations and were not at that time referred to NICE for technology appraisal. As part of the new arrangements described, all such drugs will now be referred to NICE for consideration. Potential funding for such licensed drugs can only follow consideration by NICE as there is no other funding route possible within the arrangements described in this document (save for an Individual Funding Request for patients in exceptional clinical circumstances).

Chapter 7: Administration

146. A number of administrative processes and agreements need to be in place for the effective functioning of the new scheme.

CDF Investment Group

147. The CDF Investment Group is a joint NHS England and NICE group with two main objectives:

- Approval of individual CDF Managed Access Agreements (which will include a CDF Commercial Agreement and a CDF Data Collection Arrangement); and
- Ensuring that overall CDF expenditure remains within the fixed budget (£340m in 2016/17) through the application, if required, of the expenditure control mechanism.

148. To achieve the latter objective, the CDF Investment Group will:

- Monitor the progress of drugs through the funding lifecycle, including entry and exit from the fund;
- Review expenditure and financial forecast reports;
- Ensure risks and issues are managed and escalated as appropriate;
- Operate the Expenditure Control Mechanism.

149. The CDF Investment Group is accountable to the NHS England Specialised Services Commissioning Committee.

Memorandum of Understanding and Service Level Agreements

150. A Memorandum of Understanding (MOU) is agreed and in place between NHS England and NICE outlining the key deliverables needed to establish the new CDF programme and delivery teams for delivering NICE's work in relation to the operation of the new scheme. This includes how NICE will plan, administer and coordinate the procedures necessary to deliver Technology Appraisals for all new licensed cancer drugs and significant license extensions in line with the new CDF scheme, leading to the publication of appropriate draft and final guidance.

151. A Service Level Agreement is agreed and in place between NHS England and Public Health England for a partnership which will provide NHS England with routine and bespoke information and analysis, focusing on both a) chemotherapy and activity data and b) outcome and quality metrics. This will allow monitoring of all systemic anti-cancer therapy activity to inform and underpin financial and service planning, policy development and prioritisation as part of NHS England's specialised commissioning work for cancer.

Administration Budget

152. NHS England will use up to 2% of the fixed £340m CDF budget on administrative costs. This funding will support the operational management of the CDF by funding team capacity and expertise for NICE, NHS England and Public Health England as well as supporting data collection, audit and evaluation.
153. Costs for administrative support to the CDF will not be used at provider level.

Evaluation of new scheme

154. NHS England will need to keep the operational mechanisms under continuous review, with a view to modifying arrangements as may be required. In addition, NHS England will look to undertake a more formal evaluation of the overall operation of the scheme, no later than autumn 2017.

Individual Funding Requests

155. The provision of chemotherapy is an NHS England Prescribed Service. Therefore, requests for the funding of cancer drugs where a commissioning position is not stated should be made through the NHS England Individual Funding Request route.
156. Decisions affecting individuals' treatment will be made in a timely fashion in accordance with the NHS England Individual Funding Request Standard Operating Procedure (IFR SOP).
157. It is the responsibility of the treating Trust clinician to provide all relevant clinical data to support the IFR case for consideration of clinical exceptionality. Decisions on funding will be made on the basis of exceptional clinical need and the patient's ability to benefit from treatment clinically and will not be based on social value judgements.
158. Treating clinicians will be required to apply using a valid NHS.net email address. Applications will not be accepted nor correspondence undertaken via other email networks.
159. Contact details for enquiries:

Email: england.ifr@nhs.net

NHS England IFR Standard Operating Procedure and application forms can be found at: <https://www.england.nhs.uk/commissioning/spec-services/key-docs/>

Contact Details

The operational management of the CDF is led by the National CDF Team, with certain responsibilities devolved to the Regional Teams responsible for commissioning of Specialised Services. These are based in the following Commissioning Offices:

North of England: NHS England (Cumbria & the North East Commissioning Office, Newcastle)

Midlands and East: NHS England (Central Midlands Commissioning Office, Leicester)

South of England: NHS England (Wessex Commissioning Office, Southampton)

London: NHS England (London Commissioning Office, Skipton House from September 2016)

There is an NHS England webpage dedicated to the CDF with links to the online notification systems - www.england.nhs.uk/ourwork/cdf/. Requests to the CDF should be submitted to the appropriate NHS England CDF regional team via the online CDF notification system.

The CDF regional teams have a dedicated inbox - england.cdf@nhs.net . Telephone number is 0113 8248241.

Regional teams will ensure that CDF contact information (including the link to the CDF online notification system secure email address) is made widely available to the providers in their region.

Commissioning Support Units (CSUs)

The contacts of the CSUs supporting are:

- Arden and GEM CSU - DCSupport@ardengemcsu.nhs.uk
- North of England CSU – necsu.nhsedata@nhs.net
- North East London (NEL) CSU - Nelcsu.dsc-sclon@nhs.net
- South, Central and West CSU - southcsu.dmic@nhs.net

General Enquiries:

All other general enquiries can be made to: england.cdfteam@nhs.net

Appendix One - Interim Funding Agreement



Draft – Interim Funding Agreement

For illustrative purposes; agreements will be customised for specific drugs/indications

1. Purpose of Agreement

- 1.1 The objectives of the document as a whole are to record the position on interim funding of [the named drug] for indication [...] ("the Drug" which for the avoidance of any doubt means the use of [] for indication [] only, and no other use) and to ensure that all relevant stakeholders have a common understanding of the position.
- 1.2 This Interim Funding Agreement has been drawn up by NHS England and [Drug Company].
- 1.3 For the avoidance of doubt, the parties intend commitments that are expressly given by one party to the other in this Interim Funding Agreement to be legally enforceable between them. Where this Interim Funding Agreement refers to commitments that derive from other documents, in particular but not limited to the rules of the Cancer Drugs Fund as amended from time to time, then the terms of those other documents are definitive and the reference to the commitment in this document is for convenience only.

2. Background

- 2.1 The Drug is currently being assessed through the NICE Technology Appraisal process. The [Appraisal Consultation Document, published [date]] [Final Appraisal Determination, published [date]]¹ has indicated that this drug/indication is likely to be to be recommended [for routine commissioning] [for entry into the Cancer Drugs Fund]².
- 2.2 As part of the reform of the Cancer Drugs Fund any cancer drug/indication where NICE has indicated in the course of a technology appraisal that it is likely to be to be recommended for routine commissioning or for entry into the Cancer Drugs Fund is entitled to be funded on an interim basis until either:
 - Funding for the drug/indication moves to routine commissioning; or
 - A Cancer Drug Fund Managed Access Agreement is agreed; or
 - NICE publishes final guidance that subsequently concludes that the drug/indication is not recommended for routine commissioning or for use within the Cancer Drug Fund; or
 - The relevant technology appraisal is abandoned [or it is concluded that no Cancer Drug Fund Managed Access Agreement will be agreed]³.

¹ Delete as appropriate

² Delete as appropriate

³ Delete as appropriate – only applies if recommendation is for CDF

3. Commencement of agreement

- 3.1 In accordance with the rules of the Cancer Drugs Fund, as of publication of [the Appraisal Consultation Document, published [date]] [the Final Appraisal Determination, published [date]]⁴ prescription of the Drug by those clinical centres commissioned to provide cancer therapies will be reimbursed by NHS England.

4. Price of the drug during the period of interim funding

- 4.1 During the period covered by interim funding the price charged to trusts for the Drug will be the price submitted by [Drug Company] for use by NICE in the technology appraisal.⁵
- 4.2 [At the end of the period of interim funding there will be an appraisal of the cost to the NHS of the Drug. If the price that applies following the period of interim funding is lower than the price that applied during the period of interim funding than there will be a further settlement between NHS England and the [Drug Company].
- 4.3 To arrive at the value of the settlement the “actual cost of the Drug” will be the cost incurred by NHS England through the reimbursement of trusts. The “hypothetical cost of the Drug” will be NHS England’s calculation of what the cost of interim funding would have been at the lower price. The value of the settlement will be the difference between the actual cost of the Drug and the hypothetical cost of the Drug.
- 4.4 Any settlement will be managed through an additional rebate paid by the [Drug Company].

5. [Change in recommendation at Final Appraisal Determination

- 5.1 If the conclusion of NICE in the published Final Appraisal Determination changes from that published in the Appraisal Consultation Document interim funding will continue without variation until the Final Guidance confirms or reverses the Final Appraisal Document recommendation.]⁶

6. End of agreement

- 6.1 This interim funding will continue to be provided for the Drug until Final Guidance is published by NICE in the current appraisal process or until that process is abandoned, or it is concluded that no Managed Access Agreement will be agreed.

⁴ Delete as appropriate

⁵ Section may need revision if the offer price varied from the list price

⁶ Section could be deleted if interim funding starts following a FAD

Drug is identified for routine commissioning

- 6.2 If the Drug is identified for routine commissioning in Final Guidance then interim funding will continue under the terms of this agreement for a further [90 days] [30 days]⁷, after which it will be funded from NHS England's Specialised Commissioning budget.
- 6.3 [If the price submitted by [Drug Company] for use by NICE in the technology appraisal that was used to arrive at the Final Guidance is lower than that paid by trusts during the period of interim funding then the [Drug Company] will pay NHS England a rebate as described in section 4.

Drug is identified for the Cancer Drugs Fund

- 6.4 If the Drug is identified for the Cancer Drugs Fund in Final Guidance and a Managed Access Agreement has been agreed, the Drug will be funded by the Cancer Drugs Fund under the terms of the Managed Access Agreement from the publication of the Final Guidance.
- 6.5 If the price arrived at in the Managed Access Agreement is lower than that paid by trusts during the period of interim funding, the [Drug Company] will repay NHS England the difference as described in section 4.⁸

Drug is not recommended for routine commissioning or the Cancer Drug Fund

- 6.6 If the Drug is not recommended for routine commissioning or the Cancer Drugs Fund by NICE on publication of Final Guidance it will cease to receive routine NHS funding from any source. The Drug will cease to be made available to new patients. Any patients who have been prescribed the Drug during this interim period will continue to receive the drug at [Drug Company] cost until the prescribing physician will deem it appropriate.
- 6.7 [In these circumstances the [Drug Company] agrees to repay the cost of interim funding. [Drug Company] will reimburse the actual cost of the Drug incurred by NHS England during the period of interim funding through a rebate.]⁹
- 6.8 [If the Drug had been identified for the Cancer Drugs Fund but it does not prove possible to reach agreement on a Managed Access Agreement it will be treated as if it has not been recommended for commissioning by NICE in Final Guidance and clause 6.6 and 6.7 will apply.]¹⁰
- 6.9 If due to unforeseen circumstances Final Guidance is not published the drug will be deemed not to have been recommended for routine commissioning 12 months after the date of this agreement [at which point interim funding will cease for any new patients, although the Cancer Drug Fund budget will

⁷ Delete as appropriate

⁸ Delete 6.3 to 6.5 if drug is initially recommended for routine commissioning

⁹ Delete 6.7 if the drug is initially recommended for routine commissioning; company only required to repay the cost of interim funding if the initial recommendation is CDF.

¹⁰ Delete 6.8 if drug is initially recommended for routine commissioning

continue to meet the drug costs of patients already receiving the Drug] [and clause 6.6 and 6.7 will apply]¹¹.

7. Patient access

- 7.1 Patients who will benefit from receipt of the drug will be identified by their treating clinician.
- 7.2 A notification that a clinician intends to prescribe the Drug will be made via the online CDF notification system to the Regional Commissioning team dealing with Individual Funding Requests and the Cancer Drugs Fund.
- 7.3 All patients receiving the Drug during the period of interim funding will have data on their treatment recorded on the online CDF notification system, the High Cost Drug Minimum Data Set and the Systemic Anti-Cancer Therapies database.
- 7.4 NHSE will make reasonable endeavours to make all relevant clinicians aware that the Drug is available. This will be via Specialised Services Circulars and provider letters for regional hubs to communicate to Trusts, updates to the online CDF notification system and updates to the national Cancer Drug Fund list.

8. Application of Cancer Drugs Fund Expenditure Control Mechanism

- 8.1 All drugs receiving interim funding from the Cancer Drugs Fund will become party to the Cancer Drugs Fund Expenditure Control Mechanism. [Drug Company] agrees that this condition applies to interim funding of the Drug.
- 8.2 NHS England seeks to contain the annual cost of the Cancer Drugs Fund to the annual budget allocated by the NHS England Board. This is to be achieved through a proportional rebate from companies providing drugs into the Cancer Drug Fund for any excess expenditure over the budget.
- 8.3 The Cancer Drug Fund budget is a fixed amount agreed annually by the NHS England Board. The budget for 2016/17 has been set at £340m.
- 8.4 The costs applied to the Cancer Drug Fund budget from 29 July 2016 will include costs incurred under:
 - Cancer Drug Fund Managed Access Agreements;
 - Drug/indications in receipt of interim funding;
 - Off-label drug/indications approved for funding from the Cancer Drug Fund;
 - The administrative cost of the Cancer Drug Fund (capped at 2% of the whole budget in 2016/17)
- 8.5 In addition during the transition from the Cancer Drug Fund that operated prior to 29 July 2016 costs applied to the budget will include:
 - Individual Funding Requests approved for cancer drugs up to 1 August 2016;

¹¹ Delete as appropriate; continued CDF funding only applies if the initial recommendation is for routine commissioning.

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- Existing CDF drug/indications approved for Cancer Drug Fund funding prior to 29 July 2016 that are awaiting reconsideration or appraisal;
 - The costs of drugs removed from the Cancer Drug Fund due to previous reprioritisation exercises or due to NICE/NHS England decisions, where patients commenced treatment prior to the removal and remain on treatment;
 - The cost of the Cancer Drug Fund in the period from 1 April 2016 to 28 July 2016.
- 8.6 Contributing to the rebate is a condition of having a drug funded from the Cancer Drug Fund budget. The rebate will be recovered from all companies that provide drugs in the following categories:
- Cancer Drug Fund managed access agreements;
 - Drug/indications in receipt of interim funding;
 - Off-label drug/indications approved for funding from the Cancer Drug Fund;
 - Drugs funded through the Cancer Drug Fund in the period from 1 April 2016 to 28 July 2016 where companies have agreed that they wish that the drug/indication to continue to be funded from the Cancer Drug Fund in the period from 29 July 2016. This would include the cost of those drugs in the period between 1 April 2016 and 28 July 2016 and the period following 29 July 2016 when the drug/indication may be awaiting reappraisal or where patients are still receiving the drug following reprioritisation.
- 8.7 Full details of the Expenditure Control Mechanism will be as set out in the rules of the Cancer Drug Fund as may be varied by NHS England from time to time. Subject to those rules:
- 8.8 [Drug company] will be notified of the expected total cost of any rebate required in March of each financial year. The calculation required to arrive at this amount will be partially based upon a projection of the cost and activity in the final months of the year.
- 8.9 If a rebate is required:
- [Drug company] will be issued with an invoice based upon its proportionate share of the total rebate to be recovered in March of each financial year;
 - The total rebate to be recovered will be the amount by which the costs charged to the Cancer Drugs Fund budget in that financial year exceeded the amount of that budget;
 - The proportion used will be the cost to NHS England of [Drug company]'s drugs funded by the Cancer Drug Fund as a percentage of the cost of all drugs funded by the Cancer Drug Fund in that year. This will include the drugs covered by this Interim Funding Agreement;
 - Early in the following financial year a correction to the rebate will be issued, to take account of variations between the actual and forecast activity and spending in the final months of the prior year. This could be either a further rebate or a credit. The methodology will be the same as that described above.
- 8.10 NHS England recognise that the pharmaceutical companies will need regular intelligence on their possible exposure should a rebate be required. However

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a full disclosure of the cost of the fund and each company's possible rebate contribution would be commercially sensitive information. On a quarterly basis, commencing in 2017/18 the Cancer Drug Fund Investment Group will provide an indication of the current Cancer Drug Fund expenditure showing interim funding, new Cancer Drug Fund drugs, and transitional Cancer Drug Fund drugs. In December each year a position statement will be issued stating whether a rebate is likely to be called upon and how much this could be in total. Each company will be notified of their likely share of a possible rebate. Both the likely rebate and [Drug company]'s share will be based on the best information available at that time but the estimates will only be indicative.

- 8.11 NHS England is also aware that pharmaceutical companies will want assurance that the calculation of the rebate is done in a way that is fair and accurate. The calculation of the rebate will be reviewed by independent consultants appointed by NHS England, and a statement confirming that the calculation has been independently verified will be issued with any request for a rebate.
- 8.12 Rebates will be paid within 30 days of receipt of a demand for payment unless contested on grounds which NHS England acting in good faith agrees to be substantial. The parties will co-operate promptly and in good faith to resolve any dispute concerning the level or timing or any rebate due. Resolution of substantial disputes will be managed through the Cancer Drug Fund Investment Group.
- 8.13 Rebates shall not be subject to any right of set off.

Appendix Two - Managed Access Agreement



For illustrative purposes; agreements will be added as annexes to this document and customised for specific drugs/indications

Managed Access Agreement Cancer Drugs Fund

Commercial in confidence

Date of Agreement		
NHS England		
[Drug Company]		

1. Purpose of Agreement

- 1.1 The objectives of the document as a whole are to embody the Managed Access Agreement in respect of [the named drug] for indication [...] ("the Drug" which for the avoidance of any doubt means the use of [] for indication [] only, and no other use) and to ensure that all relevant stakeholders have a common understanding of the position.
- 1.2 The Managed Access Agreement, which consists of this document and its two appendices, sets out the points raised by the NICE in its technical appraisal, the data collection arrangements intended to answer these points, and the commercial arrangements for the Drug during the period of the Agreement. This document is to ensure that all relevant stakeholders have a common understanding of the agreement and that these measures have the support of all involved and will therefore be enforced.
- 1.3 This Managed Access Agreement has been drawn up by NHS England and [Drug Company]. It applies to the supply of the Drug by [Drug Company] to NHS bodies that supply is reimbursed by NHS England only and to no other supply. For the avoidance of doubt [Drug Company] is free to supply the Drug to other entities on such terms as it thinks fit, and NHS England is free to source the Drug from any other source lawfully able to supply it on such terms as it thinks fit.
- 1.4 For the avoidance of doubt, the parties intend this Managed Access Agreement to be legally enforceable as a contract between them.
- 1.5 A confidential Commercial Agreement containing certain terms relating to the supply of the Drug agreed between [drug company] and NHS England will be annexed to this document (annex A).
- 1.6 In addition the parties agree to observe the Standard Operating Procedures of the Cancer Drugs Fund as amended from time to time.

2. Background

- 2.1 The Drug is currently being appraised through the NICE Technology Appraisal process. The Technology Appraisal Committee has indicated that this drug is to be recommended for entry into the Cancer Drugs Fund.
- 2.2 This recommendation is conditional on a Managed Access Agreement being developed and agreed.
- 2.3 For the avoidance of doubt the parties acknowledge and agree that the recommendation referred to in paragraph 2.1 above as defined in regulation 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information centre (Functions) Regulations 2013 does not apply at this point.

3. Commencement and period of agreement

- 3.1 This Managed Access Agreement shall take effect on signature or when Final Guidance is published (whichever is later).

- 3.2 This agreement will remain in place until the publication of Final Guidance by NICE following a re-appraisal of the Drug after the Cancer Drugs Fund period. This is anticipated to be within the timeframe outlined in the Data Collection Arrangement to be found at Annex A.
- 3.3 Should this re-appraisal not occur, this Managed Access Agreement shall expire automatically on the fifth anniversary of its term.
- 3.4 This Managed Access Agreement shall terminate automatically on the termination or expiry of the commercial agreement relating to the funding of the Drug and entered into between [drug company] and NHS England.

4. Patient eligibility

- 4.1 The parties agree that prescribing decisions shall remain the responsibility of a patient's supervising clinician, who will be informed by any applicable guidance.
- 4.2 NHS England will secure that an application for funding for the Drug may be made via the online CDF notification system and will be processed by the Regional Commissioning team dealing with the Cancer Drugs Fund, applying the Cancer Drugs Fund Standard Operating Procedures as amended from time to time.
- 4.3 It is a condition of funding that all patients receiving treatment through Cancer Drugs Fund funding will have data on their treatment recorded on the online CDF notification system, the High Cost Drug Minimum Data Set and the Systemic Anti-Cancer Therapies database.
- 4.4 NHS England will make reasonable endeavours to make all relevant clinicians aware that funding for the Drug is available. This will be via circular published in the normal course of business.

5. Data collection (and monitoring)

- 5.1 The details of data to be collected are contained in the Data Collection Arrangement. The Parties will observe the terms of that document as they apply to them and will co-operate with and use reasonable endeavours to support the timely collection and use of data as envisaged in the Data Collection Arrangement. The Parties acknowledge and accept that a possible consequence of a failure to collect data as envisaged in that Data Collection Arrangement is that Final Guidance published after re-evaluation may be negative or more restricted than might otherwise have been the case, or that the re-evaluation may be terminated without publication of Final Guidance, at the discretion of NICE following its published procedures.

6. Data ownership

- 6.1 For data held by Public Health England, patients will be the sole data owners. Public Health England will be a data controller as the data constitute personal data.

7. Commercial access and funding

- 7.1 The commercial terms of this agreement are contained in the CDF Commercial Agreement at Annex A.

8. Exit strategy

- 8.1 Should the Final Guidance at Re-Appraisal result in a negative recommendation for routine commissioning, the Drug will cease being funded from the CDF on publication of Final Guidance. Any patient in receipt of the Drug will continue to receive it at [drug company]'s expense until the treating clinician will determine treatment of that patient with the Drug is no longer clinically appropriate.
- 8.2 The terms of the CDF Commercial Agreement will not be assumed to apply to the Re-evaluation of the Drug.
- 8.3 If the Final Guidance recommends the Drug for routine commissioning the Drug will receive interim funding as per any other cancer drug before entering mainstream funding. The interim funding that applies at this point will be subject to a new interim funding agreement.

9. Application of Cancer Drugs Fund Expenditure Control Mechanism

- 9.1 The parties agree that all drugs receiving funding from the Cancer Drugs Fund will become party to the Cancer Drugs Fund Expenditure Control Mechanism, and that that mechanism will therefore apply to the Drug and to [drug company]
- 9.2 NHS England seeks to contain the annual cost of the Cancer Drugs Fund to the annual budget allocated by the NHS England Board. This is to be achieved through a proportional rebate from companies providing drugs into the Cancer Drug Fund for any excess expenditure over the budget.
- 9.3 The Cancer Drug Fund budget is a fixed amount agreed annually by the NHS England Board. The budget for 2016/17 has been set at £340m.
- 9.4 The costs applied to the Cancer Drug Fund budget from 29 July 2016 will include costs incurred under:
- Cancer Drug Fund managed access agreements;
 - Drug/indications in receipt of interim funding;
 - Off-label drug/indications approved for funding from the Cancer Drug Fund;
 - The administrative cost of the Cancer Drug Fund (capped at 2% of the whole budget in 2016/17)

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- 9.5 In addition during the transition from the Cancer Drug Fund that operated prior to 29 July 2016 costs applied to the budget will include:
- Individual Funding Requests approved for cancer drugs up to 1 August 2016;
 - Existing Cancer Drug Fund drug/indications approved for Cancer Drug Fund funding prior to 29 July 2016 that are awaiting reconsideration or appraisal;
 - The costs of drugs removed from the Cancer Drug Fund due to previous reprioritisation exercises or due to NICE/NHS England decisions, where patients commenced treatment prior to the removal and remain on treatment;
 - The cost of the Cancer Drug Fund in the period from 1 April 2016 to 28 July 2016.
- 9.6 Contributing to the rebate is a condition of having a drug funded from the Cancer Drug Fund budget. The rebate will be recovered from all companies that provide drugs in the following categories:
- Cancer Drug Fund managed access agreements;
 - Drug/indications in receipt of interim funding;
 - Off-label drug/indications approved for funding from the Cancer Drug Fund
 - Drugs funded through the Cancer Drug Fund in the period from 1 April 2016 to 28 July 2016 where companies have agreed that they wish that the drug/indication to continue to be funded from the Cancer Drug Fund in the period from 29 July 2016. This would include the cost of those drugs in the period between 1 April 2016 and 28 July 2016 and the period following 29 July 2016 when the drug/indication may be awaiting reappraisal or where patients are still receiving the drug following reprioritisation.
- 9.7 Full details of the Expenditure Control Mechanism will be as set out in the rules of the Cancer Drug Fund as may be varied by NHS England from time to time. Subject to those rules:
- 9.8 [Drug company] will be notified of the expected total cost of any rebate required in March of each financial year. The calculation required to arrive at this amount will be partially based upon a projection of the cost and activity in the final months of the year.
- 9.9 If a rebate is required:
- [Drug company] will be issued with an invoice based upon its proportionate share of the total rebate to be recovered in March of each financial year;
 - The total rebate to be recovered will be the amount by which the costs charged to the Cancer Drugs Fund budget in that financial year exceeded the amount of that budget;
 - The proportion used will be the cost to NHS England of [Drug company]'s drugs funded by the Cancer Drug Fund as a percentage of the cost of all drugs funded by the Cancer Drug Fund in that year. This will include the drugs covered by this Interim Funding Agreement;
 - Early in the following financial year a correction to the rebate will be issued, to take account of variations between the actual and forecast activity and

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spending in the final months of the prior year. This could be either a further rebate or a credit. The methodology will be the same as that described above.

- 9.10 NHS England recognise that the pharmaceutical companies will need regular intelligence on their possible exposure should a rebate be required. However a full disclosure of the cost of the fund and each company's possible rebate contribution would be commercially sensitive information. On a quarterly basis, commencing in 2017/18 the Cancer Drug Fund Investment Group will provide an indication of the current Cancer Drug Fund expenditure showing interim funding, new Cancer Drug Fund drugs, and transitional Cancer Drug Fund drugs. In December each year a position statement will be issued stating whether a rebate is likely to be called upon and how much this could be in total. Each company will be notified of their likely share of a possible rebate. Both the likely rebate and [Drug company]'s share will be based on the best information available at that time but the estimates will only be indicative.
- 9.11 NHS England is also aware that pharmaceutical companies will want assurance that the calculation of the rebate is done in a way that is fair and accurate. The calculation of the rebate will be reviewed by independent consultants appointed by NHS England, and a statement confirming that the calculation has been independently verified will be issued with any request for a rebate.
- 9.12 Rebates will be paid within 30 days of receipt of a demand for payment unless contested on grounds which NHS England acting in good faith agrees to be substantial. The parties will co-operate promptly and in good faith to resolve any dispute concerning the level or timing or any rebate due. Resolution of substantial disputes will be managed through the Cancer Drug Fund Investment Group.
- 9.13 Rebates shall not be subject to any right of set off.

10 Counterparts

- 10.1 This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute a duplicate original, but all the counterparts together shall constitute one agreement.
- 10.2 Transmission of the executed signature page of a counterpart of this Agreement by email (in PDF, JPEG or other agreed format) shall take effect as delivery of an executed counterpart of this Agreement unless the email is returned as undeliverable. If this method of delivery is adopted, without prejudice to the validity of the agreement thus made, each Party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter.
- 10.3 No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

11 Interpretation and miscellaneous clauses

11.1 In this Agreement the following terms have the following meanings:

CDF Commercial Agreement	Annex A to this document
Data Collection Agreement	To be attached as an annex to this document
Drug	[drug name] for indication [indication] " which for the avoidance of any doubt means the use of [] for indication [] only, and no other use).
Final Guidance	Guidance formally issued by the National Institute for Health and Care Excellence following the completion of a health technology appraisal
Parties	the parties to this agreement
Re-Evaluation	a health technology appraisal undertaken by the National Institute for Health and Care Excellence after the date of this Agreement

11.2 Neither party shall be liable to the other under this Agreement for any indirect or consequential loss howsoever arising.

11.3 This Agreement creates rights only for the Parties. It may not be enforced by any third party.

Annex A – CDF Commercial Agreement

CDFCA information for modelling		
Drug information		
	Drug	
Manufacturer		
Drug name [INN, Brand]		
Indications evaluated for CDF		
Line of treatment		
Other indications		
Drug delivery		
	Drug	Comparator
Main treatment setting (hospital, homecare, non-NHS organisation, community pharmacist)		
Other treatment setting: []		
Target population		
	Drug	Comparator
Prevalent population within CDF indications		
Expected number of patients - year 1*		
Expected number of patients - year 2*		
Patient number indicated in DCA to answer uncertainty		
* Financial years from April 1 to March 31		
Effectiveness		
	Drug	Comparator
QALY gain (from company)		
QALY gain (from ERG)		
QALY gain (from the TA Committee)		
Costs		
	Drug	Comparator
Mg per pack		
Average mg per dose		
Doses per cycle		
Cycle length		
Mean number of cycles per year		
Mean duration of treatment		
Median number of cycles per year		
Median duration of treatment		
List price / without CDFCA		
Acquisition cost (list price) per pack		
Estimated cost per dose (after wastage)		
Estimated cost per cycle		
% patients completing treatment		
Estimated cost of drug per patient per year		
Other direct costs		
Other indirect costs		
Estimated cost of treatment per patient per year		
Price including CDFCA		
Acquisition cost per pack		
Estimated cost per dose (after wastage)		
Estimated cost per cycle		
% patients completing treatment		
Estimated cost of drug per patient per year		
Other direct costs		
Other indirect costs		
Estimated cost of treatment per patient per year		
ICER		
	Drug	Comparator
ICER (from company)		
ICER (from ERG)		
ICER (from TA Committee)		
ICER with CDFCA		
Budget Impact		
	Drug	Comparator
Budget impact without CDFCA - year 1*		
Budget impact without CDFCA - year 2*		
Budget impact without CDFCA - Total		
Budget impact with CDFCA - year 1*		
Budget impact with CDFCA - year 2*		
Budget impact with CDFCA - Total		
* Financial years from April 1 to March 31		

Description of the CDFCA

Flowchart to illustrate the operational requirements and information flow

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
CENTRE FOR HEALTH TECHNOLOGY EVALUATION
Technology Appraisals Programme
Specification for Cancer Drugs Fund data collection arrangements**

1 Introduction

1.1 A cancer drug can be formally identified for entry into the Cancer Drugs Fund (CDF) at several time points during a technology appraisal:

- The first time point is when the company sends its evidence submission to NICE for a technology appraisal, and includes a proposal for data collection in this submission, covering details set out below. Identification of potential candidates for the CDF at this time point allows NICE and NHS England time to develop the potential data collection arrangements before the appraisal committee meeting;
- A second time point is during the assessment phase, at which time NICE may indicate that a drug could be a CDF candidate;
- The last time point is at the first appraisal committee meeting when the committee identifies that a drug is a CDF candidate;

In exceptional circumstances, it is possible that entry into the CDF could be formally identified at other time points (for example, after an appeal). Companies may also informally signal to NICE early in the process that a treatment is a potential CDF candidate (for example, during scoping).

2 Possible data collection sources

2.1 There are two main options for collecting further data in the context of the CDF. Both options are potentially complementary to each other. These options are:

- [Systemic Anti-cancer Therapy](#) (SACT) dataset collection, which is mandated by NHS England as part of the Health and Social Care Information Standards and collated by Public Health England. The specific information on SACT can be integrated with other relevant forms of data collection operated by the National Cancer Registration and Analysis Service at Public Health England, including the Cancer

Outcomes and Services Dataset and the Radiotherapy dataset, as well as be linked to other databases such as the Hospital Episodes Statistics (see section 5 for further details);

- Clinical studies:
 - Ongoing studies (for example, further follow-up of Phase II and III trials, or Phase IV or pharmacovigilance studies);
 - Setting up a new study/ data collection.

Theoretically, other established tumour registries could be used as data sources.

The specific arrangements and steps to be taken may differ for each of these options and they are outlined in the subsequent sections of this document.

2.2 Collecting outcome data on an intervention and relevant comparators (if appropriate) in NHS England patients via the available data sources in the National Cancer Registration and Analysis Service at Public Health England, including SACT, will always occur even if other data sources are also used for the CDF data collection. All hospitals providing systemic anti-cancer therapy services are contracted within the NHS Standard Contract to submit key data to SACT.

2.3 SACT is strongly preferred for any data collection of routine chemotherapy practice in England, because the existing infrastructure (including data protection and information governance) is already established, data are already being collected and progress can easily be monitored. Further details are provided in section 5 below.

3 Committee considerations

3.1 The appraisal committee will use published methods to determine whether a drug should enter the CDF (see [Guide to the processes of technology appraisal](#) and its [addendum](#)). When considering whether a drug is a suitable candidate, the appraisal committee will define and describe the specific area(s) of clinical uncertainty. It will make

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judgements about the feasibility of new CDF data collection (either as the sole data source for addressing the key issues of uncertainty or to complement other data sources):

- This includes establishing the minimum timeframe for providing meaningful data, the duration of which will be determined on a case by case basis. The time frame will be as short as possible, normally up to 2 years, but could be longer depending on the issues of uncertainty, the rarity of the cancer and whether the CDF data collection will be the sole source of data to address the issues of uncertainty;
- The expected population size and treatment duration will be considered using data on current relevant drug use and epidemiology of the disease in England. The appraisal committee will receive advice from the company, NHS England and Public Health England on the nature of the data already being collected through existing studies or routine population-based datasets.

3.2 The committee will consider the ethical issues raised by the Citizens Council report [Using anonymised data derived from personal care records](#), including confidentiality, privacy and data security, transparency, the public benefit of research and good scientific practice.

3.3 When the committee decides that a drug should enter the CDF, it agrees the content of either the final appraisal determination (FAD), which sets out its final recommendations, or the appraisal consultation document (ACD), which sets out its preliminary recommendations.

- If the committee's decision to enter a drug into the CDF does not require a consultation, a FAD will be issued. This can occur when the recommendation for use within the CDF is in line with the marketing authorisation or the company's proposed use and the data collection arrangements have been agreed in principle by all parties before the committee meeting. The appraisal committee chair will approve the details of the data collection arrangements before the FAD is released for consideration of appeal.

- If the committee's decision to enter a drug into the CDF does require a consultation, an ACD will be issued (see sections 3.7.26 and 3.7.27 of the [addendum](#) to the Guide to the processes of technology appraisal). The committee will then review the data collection arrangements at its subsequent meeting in light of all comments received on the ACD.

4 Steps for data collection arrangements

4.1 After the committee has specified the key clinical uncertainties that need to be addressed through data collection to inform guidance review, a data collection arrangement (DCA) working group is formed. This has representation from NICE, the appraisal committee (normally the chair or vice-chair) and the NHS England CDF clinical lead:

- When the committee has been presented with the company's data collection proposal as part of the evidence submission and agreed this in principle, the DCA group will review the data collection proposal, with independent academic input, and provide commentary to the appraisal committee;
- When it is the committee that has identified the drug as a potential CDF candidate, the DCA working group will, with independent academic input, translate the committee's key uncertainties related to clinical outcomes into a defined data collection question. This specification might include using results from studies or data sources already in progress plus Public Health England data including SACT data, or by Public Health England data including SACT data collection alone, or by new studies plus Public Health England data including SACT data collection. Public Health England will be involved when the data collection is through Public Health England data sources, and the company will be involved when data collection is from company-run clinical trials.

4.2 The population of patients to be treated, the numbers of patients needed for robust analysis in the data collection, comparators (where appropriate), the key outcomes to address the appraisal committee's

issues of uncertainty (which will subsequently be used in economic modelling in the appraisal review after the CDF), analysis plan and the timeframe for the studies and/or Public Health England data, including SACT data, will be identified by the DCA working group. Relevant stakeholders, including the company, and clinical and patient experts present at the appraisal committee meeting, will be asked to comment.

4.3 The governance arrangements for the analysis or evaluation will be defined and form part of the formal data collection arrangement. It will include information governance and data protection as well as the requirement for research ethics approval. Key governance points that will be documented include:

- Identification of data controllers and processors;
- Details of patient consent (or specify the circumstances where it is not considered necessary);
- Accountability for protocol;
- Accountability for analysis plans;
- Accountability for data collection platform (database issues);
- Accountability for monitoring and validation;
- Procedures for access to data;
- Data ownership and authorship of any publications;
- Accountability for disseminating results;
- Caldicott Guardian agreement.

These details need to be finalised before the managed access agreement, including the data collection arrangement, is approved by the CDF investment group.

5 Data collection via established registries

A. Public Health England data sources, including SACT

5.1 Data collection via Public Health England data sources, including SACT will always accompany any other data sources. The Public Health England data outcome collection could be the sole source of outcome

data. The SACT data collection process is the preferred option for data collection in the CDF for five main reasons:

- SACT dataset is a mandated dataset as part of the Health and Social Care Information Standards. This is listed as a Schedule 6 national information requirement within the NHS Standard Contract;
- SACT collects data on all systemic treatments (including previous and subsequent therapies);
- The SACT dataset is part of a wider cancer data collection landscape at Public Health England, aiming to provide a complete picture of a cancer patient's pathway from diagnosis through linkage (see section 5.2);
- All necessary governance arrangements through SACT – and other datasets brought together by Public Health England - have been established with trusts and SACT data submission by trusts has been mandatory since April 2014;
- SACT already has experience both in data liaison with trusts and with analysis of NHS outcome data.

5.2 Public Health England's National Cancer Registration and Analysis Service brings together data from more than 500 local and regional data feeds to build an understanding of an individual's treatment from diagnosis. This includes information drawn from histopathology reports, multidisciplinary team meeting decisions, radiotherapy and systemic anti-cancer treatment data (through the SACT database), administrative details such as route of admission and access to imaging information to enable accurate cancer staging. The data can also be linked to other data sets including the Diagnostic Imaging Dataset (DID), Hospital Episode Statistics (HES) and Cancer Waiting Times (CWT).

5.3 The SACT database collects information reported routinely by NHS trusts in England, on the treatment of malignant disease in four key areas:

- Patient and tumour characteristics;
- Trust and consultant details;

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- Treatment characteristics including drug names and drug combinations (regimens);
- 'Outcome' fields.

The full data standard and data dictionary are available [online](#).

5.4 When it has been decided that Public Health England's National Cancer Registration and Analysis Service data are to be used, Public Health England will deliver agreed analyses to support CDF evaluation as part of a wider commissioning agreement with NHS England.

5.5 If a drug has a draft recommendation to enter into the CDF after the NICE first appraisal committee, the DCA working group (see section 4.1) will confirm that the uncertainty identified by the appraisal committee could be answered through the data currently collected through SACT.

If so, the DCA working group will define:

- the data collection question, specifying the required data field(s) whilst in the CDF;
- the data analyses to be provided after the data collection, which will be used when the guidance is reviewed;
- the comparator, if relevant and appropriate, and how to construct analyses when there is little effectiveness data for the comparator;
- the estimated number of patients needed to answer the uncertainty and the specific patient eligibility criteria to match those of the population on which NICE has based its CDF recommendation;
- the timeline for the data collection based on the number of patients needed to answer the data collection question matched against the expected drug uptake and duration of treatment;
- the frequency of analysis updates to check the continuing validity of the timeline;

Based on the areas of uncertainty commonly identified in NICE technology appraisals of cancer drugs, existing Public Health England data sets are expected to be able to cover the vast majority of DCA requirements.

However, if the current data fields in Public Health England's datasets are not sufficient to answer the uncertainty, Public Health England has the mechanisms and governance infrastructure in place to collect agreed additional data items deemed feasible within the CDF DCA agreement timeframe.

The terms and conditions of the DCA for any Public Health England data collection will be shared with the company before the second appraisal committee for their review and comments.

Governance of evaluation conduct and data access

- 5.6 Individual patient data will remain within Public Health England premises and there will not be any data sharing of individual patient data outside of Public Health England. Public Health England will be responsible for analysing the data, publishing the methodology used and sharing the results of the data analyses with NICE and NHS England who will then be responsible for sharing them with the company and other relevant stakeholders if necessary. Where Public Health England leads on analyses using established databases within Public Health England, it is anticipated that no further requirements will need to be put in place. However, this will be reviewed on a case-by-case basis and the necessary arrangements made as applicable and appropriate.

Data ownership

- 5.7 For data held by Public Health England, patients will be the sole data owners. Public Health England will be a data controller as the data constitute personal data.

Accountability for analysis plans

- 5.8 The DCA working group will prepare an analysis plan and timescales that will include interim reporting milestones (e.g. on data quality or accruals). The company should alert NICE if it intends to specify any outcomes not routinely included in Public Health England datasets.

- 5.9 Public Health England will share the full methodology of the analysis and any assumptions with NICE and NHS England, which will then be shared with the company.

Accountability for data collection platform (database)

- 5.10 The accountability for the online data collection platform for Public Health England managed data collections (particularly the SACT portal) lies with Public Health England.

Accountability for monitoring and validation

- 5.11 The accountability for monitoring and validating SACT data in particular submitted to the SACT portal by NHS trusts lies with Public Health England. Updates on patient numbers, completeness and quality of the data, and analysis reporting should be provided at intervals agreed for each appraisal.

Accountability for disseminating results

- 5.12 NICE will publish key evidence and the committee's decision through an ACD or FAD when the original guidance is reviewed at the end of the CDF period. Any Public Health England-led analyses using available data within Public Health England will be part of the committee papers. After the first committee meeting for the guidance review, a FAD will be produced if the drug is recommended for routine commissioning in line with the original conditions for use in the CDF. In all other circumstances, an ACD will be produced.

B. Other registries

- 5.13 Other data collection sources outside Public Health England could potentially be used if the company is able to show that this would be feasible (for example, that any information governance issues could be overcome within the limited data collection timeframe). The company's proposal should include the areas listed in sections 5.5–5.12.

6 Data collection via clinical trials

C. Ongoing studies

- 6.1 Data collection via ongoing clinical studies is another useful source for the CDF. It can be assumed that the protocol (including analysis plans), governance arrangements and data ownership have already been established by the company, MHRA or academic group sponsoring the study. This would potentially enable the immediate start of data collection (depending on additional ethics approval for the use of the data in the CDF).

D. New study

- 6.2 Data collection can also be undertaken through a newly designed study but timelines would need careful consideration in light of the time-limited nature of managed access agreements within the CDF. The study can be established by the company or other organisation. If the latter, the study sponsor¹² will need to provide details to NICE on the points below.

E. Study protocol

- 6.3 The company or study sponsor should submit the study protocol at the earliest possible stage to NICE which should include details on:
- Monitoring and validation of data collection;
 - Planned analyses, including primary endpoints and any subgroup analysis;
 - Data ownership (see below on access to data);
 - Planned dissemination of data.

¹² As defined by the NHS Health Research Authority: "The sponsor is the individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

F. Research governance

6.4 The study sponsor must submit confirmation to NICE that there are appropriate arrangements in place for the following aspects of research governance:

- Ethical approval, including patient information and consent procedures;
- If using NHS data collection sites, NHS Research and Development (R&D) management review at each site;
- Information governance, including data sharing arrangements.

If any of these procedures require modification in view of the use of data as part of CDF, the study sponsor is responsible for receiving the necessary approvals and submitting them to NICE.

G. Access to data

6.5 To ensure that the appraisal process is as transparent as possible, NICE considers it essential that key evidence on which the appraisal committee's decisions are based is publicly available. For details of NICE's approach to information handling during an appraisal, see section 3 of the [Guide to the processes of technology appraisal](#). The principles outlined in the guidance on [implementing the European Medicines Agency's policy](#) on publishing clinical data should also be taken into account.

6.6 When the guidance is reviewed after data collection has been completed, information marked as confidential should be kept to an absolute minimum in the company submission. Unpublished data should be made available for public disclosure where possible; this will include any analyses by Public Health England. Data that underpin and are included in the economic analyses informing the guidance review should be made available.

7 Timing of data collection arrangements

7.1 For any cancer drug appraisal, NICE will proactively schedule CDF-related meetings of the DCA working group to begin shortly after the first

appraisal committee meeting as part of the appraisal-specific timelines. Should a cancer drug be recommended for routine commissioning or not recommended at the first appraisal committee meeting, these CDF-specific meetings will be cancelled.

- 7.2 When the appraisal committee decides that a drug enters the CDF, it will specify the uncertainty and indicate the general nature of the data that need to be collected. For data collection via established registries where the company has provided a CDF proposal with its evidence submission, the DCA working group will review and confirm that the arrangements in the proposal are fit for purpose. For data collection via established registries where the company hasn't provided a CDF proposal with its evidence submission, the DCA working group will develop the data collection question(s) and outline the analyses that are needed, as well as the duration of data collection (see section 4.2). For data collection via clinical trials, the duration will depend on the expected reporting date.
- 7.3 During the data collection period, NICE will schedule the committee meetings required for the respective CDF guidance review, to ensure as timely review of guidance as possible (for further details, see section 6 of the [addendum](#) to the Guide to the processes of technology appraisal).

Overview: Procedural steps for CDF data collection arrangements

Draft data collection agreement in place before first committee meeting

Week	Action
0	<ul style="list-style-type: none"> Appraisal committee recommends that a cancer drug should enter the CDF after reviewing a draft data collection proposal developed before the first committee meeting
3	<ul style="list-style-type: none"> Where applicable, the DCA working group (including NICE, the appraisal committee chair or vice-chair and the NHS England CDF clinical lead) confirms the research question, including the population, comparator(s), outcomes and necessary analyses Comments are requested from the company and clinical patients experts Where applicable, NICE liaises with Public Health England to ascertain the availability and feasibility of data collection Where applicable, ACD issued to consultee and commentators then published on the NICE website 5 working days later
5	<ul style="list-style-type: none"> Where an ACD is not produced because the committee is fully satisfied with the company's draft data collection agreement, FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later
7	<ul style="list-style-type: none"> In response to consultation on the ACD, amendments to the draft data collection arrangements are made for consideration by the committee
8/9	<ul style="list-style-type: none"> After consultation, appraisal committee content with data collection arrangements If through 2nd committee meeting: FAD with yes in CDF
10	<ul style="list-style-type: none"> If ACD was issued, data collection arrangements amended in line with committee's preferences expressed at the second committee meeting
11	<ul style="list-style-type: none"> Data collection arrangements finalised¹
14	<ul style="list-style-type: none"> Where an ACD has previously been produced, FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later.
¹ CDF investment control group signs off the data collection arrangements as part of the managed access agreement. Exact timings for this step may vary	

**No draft data collection agreement proposed before first committee meeting:
committee proposes inclusion in the CDF**

Week	Action
0	<ul style="list-style-type: none"> • Appraisal committee considers the treatment has potential to be a CDF candidate. • Committee requests the company prepares a data collection proposal for inclusion in the CDF
2	<ul style="list-style-type: none"> • The DCA working group (including NICE, the appraisal committee chair or vice-chair and the NHS England CDF clinical lead) defines the research question, including the population, comparator(s), outcomes and necessary analyses • Comments on the data collection proposals are requested from the company and clinical patients experts
3	<ul style="list-style-type: none"> • DCA working group agrees the most appropriate source for data collection • Where applicable, NICE liaises with Public Health England to ascertain the availability and feasibility of data • ACD issued to consultee and commentators (published on the NICE website 5 working days later)
5	<ul style="list-style-type: none"> • Company drafts data collection arrangements as appropriate for the respective source for data
7	<ul style="list-style-type: none"> • Draft data collection arrangements prepared for committee meeting/ agreement/ comment
8/9	<ul style="list-style-type: none"> • After consultation, appraisal committee content with data collection arrangements and instructs NICE to prepare a FAD for the treatment to be recommended in the CDF
10	<ul style="list-style-type: none"> • Draft data collection arrangements amended in line with committee agreement

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11	<ul style="list-style-type: none"> Data collection arrangements finalised¹
14	<ul style="list-style-type: none"> FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later.
¹ CDF investment control group signs off the data collection arrangements as part of the managed access agreement. Exact timings for this step may vary	

No draft data collection agreement proposed before first committee meeting and not recommended in ACD, but subsequent proposal for entry to the CDF is received

Week	Action
0	<ul style="list-style-type: none"> Appraisal committee does not recommend a cancer drug where there is clinical uncertainty because it does not meet other CDF decision-making criteria (for example, the drug does not show plausible potential for cost effectiveness at its current price).
3	<ul style="list-style-type: none"> ACD issued to consultee and commentators (published on the NICE website 5 working days later)
5	<ul style="list-style-type: none"> Company request permission from NICE to submit additional evidence on the form of a CDF proposal Company drafts data collection arrangements as appropriate for the respective source for data
6/7	<ul style="list-style-type: none"> Company submits in its consultation response a draft CDF data collection proposal plus, where relevant, any financial components of a managed access agreement
7	<ul style="list-style-type: none"> Draft data collection arrangements prepared for committee meeting/ agreement/ comment
8/9	<ul style="list-style-type: none"> Appraisal committee content with data collection arrangements and instructs NICE to prepare a FAD for the treatment to be recommended in the CDF Note a third committee meeting may be required if the committee is not fully satisfied by the company's proposal

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10	<ul style="list-style-type: none">• Draft data collection arrangements amended
11	<ul style="list-style-type: none">• Data collection arrangements finalised¹
14	<ul style="list-style-type: none">• FAD issued to consultee and commentators for appeal and published on the NICE website 5 working days later.
¹ CDF investment control group signs off the data collection arrangements as part of the managed access agreement. Exact timings for this step may vary	