NHS England

Standard Operating Procedures: The Cancer Drugs Fund (CDF)

Guidance to support operation of the CDF in 2014-15

DRAFT FOR CONSULTATION

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Contents

Plain Language Summary

The Cancer Drugs Fund (CDF) is managed by NHS England as part of the Prescribed Services Single Operating Model.

This document provides guidance to support the operation of the CDF in 2014-15, building on previous Department of Health Guidance, amended to reflect the new NHS England structures and responsibilities.

It also outlines single nationally consistent Standard Operating Procedures for the management of the CDF which will be managed on a regional footprint by four of the Area Teams responsible for commissioning of Prescribed Services.

The CDF applies to patients eligible for NHS services in England only.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Regard has also been had to the need to reduce health inequalities and to other matters referred to in the National Health Service Act 2006

Section A – INTRODUCTION

1. Purpose of this document

1.1 The purpose of this document is to provide guidance to the NHS on the operation of the Cancer Drugs Fund (CDF) in 2014-15. It updates and replaces the previous guidance to the NHS, "Standard Operating Procedures: The Cancer Drugs Fund 2013-14. Reference: NHS ENGLAND NHSCB/SOP04", updated in November 2013 by NHS England. This guidance has been developed by NHS England in collaboration with NHS colleagues.

1.2 Operational management of the CDF is the responsibility of NHS England. The principles underpinning the CDF are listed below. Since 1 April 2013 the CDF has been operationally managed by NHS England as part of the Prescribed Services Single Operating Model. This document outlines single nationally consistent Standard Operating Procedures for the delivery of the CDF.

1.3 The operating model for the CDF has the following features:

- single national allocation of funding
- single national list of approved drugs based on cohort policies, developed and regularly updated by the Clinical Reference Group for Chemotherapy
- Individual Patient Applications for drugs outside the cohort policies to be decided by regional clinically-led expert panels
- national clinical audit of outcomes for patients whose treatments have been funded by the CDF.

1.4 This guidance on the operation of the CDF is intended primarily for NHS England Area Teams responsible for the operational management of the CDF, the regional clinically-led CDF panels, the Clinical Reference Group (CRG) for Chemotherapy, the 12 Strategic Clinical Networks, NHS England Cancer and Blood Programme of Care, provider trusts, specialist clinicians, patient groups and patients.

1.5 'Cancer Drugs Fund 2014-15: Guidance for clinicians' and 'Cancer Drugs Fund 2014-15: Information for patients' are attached as Appendices A and B respectively.

1.6 This document builds on:

- experience since October 2010 of operating the regional arrangements for providing additional cancer drugs
- the guidance issued to support operation of the CDF in 2011-12, 2012-13, and 2013-14

- feedback to the Department of Health as a result of consultation between 27 October 2010 and 19 January 2011 on the proposals for the future arrangements for the CDF.
- experience since April 2013 of operating the national arrangements for providing additional cancer drugs

- changes to the operation of the CDF consulted on in October 2014 which includes a revised clinical prioritisation tool and re-evaluation process of CDF drugs. This re-evaluation process incorporates the assessment of both clinical benefit and the drug cost per patient into the CDF decision making process as to whether drugs should be or continue to be funded by the CDF or not.

1.7 Guidance and operational procedures will be kept under review and updated as appropriate.

2. Context

Background to the CDF

2.1 *The Coalition: our programme for government*[1] confirmed the Government's commitment to the establishment of a CDF from April 2011:

> "We will create a Cancer Drugs Fund to enable patients to access the cancer drugs their doctors think will help them"

This was reaffirmed in the White Paper, *Equity and Excellence – Liberating the NHS*.[2]

2.2 The CDF provides a means of improving patient access to cancer drugs and will be in place until March 2016.

2.3 A consultation on the Government's proposals for the establishment of the CDF took place between October 2010 and January 2011.[3] The key objectives for the CDF, as outlined in the consultation, were that it should:

- provide maximum support to NHS patients
- put clinicians and cancer specialists at the heart of decision-making, consistent with the Government's wider policy of empowering health professionals and enabling them to use their professional judgement about what is right for patients
- act as an effective bridge to the Government's aim of introducing a value-

[1] The Coalition: our programme for government, May 2010
[2] Equity and excellence – Liberating the NHS, July 2010
[3] The Cancer Drugs Fund – a consultation, 27 October 2010, Gateway reference 14909

based pricing system for branded drugs**.**

Funding for 2014-16

2.4 £560 million is being made available in the financial years 2014-16 for the CDF and NHS England will plan on this basis.

2.5 The total available funding of £560 million in 2014-16 is available to the NHS only for the purposes of the CDF.

2.6 NHS England is accountable for the management of the CDF.

2.7 Since April 2013, the CDF has been a single fund for patients in England. NHS England is accountable for the CDF. Four of the ten NHS England Area Teams also take a lead in the operational management of the CDF. These will be based in the following Area Team offices:

- North of England:
  NHS England Area Team Cumbria, Northumberland, Tyne & Wear
- Midlands and East:
  NHS England Area Team Leicestershire and Lincolnshire
- South of England:
  NHS England Area Team Wessex
- London:
  NHS England Area Team London

2.8 NHS England Area Teams responsible for the CDF in their region are enabled to deliver the operational responsibilities of the CDF and to coordinate the work of the regional clinically-led panels. The four Area Teams work with the CDF panel chairs to drive and retain local clinical engagement across the wider geographical area.

2.9 To assist with monitoring usage of the CDF, nominal regional allocation of the annual budget will be calculated using historic usage data for the providers in each region. In-year assessment of demand against the allocation will be made and funding adjusted between regions where appropriate.

Links to existing processes

2.10 NHS England policies set out clearly how the CDF and other national, cancer drug funding arrangements interrelate. Patients and their clinicians will be supported in seeking funding through the most appropriate mechanism. See Appendices A and B for guidance for clinicians and for patients.

2.11 As set out in the NHS Constitution, patients have a right to expect decisions on funding of drugs and treatments to be made rationally following a proper consideration of the evidence.

2.12 Treating clinicians, working with local NHS managers, should fully explore all reasonable commissioning avenues for securing NHS funding before using the CDF. In these situations, clinicians should consider:

- whether the National Institute for Health and Care Excellence (NICE) has issued a positive Technology Appraisal for the treatment of the relevant indication. If so, such treatment will be made available on the NHS in line with NICE recommendations
- whether NHS England has an agreed chemotherapy algorithm applicable to the specific condition. This should be reviewed to clarify the regimen options that are commissioned routinely by NHS England.
- whether NHS England has a current policy and/or commissioning arrangement to routinely fund the treatment

If such NHS arrangements to fund the treatment are in place, it will be made available on the NHS and not through the CDF.

2.13 The provision of chemotherapy is an NHS England Prescribed Service. Therefore, requests for the funding of cancer drugs should not be made through the Clinical Commissioning Group Individual Funding Request (IFR) route.

2.14 The CDF is for additional drugs/indications that would not otherwise be funded by the NHS. In these circumstances, clinicians should consider the options for application to the CDF as described in this document.

Section B – PRINCIPLES AND SCOPE OF THE CDF

3. Principles underpinning the CDF

3. 1 The following are the principles determining the release of CDF funding:

- The CDF applies to patients ordinarily resident in England; or otherwise the commissioning responsibility of the NHS in England (as defined in "Who Pays?: Establishing the responsible commissioner" and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges)

- Patients of all ages are eligible for CDF funding. As such, drug treatments in the national CDF Cohort Policy List should be considered to be approved for use in the same indication in paediatric patients treated under the supervision of a paediatric oncologist or haematologist. It should be recognised that this use in paediatric patients will often not be a licensed use and therefore that this use should be within the treating Trust's governance framework.

- In line with the arrangements for the commissioning of Prescribed Services under NHS England from 1 April 2013, the operational responsibility for CDF requests is determined by the geography of the provider of treatment, rather than the patient's GP.

- Decisions on the funding of a cancer drug to meet the healthcare needs of groups of patients must always take account of the resources available within the CDF.

- The CDF is intended to pay for the procurement of medicines (including VAT where applicable). NHS England is expected to meet the associated service costs related to delivery of medicines.

- Drugs will only be reimbursed at the actual net cost of the drug (including VAT rebates etc.) i.e. there will be no add-on costs allowed for drugs funded through this process.

- CDF funding is effectively a pass through payment just like for other high cost drugs, and is not therefore eligible for Commissioning for Quality and Innovation (CQUIN) payments.

- Molecular diagnostic testing, which is necessary to help optimally target the use of drugs to patients who are most likely to benefit, is funded through routine commissioning arrangements. However, in exceptional circumstances, the CDF may be used to fund these tests where it is deemed appropriate to provide funding outside existing mechanisms. Therefore the management arrangements for the introduction of molecular tests for a cohort of patients potentially eligible for the specific

targeted drug could be considered for CDF funding following discussion with the key stakeholders, including the relevant pharmaceutical company. In such circumstances, the costs will be picked up by the CDF, including the costs of "negative" tests.

- Many of the drugs on the CDF cohort policy list will be going or have gone through a National Institute for Health and Care Excellence (NICE) appraisal and may come to NICE with a discount via a Patient Access Scheme (PAS). It is expected that manufacturers of drugs offering a PAS in the context of a NICE appraisal (whenever this occurs in the NICE appraisal process) will automatically offer the same PAS to the CDF with immediate effect. If this does not occur the panel will not consider the drug for addition to, or will remove the drug from, the cohort policy list.

- NHS England will manage the CDF within its available annual budget. The CDF will have an assessment process of evaluating clinical benefit in relation to drug cost. It will use this evaluative process to bring in new and more effective treatments but also remove drugs from the CDF which offer least clinical benefit and least value for money in order to stay within its budget.

- Retrospective funding will not be available for the cost of drug treatments provided prior to the decision to fund that drug treatment for that patient or cohort of patients under the CDF.

- Decisions on access to drug treatments via "compassionate use"/ "early access" programmes will generally not be expected to be made by NHS England until a price and therefore potential budget impact is known. Trusts agree to these programmes at their own risk and in the knowledge that the CDF and/or NHS England will not pick up any costs for drugs in these programmes until a CDF cohort policy or NICE Technology Appraisal Guidance is published that approves use of the drug. No retrospective funding will be provided.

- The CDF will not be used to support the use of drugs that are not licensed for any indication by the European Medicines Agency (EMA). The EMA process assesses the safety and quality of the product and NHS England cannot replace this process.

- It is in patients' interests that the CDF operates effectively and that it contributes to clinical audit, both regionally and nationally. NHS England may use up to 1% of the CDF on outcomes audit and management costs but this will need to be managed within this cost limit. It is not expected that the costs for administrative support to the CDF be diverted to a provider level.

- It cannot be assumed, if CDF funding is in place for a drug treatment which subsequently becomes the standard treatment in an arm of a new

trial, that CDF funding for that treatment will be in place for the lifetime of that trial. Therefore the CDF can only be used to fund drugs as part of a clinical trial where ALL of the following criteria are met:

- the drug being funded by the CDF is in at least the standard treatment arm of the trial
- the trial criteria for use of the drug matches the CDF criteria exactly
- there is an explicit written agreement from the trial sponsor that recognises that if the drug is deprioritised from the CDF cohort policy list there will no longer be CDF or NHS England funding available for new patients recruited to the trial to receive the drug. In the case of commercial studies the sponsor should be clear whether they would support the drug costs in new patients were the drug to be deprioritised.

4. Scope of the CDF

4.1 With the exception of individual funding requests access to the CDF will be based primarily on ranking of the drug treatment versus others based on the strength and quality of the evidence of clinical effectiveness combined with an assessment of drug cost (the median drug cost per patient). For the avoidance of doubt this assessment of cost looks at direct drug cost only. It does not take into account the costs of or any savings made in associated service delivery. Assessment of the degree of clinical benefit will be undertaken using the National Cancer Drug Fund Scoring Tool (which assesses clinical benefit) in conjunction with a scoring system which assesses median drug cost per patient at the price set by and offered by the manufacturer to the CDF and scores that cost against bands set by the CDF.

4.2 Formal estimates of overall cost-effectiveness (as opposed to the scoring of clinical benefit and the scoring of cost referred to in paragraph 4.1 above) will not be considered as a standard part of the decision making process. Where ranking scores of clinical benefit in combination with the score of median drug cost per patient do not differentiate between different therapies, overall cost effectiveness may be considered using independently calculated QALYs from the National Institute for Health and Care Excellence (NICE), if available.

4.3 The CDF is a limited fund and so consideration of affordability is important in order to derive the maximum benefit for the population within the budget, as well as supporting innovation and ensuring that exhaustion of funds does not mean that applications on behalf of new patients for approved indications cannot be supported. Affordability is taken into account by setting the scoring threshold for drugs/indications (see below) at such a level that predicted demand for approved drugs should be within the CDF total budget.

4.4 The CDF will be used to fund cancer medicines, including radiopharmaceuticals conjugated with drugs, for patients who have been unable to access a drug recommended by their consultant cancer specialist (Oncologist, Haemato-oncologist or Paediatric Oncologist) via normal NHS funding routes. The CDF will not be used to fund interventional procedures or

medical devices used in the treatment of cancer.

4.5 Funding will only be considered for cancer drugs that meet one or more of the following criteria. That they are:

- drug/indication (alone or within a treatment combination) appraised by NICE and not recommended on the basis of insufficient overall cost effectiveness, or where the recommendations materially restrict access to the treatment to a smaller group of patients than the specifications set out in the marketing authorisation (an 'optimised' recommendation)
- drug/indication (alone or within a treatment combination) on which NICE has not, or not yet, issued appraisal guidance or the guidance has not yet been implemented for routine funding
- drug/indication (alone or within a treatment combination) which NICE is not going to consider
- drug/indication (alone or within a treatment combination) that has not been prioritised through the NHS England Cancer Drugs Prioritisation Process and therefore have not received routine commissioning support for the required indication

4.6 NHS England recognises the importance of clinical trials. As such patients should be considered for entry into clinical trials before an application is made to the CDF. In all cases patients have the choice of whether they are entered into the trial.

4.7 Drugs that have not been supported by NICE due to non-submission of data by the pharmaceutical company for the indication in question will not be eligible for consideration under the CDF process. This is to avoid a potential pathway for circumventing the NICE process.

4.8 The Cancer and Blood Programme of Care (PoC) Board as advised by the CRG for Chemotherapy is responsible for determining what is within the scope of the CDF. The national list of agreed CDF drugs (see section 5) will be agreed by the CRG for Chemotherapy and formally reported to the Medical Directorate of NHS England through the Cancer & Blood PoC Board.

4.9 These clinically-led groups will take a sufficiently broad view of 'cancer' in determining the drugs that are eligible for consideration from the CDF, for example to include pre-cancerous conditions where they consider this appropriate.

Section C – GUIDANCE ON THE OPERATION OF THE CDF

5. Routes to CDF funding

5.1 There are two mechanisms for clinicians and patients to access drug treatments that are not available through normal NHS funding routes via the CDF:

The national CDF Cohort Policy List

NHS England has already reviewed a number of drug treatments that are not available for use in particular groups of patients through normal NHS funding routes (see section 4.5) and added these to the national CDF Cohort Policy List. In order to commence these drug treatments for individual patients clinicians should notify the relevant CDF Local Area Team of their intention to commence treatment using the relevant online prior notifications system. Where the relevant criteria are met funding should be confirmed automatically although it should be noted that treatment should not be commenced until confirmation of funding is received.

More detail on the notification and confirmation process can be found in section 8.4.

Individual CDF Requests (ICDFRs)

This route is to access drug treatments that are not available through normal NHS funding routes (see section 4.5) nor through the national CDF Cohort Policy List. ICDFRs can be submitted for consideration by regional clinically-led panels on behalf of the NHS England. Named patient applications can be made to the CDF where the patient does not meet the cohort policy criteria. Appendix Cis a standardised form for the submission of such requests.

More details of the ICDFR submission process and criteria can be found in section 8.4

Regional CDF panels can only consider funding by the CDF (through the ICDFR route) for patients unable to access treatment through NHS England routine commissioning arrangements for cancer drugs and where the patient does not represent a cohort.

5.2 All funding requests for consideration as an ICDFR will need to be approved by the provider Trust. Where established Trust governance mechanisms for approving and or forwarding this type of request to ATs are in place these should be used. Where this is absent it is recommended that, at the very least, the Trust Chemotherapy Lead or equivalent and the Lead Chemotherapy Pharmacist or equivalent are involved in the Trust approval process.

5.3 All requests should be made to the responsible Area Team who will process applications on behalf of NHS England in line with these standard operating procedures.

6. The national CDF Cohort Policy List

Development and review

6.1 The use of an agreed list of drugs/indications to be funded by CDF if specific criteria are met was extended in 2013/14 with the creation of a nationally agreed list of drugs/indications and related criteria. Requests for drugs covered by this national CDF Cohort Policy List will therefore be suitable for approval on a notification and confirmation basis.

6.2 There are three approaches to identifying further candidate drugs/indications for inclusion on a national cohort list:

a) Members of the CRG for Chemotherapy regularly horizon-scanning for:

- new NICE Guidance
- newly licensed drug / indication combinations
- new drugs coming to market
- new off-label indications for existing drugs

The CRG for Chemotherapy will be representative of oncology (adult and paediatric) and haemato-oncology clinicians in the country and will act as a conduit for information on new drugs/indications from clinicians to the NHS England.

b) Aggregated national data on ICDFRs will also inform the list. If more than 20 cases per year have been requested by this route, thus representing a potential cohort, consideration will be given to including the drug/indication on the national list.

c) Applications directly to the Chemotherapy CRG from the pharmaceutical industry and/or from clinicians for drugs for potential cohorts of patients.

6.3 The National CDF (NCDF) panel is a sub-group of the Chemotherapy Clinical Reference Group (CRG) of NHS England and is constituted by members of the Chemotherapy CRG, with co-opted members as appropriate. It will manage the NCDF on behalf of the Chemotherapy CRG and thus on behalf of NHS England. The NCDF panel will be chaired by the chair of the Chemotherapy CRG or by a nominated deputy if the CRG chair cannot attend. The NCDF panel will be quorate if 6 or more members are present.

6.4 A population or cohort-based decision will be made for cancer drugs/indications to be included in the national list (see below). A cohort in this context is where there are likely to be 20 or more patients in England per year that could benefit from the drug for a specific indication. Evidence has shown that a cohort approach provides transparency, equity and speed of decision-making, reduces the burden on clinicians and managers, and

supports forward planning.

6.5 Decisions on which drugs and related indications and criteria will appear on the single national list will be informed by a nationally co-ordinated horizon-scanning and prioritisation process where drugs will ideally be identified and considered prior to the point of licensing and cohort policies developed in readiness. This will avoid delays in making the drugs available via the CDF once licensed. Acceptance onto the national list will be dependent on the level of prioritisation of clinical effectiveness achieved by the drug under consideration in conjunction with an assessment of the median drug cost per patient, its budgetary impact and the projected expenditure of the whole CDF at the time (taken into account by way of the minimum score needed for approval). If two interventions have the same overall prioritisation score, any independently developed QALYs from NICE may be used as a "tie breaker". This process will be led by the CRG for Chemotherapy and supported by the NHS England Clinical Effectiveness Team for specialised services and public health specialists.

6.6 Updates and changes to the list will be made by the CRG for Chemotherapy and formally reported to the Medical Directorate of NHS England through the Cancer & Blood PoC Board.

6.7 Decisions will be based on the national CDF Prioritisation Tool (see Appendix D) in conjunction with an assessment of median drug cost per patient. This evaluation will be completed for each drug/indication under consideration and will result in an overall score based on a number of factors, including:

- evidence of clinical effectiveness
- survival and quality of life benefit
- toxicity/safety
- unmet need
- median drug cost per patient

Drugs on the national list will be subject to an affordability test within the overall CDF budget, being added or removed according to their relative aggregate score using the national CDF Prioritisation Tool of clinical benefit in conjunction with the assessment of drug cost per patient. Drugs whose aggregate score is below the threshold applicable at the time will not be added/will be removed from the list.

6.8 If a new addition to the national list by the national CDF panel is likely to extend the CDF beyond the total budget, then consideration will need to be given to:

- not including the new drug on the national list. This would not preclude a future review should there be a change that would affect the score for the drugs e.g. further evidence of benefit or reduced cost
- a reconsideration/narrowing of the cohort of patients who could access the drug, based on clinical criteria
- re-prioritisation. Whether a drug is funded depends on where it sits in the whole ranked list, as determined by clinical effectiveness and the

median drug cost per patient, and then where the funding threshold lies

- removal of a drug currently on the list which has a demonstrably less benefit as scored by the combination of the National CDF Prioritisation Tool and the assessment of median drug cost per patient and agreed by the CDF panel on behalf of the CRG for Chemotherapy.

6.9 It is planned that reprioritisation of drug treatments in the national CDF Cohort Policy List will be undertaken on an annual basis although NHS England reserves the right to do this more frequently if necessary.

6.10 Where a drug has been removed from the national CDF Cohort Policy List as a result of the re-prioritisation process and it has not been commissioned by the NHS England as part of a national chemotherapy funding policy or in response to a positive NICE Technology Appraisal, any patients currently receiving the treatment under the CDF will normally have the option to continue treatment until they and their clinician consider it appropriate to stop.

6.11 All decisions by the CDF panel will be published along with the national CDF prioritisation scores of clinical benefit. The scores of median drug cost per patient are confidential, as are also the overall combined scores of clinical benefit and drug cost. This confidentiality is necessary to protect the commercial in confidence discounts offered by the manufacturers to the CDF. These decisions are open to review in response to new evidence or altered pricing. If however agreement cannot be reached with a manufacturer on fair pricing so as to enable a medicine to be included in the CDF, the Panel then reserve the right to explain publicly why a negative decision was necessary.

6.12 For drugs which have been considered but not prioritised for the national CDF Cohort Policy List, clinicians can apply to the regional CDF panel for funding only on the grounds of clinical exceptionality from the cohort for which the decision not to fund has been made. However this will be influenced by the existing judgement of the clinical merit of the drug.

6.13 Where a drug has been removed from the national CDF Cohort Policy List following its recommendation by NICE or the agreement of a NHS England chemotherapy commissioning policy, treatment will be available on the NHS, subject to any clinical criteria set out by NICE/the NHS England policy. In these cases, NHS England would normally be expected to assume responsibility for patients whose treatment had previously been supported by the CDF. This will be from the point at which NHS funding is available.

6.14 It is intended that the national CDF Cohort Policy List will be a continually changing one. It should not be viewed as restrictive and will be kept under regular review to take account of NICE appraisal recommendations, other new evidence, changes in drug pricing, availability of new treatments and fluctuations in the numbers of patients presenting for treatment. Should a NICE Technology Appraisal Guidance support the use of a cancer drug which is already on the national list, it will be removed from the list within 90 days of the NICE review being published and become routinely

commissioned by the NHS.

6.15 Given the dynamic nature of the CDF in terms of potential NICE approvals and applications for new drugs/indications, the national list will be reviewed at least quarterly by the CDF panel on behalf of the CRG for Chemotherapy.

6.16 Trusts should ensure the implementation of 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 Area Team within 30 days of the CDF decision being published.

6.17 Local clinicians can make representations for the inclusion of specific treatments in the national CDF drug list via their relevant Area Team responsible for the administration of the CDF or their clinical representatives in the regional Clinical Senates. Oncologists and haematologists can also apply direct to the National CDF for consideration of new cohort policies, as can their network, regional or national specialist groups. The national CDF Prioritisation Tool should be used to present the clinical case for inclusion of a drug (see Appendix D) as well as submission of the relevant literature. The Chemotherapy CRG will meet at least quarterly to review such applications. The full process for making such applications including the scheduled dates of the NCDF panel for reviewing such applications will be published on the NHS England website.

www.england.nhs.uk/ourwork/cdf/

6.18 Close monitoring of ICDFRs submitted to the Area Teams will identify such cohorts at an early stage i.e. before the requests amount to 20 in England in any 12 month period. It is expected that the horizon-scanning process will identify in advance a requirement to consider such new drug/indication combinations.

6.19 The CDF process for prioritisation and evaluation of drugs/indications is described more fully in Appendix G.

7 Consideration of Individual CDF Requests (ICDFRs)

7.1 Terms of Reference for regional CDF panels and CDF review panels are in Appendices E and F.

7.2 Applications for funding from the CDF for treatments for individual patients which cannot be accessed through NHS England routine commissioning arrangements and which fall outside the routine CDF list/criteria of the cohort policies can be made by consultant cancer specialists (oncologists (adult &paediatric) and haemato-oncologists) on behalf of their patient. Decisions on the appropriate use of CDF resources in such cases will be taken by a regional CDF panel. These clinically-led panels will take into

account the content of this guidance in coming to their decisions.

7.4 Regional CDF panels will only make a decision on funding for individual patients, defined as patients:

- whose condition is particularly rare (likely to present in England in fewer than 20 patients per year). Identification of rarity will be made using published incidence and prevalence data and the specialist expertise supporting the CDF process

OR

- for whom the clinician can demonstrate clinical exceptionality. For drugs which have been considered but not prioritised for the national CDF Cohort Policy List, clinicians can apply to the regional CDF panel for funding on the grounds of clinical exceptionality from the cohort for which the decision not to fund has been made.

In considering the above it should be noted that requests for treatments within their licensed indication, or in indications for which a licence is pending, will be considered treatments for cohorts of patients by default. These will be managed through the process for developing national CDF Cohort Policies and not as ICDFRs.

7.5 If appropriate, ICDFRs should demonstrate clinical exceptionality as follows:

- that the patient is significantly different to the general population of patients with, and at the same stage of, the condition in question

AND

- that the patient is likely to gain significantly more clinical benefit from the intervention than might be normally expected for patients with that condition.

The fact that a treatment is likely (or has proven) to be efficacious for a patient is not, in itself, a basis for exceptionality.

7.6 If the patient represents a cohort of patients not covered by a CDF cohort policy (including subgroups of patients not meeting CDF policy criteria), then representation to the CRG for Chemotherapy for inclusion of the cohort in the national CDF Cohort Policy List should be made. Such cases cannot be considered as ICDFRs (except in instances where there is a case for clinical exceptionality from the cohort – see 7.7). There will be no regional decisions made on CDF drugs for cohorts of patients. In practice, it is expected that there will be few requests in this category as a programme of horizon-scanning should identify such cohorts at an early stage. This process will be kept under review by the NCDF panel for its responsiveness and timeliness.

7.7 While a treatment is being referred to and considered by the NCDF panel for national CDF Cohort Policy, clinicians can only apply to the regional CDF panel for funding via an ICDFR if there is a case for clinical exceptionality from the cohort that is under consideration by the panel.

7.8 Decisions affecting individuals' treatment will be made in a timely fashion. Responsible Area Teams will ensure that the process put in place supports timely decision-making, bearing in mind the 31-day cancer treatment standard. Clinical decision-making is routinely much quicker than this standard. In recognition of this, clinically-led panels are encouraged to set more challenging timescales for decision-making under the CDF. Standards for CDF response times are set out in section 8 of this document.

7.9 Clinically-led panels must provide both the reasons for refusal to fund and the opportunity to have cases reconsidered in the light of new evidence or if relevant information was missed (see section 8). NHS England Area Teams will ensure that there is a single, consistent, clear process in place for considering appeals against funding decisions. Area Teams will ensure that these processes support timely consideration.

7.10 The involvement of a lay perspective in the operation of the CDF helps to support patient confidence in the process. There will be lay representation on the regional CDF panels to secure a lay perspective as part of the decision-making process. (See CDF panel membership in Appendix E).

7.11 Arrangements for the review of CDF panel decisions will be in place and information for clinicians and patients made freely available. (See Terms of Reference for the CDF Review Panel in Appendix F).

7.12 As with consideration of funding for cohorts, the scope of the CDF for individual named patients is as outlined in section 4. It will be the responsibility of the clinician to provide all relevant clinical data to support the application. The relevance to the individual case of the evidence presented should be outlined by the requesting clinician in the request form at Appendix C. This will facilitate the independent review of such submissions by the clinically-led regional CDF panels.

7.13 Clinically-led panels will be aware of rarity when assessing the evidence base and make appropriate allowances for potential limitations in the evidence base on treatments for rarer cancers (e.g. cancers in a paediatric population) and will obtain expert input where appropriate. CDF panels can also consider the biological plausibility of benefit.

7.14 Clinically-led panels from each NHS England region will collaborate on evidence assessment and share expertise, particularly in cases where the published evidence may be limited, such as for rare cancers. However, the responsibility for decision-making will remain with the responsible regional clinically-led panel.

7.15 Decisions on funding will be made on the basis of clinical need and the patient's ability to clinically benefit from treatment and will not be based on social value judgements.

7.16 Drugs will not be funded under the ICDFR route if there are suitable alternatives that are already funded by NHS England. In these circumstances clinicians will have to demonstrate why they would need to access the requested drug rather than already commissioned therapies.

7.17 The CDF panel will strive to provide equal opportunities for treatment in the same clinical circumstances.

7.18 Area Team CDF/IFR leads will routinely share information on ICDFRs with each other, with their respective CDF panels, and with the NCDF panel. Such close working will support the identification of potential candidate drugs for the national CDF Cohort Policy List (i.e. where the number of cases across England is approaching 20 per year).

7.19 Using this information, Areas Team CDF/IFR leads and the NCDF panel will consider the need for referral of potential candidate drugs for consideration for assessment for the national CDF Cohort Policy List.

7.20 Requests approved for CDF funding will require specific information to be submitted to inform the national audit of the CDF. See section 9.

7.21 Clinicians and provider trusts will be required to provide detailed information about the use of the drug (including accurate treatment start and stop dates and number of cycles of treatment administered) plus outcomes for their patients, in line with the national audit arrangements for the CDF. Payment of trust invoices will be contingent on full data being returned in a timely way.

8 The CDF application process

From April 2013, the CDF has been a single fund for patients in England. Although NHS England will remain accountable for the CDF, operational management of the CDF has been devolved to four of the 10 Area Teams responsible for commissioning of Specialised Services. These are based in the following Area Team Offices and contact details are outlined in Appendix A.

North of England:

NHS England Area Team Cumbria, Northumberland, Tyne & Wear

Midlands and East:

NHS England Area Team Leicestershire and Lincolnshire

South of England:

NHS England Area Team Wessex

London:

NHS England Area Team London

In line with NHS England direct commissioning for Prescribed Services, each Area Team will handle requests for the CDF from providers in their region. This is irrespective of the residence of the patient or their GP.

The following sections broadly outline the processes for application to the CDF from 1 April 2013:

8.1 There will be a single NHS England webpage dedicated to the CDF with detailed information on CDF policies and processes plus links to the regional Area Teams' online application systems.www.england.nhs.uk/ourwork/cdf/

8.2 Requests to the CDF should be submitted to the appropriate NHS England Area Team via their online submission website. The Area Teams will also have a dedicated NHS.net email. Area Teams will ensure that CDF contact information (including the CDF submission website and secure email address) is made widely available to the providers in their region.

8.3 Notification of the use of drugs on the national CDF Cohort Policy List.

- An online submission will be required to request funding for drugs on the agreed national CDF Cohort Policy 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. Applications will not be accepted nor correspondence undertaken via other email networks.

- Nationally standardised online submission forms will be developed using clinical criteria supplied by the Chemotherapy CRG as part of the development of national cohort policy 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.

- The standard for the response to notification of the use of a CDF drug on the national 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.

- A requirement for funding will be for clinicians or Trust co-ordinators to submit treatment data such as start date. Treatment should be started within three months of receiving confirmation of CDF funding although it is expected that in the vast majority of successful applications, treatment will commence very shortly after approval has been obtained. CDF funding of treatment started more than three months after notification/confirmation will need to be re-submitted as the patient's condition may have changed. Trusts will be treating at their own financial risk without a resubmission.

- In cases of exceptional clinical urgency, a retrospective application to the CDF will be considered if received within two working days of the treatment commencing. Trusts commencing treatments prior to an application to the CDF do so at their own financial risk. Invoices sent to the CDF for cycles of treatment administered prior to application for

funding (or >two days prior to application for funding, in urgent situations) will not be paid. To be clear, invoices will only be paid for cycles of treatment administered to a patient after approval of funding or within two days of successful application for funding. The financial responsibility for treating patients prior to confirmation of funding rests with the provider trust.

- Invoices must be submitted for each cycle of treatment within three months of each cycle being administered or dispensed to the patient. All CDF drugs will be funded at cost; no additional charges will be accepted and no gain sharing will be allowed with drugs funded via the CDF. Local agreements may be made with AT commissioners on charges to meet the additional costs to Trusts of delivering savings on these drugs e.g. the fee for homecare delivery where it would be expected that any VAT savings would be passed on to the CDF.

- Requesters will get an automated response for requests which do not meet the cohort policy criteria. This will advise them of the further options available from the CDF.

- Clinicians or Trust co-ordinators notifying the CDF of use of drugs on the national CDF Cohort Policy List will be required to provide further clinical data on treatment start and stop dates and contribute clinical outcome data to the national audit of the CDF. It is expected that updates on each patient CDF record will be routinely made by their treating clinician or Trust co-ordinator. Payment of trust invoices will be contingent on the full SACT database record applicable to the drug being completed and this information being made available in a timely way.

8.4 Applications for CDF drug funding via the ICDFR panel route

- 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.

- All funding requests for consideration as an ICDFR will need to be approved by the provider Trust. Where established Trust governance mechanisms for approving and or forwarding this type of request to ATs are in place these should be used. Where this is absent it is recommended that, at the very least, the Trust Chemotherapy Lead or equivalent and the Lead Chemotherapy Pharmacist or equivalent are involved in the Trust approval process.

- For requests which need to be considered by the regional clinically-led panel, only fully completed applications received on the appropriate application form will be considered. This form will be standard across England and will include mandatory fields e.g. patient performance status.

- Clinicians will be expected to provide supporting evidence for their

requests and ensure that a description of how the evidence relates to their case is included in the body of the application form. Evidence provided should include original clinical papers, which demonstrate the predicted clinical benefit over the previous standard of care, quality of life, where available. Submissions for funding must include criteria for stopping therapy.

- A retrospective application to the CDF will be considered if received within two working days of the treatment commencing. Trusts commencing treatments prior to an application to the CDF do so at their own financial risk. Invoices sent to the CDF for cycles of treatment administered prior to application for funding (or >two days prior to application for funding, in urgent situations) will not be paid. To be clear, invoices will only be paid for cycles of treatment administered to a patient after approval of funding or within two days of successful application for funding. The financial responsibility for treating patients prior to confirmation of funding rests with the provider trust.

8.5 Screening and approval of an ICDFR

- Requests submitted on an ICDFR form will be screened by the CDF officer and the Area Team Cancer Pharmacists and/ or specialised services public health specialist to ensure that complete information is provided, that the request is appropriate for consideration by the CDF panel and that the drug in that indication is not already used as standard in the rest of the region.

- If the data in the form is insufficient to take the request to panel, the CDF team will contact the requester for further information.

- Requests which do not meet the criteria for consideration by the CDF panel will be returned to the requester with appropriate advice about the options available for the request.

- In the absence of a full list of chemotherapy drugs and regimens commissioned by NHS England being available and as part of the screening process, any requests for low cost and/or low volume drugs and regimens should be discussed with the Area Team Cancer Pharmacists and the AT Pharmacy Leads in the region. Where it is assessed that the drug or regimen is in standard use across the majority of other provider Trusts in that region it should be considered to be in baseline commissioning across all ATs in the region as an interim measure and the requestor informed. The CDF teams should ensure this decision is communicated to the LAT Pharmacy Leads. In this situation the request will not need to be forwarded to the panel.

- Screeners will have three options available to them:
  - Approve the request if covered by an existing contract with the provider or a commissioning policy and the patient meets the relevant

criteria.
    - Refuse the request without referring the case to the ICDFR Panel, on the grounds that it does not meet the criteria for consideration as an ICDFR (as outlined in the section 7).
    - Refer the case to the ICDFR Panel. The requesting clinician will be contacted and asked to comment on whether any additional information should be included in the Treatment Request Form.

- Where there is uncertainty or doubt about the application of the ICDFR policy, the case will be referred to the ICDFR Panel.

- All decisions made by the Screening Pair will be recorded in the request record and reported to the ICDFR Panel on a quarterly basis.

- Decisions on drug or regimens that are considered to be within baseline commissioning should be sent to the Chemotherapy CRG on a monthly basis to ensure the development of consistent NHS England commissioning policy.

- Requests which meet the criteria for consideration by the CDF panel and which are for drugs not already considered to be in use as standard treatment in the region will be forwarded to the panel via secure email without patient or requester identifiers. Making the request anonymous in this way will ensure that decision-making is focused on clinical criteria.

- The screening of the ICDFR will be completed within three working days from submission of complete information by the requester.

- If a request is declined at the screening stage there is no right of appeal to the ICDFR Panel and there is no right to request that the decision should be reviewed by the ICDFR Review Panel. However the patient has a right to make a complaint under the NHS Complaints Procedure. One outcome of such a complaint could be to require the screening process to be reconsidered or for the case to be referred to the ICDFR Panel for consideration.

- However, if a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they feel may have made a difference to the decision made, then the clinician can submit a new ICDFR application with this new evidence.

8.6 The regional CDF clinically-led panel has the following way of working:

- A clinically-led panel will commence consideration of each fully completed application on receipt. See Appendix E for the membership and Terms of Reference for the CDF panel.
- CDF panels will discuss cases via group email correspondence and by teleconference/WebEx. At least two face to face meetings will maintain

the group dynamic and discuss relevant issues relating to the working of the CDF.

- Email discussions and teleconference/WebEx and face to face meeting minutes outlining discussion of individual cases (including a summary document) will be securely archived and form part of the request record.
- The standard for response time for ICDFR decisions is for them to be made within ten working days of complete submission by the requester.
- Standards for quoracy and voting rules for the CDF panels are outlined in the Terms of Reference (see Appendix E).
- The referring clinician will be sent notification of the panel's decision within one working day of that decision being communicated to the Area Team.
- This will include a summary of the reasons for the decision in sufficient detail to make clear the decision-making process and justify the outcome.

8.7 ICDFR review process

- A request for a review of a CDF decision can be made by the referring clinician to their NHS England regional Medical Director. The four regional Medical Directors will be responsible for assessing the decision-making processes for ICDFRs in their region where a request for a review is made. They will not re-visit the merits of the application but consider the process under which it was considered. See Appendix F for the Terms of Reference for the CDF review panel, including membership.
- The request for a review of an ICDFR decision should be made in writing to the NHS England regional Medical Director and must be lodged within 20 working days of the original decision being notified.
- The request for review must set out the grounds on which the CDF decision is being challenged. A review can be requested only on two grounds, if it is believed that:
- the CDF panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed

OR

- The CDF panel did not take into account, or weigh appropriately, all relevant evidence and funding available.
- The NHS England regional Medical Directorate Review Panel will either uphold the decision of the CDF panel or it will instruct the CDF Panel to reconsider the application.
- The decision of the NHS England regional Medical Directorate Review Panel is final. However, patients and clinicians have recourse to the NHS complaints procedure including onward referral to the Health Service Ombudsman and, ultimately, Judicial Review.

9. Monitoring and audit of the CDF

9.1 The level of annual funding in 2014/15 and 2015/16 for the CDF will be £280 million per year. Thus a total of £560m will be available to the CDF over the two year period of 2014/15 and 2015/16. The CDF budget is fixed and finite. The changing profile of available treatments, NICE supported drugs and potential fluctuations in the numbers of patients presenting for specific treatments will require accurate monitoring of committed and actual spend against the total budget. This monitoring will be the joint responsibility of the four Area Teams who will make monthly reports to the CDF on behalf of the CRG for Chemotherapy and NHS England. The report will be at a high level to protect patient confidentiality. It will be consistent across the four teams and will include the total applications received each month for each drug and the estimated financial commitment and total spend to date.

9.2 In order to assess the impact of supporting access to cancer medicines, feedback on outcomes is a mandatory condition to the trust receiving payment for the requested drug. Responsible Area Teams will set a clear expectation that clinicians will provide clinical outcome data for the national CDF Audit on patients whose treatment is supported by the CDF. Area Teams will routinely review the level of completion of this data and withhold payment of trust invoices where the data is not provided.

9.3 The provision of this data will be mandated in contracts with providers, subject to compliance with Data Protection laws.

9.4 The audit will collect the following data items for drugs funded via the CDF:

- patient NHS number
- patient date of birth
- primary diagnosis
- ICD10 code
- drug name
- line of treatment
- regimen
- treatment approved but not started (Y/N)
- date treatment started (actual date)
- date treatment stopped or, if unavailable, date of decision to stop treatment or date of the start of the last treatment cycle
- date of death, where applicable
- General Practice postcode

9.5 Responsible Area Teams will submit data to the national CDF Audit to agreed timescales and subject to compliance with the Data Protection Act 1998. It is expected that all Area Teams will provide prospective data from April 2013. This will ensure a complete dataset for the CDF, from April 2011 through to the present. As the CDF audit data is covered by the normal mandated Systemic Anti-Cancer Therapy (SACT) data collection under the NHS Standard Contract from April 2014, all available contractual mechanisms will be pursued to ensure completeness of data collection.

9.6 All providers will have a process to identify spending to the CDF Area Team and demonstrate that:

- the costs are purely for the drugs approved without on costs
- the treatment was started within three months of CDF notification/ICDFR approval
- treatment has ceased as soon as criteria for stopping therapy were met
- feedback on patient outcomes has been provided.

9.7 Area Teams will ensure that appropriate arrangements are in place to secure meaningful information for the national CDF Audit and to monitor use of the funding that has been made available for the CDF. This will:

- support effective allocation of the funding
- provide assurance that the funding is being used in accordance with agreed national arrangements
- help to improve the available evidence on how these drugs perform in real world clinical practice

9.8 The Area Team will collect and publish data on request to decision response times, in line with the standards in this document:

- notification of CDF Cohort Policy List drugs should be confirmed within two working days in 95% of cases. CDF panel decisions should be communicated within 10 working days of receipt of complete information from the requester in 95% of cases
- CDF Review panel decisions should be communicated within five working days of submission of a request for a review (which outlines clearly the basis for the request) in 95% of cases
- outcomes of requests at each stage of the process: notification, screening of ICDFRs, panel decisions and review panel decisions.
- numbers of requests by drug/indication approved/declined
- feedback from requesters and patients on their experience of the CDF process.

10. Information about the CDF for patients

10.1 *Improving Outcomes: A Strategy for Cancer*[4] states that one of the priorities in the Cancer Strategy is to enhance the information available to patients on the benefits and toxicities of treatment. The National Clinical Director for Cancer will work with cancer charities and the pharmaceutical industry to support the availability of such information. The National Cancer Patient Information Pathway programme has developed tumour specific cancer information pathways[5]. Work is also continuing to develop the use of information prescriptions[6] throughout the cancer pathway.

10.2 Patients will need appropriate information on the available options to support them in making informed decisions about the treatments available for their condition. Clinicians and other treating health professionals should have open discussions with patients about the relative merits of drug treatment options, palliative care and end of life care. Written information on the likely benefits and possible side effects of treatments should be made available to the patient by the responsible clinicians.

10.3 A requirement of the CDF notification/application process will be that the clinician confirms that informed patient consent to treatment has been obtained.

10.4 Up-to-date information on the CDF, its principles, and processes are available on the NHS England website with links to the four Area Teams' online application systems. Guidance for clinicians can be seen in Appendix A. A patient information leaflet can be seen in Appendix B.

10.5 Detailed information on the arrangements that have been put in place, including the standards for response time for CDF requests will be readily available and accessible via the internet, and clinicians should help to support patients who are unable to access this information themselves.

10.6 The prioritisation process to identify drugs that will be funded routinely from the CDF (the national CDF Cohort Policy List) will be readily available, including how information on candidate drugs can be submitted by clinicians. The national CDF Prioritisation Tool for assessing clinical benefit is available at Appendix C. The Terms of Reference for how the NCDF panel works is set out in Appendix G.

[4] Improving Outcomes: A Strategy for Cancer, Department of Health, January 2011, Gateway 15109
[5] which can be found at www.cancerinfo.nhs.uk
[6] Information prescriptions guide people to relevant and reliable sources of information to allow them to feel more in control, better able to manage their condition and maintain their independence (www.informationprescription.info)

10.7 Area Teams will jointly make nationally aggregated data on CDF activity and expenditure available on the CDF website. Activity data will include the number of applications and approvals nationally by drugs and indication. This information will be updated 3-monthly.

11. Documents that have informed this guidance

This document is an amendment to and supersedes:

- Department of Health. The Cancer Drugs Fund – Guidance to support operation of the Cancer Drugs Fund in 2012-13. [Gateway reference 17340]. April 2012.

This document is informed by:

- Department of Health. The Cancer Drugs Fund: A consultation [Gateway reference 14909]

12. Target audience and circulation

The target audience is NHS England regional Medical Directors, NHS England Area Team Directors, Medical Directors and Finance Directors, Chairs of the regional clinically-led panels for the CDF, the Chair of the CRG for Chemotherapy and the CRG for Specialised Cancer, the Chair of the Cancer and Blood PoC, the Chair of the Strategic Clinical Networks, provider trusts and specialist clinicians (medical, nursing and pharmacist).

Circulation will be to NHS England Regional and Area Teams, NHS Trust Chief Executives, NHS Foundation Trust Chief Executives, Medical Directors, Chief Pharmacists and Directors of Finance.

13. Date of review

April 2015

Appendix A. Cancer Drugs Fund 2014-15: Guidance for clinicians

1. Who can make an application to the Cancer Drugs Fund (CDF)?

Consultant-led specialist oncology (adult & paediatric) and haemato-oncology clinicians can apply to the CDF on behalf of their patients. Applications can be made on behalf of the lead consultant by any senior doctor in their team. Provider trust specialist pharmacists must also be named in the request. All Individual CDF requests (i.e. out with the cohort policies on the National CDF list) need to be endorsed by the Trust chemotherapy lead or equivalent.

Contact details, including NHS.net email addresses should be provided for correspondence by the requesting clinician. The nhs.net emails of specialist pharmacists working in the relevant clinical areas should also be provided.

2. Who do I apply to for funding under the CDF?

From April 2013, the CDF has been a single fund for patients in England. Although NHS England remains accountable for the CDF, operational management of the CDF is devolved to four of the 10 Area Teams responsible for commissioning of Prescribed Services.

These will be based in the following Area Team offices.

- North of England
  NHS England Area Team Cumbria, Northumberland, Tyne & Wear

- Midlands and East
  NHS England Area Team Leicestershire and Lincolnshire

- South of England
  NHS England Area Team Wessex

- London
  NHS England Area Team London

In line with NHS England direct commissioning for Prescribed Services, each Area Team handles applications to the CDF from providers in their region. This is irrespective of the residence of the patient or their GP.

The CDF is available for patients eligible for NHS services in England only.

Further information about the CDF can be found at:

www.england.nhs.uk/ourwork/cdf/

3. How should I decide whether to make a request to the CDF?

Clinicians are advised to review the whole of this document for fuller details of what is covered by the CDF.

The CDF will be used to fund cancer medicines, including radiopharmaceuticals[7], for patients who have been unable to access a drug recommended by their consultant cancer specialist (Oncologist, Haemato-oncologist or Paediatric Oncologist).

Funding will only be considered for cancer drugs that meet one or more of the following criteria. That they are:

- drug/indication (alone or within a treatment combination) appraised by NICE and not recommended on the basis of poor cost effectiveness, or where the recommendations materially restrict access to the treatment to a smaller group of patients than the specifications set out in the marketing authorisation (an 'optimised' recommendation)
- drug/indication (alone or within a combination) on which NICE has not, or not yet, issued appraisal guidance or the guidance has not yet been implemented for routine funding
- drug/indication (alone or within a treatment combination) which NICE is not going to consider.
- drug/indication (alone or within a treatment combination) that has not been prioritised through the NHS England Cancer Drugs Prioritisation Process and therefore have not received routine commissioning support for the required indication

It should be noted that the CDF will not be used to support the use of drugs that are not licensed for any indication by the European Medicines Agency (EMA).

NHS England recognise the importance of clinical trials. As such patients should be considered for entry into clinical trials before an application is made to the CDF. In all cases patients have the choice of whether they are entered into the trial.

Drugs that have not been supported by NICE due to non-submission of data by the pharmaceutical company for the indication in question will not be eligible for consideration under the CDF process. This is to avoid a potential pathway for circumventing the NICE process.

4. How do I access CDF funding?

There are two mechanisms for accessing CDF funding:

- **The national CDF Cohort Policy List**

  Prior notification of the use of drugs in accordance with an agreed national CDF Cohort Policy List. Applications for drugs covered by a criteria-based cohort policy are to be submitted online on a notification basis. Where the relevant criteria are met, funding will be confirmed. Notification and receipt of funding confirmation

[7] Radiopharmaceutical: any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes)included for a medicinal purpose, Directive 2001/83/EC of the European Parliament and of the Council

should be done prior to the delivery of treatment. See section 6 of the Guidance and Standard Operating Procedures document (NHSCB/SOP/03) for more details.

- **Individual CDF Requests (ICDFRs)**

  ICDFRs can be submitted for consideration by regional clinically-led panels on behalf of the NHS England. Named patient applications can be made to the CDF for conditions where there is no cohort policy, or where the patient does not meet the cohort policy criteria. Appendix C is a standardised form for submission of such requests.

  Regional CDF panels can only consider funding by the CDF for patients unable to access treatment through NHS England routine commissioning arrangements for cancer drugs.

  See section 7 of the Guidance and Standard Operating Procedures document (NHSCB/SOP/03) for more details.

  All funding requests for ICDFRs need to be endorsed by the Trust chemotherapy lead or equivalent.

All requests should be made to the responsible Area Team who will process applications on behalf of the NHS CB in line with the guidance and standard operating procedures.

5. How do I notify the CDF that I wish to start a patient on a drug on the national CDF Cohort Policy List?

Online submission will be the standard way for clinicians to apply to the CDF for funding of drugs on the agreed national CDF Cohort Policy List. Clinicians will be required to register using a valid NHS.net email address. Applications will not be accepted nor correspondence undertaken via other email networks.

Nationally standardised submission forms will be used to match the request against relevant clinical criteria. If the request meets the agreed criteria, approval of funding will be confirmed. Requesters should expect to receive confirmation of funding within 2 working days. This will be immediate if an online submission is made.

If funding is confirmed, requesters will be required, at a later date, to provide information to contribute to the national CDF outcomes audit e.g. a confirmed treatment start date (see below for more on the audit). Treatment should be started within 3 months of the notification. If treatment is delayed beyond three months, a new notification should be submitted to ensure the patient is still eligible.

For requests which do not meet the cohort policy criteria, requesters will receive an automated response to let them know and to offer guidance on the options available.

6. How do I make an individual CDF request (ICDFR)?

If there is no national CDF cohort policy for the treatment, or the patient has not met the cohort policy criteria, clinicians should consider whether there are specific aspects of the patient's case which justify an application to the CDF via the regional

CDF panel by completing and submitting the form 'Requests for funding for a named patient under the CDF' (see Appendix C).

Requests to the CDF panel should be submitted to the appropriate NHS England Area Team via the online submission website or dedicated NHS.net email.

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.

For requests which need to be considered by the regional clinically-led CDF panel, only complete applications received on the appropriate application form will be considered. This form will be standard across England and will include mandatory data fields e.g. patient performance status.

Clinicians will be expected to provide supporting evidence for their requests and ensure that a description of how the evidence relates to their case is included in the body of the application form. Evidence provided should include original clinical papers, which demonstrate the predicted clinical benefit over the previous standard of care, quality of life and cost effectiveness data, where available. Submissions for funding must include criteria for stopping therapy.

They will also need to confirm that the patient has given informed consent to the request being made.

7. What are the criteria used for considering ICDFRs?

Applications for funding from the CDF for treatments which fall outside the list/criteria of the cohort policies can be made by consultant cancer specialists (Oncologists (adult & paediatric) and haemato-oncologists) on behalf of their patients. Decisions on the appropriate use of CDF resources in such cases will be taken by a regional CDF panel. These clinically-led panels will take into account the content of this guidance in coming to their decisions.

Regional CDF panels will only consider funding by the CDF for patients unable to access treatment through NHS CB routine commissioning arrangements for cancer drugs.

Regional CDF panels will only make a decision on funding for individual patients:

- whose condition is particularly rare (likely to present in England in fewer than 20 patients per year). Clinicians should provide published evidence relating to incidence and prevalence of the condition and clinical characteristics of the patient in the submission

OR

- for whom it is possible to demonstrate clinical exceptionality. For drugs which have been considered but not prioritised for the national CDF Cohort Policy List, clinicians can apply to the regional CDF panel for funding on the grounds of clinical exceptionality from the cohort for which the decision not to fund has been made. However this will be subject to previous considerations of the clinical merit of the drug.

If appropriate ICDFRs should demonstrate clinical exceptionality as follows:

- the patient is significantly different to the general population of patients with, and at the same stage of, the condition in question

AND

- the patient is likely to gain significantly more clinical benefit from the intervention than might be normally expected for patients with that condition.

The fact that a treatment is likely (or has proven) to be efficacious for a patient is not, in itself, a basis for exceptionality.

If the patient represents a cohort of patients not covered by a CDF cohort policy (including subgroups of patients not meeting CDF policy criteria), representation to the CRG for Chemotherapy for inclusion of the cohort in the national CDF Cohort Policy List should be made.

Submission of a candidate drug/indication for a cohort policy should be done using the national CDF Prioritisation Tool in Appendix D.

Such cases cannot be considered as ICDFRs. There will be no regional decisions made on CDF drugs for cohorts of patients.

In practice, it is expected that there will be few requests in this category as the national programme of horizon-scanning should identify such cohorts at an early stage. This process will be kept under review by the CRG for Chemotherapy for its responsiveness and timeliness.

8. Should I submit an ICDFR application to ensure "all reasonable commissioning avenues for securing NHS funding" have been exhausted?

If the clinician is clear that the possible ICDFR in actual fact represents a cohort and lacks evidence of exceptionality and/or of clinical benefit and therefore is unlikely to be approved, then they can consider all reasonable commissioning avenues for securing NHS funding have been exhausted.

9. How can I get advice on what to put in my ICDFR?

Clinicians can contact the NHS England Area Team responsible for their trust for advice on whether to submit a treatment request form and what to include.

10. Who will make the decision as to whether the ICDFR is approved?

All new ICDFRs are screened by a senior health specialist (public health consultant and/or specialist cancer pharmacy lead) and the CDF officer within the relevant Area Team to decide whether the request meets the criteria for consideration as an ICDFR. They will also assess the completeness of the information and contact you if

essential information is missing e.g. performance status or supporting evidence in the context of the patient.

Complete requests which meet the criteria for consideration by the CDF panel will be forwarded to the panel via secure email without patient or requester identifiers. Making the request anonymous in this way will ensure the decision-making is focused on the clinical aspects of the case.

A clinically-led panel comprising of specialist oncology (adult and paediatric) and haemato-oncology clinicians and lay members (supported by non-voting public health, commissioner and pharmacist advisors) will commence consideration of each fully completed application on receipt.

11. How will I be informed of the decision?

Clinicians can expect a response to a request for funding from the CDF within 10 days from receipt of a completed form.

The panel decision letter will be emailed to the requesting clinician and will include a summary of the reasons for the decision in sufficient detail to make clear the decision-making process and justify the outcome.

12. Can either the patient, or a clinician involved in their care, attend the panel?

No. The panel will only consider the written evidence that has been submitted so it is very important that all the evidence is presented in the treatment request form. The discussion of the case by the CDF panel will usually be conducted virtually e.g. via email and/or teleconference.

13. Can I, or my patient, appeal against the CDF panel decision?

A request for a review of a CDF decision may be made by the referring clinician to the NHS England Regional Medical Director. They will assess the decision-making process only. They will not re-hear the application or re-visit the merits of the application.

The request should be made in writing to the relevant NHS England Regional Medical Director and must be lodged within 20 working days of the original decision being notified.

The request for review must set the grounds on which the CDF decision is being challenged. A review can be requested only on two grounds, if it is believed that either:

- the CDF panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed

OR

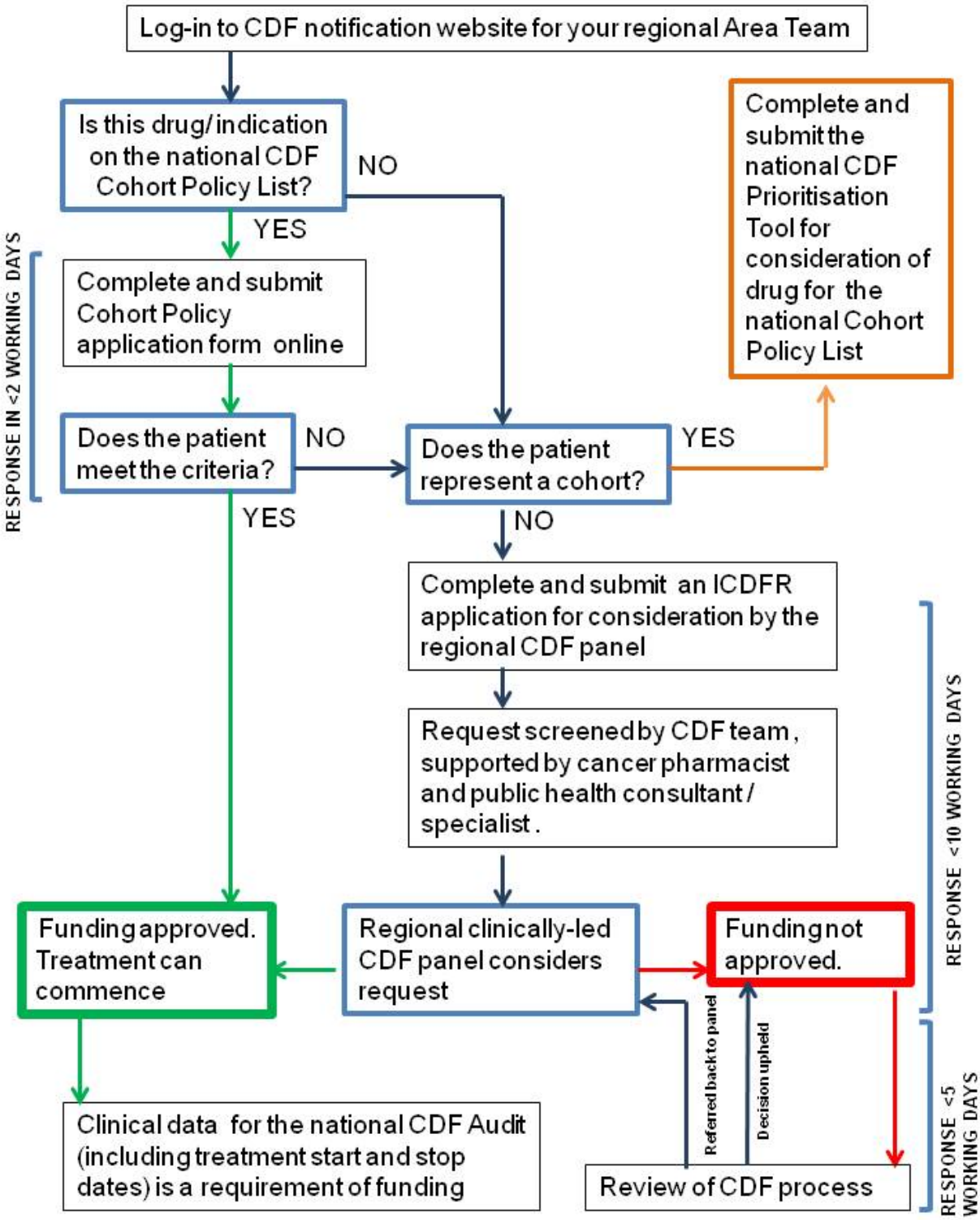
- the CDF panel did not take into account, or weigh appropriately, all relevant evidence and funding available.

The CDF Review Panel will usually respond to a request for a review within five working days of submission.

14. What are my responsibilities with regard to the audit of CDF outcomes?

For approved CDF requests (including those for drugs on the national CDF Cohort Policy List) requesting clinicians will be required to provide further clinical data on treatment start and stop dates and contribute clinical outcome data to the national audit of the CDF. It is expected that updates on each patient CDF record will be routinely made by their treating clinician. Payment of trust invoices will be contingent on this information being made available in a timely way. More information on the monitoring and audit of the CDF is in section 9 of the “Guidance and Standard Operating Procedures” document (NHSCB/SOP/03).

Request to the CDF



Appendix B. Cancer Drugs Fund 2014-5: Information for patients

Introduction

The Cancer Drugs Fund (CDF) was launched in April 2011 to enable patients to access the cancer drugs their doctors think will help them that would not otherwise be available from the NHS.

£200 million pounds was made available in each year of the Fund's operation until April 2014. £560 million is being made available in the financial years 2014-16 for the CDF and NHS England will plan on this basis.

From April 2013 NHS England assumed responsibility for the CDF. Single, consistent, national processes for accessing the CDF and a nationally agreed list of drugs to be funded have been developed. These are intended to promote equitable access and consistency of funding decisions for the CDF. The fund is managed through four of the NHS England Area Teams: North of England; the Midlands & East of England; the South of England; London.

NHS England have tried to make the process of applying to this fund as simple and as fair as possible. This information leaflet sets out how the process works. If you have any more questions you should speak to your clinician in the first instance.

Who can apply to the CDF?

Funding requests can only be made by a cancer specialist (Oncologist, Haemato-oncologist or Paediatric Oncologist), supported by their hospital trust, on behalf of an individual patient or patient group The main reason for this is that other services are needed to help administer the drugs and the hospitals must be able to provide them. This means that your doctor would need to make an application on your behalf.

CDF support can be requested for patients of all ages.

In what circumstances can my doctor make an application to the CDF?

If your doctor feels that you will benefit from the treatment and all other options for accessing cancer drug funding have been explored, they can apply to the CDF on your behalf.

Will the CDF pay for any cancer drug?

There are a set of criteria which cancer drugs need to meet in order to be considered for funding under the CDF. This will include:

- drug/indication (alone or within a treatment combination) that has been appraised by the National Institute for Health and Care Excellence (NICE)[8]

[8]NICE is the national body which reviews the clinical evidence to decide which services and drugs the NHS should routinely provide for patients. Drugs which meet the NICE criteria may include drugs

and is not recommended on the basis of cost effectiveness; or where the recommendations materially restrict access to the treatment to a smaller group of patients than the specifications set out in the marketing authorisation (an 'optimised' recommendation)

- drug/indication combinations on which NICE has not, or not yet, issued appraisal guidance (this may include drugs that are not licensed for the clinical indication of interest but where the clinician considers such a treatment to be the most appropriate based on clinical need).

- drug/indication (alone or within a treatment combination) which NICE is not going to consider

- drug/indication (alone or within a treatment combination) that has not been prioritised through the NHS England Cancer Drugs Prioritisation Process and therefore has not received routine commissioning support for the required indication

A national list of drugs has been drawn up which clinicians agree will be supported by the CDF. This means that you will be able to access the drugs on this list no matter where you live in England. Other drugs which do not appear on this national list will also be considered on a case by case basis.

There are some circumstances where cancer drugs will not be funded by the CDF:

- drugs will not be funded under the scheme if there are suitable alternatives that are already routinely paid for by the NHS
- the CDF will not be used to fund drugs that are not licensed by the European Medicines Agency (EMA)
- drugs may not be funded where there has been no NICE appraisal as a result of the manufacturer refusing to cooperate with the NICE appraisal process.

How will a decision be made about whether or not to approve my doctor's request for funding?

The funding decision for drugs which are on the agreed national CDF list, will be made automatically. If your clinical circumstances match the agreed criteria, funding will be confirmed. Your clinician can expect this confirmation within 2 working days. If the request is submitted online, the response will usually be immediate.

Decisions on funding requests not covered by, or not meeting the criteria on the national CDF drug list will be made by a panel of clinicians who specialise in cancer. It also includes pharmacists, public health specialists and patient representatives. This panel will make a decision based on the evidence provided by your referring clinician, which sets out how you, the patient, would significantly benefit and that it would be an effective use of this limited fund. The panel will consider requests for funding and will usually respond within ten days of receiving a complete application

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which are considered effective by clinically-led groups (set up to make recommendations to the NHS CB) but have not been supported nationally to be routinely funded.

as it is recognised as important to make decisions quickly to help patients who are seriously ill.

Could my doctor reapply for funding or appeal against the panel's decision if they turn down the request?

If the panel turns down a request for funding your doctor would be able to reapply if:

- there was a change in your condition that would mean that you would gain more benefit from the drug

OR

- there was additional good quality research published about the drug which suggested that you would derive greater benefit.

Your doctor could only seek a review against the panel's decision not to agree funding for your treatment on two grounds if he or she believed that:

- the CDF panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed
  OR
- the CDR panel did not take into consideration, or weight appropriately, all relevant evidence and funding available.

A CDF review panel for any appeals will be led by the NHS England Regional Medical Director for your area**.** The review panel will either uphold the decision of the CDF panel or it will instruct the panel to reconsider the application.

Your clinician can expect a response to a request for a CDF panel review within five working days.

Further information

For specific questions about individual cases please contact your clinician in the first instance.

More information about the Cancer Drugs Fund is available at:-

www.england.nhs.uk/ourwork/cdf/

Appendix C. Application for funding for a named patient under the CDF

1.PATIENT PERSONAL DETAILS

Patient Name:

Date of Birth:

NHS Number:

GP Name & Practice Details (including postcode):

2. DETAILS OF REQUESTER

Name: Designation:

Provider Trust:

Contact Telephone Number:

Secure Email or Postal Address for correspondence:

Must be **NHS.net email**. Only NHS.net can be used for correspondence re CDF requests.

Provider Trust Clinical Director Support:

(signature of Clinical Director)

Provider Trust Approval (please indicate as appropriate).

Multidisciplinary team (MDT)……	YES	NO

Date to MDT:

If discussed and supported by an appropriate MDT, please provide notes here:

3. CONSENT

I confirm that this Individual Cancer Fund Request (ICDFR) has been discussed in full with the patient.

The patient is aware that they are consenting for the Individual Funding Request Team to access confidential clinical information held by clinical staff involved in their care about them as a patient to enable full consideration of this funding request

YES / NO

[*Please indicate*]

Signature of Requester: **Date:**

Please note that all personal information will be removed prior to the consideration by the Cancer Drugs Fund Panel. **Do not use patient or clinician/trust identifiers in the remainder of the form**

The requesting clinician is responsible for presenting a full submission to the ICDFR Team which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment. All necessary information including research papers must be submitted with this form.

Requests can only be considered based on the information provided. Incomplete forms providing insufficient information will be returned.

4. TREATMENT REQUESTED

Drug Name:

Regimen:

Line of Therapy:

5. DIAGNOSIS

PRIMARY DIAGNOSIS:

Stage of disease:

ICD10 Code:

SECONDARY DIAGNOSIS:

Stage of disease:

ICD10 Code:

SUPPORTING INFORMATION

Please provide all the information requested to avoid delays in processing this request.

6. CLINICAL BACKGROUND

Outline the clinical situation. Please include details of:

- previous therapies tried and the response, including intolerance
- current treatment and response, including intolerance
- current performance status and symptoms
- anticipated prognosis if treatment requested is not funded (include what alternative treatment will be given).

7. INCIDENCE

Definition of Incidence in the context of the CDF:

This drug is expected to be required for 20 or fewer patients with the condition outlined above per year in England

References are to be provided for stated incidence.

What is the anticipated need for this treatment per 1000 head of population i.e. how often per year would you expect to request this treatment for this condition at this stage of progression of the condition for a given size of population?

8. Is the drug licensed for the intended use?

9. What is the evidence base for the use of this treatment?

Please outline the key research results with respect to:

- clinical effectiveness (impact on progression free survival and/or overall survival)
- safety/toxicity profile
- impact on quality of life
- cost effectiveness

Has it been subjected to NICE appraisal or other scrutiny?
If Yes please provide details

Is the procedure/treatment part of a current or planned national or international clinical trial or audit? If Yes please provide details

Please include copies of all relevant clinical research to support the evidence base.

10. What are the anticipated clinical benefits <u>in this individual case</u> of the treatment requested over other available options?

11.Why are standard treatments (those available to other patients with this condition/stage of the disease) not appropriate for this patient?

12. How will the benefits of the procedure/treatment be measured?

- What are the intended outcomes and how will these be determined?

- What 'stopping' criteria will be in place to decide when the treatment is ineffective? (The NHS England Area Team will require regular feedback on the outcome if the treatment is approved).

13. What is the cost of the treatment/procedure and how does this compare with the cost of the standard therapy it replaces?

Please ensure you include all attributable costs that are connected to providing the treatment e.g. drug costs, molecular testing.

14. How will the treatment/procedure be given to the patient (e.g. oral/IV) and where will the treatment take place?

Is this a single treatment/procedure or part of a course?

- If part of a treatment course, what is the number of doses that will be given and at what intervals?
- What is the total length of time of the proposed course of treatment?

15. Clinicians are required to disclose all material facts to the NHS England Area Team as part of this process.

This includes relevant honoraria, meeting support or research grants. Are there any other comments/considerations that are appropriate to bring to the attention of the CDF panel?

Please complete and return this form to the Area Team as per contact details

Appendix D. National Cancer Drugs Fund Prioritisation Tool

A. Background

1	Requesting Clinician and contact details			
2	Cancer Network			
3	Medicine			
4	Brand name (if available)			
5	Tumour site(e.g. Haem))			
6	Manufacturer			
7	UK Licensed status	Licensed Y/N	In development Y/N	Licensed but off-label use Y/N
8	Proposed indication			
9	Proposed place in therapy (e.g. line of treatment or adjuvant use)			
10	Licensed indication (if different to that proposed)			
11	What is the current standard alternative treatment? If no active treatment available, specify Best Supportive Care, where appropriate.			
12	NICE Decision: Click Here NICE Due date: Click Here			
13	SMC Decision: Click Here SMC Due Date- Click Here			
14	AWMSG Decision: Click Here AWMSG Due Date: Click Here			
	Average cost per cycle (using BSA 1.75m^2, ABW 80kg, and VAT at 20%)			
	Proposed number of cycles. If to progression, specify median number of cycles given in registration study.			
	Number of patients eligible for treatment, per 100,000 or per Network, please specify			

B. Pivotal Trial(s) & Key data, enter each trial's detail separately

Trial Name:			
Phase	*Phase I/Phase II/Phase III*		
Trial Design	*e.g. Non-Inferiority*		
Numbers	*No. randomised*		
Participants	*Eligibility criteria*		
Randomised?	*Yes or No*	**Y/N**	
Blinded?	*Yes or No*	**Y/N**	
RESULTS		**New treatment =**	**Existing treatment =**
Outcome(s)	*e.g. Overall survival 26.4 v 21.8 months respectively*		
Precision	*Hazard ratio (HR)= 0.821: 95% CI, 0.673 to 1.001, p= 0.051*		
Harms	*Important adverse effects or side effects*		

C. Details of New Regimen compared to existing Treatment/Regimen

	New Treatment	**Existing Treatment**
Name of Drug/Regimen		
Dose & Route		
Frequency of Administration		
Frequency of inpatient stays		
Frequency of outpatient consultations		
Maximum number of cycles		
List associated medication e.g. pre-meds, anti-emetics, growth factors		
List any side-effects requiring nursing input or additional medicines e.g. neutropenic sepsis		
Location for treatment, e.g. day case, outpatient		

D. Scoring Tool

Drug	
Indication	
Regimen (where appropriate)	

1 **Magnitude of Survival Benefit (progression free survival and overall survival)**

- **Additional incremental benefit over comparator treatment in pivotal Phase III trial.**
- **Phase II data allowable only for: rare cancers or rare subgroups, e.g. of common cancers or patients with refractory/relapsed disease when Phase III trial is unlikely because of rarity of condition and small case numbers. Quality trial criteria would be when a valid historical control group is available or there are several preferably large studies with similar patient eligibility or inclusion criteria and specified patient outcomes.**
- **Score half the points for Phase II evidence (PFS only) i.e. divide PFS score by 2. For phase II trials, do not score for OS. Phase I data is not appropriate. Record exact score to one decimal place if necessary (e.g. 2.5).**
- **Specify where Phase III data may be in progress, where Ph II data have been quoted.**

NB where the time falls halfway between two scores, use the higher score.

1.A	**Disease Free Survival, Progression Free Survival, Time to Treatment Progression (Specify)**	**DFS**	**Y/N**	**PFS**	**Y/N**	**TTP**	**Y/N**	**Other** (specify)	

Of trials which report measures of PFS,DFS and TTP, it is the primary specified outcome measure for the trial which is to be used for scoring purposes

Criteria	**Score**	**Absolute values for benefit** e.g. 12.3 months versus 8. 4 months = 3.9 months (Please quote *p* value below)	**Recorded Score**
Less than 2 months	**0**		
2.0 to 3.0 months	**2**		
4 to 5 months	**3**		
6 to 7 months	**4**		

	8 to 9 months	**5**		
	10 to 11 months	**6**		
	12 to 13 months	**7**		
	14 to 15 months	**8**		
	16 to 17 months	**9**		
	18 to 19 months	**10**		
	20 to 21 months	**11**		
	22 to 23 months	**12**		
	≥ 24 months	**13**		

	Precision of PFS/DFS/TTP (Please quote *p* value)	
	HR (quoted in trial)	**Absolute values** *(HR) e.g. 0.821 ; 95%CI 0.673 to 1.001 ; p= 0.051*
	Hazard Ratio	[ ]

1.B **Overall Survival**

If Phase II data, the score for OS benefit will automatically be set at zero, unless there is a very robust comparison possible with a contemporaneous study of equivalent patients who did not receive the treatment under evaluation.

	Criteria	**Score**	**Absolute values for benefit** **e.g. 12.3 months versus 8. 4 months = 3.9 months (Please quote *p* value below)**	**Recorded Score**
	Less than 2 months	**0**		
	2 to 3 months	**2**		
	4 to 5 months	**3**		
	6 to 7 months	**4**		
	8 to 9 months	**5**	[ ]	[ ]
	10 to 11 months	**6**		
	12 to 13 months	**7**		
	14 to 15 months	**8**		
	16 to 17 months	**9**		
	18 to 19 months	**10**		
	20 to 21 months	**11**		

	22 to 23 months	**12**		
	≥ 24 months	**13**		

	Precision of OS (Please quote *p* value)	
	HR (quoted in trial)	**Absolute values** *(HR) e.g. 0.821 ; 95%CI 0.673 to 1.001 ; p= 0.051*
	Hazard Ratio	

2	**Quality of life**		
	Criteria	**Score**	**Recorded Score**
	Published evidence of significant improvement in overall Quality of Life (QOL), using a validated tool.	**2**	
	Measurable evidence of significant improvement in relevant aspect(s) of QOL using a validated tool or evidence of lack of deterioration in overall QOL using a validated tool or clear evidence of major improvement in QOL without validated tool (e.g. clinically significant reduction in blood transfusion)	**1**	
	No QOL data collected in the trial or QOL data not analysed	**0**	
	Measurable evidence of significant deterioration in relevant aspect(s) of QOL using a validated tool or clear evidence of major deterioration in QOL without a validated tool (e.g. clinically significant increase in incidence of febrile neutropenia)	**Minus 1**	
	Published evidence of significant deterioration in overall QOL using a validated tool.	**Minus 2**	

3	**Toxicity compared to the existing active standard therapy.**		
	Criteria	**Score**	**Recorded Score**
	Significant improvement	**2**	
	Improved	**1**	
	Equal	**0**	
	Worsened	**Minus 1**	
	Significantly worsened	**Minus 2**	

4	**Degree of clinical unmet need, i.e. either the first demonstration of efficacy of a systemic therapy for the disease concerned or a step change for the clinical setting concerned.** **N.B. If there has been no score in section 1 of this tool, then no score can be assigned for this section unless case made for exception**

	Criteria	Score	Recorded Score or N/A
	No alternative treatment	3	
	Alternative *Active* standard treatment exists	0	

5 Cost per QALY – if available. The Costs per QALY calculated by NICE in the course of an appraisal are the most accurate costs per QALY for use in England and Wales. NB Cost per QALY scores will only be used as a tie-breaker for prioritisation in the event of the overall scores incorporating evaluation of clinical efficacy and median drug cost being equal and cost per QALY data is available for compared options at the same drug prices offered to the CDF. The NICE TA number must also be identified below.

Cost per QALY, NICE TA identification number and confirmation that this cost/QALY has incorporated the same price as offered to the CDF must be set out here.

6 Cost

A further score will be given depending on the median cost of the drug under evaluation. This score will depend on the cost bands used by the CDF panel. This scoring system and the score for a drug in this scoring system remains commercially confidential as it would provide an indication of the cost at which the drug was offered to the CDF.

7 Treatment pathway and other key clinical issues

Describe the place in the treatment pathway that this application refers to.

Set out what the standard comparators are to this application in terms of everyday practice in England

State the treatments that this drug will replace and thus be potentially eligible for de-commissioning

State whether introduction of this drug/indication into the treatment pathway will increase, decrease or not change the other treatment options in the pathway

Set out the eligibility criteria for treatment with this drug/indication

State what the rules should be for continuation and discontinuation of the drug/indication

Set out the evidence of national support for this application

8 Strength of Evidence

Criteria	Grade	Recorded Grade
Two or more good quality Phase III Randomised Controlled Trials, both published	A	
One good quality Phase III Randomised Controlled Trial, published	B	
Comparative Phase II trial, published	C	
Non-Comparative Phase II, published	D	
Unpublished data (in abstract form only)[1]	U1	
Unpublished data (in abstract form only)[2]	U2	

[1]Appropriate methodology for the treatment setting, presented at an international meeting

[2]Methodology inappropriate for treatment setting and/or not presented at international meeting

9 Overall score

The overall score will take into account the score of clinical benefit in conjunction with the assessment of median drug cost. This score is subject to interpretation and modification by the CDF panel if the scoring tool does not adequately reflect the assessed clinical benefit. This overall score is commercial in confidence as it includes the price at which the drug is made available to the CDF.

10 References and Search Strategy:

PubMed Search Strategy: Indicate below e.g.: Search terms (MeSH Terms) used in PubMed searches and dates of access for websites viewed.
References: Please provide Word, 'pdf' or hard copy references with the application

11	**Additional Information:** **For example:** • **Definitive benefits of new treatment not captured above** • **Trial data planned to prove non-inferiority with existing standard treatment.** • **No unpublished/'In-House/Data on File' Pharma contributions to be submitted**

For CDF panel use only	
Total Score	] and a confidential cost score
Additional Notes	

Appendix E. Terms of reference for regional clinically–led CDF panels

1. Membership

The regional Cancer Drug Fund (CDF) panel will have a core membership of representative consultant oncology (adult and paediatric) and haemato-oncology specialists from providers within the geographical region of the Area Team. Core membership will also include patient and/or lay representative(s).

Specialist advice to the panel will be provided by the NHS England Area Team cancer pharmacist, consultant / specialist in public health and the CDF officer.

For 2014/15, recruitment of the regional CDF panel membership will be led by existing CDF panel Chairs using established clinical contacts, expanded to ensure that opportunity to be part of the CDF panel is open to appropriately specialised clinicians in all providers in the region.

Membership should be representative of a wide range of specialist cancer clinicians and will, as a minimum have five oncologists (adult), five haemato-oncologists and two paediatric oncologists. The maximum size of any of the four CDF panels will be 25 in order to ensure that effective decision-making is possible

Should any of the regional CDF panels be oversubscribed, selection of members will be mediated by the Clinical Reference Group (CRG) for Chemotherapy to ensure that membership is equally representative of cancer types.

The NHS England Area Team will provide administrative support to the panel. The CDF officer in the Area Team will record the decision of the panel, including reasons for the decision and ensure that this is relayed to the clinician applicant.

2. Chair of the Panel

The panel will be chaired by a nominated and seconded clinician from the core membership above. A Vice Chair will also be identified in the same way.

3. Purpose

To provide a process to enable specialist cancer clinicians to make evidence-based treatment decisions in respect of individual funding requests to ensure that patients with cancer in England benefit from equitable access to the CDF.

The panel will consider applications for individual funding from the CDF made between April 2014 and March 2015. It will operate in a fair and transparent way and act in accordance with the principles set out in the CDF national “Guidance and Standard Operating Procedures” (NHSCB/SOP/03).

4. Operating Arrangements

- Preparation of cases for consideration by the CDF panel, the setting up of teleconferences/meetings and day to day work generated by the work of the CDF panel, including the communication of decisions, will be undertaken by the Area Team CDF officer.

- The majority of the decision-making will be carried out virtually by email as required. The CDF panel will have teleconferences/WebEx arranged every two weeks so that more complex decisions can be discussed in real time. Any such adjustments will be agreed across all four CDF panels, mediated by the NHS England Area Team leads.

- Quarterly face to face meetings of the CDF panel members is recommended, as is an annual meeting of all CDF panels with the NCDF panel and the National CDF Audit team.

- The Area Team supporting the panel will make all cases anonymous before consideration by the panel.

- Applications will normally be considered and a response provided by the panel to the Area Team within 10 working days of a complete application being received.

- The Chair of the CDF panel (or Vice Chair in their absence) will ensure that the decision is communicated to the Area Team in a timely way, including a summary of the reasons for the decision.

- The referring clinician will receive written notification of the outcome of the panel and the reasons for the decision. This will be via secure email.

- Records will be kept of the proceedings, decisions and advice of the panel including a detailed decision summary document for each request considered. The Area Team CDF officer will ensure that such records are collated and archived as appropriate.

- The requesting clinician and the patient/carers will be invited to comment on the process and how this can be improved.

5. Members' Responsibilities

The members of the panel:

- will act as an expert, independent clinical decision-making body on behalf of NHS England and make decisions about access to the CDF for patients who fall outside the agreed clinical criteria for the national CDF Cohort Policy List

- will participate in discussions about cases mediated via email and teleconference. This will require prompt responses to emails and a willingness to engage fully. Responses to CDF panel emails should always be made ‘reply all’ to ensure capture of all relevant panel comments and the smooth running of decision-making

- will base their decision on the criteria outlined in this document. The criteria for access to the CDF will be based primarily on evidence of clinical effectiveness and anticipated delivery of measurable outcomes such as improved overall survival, progression-free survival, improved quality of life, reduced toxicity

- will work with the NHS England CDF/IFR Area Team to manage the CDF and ensure that access to the CDF is consistent with existing NHS England commissioning policies and ethical decision-making frameworks
- will consider requests for cancer drug treatments for patients eligible for NHS treatment in England.
- will consider requests for cancer drug treatments from provider trusts in their geographical area/region, irrespective of the patient' home address or GP
- will consider requests for cancer drug treatments only (including therapeutic radiopharmaceuticals) but not including non-cancer supportive treatments
- will consider one-off individual patient requests only where existing funding opportunities have been explored and exhausted
- will not be a voting member for a case where they knowingly have had any clinical involvement
- will not take decisions on the funding of a drug for a patient representing a cohort. This is defined as a request where 20 or more patients are likely to need the drug per year in England
- will offer advice and facilitate submissions by requesters of candidate drug/intervention for review by the national CDF panel, for consideration for the national CDF Cohort Policy List. This should be done using the national CDF Prioritisation Tool at Appendix D
- will proactively identify and refer potential candidate drugs / indications to the national CDF panel for consideration for the national CDF Cohort Policy List
- will where there is a need, as defined by the NCDF panel, assess individual cases for drugs approved via the NCDF cohort policy list to ensure that they are appropriate and meet the NCDF criteria (e.g. ensuring requests for retreatment with monoclonal antibodies in metastatic colorectal cancer commencing after the time defined in the NCDF cohort policy list are following unplanned rather than planned treatment breaks)
- will monitor and review regular information including audits, evaluations and projected current expenditure of cancer drugs approved through the CDF
- Will have regard to all relevant equality considerations.

6. **Voting Rights**

Panel members will seek to reach decisions by consensus where ever possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote of the core membership with each panel member having an equal vote. If the panel is equally split then the Chair of the panel will have the casting vote. A clinician member who is making an application to the CDF will not be able to vote on that application. Advisory members of the panel are non-voting members.

Oncology applications will be considered by at least three oncologists and haematology applications will be considered by at least three haematologists. At least one paediatric oncologist will consider requests for a paediatric patient.

7. **Quorum**

The panel will be quorate if five of the clinical members of the panel participate by voting. A paediatric oncologist is not required for the panel to be quorate.

8. Authority

The panel has delegated authority from NHS England to make decisions in respect of funding of individual cases only. It is not the role of the panel to make commissioning policy decisions on behalf of NHS England

9. Accountability

The panel is accountable to the board of the NHS England.

10. **Reporting and Monitoring**

The Area Teams will produce monthly reports on the activity of the CDF panel and the expenditure for submission to the NHS England Medical Directorate Clinical Effectiveness Team, the Area Team Medical Director and the NCDF panel. This will be in accordance with the national report templates. Quarterly returns will be made to the National Audit Registry at the Oxford Cancer Intelligence Unit (CIU).

Feedback on the process by applicants to the CDF will be considered at quarterly meetings between Area Teams and the NHS England Medical Directorate Clinical Effectiveness Team. Changes to processes will be made with the agreement of the Chairs of all four regional panels supported by pharmacy, public health, communications leads and patient representatives.

Appendix F. Terms of reference for the CDF Review panels

1. Membership

A specific CDF review panel will be convened to manage a request for review of a decision made by the CDF panel. Membership will consist of the regional Medical Director or nominated deputy, an Area Team public health consultant, a regional Cancer & Blood Programme of Care Lead. None of the panel members will have been involved in the case prior to acting on the review panel.

Members of the review panel should be mindful of the need to provide cover for their role in the event of annual leave, given the tight timescales for responding to a request for a review of a CDF panel decision.

The review panel will not consider either new information that was not available to the CDF panel or receive oral representations.

2. Purpose

The review panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the review panel will consider whether the process followed by the CDF panel was consistent with that detailed in the document 'Standard Operating Procedures: The Cancer Drugs Fund: Guidance to support operation of the CDF in 2014-15'.

- The review panel will consider whether the decision reached by the panel:
    - was consistent with the above document
    - had taken into account and weighed all the relevant evidence
    - had not taken into account irrelevant factors
    - indicates that members of the panel acted in good faith
    - was a decision which a reasonable panel was entitled to reach.

- The review panel will be able to reach one of two decisions:
    - to uphold the decision reached by the CDF panel

    OR

    - to refer the case back to the CDF panel with detailed points for reconsideration.

3. Operating Arrangements

The review panel will be held virtually or by teleconference in order that decisions can normally be taken within five working days of receiving a request for a decision to be reviewed.

4. Voting Rights

The review panel members will seek to reach a decision by consensus. If this is not possible a decision will be made by a vote with each member having one vote.

5. Quorum

A minimum of full panel members must participate in the review panel.

6. Process

- The panel will consider written requests for review submitted to the review panel chair by the patient's Oncologist/Haematologist within 20 days of the date of the letter of the CDF panel's decision. The review panel will only consider the following written documentation:
    - the original application including the grounds submitted by the referring clinician in their request for review
    - the process records in handling the request
    - the CDF panel records and any additional information it considered in reaching the decision.
- The review panel will not consider new information or receive oral representations.
- Decisions will be made within five working days of a request for a review.
- Decisions will be communicated to the requesting clinician within one working day from the date of the panel's decision.
- Panel decisions together with supporting evidence on the process of decision-making will be recorded in writing and the appropriate correspondence, communicating the outcome and the reasons behind it, will be sent to the clinician applicant.
- The decision of the review panel is final. If the panel upholds the original decision not to fund an intervention, the patient may choose to complain about the decision using the NHS complaints procedure and, ultimately, Judicial Review.
- All correspondence relating to the original CDF panel decision will be provided by the Area Team CDF officer. Review panel activity will be recorded by the panel and provided to the Area Team CDF officer on completion of the review. All documentation will be archived with the original request.

7. Authority

The review panel has delegated authority from NHS England to undertake a review of CDF panel decisions in respect of the funding of individual cases. Whilst the review panel may uphold the decision of the CDF panel, it is not the role of the review panel to substitute its decision for that of the CDF panel of an application to the CDF nor does the panel make commissioning policy.

8. Accountability

The review panel is accountable to the Board of the NHS England.

9. Reporting and Monitoring

Area Teams responsible for CDF will produce a quarterly report on the activity of the CDF review panel for submission to NHS England and the chair of the review panel. It will document CDF review panel decisions. The chair of the review panel will provide reports to NHS England.

Feedback on the process by applicants to the CDF will be considered on a monthly basis by the Chairs of both CDF and CDF review panels supported by pharmacy, public health and communications leads. Changes to processes will be made as necessary.

Appendix G. Terms of reference of the NCDF panel

1. Background and key principles

1.1. The shadow NHS Commissioning Board reviewed in early 2013 a number of drug treatments common to the regional CDF approved funding lists that were not available for use in particular groups of patients through normal NHS funding routes (see section 4.5) and included these in the national CDF Cohort Policy List in April 2013. In order to commence these drug treatments for individual patients, clinicians have to notify the relevant CDF Local Area Team of their intention to commence treatment using the relevant online prior notification system. Where the relevant criteria are met, funding should be confirmed automatically although it should be noted that treatment should not be commenced until confirmation of funding has been received.

1.2. The use of an agreed list of drugs/indications to be funded by the NCDF if specific criteria are met has been extended since April 2013 with the creation of a nationally agreed list of drugs/indications and related criteria. Requests for drugs covered by this national CDF Cohort Policy List remain suitable for approval on a notification and confirmation basis.

1.3. There are three approaches to the development of a national cohort list:

- 1. Members of the CRG for Chemotherapy regularly horizon-scanning for:
    - new NICE Guidance
    - newly licensed drug / indication combinations
    - new drugs coming to market
    - new off-label indications for existing drugs
- The CRG for Chemotherapy will be representative of oncology (adult and paediatric) and haemato-oncology clinicians in the country and will act as a conduit for information on new drugs/indications from clinicians to the NHS England.
- 2. Aggregated national data on ICDFRs will also inform the list. If more than 20 cases have been requested by this route, representing a potential cohort, consideration will be given to including the drug/indication on the national list.
- 3. Applications directly to the CDF panel on behalf of the Chemotherapy CRG from the pharmaceutical industry and/or from clinicians for drugs for potential cohorts of patients.

1.4. A population or cohort-based decision will be made for cancer drugs/indications to be included in the national list (see below). A cohort in this

context is where there are likely to be 20 or more patients in England per year that could benefit from the drug for a specific indication. Evidence has shown that a cohort approach provides transparency, equity and speed of decision-making, reduces the burden on clinicians and managers, and supports forward planning.

1.5. Decisions will be made by the CDF within a formal process as to which drugs and related indications and which criteria for use are approved for the single national CDF approved list . This will involve a nationally co-ordinated horizon-scanning and prioritisation process where drugs will be identified and considered prior to the point of licensing and cohort policies developed in readiness. This will avoid delays in making the drugs available via the CDF once licensed. There is one caveat to this: that the prepared cohort policy implementation will be dependent on gaining a sufficient level of prioritisation of clinical effectiveness achieved by the drug under consideration in conjunction with assessment of the median drug cost per patient, its budgetary impact and the projected expenditure of the whole CDF at the time.

1.6. Updates and changes to the list will be made by the CDF panel on behalf of the CRG for Chemotherapy and formally reported to the Medical Directorate of NHS England through the Cancer & Blood PoC Board. The process will take into account recommendations from the clinically-led regional CDF panels, the 12 Strategic Clinical Networks and the Cancer & Blood PoC. These groups will be representative of all oncology (adult & paediatric) and haemato-oncology clinicians.

1.7. Decisions will be based on the national CDF Prioritisation Tool (see Appendix D) in conjunction with an assessment of the median drug cost per patient. This evaluation will be completed for each drug/indication under consideration and will result in an overall score based on a number of factors, including:

- impact on progression-free survival
- impact on overall survival
- impact on quality of life
- impact on toxicity/ safety
- an assessment of unmet need according to the CDF definition
- the median drug cost per patient
- an overall assessment of value for money incorporating all of the above.

1.8. Drugs on the national list will continually be subject to an overall value for money test within the overall CDF budget, being added or removed according to their relative aggregate score using the national CDF Prioritisation Tool in conjunction with the assessment of median drug cost

per patient. Drugs whose aggregate score is below the threshold applicable at the time will not be added/will be removed from the list.

2. Purpose of the National Cancer Drugs Fund (NCDF) Panel

2.1 The NCDF panel is a subgroup of the Chemotherapy Clinical Reference Group (CRG) of the NHS England and is constituted by members of the Chemotherapy CRG, further lay representation and co-opted members as appropriate. Its terms of reference are determined by the Chemotherapy CRG. It will manage the NCDF on behalf of the Chemotherapy CRG and thus on behalf of NHS England. The NCDF panel will be chaired by the chair of the Chemotherapy CRG or by a nominated deputy if the CRG chair cannot attend. The NCDF panel will be quorate if six or more members are present.

2.2 A Declaration of Interest must be submitted by all NCDF panel members at each meeting to identify any potential conflicts of interest in relation to there being any personal/non-personal/ pecuniary/non-pecuniary interests or potential ones. These could relate to the drug concerned and its manufacturer, or a competitor drug and its manufacturer or to entirely different drugs but manufacturers common to the application or its competitors.

2.3 Declaring an interest means that these have to be considered in the light of the opinions expressed by individual members. Any CDF panel member will not be allowed to participate in the final decision making part of a consideration of a drug/indication e.g. he/she will not be allowed to have a vote in situations where there is not a consensus within the committee.

3. Role of the NCDF Panel

The Role of the NCDF panel is to manage the NCDF on behalf of the Chemotherapy CRG and therefore on behalf of NHS England. Its remit is to:

3.1. Monitor activity and expenditure of the NCDF through receiving monthly reports from the four Area Teams

3.2. Support the management of the NCDF budget to maximise the overall clinical value to NHS patients and value for money to NHS England within the allowable spend

3.3 Set the threshold total score below which a drug will not normally be admitted to the CDF on a cohort basis. The threshold will be set at such a level that the projected spend of the CDF is within the CDF's budget, and may be reviewed from time to time to ensure that this remains the case.

3.4. Assess and score new applications for cohort funding from the NCDF

3.5. Prioritise new applications against those drugs/drug applications which are in the approved NCDF list

3.6. Decide whether new applications should be included in the NCDF list

3.7. Re-evaluate and decide whether there should be drugs/drug indications removed from the NCDF list if such indications are judged to offer insufficient clinical value or insufficient value for money within the available CDF budget.

3.8. Remove NICE approved drugs/drug indications from the NCDF list

3.9. Horizon scan with the support of the National Clinical Effectiveness Team and from liaison with NICE and the pharmaceutical industry

3.10. Monitor the outcomes of the national audit and to perform other audit as appropriate of NCDF activity

3.11. Make regular reports to the Chemotherapy CRG and NHS England

3.12. Publish quarterly activity data on the NHS England website.

3.12. Draft an annual report on activity and expenditure

4. Meeting frequency

4.1 The NCDF panel will meet at least quarterly and the rolling programme of meeting dates and relevant deadlines will be published on the CDF pages of the NHS England website. The NCDF panel will hold six kinds of meeting:

- the NCDF panel will meet in public to assess requests for inclusion in the NCDF list and examine the clinical impact of an applications according to the criteria set out within the CDF Prioritisation Tool
- the NCDF panel will meet in private after the open meeting in order to consider the clinical impact of a drug/indication, will score the application formally using the CDF Prioritisation Tool and assess the impact of the median drug cost per patient on the overall CDF score and thus whether a drug indication remains or comes into the CDF or not
- The NCDF panel will meet in a closed session to set the appropriate threshold for admission to the NCDF list

- delegated members of the NCDF panel will meet with the applicant or relevant manufacturer to inform them of the outcome(s) of the NCDF panel meeting and the reasoning behind such decisions. For drugs/indications which have failed to be approved by the NCDF panel on account of a failure to achieve sufficient value for money, the manufacturer has the option to consider a commercial in confidence arrangement which offers an end effect of a discount on drug price. Such a discussion would take place at this confidential meeting

- delegated members of the NCDF panel will meet with patient groups, clinicians, manufacturers and other stakeholders after the outcomes of each NCDF panel meeting have been made public. Only the details of the clinical scoring and other relevant clinical information will be discussed at this meeting

- the NCDF panel will meet on an ad hoc basis by teleconferencing to discuss urgent issues in relation to the content of the approved NCDF list.

5. Horizon scanning

5.1. Section 6.2 of the CDF Standard Operating Procedure states that there are three approaches to the development of a national cohort list:

- 1. Members of the CRG for Chemotherapy regularly horizon-scanning for:
  - New NICE guidance
  - Newly licensed drug/ indication combinations
  - New drugs coming to market
  - New off-label indications for existing drugs

The CRG for Chemotherapy will be representative of oncology (adult and paediatric) and haemato-oncology clinicians in the country and will act as a conduit for information on new drugs/indications from clinicians to the NHS England.

- 2. Aggregated national data on ICDFRs will also inform the list. If more than 20 cases have been requested by this route, representing a potential cohort, consideration will be given to including the drug/indication on the national list.

- 3. Applications directly to the Chemotherapy CRG from the pharmaceutical industry and/or from clinicians for drugs for potential cohorts of patients.

5.2. It should be noted that the NCDF panel require applications for licensed drugs or drugs which are due to be licensed within 6 months for that indication to be submitted by the manufacturer or clinicians but applications for off-label indications to be submitted by clinicians.

5.3. This guidance therefore outlines the processes and timelines for all cohort applications which will, in effect, be submitted directly to the NCDF Panel.

6. Aims

6.1. In the case of licensed drugs and indications, the NCDF panel aims to make decisions on submissions to it within eight weeks of a license being granted by the European Medicines Agency (EMA). This will require the active support of the manufacturer through submission of all information required in a timely manner that allows the NCDF panel to come to a decision within these timescales.

6.2. Manufacturers are encouraged to submit applications within a 2-6 month window prior to launch of the product for the expected indication and place in the treatment pathway in NHS England. Pricing information (including any discounts to be offered) can be provided in the initial application or as an addition at any point up to the submission deadline of four weeks prior to the NCDF panel meetings. This information will be treated as commercial in confidence and will only be shared with panel members. **IF THE FINAL PRICE TO THE CDF (INCLUDING ANY DISCOUNTS TO BE OFFERED) IS NOT CONFIRMED BY FOUR WEEKS PRIOR TO THE NCDF PANEL MEETING, THE APPLICATION WILL BE DEFERRED TO THE NEXT MEETING.**

6.3. In the case of off-label indications for licensed drugs, clinicians are encouraged to submit applications as soon as possible in advance of the intention to commence treatment in a cohort of patients. In such situations, clinicians must recognise that the NCDF panel will only meet to review applications every 8-12 weeks and that submission deadlines will be four weeks prior to each meeting.

6.4 The NCDF panel will aim to make all decisions public on applications within 10 working days of the panel meeting and within 6 weeks of the submission deadline for each meeting. The exception to this aim is if the NCDF panel is instructed to defer the release of the decisions by NHS England.

6.5 The delegated subgroup of the NCDF panel will meet with the individual applicant or pharmaceutical company after each NCDF panel meeting to discuss the outcomes of the panel's deliberations and the influence of the assessment of median drug cost per patient on the final decision.

7. Stage 1 – Notification

7.1. Individual clinicians or manufacturers planning to submit an application should notify the NCDF panel of that intention using the form provided on the NHS England CDF webpages (Appendix I) as soon as possible and within the 2-6 month window prior to launch or intended use of the product in the indication. Notification should be sent to davidthomson1@nhs.net

7.2. The titles of the submissions and logistical details of the NCDF panel meeting it will be submitted to will be posted on the CDF webpages on the NHS England website.

7.3. Where an application is submitted for a drug in an indication for which the Cancer Drug Fund already funds another drug(s) the manufacturer(s) of the alternative products will be notified and will also be asked to prepare an updated submission and presentation for the same NCDF panel meeting.

7.4. Where an application is submitted by a clinician for an off-label use of a licensed drug the manufacturer of that product will be notified and will be invited to attend the NCDF panel meeting for their information if they wish.

7.5 Agendas, including all the topics to be discussed at the NCDF panel meetings will be published on the NHS England CDF webpages at least two weeks prior to the meeting.

8. Stage 2 - Application

8.1. Application forms are available on the NHS England CDF webpages. These contain instructions for completion which should be followed by all applicants and should be completed in full.

- The application form has a scoring system for the clinical impact of a drug/indication on progression free survival, overall survival, quality of life, toxicity and unmet need.
- In addition, the application form must state the median drug cost per patient. If this cost is commercial in confidence, then this information should be submitted on a separate form (provided).
- The application must also make clear the following:
- where the new treatment sits in the patent treatment pathway for that disease
- what the standard comparator treatment is
- whether it replaces another treatment in baseline commissioning or the CDF
- whether it increases, decreases or makes no difference to other treatment options in the treatment pathway
- what the selection criteria for use of the drug/indication should be
- and what the continuation and discontinuation rules should be for the administration of the drug.

8.2. Completed application forms should be submitted, at the latest, by the submission deadline for the meeting to davidthomson1@nhs.net. The submission deadline will be two weeks prior to the NCDF panel meeting. In addition applicants should supply pdf copies of the relevant key papers used to support their prioritisation scores. **SUBMISSIONS RECEIVED AFTER THE DEADLINE FOR NEW APPLICATIONS WILL AUTOMATICALLY BE DEFERRED TO THE NEXT NCDF PANEL MEETING**. IF SUBMISSIONS FOR RE-EVALUATION OF CURRENTLY APPROVED DRUGS/INDICATIONS ARE LATE, THE CDF PANEL RESERVE THE RIGHT

TO AUTOMATICAALY REMOVE THAT DRUG/INDICATION FROM THE NCDF LIST.

8.3. The application form asks for costing details which will inform the panels estimations of budget impact, however, the NCDF panel will additionally accept budget impact models developed by pharmaceutical companies for review.

8.4. As noted in point 2.2, the proposed price of the drug (including proposed discounts where relevant) must be received by the NCDF panel by the submission deadline in order to avoid potential delays to the panels decision-making. This information will be treated as commercial in confidence and shared only with NCDF panel members. **IF FINAL PRICE TO THE CDF (INCLUDING ANY DISCOUNTS TO BE OFFERED) FOR NEW DRUGS IS NOT CONFIRMED BY FOUR WEEKS PRIOR TO THE NCDF PANEL MEETING, THE APPLICATION WILL BE DEFERRED TO THE NEXT MEETING.**

9. Stage 3 – NCDF Panel Review

The NCDF Panel Review will have four parts:

9.1. A pre-meeting review by the NCDF Panel

- After receipt of applications the NCDF panel Chair and NCDF Pharmacist will review the applications and the budget impact models. If any immediate questions arise they will contact the applicant(s) for clarification.
- • Applications will be circulated to panel members for review and for initial scoring using the prioritisation tool. These scores will be returned to the NCDF Pharmacist by a deadline of 48 hours before the meeting.
- NCDF panel meeting agendas will be sent out to panel members, the applicants, and other relevant stakeholders.

9.2. An open meeting with applicants and other stakeholders

- At the open NCDF panel meeting, applicants will be asked to present a brief summary of their case. It is suggested that this presentation is laid out as follows:
- Brief summary of the drug, the condition in which it is indicated, its place in the treatment pathway and its standard comparator(s).
- Evidence and prioritisation tool score for disease free survival (DFS) /progression free survival (PFS)/ time to progression (TTP)
- Evidence and prioritisation tool score for overall survival (OS)
- Evidence and prioritisation tool score for quality of life (QoL)
- Evidence and prioritisation tool score for toxicity
- Evidence and prioritisation tool score for degree of clinical unmet need

- The clinical criteria for use of the drug, the rules to be employed for continuing and discontinuing the drug, the effect on the treatment pathway and evidence of national support for the application
- The median drug cost per patient and annual budget impact in NHS England in-year and in the two following financial years. Any commercial in confidence discounts should not be presented in this open meeting and instead budget impact based on list price should be presented.
- Each applicant will have present their application and there will be a Q&A session with the panel. All applicants are invited to attend the full open meeting.
- Computer and projection facilities will provided and presentations should be prepared using Microsoft PowerPoint.•
- The individual scores for each aspect of the prioritisation tool will be noted as given by the applicant and subsequently debated, as will all the clinical aspects relating to the drug concerned and its clinical consequences, The median drug cost per patient and the budgetary impact in England will be noted according to the list price. Any additional issues relevant to decision-making will also be also discussed.
- The criteria setting out the conditions of use in the NHS will be ascertained for potential inclusion in any NCDF application proforma.
- Once all presentations have been made and discussed the open session of the NCDF Panel will finish. No NCDF Panel decisions will be made at the open meeting.

9.3. A closed meeting of NCDF Panel members

- The NCDF Panel will immediately afterwards meet in a closed private session to make final decision(s) on the application(s) received and presented.
- The NCDF Panel will consider all the evidence of the new applications in the light of: the NCDF cohort list and the clinical value of the currently approved drugs/indications, the NCDF activity for all applications, the NCDF expenditure (both actual and projected) and any NICE guidance that has been issued.
- Assessment and scoring of clinical impact will primarily be on the level playing field of various domains of clinical effectiveness (PFS, OS, QOL, toxicity, unmet need) with the proviso that the NCDF panel can also use its clinical judgement alongside these scores from the prioritisation tool. The NCDF panel will also be expressly required to consider any relevant equality considerations, bearing in mind that each illness will have its own specific patient profile and that that fact alone would not necessarily raise an equality issue. The NCDF panel will also assess the clinical support for the application and the strength of the evidence for this. The formal scores for each domain will be recorded for each topic considered.

- The NCDF panel will then score the median drug cost per patient according to its 2 scoring systems, one for drugs for very rare indications and the other for all other drugs/indications. The details of these scoring systems are confidential as making both these and the ensuing individual drug scores public would allow the determination of the commercial in confidence prices offered to the CDF. Two scoring systems are necessary as the CDF recognises that drugs developed for very rare indications should receive a higher level of reimbursement than those with multiple indications and/or for larger groups of patients
- An overall aggregated score which combines both the scores of clinical benefit and the median drug cost per patient will then be determined by the NCDF panel. These scores are also confidential as these too contain information that may be commercial in confidence and thus cannot be made public..
- The NCDF Panel will consider the individual applications with their aggregated scores and place them in context of all the other approved drugs/indications and alongside the likely budgetary impact of the new applications and estimated NCDF expenditure within the live NCDF cohort list.
- The NCDF panel will then make decisions on behalf of the Chemotherapy CRG and NHS England as to which drugs should be added to the NCDF cohort list and which should be de-prioritised from this list.

9.4 A closed meeting between delegated members of the NCDF panel and individual pharmaceutical companies

- The NCDF panel will inform the pharmaceutical company of the score of clinical benefit, the score of the median drug cost per patient and the final overall score
- The NCDF panel will inform the pharmaceutical company of the decision as to whether the drug enters the approved CDF list or not or whether it remains in the approved CDF list
- A written record of the outcome of these individual meetings will be made by the NCDF panel and sent to the relevant manufacturer.

9.5 The NCDF panel chair will meet with patient groups, clinicians and the pharmaceutical companies after the decisions are made public by the NCDF panel as to inclusion or retention of drugs within the CDF. This meeting is to explain the reasoning why the panel made its decisions. Only the scoring of clinical impact will be made public at this meeting. If however an agreement has not been reached with a manufacturer on fair pricing, so as to enable a medicine to be included in the CDF, the Panel then reserve the right to explain publicly why a negative decision was necessary.

9.6. Re-evaluation and re-prioritisation of drugs in the National Cancer Drugs Fund cohort list

- Re-evaluation and re-prioritisation are necessary as new and better treatments are continually being licensed and the NCDF budget is fixed.
- Re-evaluation and re-prioritisation of drug treatments in the national CDF Cohort Policy List is planned to be undertaken on an annual basis although the NHS England reserves the right to do this re-evaluation and re-prioritisation process more frequently if necessary in order to manage the CDF budget.
- A CDF drug will not be removed from the CDF if it is the only systemic therapy available for that particular cancer indication. If the CDF drug indication is the only such therapy available for any NHS patient, it will not be subject to the de-listing process.
- The need to keep projected future expenditure within the CDF budget will determine which level (s) of aggregated scores of clinical benefit and median drug cost per patient are applied in the de-prioritisation process at any one time.
- The NCDF prioritisation tool of clinical impact has four domains which yield five separate component scores on which all applications can be and are scored. In addition, there is the score obtained from assessment of the median drug cost per patient. Both these scores are added together to give a total score. For each drug with its associated indication, the total score results it being placed in a ranking order, although the individual domain scores will differ from drug/indication to drug/indication within each total score level, as will the scores of median drug cost per patient differ too.
- The NCDF prioritisation tool provides a mechanism whereby phase II and phase III trial data can be included for consideration of prioritisation, thus incorporating assessment and ranking of treatments for common and rarer diseases, for solid tumour oncology and haematological malignancy and for paediatric, teenage and young adult and adult practice.
- The domains used to provide a ranking are as follows:
    - Domain 1A is for scoring of progression-free survival
    - Domain 1B is for scoring of overall survival
    - Domain 2 is for scoring of quality of life
    - Domain 3 is for scoring of toxicity
    - Domain 4 is for scoring of unmet need
    - The score from the assessment of median drug cost per patient
    - The overall score is obtained by adding all of the above
- The re-prioritisation process requires the ranking of each drug/indication and is as follows:

1. Select drugs/indications with lowest total score and examine each individual domain scores

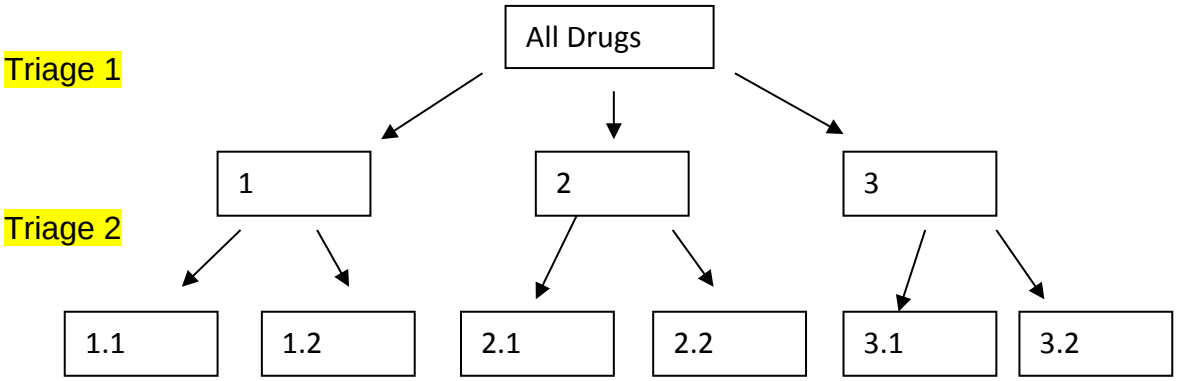
2. Are the results published in a peer-reviewed journal? If they are only published in abstract form the drug will be placed at bottom of triage.

3. The domains of the prioritisation tool are then used to rank sequentially the remaining drugs/indications in this order:

- first triage is according to the score for unmet need (in domain 4)
- second triage is according to the scores for overall survival benefit (domain 1B)
- third triage is according to scores for Quality of Life (domain 2)
- fourth triage is according to score for toxicity (domain 3)
- fifth triage is according to the score for median drug cost per patient

Final triage is for cost-effectiveness as determined by a NICE-assessed incremental cost-effectiveness ratio (ICER). However, all the remaining drugs/indications at this stage in the triage process must have NICE ICERs available (for the price that the NCDF pays) for this stage in the triage process to proceed.

In each case, drugs ranked equally at one stage in triage are then subdivided at the next stage, drugs ranked equally at that stage are further subdivided and so on, represented graphically as:



and so on

4. Ranking proceeds in this way and in this order at each level in the triage process within each single total score figure.
5. Once ranking has been achieved, the estimated savings required will determine where the threshold will be for remaining prioritised within the NCDF and being de-prioritised from the NCDF. This will be determined by the NCDF panel.
6. The above process is repeated at the next prioritisation tool total score until sufficient savings on expenditure are achieved.

The NCDF panel is also expressly required to consider any relevant equality considerations in every decision within its remit, bearing in mind that each illness will have its own specific patient profile and that that fact alone would not necessarily raise an equality issue.

10. Stage 4 – Communication of decisions

10.1. The applicant will be informed of a final decision at the closed meeting with individual applicants (see 9,4 above). Applicants are asked not to share this

decision until NHS England publishes the decision and an updated CDF Cohort List. It is expected that any delay to the final decision making process will be short if new commercial in confidence arrangements as to drug pricing are being put in place. It is still expected for any new pricing arrangements to be submitted back to the CDF within 1 week of the date of the closed meeting between the CDF and an individual pharmaceutical company (as in 9.4 above).

10.2. The NCDF panel will also:

- Prepare and send to the four regional panels application forms which include the agreed criteria for use of the drug for upload onto the regional databases.
- Prepare an updated national CDF cohort list, a completed scoring tool of clinical benefit and a decision summary for publication on the NHS England website. There will be no declaration of the score obtained for the median drug cost per patient nor of the overall final score as this would lead to commercial in confidence arrangements as to pricing being made public.

10.3. Decisions will be made public within ten working days of the NCDF panel meetings and will generally be of one of four types:

- Approved for addition to the NCDF Cohort List
- Pending approval based on further information being required
- Not approved for addition to the NCDF Cohort List
- De-prioritisation and removal from the NCDF Cohort List

10.4. Clinicians will be able to access drugs added to the NCDF Cohort List via the normal regional application and notification systems, where the agreed criteria are met, from the time of publication of the decision on the NHS England website.

10.5. Experience to date has demonstrated the importance of keeping the national CDF Cohort Policy List dynamic. It should not be viewed as restrictive and will be kept under regular review to take account of NICE appraisal recommendations, other new evidence, modified pricing arrangements if applicable, availability of new treatments and fluctuations in the numbers of patients presenting for treatment.

10.6. Where a drug has been removed from the national CDF Cohort Policy List following its recommendation by NICE or the agreement of a NHS England chemotherapy commissioning policy, treatment will be available on the NHS, subject to any clinical criteria set out by NICE/the policy. In these cases, NHS England would normally be expected to assume responsibility for patients

whose treatment had previously been supported by the CDF. This will be from the point at which NHS funding is available.

10.7. For drugs within the NCDF cohort list that subsequently receive positive NICE Technology Appraisal Guidance, it will be expected that NHS England funding will be available within three months of that guidance being issued. If NICE issues 'optimised' guidance (i.e. for a subgroup of the indication that is in the NCDF approved list), then this will trigger an automatic review of the remaining patient groups within the NCDF cohort list.

10.8. A notice period of two months will be given for de-prioritisation of drugs from the NCDF cohort list. For drugs which are de-prioritised from the NCDF list, continued treatment of individual patients whose treatment was approved prior to its de-prioritisation and removal from the CDF Cohort list will continue to be funded by the NCDF.

10.9. For a drug under consideration for prioritisation which potentially displaces a drug which is in the NCDF approved list and is at the same position in the treatment pathway, both drugs will be reviewed at the same time so that their overall benefits, costs to the NCDF and the consequences of potentially including either one or the other or both in the NCDF list can all be discussed in public before the NCDF makes a decision.

10.10 Individual funding requests on the ground of exceptionality are still possible for drugs which fail to enter the CDF or for drugs which are removed from the CDF.

10.11. There is a formal complaint process for applicants and also for clinicians who are dissatisfied with the outcome of either inclusion or exclusion of a drug in respect of the NCDF approved list. This will be through a written letter to the chair of the NCDF panel outlining the reasons for complaint.

10.12. There is a formal review process by which applicants can challenge the process of the decision-making.

11. Formal Reviews to a Decision of the NCDF Panel

11.1. A request for a review of an NCDF Panel decision can only be made by the clinician or pharmaceutical industry representative that made the original application.

11.2. The request for such a review is made to the NHS England Programme Board for Specialised Blood and Cancer. This is the NHS England committee that has direct oversight of the Chemotherapy CRG. In reviewing the appeal, the

Programme Board will not revisit the merits of the application but will consider the process under which it was considered.

11.3. The request for a review should be made in writing to the Chair of the NHS England Programme Board (Specialised Blood and Cancer) and must be lodged within 20 working days of the original decision being notified.

11.4. The request for a review must set out the grounds on which the NCDF Panel decision is being challenged. A review can be requested only on two grounds, if it is believed that:

- The NCDF panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed

Or

- The NCDF Panel did not take into account relevant evidence presented to it in reaching its decision.

11.5. The NHS England Programme of Care Board will either uphold the decision of the NCDF Panel or it will instruct the NCDF Panel to reconsider the application.

11.6. The decision of the NHS England Programme of Care Board is final. However, applicants may have recourse to the NHS complaints procedure including onward referral to the Health Service Ombudsman and ultimately judicial review.

Appendix H. NCDF Notification Form

1. Applicants details*

Applicants name	
Position	
Employing organisation	
Email address	

2. Application details

Medicine			
Brand name (if available)			
Tumour site (e.g. Haem))			
Manufacturer			
UK Licensed status	Licensed Y/N	In development Y/N	Licensed but off-label use Y/N
Proposed indication			
Proposed place in therapy (e.g. line of treatment or adjuvant use)			
Licensed indication (if different to that proposed)			

3. Key dates

3.1 Licensed products	
a. Expected date of license	
b. Expected date of launch	
3.2 Off-label products	
Proposed date of commencement of treatment in cohorts	

4. Please indicate below at which NCDF panel meeting date you wish the application to be discussed (tick the appropriate box)

November 2014		May 2015	
January 2015		July 2015	
March 2015			

*By completing this form and submitting it to the NCDF panel you are agreeing to your details being posted on the NHS England website as the lead for this topic.

Completed forms should be sent by email to davidthomson1@nhs.net