NHS England

NHS England consultation: Proposals for a sustainable Cancer Drug Fund

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NHS England Consultation: Proposals for a sustainable Cancer Drug Fund

A guide to the consultation on proposals for a sustainable Cancer Drug Fund – why we are consulting and how to respond.

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Introduction

1. The Cancer Drugs Fund (CDF) has been a success in enabling cancer patients to access the drugs that would not otherwise have been available from the NHS. More than 55,000 patients have now accessed treatment since the fund was established in 2010.

2. However, in order that the CDF continues to offer maximum benefit to patients within its budget, i.e. offer drugs with the greatest clinical benefit at appropriate costs, it requires a degree of change in the way it operates, in order that it can better meet the demand for new drugs. This demand continues to rise, and means that the CDF is now facing growing financial pressure.

3. We need to ensure that the fund operates in such a way that it can continue to provide a high quality and effective service to patients. We must take urgent action to ensure that the CDF remains sustainable for the longer term.

4. In August this year, NHS England pledged an additional £160 million over two years to strengthen the fund. There were also proposals put forward by experts in the field of cancer care, to review the drugs currently on the CDF list, to ensure that only those demonstrating the greatest degree of clinical benefit, at appropriate costs, remain on the list. It is necessary to seek and consider the views of stakeholders before finally deciding whether to adopt those proposals.

5. This re-evaluation of existing drugs would – for the first time – assess the clinical benefit delivered in treating a patient with a drug, in relation to the cost of that drug. This process would enable drugs of limited clinical benefit to be removed from the list, paving the way for other drugs to be added which would still offer substantial clinical benefit, but at a lower cost. A pharmaceutical company would have the option, as part of the proposed new process, to make a confidential adjustment to its drug price to allow the drug/indication to remain in the CDF.

6. The concept of re-evaluating the CDF list is not new. A re-evaluation process is described in NHS England's current Standard Operating Procedure (SOP) for the CDF.

7. However, in order to implement the proposals for the future sustainability of the CDF, as agreed this summer, we need to revise this SOP and incorporate the new proposals for assessing clinical benefit in relation to drug costs.

8. This is a significant change to the way we do things, and therefore we feel it is important that we test out our proposals with as many people as possible who have an interest in the fund, and in particular through this consultation that we involve patients in our decision making.

9. Over the next four weeks, we want to provide an opportunity for – patients; patient groups; clinicians; commissioners, pharmaceutical companies, and others – to make their views known about our proposals for change. This short guide summarises the context, and objectives for this consultation, as well as details about how you can make your views known, and next steps.

Background

1.1 What is the Cancer Drug Fund?

10. The Cancer Drugs Fund (CDF) was fully established in April 2011 (interim from October 2010) in response to concerns regarding the lack of availability of some cancer drugs in England. The main concerns related to two types of cancer drug: those drugs which had been reviewed by NICE, and were viewed as not cost-effective; and those drugs used in the treatment of rarer cancers, which did not fall within NICE's scope. Neither of these types of drug were being routinely commissioned.

11. The NHS spends approximately £1.3 billion annually on the provision of cancer drugs within routine commissioning. The CDF was established as an additional funding source to this.

12. The remit of the CDF was to provide maximum support to NHS patients by improving access to cancer drugs in England; put clinicians and cancer specialists at the heart of decision-making, enabling them to use their professional judgement in making decisions about patient care; and to act as an effective bridge towards the Government's aim of introducing a value-based assessment system for branded drugs. The CDF is part of the NHS's wider national strategy on improving outcomes in cancer.

13. *The Coalition: our programme for government* confirmed the Government's commitment to the establishment of the CDF from April 2011 totalling £200million per year. The fund was regionally administered from its inception, to the end of March 2013, and each of the 10 regions managed the fund through a process of clinical decision-making. This benefited patients by putting clinicians and cancer specialists at the heart of decisions about patient treatment, but resulted in increased variation in access to drugs as policy lists differed across the country, thereby introducing a post code lottery for drugs available within the various regional funds.

14. NHS England took on responsibility for the operational management of the CDF on 1 April 2013. As a single, national commissioner, NHS England operates a single, national list of drugs and indications which it will routinely fund, and has published standard operating procedures, describing the process for the fund's administration. The initial national list of drugs and indications was compiled before 1 April 2013 by the NHS England Clinical Reference Group (CRG) for Chemotherapy, working with the local clinicians

who previously oversaw the administration of the regional funding arrangements.

15. The formation of a single, national list of drugs and indications in April 2013 ensured a consistent approach to the funding of cancer drugs across the country. A national panel of clinicians, cancer specialists, and lay representatives now considers applications to add drugs/indications on to the list using a CDF prioritisation tool, administered through an open and transparent process. The CDF prioritisation tool currently assesses the clinical impact of treatment on patients by examining the effect of a drug on:

    - Progression-free survival
    - Overall survival
    - Quality of life
    - Toxicity
    - Unmet need i.e. whether it is the first demonstration of efficacy of systemic therapy in a disease.

    The clinical impact of some drugs cannot be fully captured by the CDF prioritisation tool alone. In addition to the tool, the national, clinically-led decision-making panel, which includes patient representation, uses its expert judgement to decide whether or not drugs/indications should be included in the national CDF approved list. Since April 2013, the national CDF panel has recorded its scoring, reasoning and decisions on the CDF web page on the NHS England website.

16. In 2013/14, the national CDF panel considered 55 new cohort policies, approving 22 and declining 33. The national list has been updated seven times to date. There are now 41 drugs for 83 indications available for routine access. Clinical impact has been the sole determinant of what has been prioritised into the CDF up until now.

17. The Government announced a further £400m investment in the CDF in 2013 (£200m per year) meaning that the fund will extend to the end of March 2016. This policy, in conjunction with the announcement by Simon Stevens in August 2014, means that the budget for the CDF is £280m per year for 2014/15 and 2015/16.

1.2 The Standard Operating Procedure (SOP)

18. The current SOP was published in April 2013 (and updated in January 2014) and sets out, in detail, the way in which NHS England will administer the national CDF. It describes the single, national allocation of funding; and the process for arriving at a national list of approved drugs. It also describes the management of the fund for Individual Funding Requests (IFRs) via four regional clinical panels, which are administered by nominated NHS England area teams.

19. The published SOP allows for the relative prioritisation of drugs, on the basis of their clinical effectiveness. Applications for inclusion on this national list are assessed primarily on the strength and quality of the evidence of this, as well as the anticipated delivery of measureable outcomes, such as improved survival rates and quality of life. Drugs are ranked according to their clinical value and are scored.

20. This process is carried out by the national CDF panel, on behalf of NHS England's Chemotherapy Clinical Reference Group (CRG).

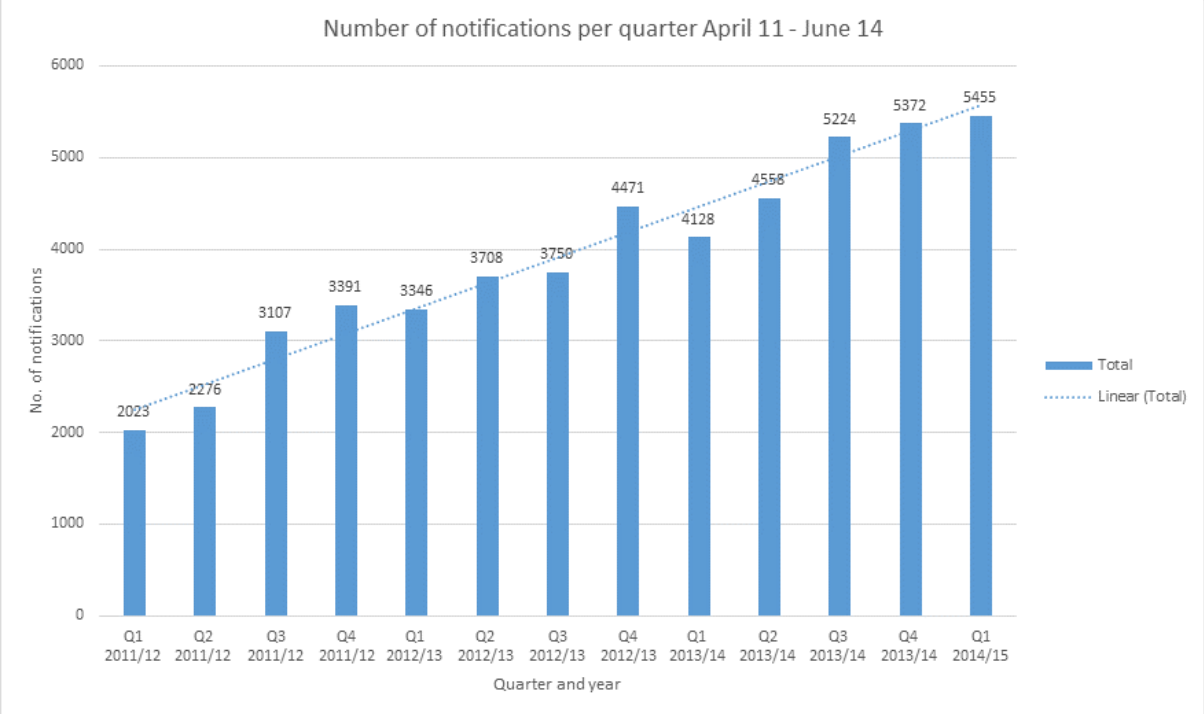
The case for change

21. The CDF has had a positive impact on cancer treatment for patients in England by providing options for therapy that are not available routinely in the NHS. NHS England has maintained the promise to ensure clinicians and cancer specialists are at the heart of decision-making by establishing the national clinical panel to maintain the drug list, and regional clinical panels to consider individual patient cases. However, demand on the CDF has increased since its establishment in 2011, with approximately 2000 new patients currently gaining access every month.

22. Rising demand has been driven by the emergence of new drugs, and new lines of therapy, which have provided clinicians and their patients with additional options in treatments. There has been a steady increase in the pricing of new cancer drugs over the last five years, with a marked increase seen in the cost of treatments in the last two years.

23. Graph 1 highlights the total number of applications against the national list. This does not include those cases considered through the Individual Funding Request (IFR) route (approximately 5% per year).

Graph 1



24. The total CDF spend of £230,539,005 for 2013-14 represents a £30.5 million overspend on the then £200 million budget. This position was forecast early in 2013-14.

25. Spending of the CDF on cancer drugs is in addition to expenditure on other aspects of cancer treatment, and in addition to expenditure on cancer drugs through routine commissioning by NHS England. This means that an additional £30 million was taken from NHS England's budget to manage this overspend. The consequence of this is that this money was not available to fund other forms of care and treatment for cancer patients or for other disease areas.

26. For 2014/15 the projected spend based on the current CDF list and potential new drugs / indications is even higher than the increased budget of £280 million. Whilst this in part relates to increasing patient numbers, it also reflects the rising costs of some new individual cancer drugs.

27. In this context NHS England believes it is important to manage the CDF within its approved budget. Allowing unplanned overspends within future years would mean that either:

- treatment of individual patients with cancer would have to be curtailed later in each year, i.e. once that year's fund is exhausted, patients who would otherwise have been suitable for treatment with a drug funded by the CDF would not be able to receive that treatment. This would not be acceptable as it would mean patients would receive a different standard of care depending on when an application to the CDF was made; or

- funds earmarked for other NHS budgets in any year in which the CDF overspends would have to be used to support the CDF. This is likely to compromise the treatment of patients with cancer who require other types of cancer treatment, such as radiotherapy and/or surgery, and patients with other conditions who would otherwise have been treated from funds within those budgets. NHS England considers that such an approach would be unfair to these patients (who may also have life-threatening or life-limiting conditions, or otherwise be suffering significant impact from their health conditions).

28. This is why NHS England is considering changes to the CDF to ensure that it can operate in the future within its annual budget. NHS England also considers that, within its budget, the CDF will be able to be managed so as to achieve the best overall benefit for patients and the NHS from the very significant but limited funding given to it.

29. Whilst the CDF currently funds drugs of greater clinical benefit to patients it also includes a number of drugs with much less clinical impact. This latter group of drugs offers a very modest or no proven impact on survival and, in many cases, there is uncertainty as to whether quality of life is improved or not.

30. For applications received against the national list for 2014/15 so far:

- 63% have been for indications which have been deemed not cost effective by NICE;
- 22% were for indications still being considered through the NICE process;
- 12% have been for indications not being considered by NICE;
- 3% were for off label indications.

31. There are some new drugs which are likely to offer very significant clinical benefit, particularly for less common cancers, that will need to be considered during the remainder of 2014/15. Through our horizon scanning, we know that in 2015/16 there will be more new drugs, some having indications in the more common cancers.

32. The pressure on the CDF budget will therefore continue to rise. As part of managing a budget that can accommodate new drugs coming on to the list, we will need to constantly review whether the drugs currently on the list remain and continue to offer the CDF sufficient value for money (i.e. clinical benefit in relation to drug cost) as new drugs or alternative treatments.

33. As well as putting £160m more money over the next two years to ensure that patients can continue to access new cancer drugs, which offer sufficient value for money, we need to create the space to add those new drugs to the list, without increasing the overspend still further. To address this, we need to change the way we do things, hence the need for consultation.

Consultation

1.3 What are we consulting on?

34. NHS England is consulting on a number of proposed changes to the CDF SOP which experts believe will address the need for a more sustainable approach to managing the CDF effectively for all cancer patients and the NHS as a whole.

35. The purpose of a SOP is to set out how the CDF will be managed and how applications to the fund are assessed – both for drugs with identified cohorts of patients and for individual requests. It includes further guidance for clinicians on patient eligibility and the clinical evidence required for applications. It also sets out information specifically for patients. This document has been published on the NHS England website since 1 April 2013.

36. The main changes proposed are clearly marked in the draft, revised SOP, and relate to the process of re-evaluation and prioritisation of drugs in, and potentially for inclusion in, the CDF. They are:

- **Proposal A**: The CDF will implement a re-evaluation process which will assess the drugs on the current national list and remove those which represent the lowest levels of such clinical benefit.

  Please note that:

  A drug/indication will not be removed from the CDF if it is the only proven drug treatment therapy for a particular condition.

  Patients who are already receiving a drug/indication which is to be removed from the CDF will continue to be treated with that drug until they and their clinicians consider it appropriate to discontinue treatment.

  Drugs removed from the CDF will continue to be available via Individual Funding Requests on an individual basis if the patient meets the clinical exceptionality criteria.

- **Proposal B:** The CDF will incorporate into this re-evaluation system a confidential element which assesses the median drug cost per patient in relation to the clinical benefit delivered. It is thought that this part of the process has to remain confidential due to the need to protect commercial confidence.

- **Proposal C**. Drugs which are highly priced in relation to the clinical benefit they deliver will be removed from the CDF. The new process allows the pharmaceutical company the option of making an appropriate and confidential adjustment to its drug price to allow the drug/indication to remain in the CDF.

37. To date, clinical impact has been the only factor determining which drugs have been included on the national CDF list. The increasing cost of drugs now has to be considered to ensure that cancer patients, and NHS patients as a whole, get the most value out of the fixed amount of money allocated to the CDF and to the NHS.

38. It is proposed that an additional score be added to the scoring tool, that of the median cost of the drug. For drugs that have high costs to the CDF, the score for cost may outweigh its score for clinical benefit, which may result in it being removed from the list.

1.4 Objectives of the consultation

39. NHS England is seeking the views of the public and other stakeholders on the proposed changes set out above which, if agreed, will clearly outline the process by which the CDF will be managed for the remainder of 2014/15 and for 2015/16. This is to ensure we have a CDF that is fit for purpose, ensuring maximum clinical value for money within the available CDF budget, and thus the sustainability of the fund.

40. NHS England recognises the importance of new cancer drugs and wants to bring the drugs of greatest benefit and value into practice as soon as possible. NHS England also recognises that difficult choices have to be made, ones based on the degree of clinical benefit in conjunction with the cost of the drugs.

1.5 Transitional arrangements

41. If the proposals set out in this consultation document are adopted, NHS England proposes the following arrangements:

- Any patient already receiving a treatment funded through the CDF would be able to continue to receive that treatment funded by the CDF until they and their NHS clinician considered it appropriate to stop.
- Drugs which are the only systemic therapy for the indication in question will not be removed from the CDF even if their total score falls below the threshold total score.
- A two-month notice period will be given to the NHS of a drug's removal from the CDF.

42. A drug/indication removed from the CDF on a cohort basis will not be funded by NHS England for that cohort of patients. Funding may be available from the CDF following an individual funding request, if the conditions for such a request meet clinical exceptionality.

1.6 How can I make my views known?

43. NHS England is opening a public consultation for four weeks from 3rd October until midnight on 31st October 2014. This is line with Cabinet Office guidance on consultations. Comments received after midnight on 31st October will not be considered.

44. NHS England would like to receive responses to the following questions, as well as your views on the future operation of the CDF generally:

- **Question 1**: Do you agree with, or have any comment to make about, proposed change (A) – the implementation of a re-evaluation process which will assess the drugs on the current CDF list in respect of clinical benefit.

- **Question 2**: Do you agree with, or have any comment to make on, proposed change (B) - the list will be re-evaluated taking into consideration both clinical benefit **and** cost?

- **Question 3**: Do you agree with, or have any comment to make about, proposal (C) – that drugs which are highly priced in relation to clinical benefit should be removed from the list?

- **Question 4**: Do you agree with, or have any comment on, the proposal that, in order to protect current and potential future pricing arrangements between pharmaceutical companies and NHS England, which differ from the public list price of drugs, the proposed process should treat the scoring bands for assessment of drug cost and the individual cost scores of drugs as confidential.

- **Question 5**: Are there any other considerations that you think should be addressed in developing a process for prioritising drugs for inclusion within the CDF list?

- **Question 6:** Please provide any comments that you may have about the potential impact on health inequalities which might arise as a result of the proposed changes that we have described. Please also comment on any impact you consider there may be on equality matters more broadly.

45. Responses to these questions can be made through the online consultation.

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

46. We would like to hear from anyone with an interest in the subject matter of the consultation. We are committed to involving patients, and potential future patients, in the planning and consideration of the future sustainability of the CDF, and are particularly keen to hear from as many patients, carers and

patient representatives as possible, to inform decisions on proposals concerning the fund.

47. Responses will be public documents and all, or any part of a response, may be put in the public domain. If you wish to refer to any confidential information in your response, it must be included in a separate document which is very clearly marked as confidential on each page. NHS England is governed by the Freedom of Information Act. While it would seek to respect the confidentiality of any information provided to it, respondents should be aware that it may be obliged to release even confidential information under that Act.

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

Post-consultation

49. Following this consultation, NHS England will review all feedback received. All relevant feedback will be considered. NHS England will make a decision whether or not to approve the proposals, with, or without, amendments, or to reject them. Due to the likely volume of responses, feedback is likely to be presented in the form of a report capturing all material issues. The report will be published on the NHS England website.

50. The final SOP will be published on the CDF web page of the NHS England website during November.

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

Glossary

Cancer Drug Fund (CDF)	The CDF was established in an interim form in 2010, providing funds to enable patients to access cancer drugs which are not routinely funded by the NHS. The management of the CDF is set out in Standard Operating Procedures. The fund, which was formally established in 2011, includes a single, national list of drugs and indications that the CDF will routinely fund. It is due to operate until the end of March 2016. Further information about can be found on the CDF web page of the NHS England website.
Clinical Commissioning Groups (CCGs)	Established as statutory organisations from 1 April 2013, these are groups of GP practices which are responsible for buying the majority of hospital and community-based health services for patients within their local communities, taking over the role previously performed by Primary Care Trusts.
Clinical Reference Groups (CRGs)	There are 77 CRGs, covering the full range of specialised services, as well as armed forces and health and justice commissioning, and medicines optimisation. The CRG membership includes patient representatives, clinicians, commissioners, and others, and provide clinical advice in support of NHS England's direct commissioning function. Further information about CRGs can be found on the National programmes of care and clinical reference groups webpage of the NHS England website.
Cohort policies	A policy that affects a group of patients with the same clinical condition
Indications	An 'indication' for a drug refers to the use of that drug for treating a particular disease. For example, prostate cancer is an indication for docetaxel. Another way of stating this relationship is that docetaxel is indicated for the treatment of prostate cancer.
Individual Funding Requests	In some circumstances, a clinician (usually a consultant) may consider that a patient has exceptional clinical

	circumstances and may benefit from a treatment which is not routinely provided via the CDF. Requests for such treatment must be made through an Individual Funding Request (IFR).
Median drug cost per patient	The likely cost of treating a typical patient - the median value falls halfway between the range of values for a range of patients.
National Institute for Health and Care Excellence (NICE)	NICE provides independent advice about which treatments should be routinely available on the NHS in England. For more information visit the NICE website.
Off-label indications	There are clinical situations when the use of a medicine outside the terms of its licence (i.e. 'off-label'), may be judged by the prescriber to be in the best interest of the patient on the basis of the available evidence. Such practice is relatively common in certain areas of medicine, for instance, in cancer, where some medicines are used off-label.
Overall survival	The overall benefit in survival (often given in months) of a particular drug treatment.
Progression-free survival	The length of time during and after medication or treatment during which the disease being treated does not get worse
Quality of life	The overall enjoyment of life. Many clinical trials assess the effects of cancer and its treatment on the quality of life. These studies measure aspects of an individual's sense of well-being and ability to carry out various activities.
Relative prioritisation	In the context of this document this means the ranking of drugs by their score of clinical benefit
Standard Operating Procedure (SOP)	A detailed explanation of how a policy will be implemented (i.e. the detailed explanation of how the Cancer Drugs Fund is operated by NHS England)
Toxicity	The degree of harm a drug causes the patient
Unmet need	Where there are no other available treatment options for a defined group of patients (e.g. with a particular condition)