

# **Consultation on proposals for a new Cancer Drugs Fund (CDF) operating model: Q&A**

**NHS England INFORMATION READER BOX****Directorate**

<b>Medical</b>	Commissioning Operations	Patients and Information
Nursing	Trans. & Corp. Ops.	Commissioning Strategy
Finance		

**Publications Gateway Reference:****04654**

<b>Document Purpose</b>	Consultations
<b>Document Name</b>	Consultation on Proposals for a new Cancer Drugs Fund (CDF) Operating Model from 1st April 2016: Q&A
<b>Author</b>	NHS England/NICE
<b>Publication Date</b>	27 January 2016
<b>Target Audience</b>	Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, All NHS England Employees, Directors of HR, Directors of Finance, GPs, Communications Leads, NHS Trust CEs
<b>Additional Circulation List</b>	Patients and the public; all NHS organisations; Department of Health; other Government departments; cancer charities; members of the pharmaceutical industry; plus any other stakeholders who wish to
<b>Description</b>	This Q&A is based on discussions with stakeholders during the consultation period. It is intended as supporting information only, and should be read in conjunction with the main consultation document.
<b>Cross Reference</b>	Consultation on Proposals for a new Cancer Drug Fund (CDF) Operating Model from 1st April 2016
<b>Superseded Docs (if applicable)</b>	N/A
<b>Action Required</b>	Supporting information
<b>Timing / Deadlines (if applicable)</b>	<b>Responses to consultation no later than midnight on 11 February 2016</b>
<b>Contact Details for further information</b>	Clinical and Scientific Policy and Strategy Team NHS England, Medical Directorate 5W06 Quarry House Quarry Hill LS2 7UE 0113 825 1125  <a href="http://www.engage.england.nhs.uk/consultation/cdfconsultation">www.engage.england.nhs.uk/consultation/cdfconsultation</a>

**Document Status**

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.

# **Consultation on proposals for a new Cancer Drugs Fund (CDF) Operating Model from 1<sup>st</sup> April 2016**

## **Q&A**

First published: 27 January 2016

Prepared by: Medical Directorate, NHS England, and NICE

Classification: Official

## Introduction

This Q&A is based on the content of discussions with stakeholders during consultation on proposals for a new Cancer Drugs Fund (CDF) operating model.

It should be read in conjunction with the main consultation document, which can be found at [www.engage.england.nhs.uk/consultation/cdf-consultation](http://www.engage.england.nhs.uk/consultation/cdf-consultation) and is intended as supporting information only, to record some questions and answers on the consultation, and for the benefit of people who could not attend our discussions with stakeholders.

This document will be updated as additional questions are asked, which are not already covered.

## Issues raised during consultation

**Q1: What happens to medicines that are reappraised? Will the new system be applicable to new indications in their first appraisal, or only to licensed ones which go through reappraisal?**

A: The appraisal methods proposed in the CDF consultation document are largely unchanged from NICE's current methods, but they do allow companies to make commercial proposals. Companies might, therefore, want to refocus their submission on the value propositions to NICE.

The Appraisal Committees will include the new CDF arrangements in their consideration of all newly licensed drugs and new indications as soon as the new arrangements are finalised and agreed. The new arrangements will also apply to all re-considerations of current CDF drugs.

It is anticipated that all products that are in the current CDF and that NICE has appraised in the past will have been reappraised by March 2017 if companies make a submission. NICE has written to the companies involved already in relation to plans for the re-consideration of these topics, and is consulting with relevant stakeholders on the re-consideration process.

**Q2: How many more cancer medicines will be recommended for use in the new CDF, compared to the process it will be replacing? If the answer is 'more', will that be a subtle difference, or a step change?**

A: The proposals for the new CDF are not necessarily about more cancer medicines being recommended for use in the CDF, but about the right ones being recommended. We need to be rigorous in carrying out the right assessments on the

right drugs, and the aim should always be to get effective drugs into baseline commissioning in the NHS. The new CDF process allows clinical uncertainties to be addressed for potentially cost effective drugs through the maturation of trial data or the collection of real world data in the NHS or both.

We also suggest that just the number of drugs or indications that are available through the CDF will not be a good way to measure the success of the scheme. Rather, the scheme aims to allow patients to access effective and cost-effective treatments while critical uncertainties in the evidence are addressed.

**Q3: Has there been any discussion with the devolved nations about how the new NICE processes will apply?**

A: The regulations underpinning the Health and Social Care Act specify that NICE produce guidance for England. The Welsh and Northern Ireland governments have decided to adopt NICE guidance where relevant. It will be up the devolved nations how they respond to the consultation and the effects of it on their adoption of this guidance.

The Chief Pharmaceutical Officers of all nations meet regularly with the Department of Health, so they are all aware, at a high level, of the consultation. The Department of Health is formally responsible for liaison with the devolved nations.

**Q4: The consultation is not an easy read, and is therefore difficult to engage patients with. Will a Plain English version of the document be produced?**

A: We acknowledge that the content and the terminology in the consultation document may be difficult to understand because of its highly technical content.

NHS England and NICE are trying to adopt as many different approaches as possible in engaging with audiences about the content of this consultation, as we know that any future CDF will impact many people. We have already held three webinars with a broad range of stakeholders, and will be holding further webinars later this month, as well as holding two large-scale face-to-face meetings. We will also be attending a number of smaller meetings, and conferences, to talk about the consultation.

If anybody wishes to ask a question about the consultation document, or its content, which cannot be addressed via a meeting or webinar, please get in touch via the generic consultation email address: [england.futurecdfconsultation@nhs.net](mailto:england.futurecdfconsultation@nhs.net)

**Q5: What sort of metrics and evidence will be taken into consideration when you are gathering real world evidence while a drug is in the CDF, and how will you ensure that data is sound and robust?**

A: NHS England and NICE are keen to work with companies, patient and professional organisations to develop appropriate approaches, processes and methods for the collection of real world data – both for the CDF as a whole and for individual drugs. We also need to establish the clinical, operational and informatics needs of implementing such a process.

For each drug recommended for inclusion on the CDF, the Appraisal Committee will decide on the research questions to be addressed and what data are needed. We will then engage with all stakeholders to ensure the data are collected robustly and within the time available.

NICE will also use its Observational Data Unit to support the consideration of evidence collected in the NHS, and its relationship with the other evidence being collected by the company and academics.

NICE already appraises medicines early in their life cycle and is, therefore, used to looking at data that are immature. NICE mitigates that through disease modelling and economic modelling provided by companies and through the use of sensitivity and scenario analyses in areas of uncertainty.

It is expected that the data collected in the NHS during the two years that a drug is in the CDF will not be the only additional evidence that is collected in this time. Other data that has emerged during these two years, for example follow up studies from the original randomised control trials, phase 4 studies, pharmacovigilance studies or any other observational data will be taken into account, to confirm the value proposition of the company and to better understand the benefits of the drug for patients. We believe that data collection activities ought to be part of a wider package for consideration by the NICE appraisals committee.

**Q6: The consultation document states that ‘all new cancer drugs and significant new licensed indications for cancer drugs will be referred to NICE for appraisal’ (para 2.3.3, p.19). Does this mean that all new cancer drugs with significant new indications will be referred to NICE for appraisal, or could some indications be left out? What will be the criteria for defining a ‘significant new licensed indication’?**

The 2007 cancer reform strategy indicated that NICE should look at most cancer products. NICE has done so, although it has not looked at a small number of cancer products that were indicated for very small populations, where it was thought that a NICE appraisal would not add value. This will now change and NICE will be appraising all cancer drugs. NICE will therefore also appraise licensed drugs in the CDF which it has never looked at before, and will do this as soon as possible.

This ensures NHS England has the information it needs to support the commissioning process, and that all drugs are appraised in a transparent, consistent and fair manner. )

It may be that NICE does not consider that an indication requires a full Technology Appraisal, and might channel it through another part of NICE. The exact arrangements for this are still to be developed, as they do not just relate to cancer products.

**Q7: In terms of conditional 'yes' pathways – what happens if the CDF runs out of money?**

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

A range of budget control measures, which could be applied singly, or in combination, depending on the circumstances, has been considered. For drugs in the CDF, it is proposed to introduce a prospective contingency provision and a cost cap for the total cost of each drug, ensuring patients continue to be able to access cancer drugs in a predictable and sustainable way. Therefore, to the greatest degree possible, our intention is to avoid unplanned demands on the CDF and to avoid it running out of money.

**Q8: What if a company does not want to take part in an evaluation study?**

A: If NICE considers a drug to be a candidate for the CDF but the company, for whatever reason, does not want to sign up to the specific terms for receiving CDF funding then unfortunately that drug will not receive CDF funding.

**Q9: The consultation document states:**

***“If, and when, NICE determines that a drug should not be recommended for routine commissioning, that drug will cease to receive funding from the CDF, with the company expected to pay for the drug for those patients who had previously received it. The exception to this will be for those drugs that remain in the CDF as at 31<sup>st</sup> march 2016. Should one of these drugs receive a ‘not recommended’ decision at first appraisal, then funding for existing patients will continue to be met from the CDF budget” (para 39, p.14)***

**This could be interpreted in different ways – does it mean that the company rebates back the price of the drug spend for those patients, or is the company expected to pay from that point onwards?**

A: At the point that NICE determines that a drug should not be recommended for routine commissioning, the company will supply drugs to the NHS at no cost to the

NHS, the exact mechanism of this arrangement being agreed between NHS England and the company concerned.

**Q10: The challenge that companies are facing in terms of the consultation proposals is that they put all the financial risk on companies, and that is an unquantifiable financial risk. Can the risk be better quantified?**

A: Companies are used to exploring the financial risks of their decision-making in regard to their products. They determine the gains and losses when they determine the list price, and any patient access scheme that they may offer to the NHS, in the light of the many factors operating which would determine their market strategy, e.g. the benefits of their treatment in terms of efficacy and toxicity, a comparison with direct competitors etc.

The risks in the proposed CDF are similar in nature, but principally relate to:

- The difference between the price submitted to NICE and the one necessary to enter the CDF and;
- The cost of the patients still receiving treatment after data collection is complete, in case NICE issues negative guidance after the period of data collection.

The financial risks to companies are balanced by the opportunity to receive reimbursement for their product, while they collect the evidence needed to allow the product to be recommended for routine commissioning. This also has the crucial benefit of ensuring patients are able to access new drugs, without delay, when additional evidence is needed.

**Q11: If you are aiming for a NICE positive recommendation, without going via the CDF, how does that affect timelines?**

A: The submission process and timelines up to any first Committee meeting will be the same for all cancer drugs, whether they are seeking to enter the CDF or not. The commitment to produce NICE guidance within 90 days of Marketing Authorisation will apply to all cancer products appraised by NICE, irrespective of the resulting recommendation. This means that for all products, companies must make sure that, at the time of submission – which is determined by NICE – they have all relevant information, such as any Patient Access Scheme or commercial access arrangements in place.

**Q12: If this is a 'commissioning through evaluation approach', it is essential to know what data will be collected, by whom, and how. Will NICE be collecting the data themselves before reviewing it, or will it be commissioned from somewhere else?**



A: Companies will be expected to be involved in the data collection in England in the context of the CDF. Before a drug can enter the CDF the company will normally need to agree to fund the collection of a pre-determined data set. However, it is hoped that the Systemic Anti-Cancer Therapy (SACT) database will also be able to collect and make available, many of the necessary data items.

The data collection specification, process and funding, forming the managed access agreement, will need to be clearly identified before a drug enters the fund, and the protocols and resources will need to be in place to manage it. We will implement clear research governance principles and a collaborative approach to determining how the data collection would work, and it would be monitored by NHS England, NICE, the pharmaceutical company, and the organisation which is performing the data collection.

We need to remember is that data collection itself in England alone for the period of two years will probably not resolve all of the relevant uncertainty in the clinical effectiveness. We would anticipate that data will continue to be generated outside England as well during this time, and all of the relevant data should be made available after the CDF period and will be considered in the reappraisal by NICE.

**Q13: You say the budget will be fixed, based on horizon scanning, so will it change every year, depending on what you can foresee, or fixed at a certain level, and horizon scanning says what it is in/out?**

A: The CDF budget will be fixed, within the wider drug budget, however many drugs are being funded and evaluated. If the number of drugs, and consequent costs, potentially exceed the budget, there is a planned cost control mechanism which reduces the reimbursement to the participating companies according to the level of potential overspend.

**Q14: The general principle in the consultation document is that allocation of funds will be influenced by the number of patients in the UK, and this is linked to the collection of data required. Trial data, however, is not directly linked to UK patients, so what is the weighting of that trial data?**

A: We acknowledge that the evidence for the reappraisal by NICE after two years will not all come from UK patients but, at the same time, we have to also recognise that the CDF has limited funds that need to be allocated fairly. It is for this reason that the consultation document proposes to restrict funding to patients that contribute to the development of the evidence base for NICE reappraisal.

The weight to give to any particular trial data will be a matter for the expert judgement of NICE appraisal committees, as now. They already use trial data including patients outside the UK.

**Q15: If that number isn't the total number of patients for which the drug has a licensed indication, what would happen then? Would all patients still have access?**

A: In these circumstances, the company would not be reimbursed for those additional patients. Whether that means there is no access for them would depend on the specific arrangements made in the commercial access agreement.

**Q16: How much engagement will a company have in trying to work out how data is collected? Will it be able to have an active conversation about how to overcome uncertainty?**

There are two ways in which a drug can be included in the CDF:

- The company can recognise the uncertainty in the clinical data, and can make a proposal for further data collection in its submission to NICE
- The Appraisal Committee may decide that the clinical uncertainty is too great for a drug to enter routine commissioning (independent of whether or not the company has proposed any data collection) and advise that the drug is suitable for the CDF.

In either case, commercial access agreements may be necessary for the drug to be considered acceptable for the CDF, and these need to be in place before a company submits to NICE.

We recognise that this is tricky and complex, not least because the English company affiliates may need to liaise with their global colleagues regarding any data collection activities. However, for these proposals to work, and to ensure NICE is able to produce prompt, timely guidance, it will be essential to begin planning of data collection in advance and ideally through the company's submission.

**Q17: In relation to interim funding (p.13), the consultation document states that "...where the manufacturer has submitted the necessary information to NICE on a timely and comprehensive basis...but where NICE has not been able to make an interim decision at the point of marketing authorisation..." (para 38, p.13). What reasons might there be for NICE not being able to make an interim decision?**

A: The ability to publish final NICE guidance within 90 days of marketing authorisation depends on the exact date of the Committee for Medicinal Products for Human Use (CHMP) opinion and EC decision. There may be occasions when those date slip, or other unforeseen circumstances arise, so paragraph 38 refers to occasions such as those.

**Q18: Section 51 of the consultation document (p.16) states that “The process of appraising drugs currently in the CDF in line with the new CDF criteria will be completed during the course of 2016/17”. That means that the NICE workload is doubled in transition year. How can NICE be expected to handle all that work?**

A: NICE and NHS England acknowledge that there will be additional workload during the transition, but we are confident that we have sufficient staffing and skills to meet these demands. Arrangements are being put in place to manage the work during 2016/17 and NHS England and NICE are working closely with one another, and with our stakeholders, to deliver the transition from one scheme to another, without disadvantaging other products in NICE’s work programme, and embedding a new CDF process so that it becomes business as usual, adhering to new standard operating procedures.

**Q19: ‘Significant new licenced indications’ – does that include drugs that have been delisted from the current CDF? Can they go through the new model?**

A: NICE has developed a structured approach to the transition for drugs currently on the CDF, and has communicated about those with companies and other stakeholders. Drugs no longer on the CDF and appraised by NICE in the past will have to follow the normal review process. If new evidence emerges, including a new commercial proposition, that is likely to change the existing recommendation, NICE will initiate such a review process. If NICE decides to review the guidance, this will take place after 1 April 2016, and hence will take into account the new CDF process and methods.