

## **Cancer52 Briefing Paper**

### **New Cancer Drugs Fund Operating Model**

#### **Introduction**

This is a Cancer52 briefing paper on the new Cancer Drugs Fund (CDF) operating model. Below we provide an overview of the key features of the new model and the current Cancer52 position on the impact it may have on access to cancer drugs in England.

#### **About Cancer52**

52 per cent (recent statistics show an increase to 54%) of UK cancer deaths are from the less common cancers. Despite this, rare and less common cancers remain severely under represented and under-funded across all areas, including policy, services and research. Cancer52 is an alliance of 90 organisations working to address this inequality and improve outcomes for patients with these highly challenging diseases. You can find out more information on our website: <http://www.cancer52.org.uk/>

#### **Overview of the new CDF operating model**

The National Institute for Health and Care Excellence (NICE) officially launches a revised Cancer Drugs Fund (CDF) on Friday 29 July. This replaces the previous CDF, which had been in place since 2010.

The new CDF will operate as part of the NICE process and will operate managed access arrangements to reduce the uncertainty on selected drugs. As well as issuing positive and negative guidance, the new CDF will also allow NICE a “conditional approval” option for cancer drugs. This will allow cancer drugs to be made available for a period of time, whilst further information is collected to demonstrate its value to the NHS. It is likely to apply for drugs where there is “marginal uncertainty” around their value to the NHS.

The further information will consist of usage and outcomes data collected in an agreement between the pharmaceutical company, NHS England and NICE. Following the period of data collection, NICE will conduct a reappraisal of the drug based on the new evidence and make a “stop-go” decision on whether to continue to provide funding for the drug on the NHS.

During the period of time that the drug is made available through NICE CDF conditional approval, the NHS will only pay a price for the drug that is deemed cost-effective (although this may change if the data collected under the managed access arrangement supports its use).

The CDF will not be allowed to overspend. If it does overspend, pharmaceutical companies with drugs made available through the Fund will have to pay an increment back to NHS England via a rebate.

## **Further changes to NICE for cancer drugs**

The addition of the CDF into NICE forms part of a suite of changes to their process for assessing cancer drugs. To speed the NICE process up, NICE will be able to issue a draft recommendation prior to a drug being licensed at the European level (i.e. at Committee for Medicinal Products for Human Use (CHMP) stage) and NICE will issue a final recommendation within 90 days of being granted a licence.

Drugs that have a draft “yes” by NICE will be eligible for interim funding via the CDF budget. This means that a company can apply for immediate funding from the CDF budget, rather than waiting for routine funding to come into play (which usually takes about three months from final approval). However, pharmaceutical companies are only eligible for this funding if they agree to the mechanisms for keeping the CDF within budget (i.e. they would have to agree to be part of the rebate system mentioned above). This option will be available to companies for drugs that have received draft approval under the CDF and also through normal NICE process.

## **Drugs that were previously available through the CDF**

At its inception, the CDF was envisaged as a temporary policy that would expire at the end of March 2014. It was planned to be replaced with a more sustainable drug pricing model that would provide long term access to cancer drugs and better value to the NHS.

However, a continuing lack of agreement about the replacement of the CDF and a failure to keep a check on the number of drugs made available through the CDF, led to a major overspend. As a result of this, NHS England performed a cost-based reassessment of the drugs approved on the CDF and “delisted” treatments that were not considered of sufficient value to the NHS.

Whilst drugs still remain approved through the CDF following the delisting, NICE is currently assessing these drugs in line with the new CDF model. There is therefore the chance that some approved drugs may be removed from the CDF again, depending on the results of the NICE assessment.

## Cancer52 comments on the new CDF operating model

### General comments

1. Cancer52 welcomes government policies designed improve access to new cancer drugs. We very much hope that amalgamating the CDF into NICE will achieve these aims and we will work to support NICE, NHS England and the pharmaceutical industry to ensure that the CDF is fit-for-purpose.
2. Up until recently, the detail of the new operating model for the CDF has been limited. We therefore welcome the information contained within the new CDF SOP, particularly the clarification on how more complex aspects of the model will work, in particular, the nature of the managed access arrangements. However, there is still uncertainty as to how it is going to work in practice.
3. We welcome the collaboration that has taken place by NHS England, NICE and other stakeholders, including for the first time Public Health England (PHE) who will play a key role in the data collection component of the CDF, to ensure that a new model has been developed. We hope this is sustained throughout the implementation of the Fund, as drug development and access should be seen as a collaborative effort.
4. We hope the changes to the NICE process, such as faster draft guidance, will lead to quicker access to new medicines that receive positive approval through the NICE and new CDF process. Attention should be paid to the impact this has on the workload and capacity of NICE

### New operating model and managed access arrangements

5. The new CDF will offer a new mechanism within the NICE process, which will allow new drugs with marginal uncertainty (i.e. where NICE is not fully sure of the value to the NHS) to be made available, while the uncertainty is reduced. Whilst detail has been set out, it is very difficult to ascertain whether it will lead to a substantial increase in access to cancer medicines. A key issue is whether the data collected through the CDF will lead to a reduction in uncertainty (i.e. will the information help NICE turn a conditional “yes” into a full “yes”) or whether the NHS England data collection systems are fit-for-purpose.
6. Key issues with the data collection element of the managed access arrangements are:
  - a. The extent of e-prescribing across the NHS in England. Whilst this will be monitored and incentivised, in practice this will be difficult to implement to the extent required by the CDF
  - b. The immaturity and lack of compliance with Systemic Anti-Cancer Treatment (SACT) dataset compliance
  - c. The extent to which the SACT data returns are able to meet the data field requirements that are likely to be incorporated in a data collection arrangement
  - d. The capability, capacity and commitment of all involved bodies to collect robust and accurate data and the possibility they have to reduce identified clinical uncertainties
  - e. The ability of the systems to define and collect robust outcomes data and also data on quality of life (which assists the QALY assessment)
  - f. For rare cancers in particular, it is difficult to see whether these data systems will be able to capture information for very small groups of patients

7. It is very difficult, at this stage, to foresee which drugs would be eligible for receiving approval through the CDF or how NICE committees would reach a decision on this during an appraisal (it is likely to feature an element of flexibility). Whilst guidance has been given to NICE committees on CDF-eligible drugs, this has not yet been made available and will be subject to interpretation.
8. It is also difficult to see how the evidence collected through the CDF, will be used in the reappraisal of the drug and how it would be weighted.
9. It is very unclear what incentive pharmaceutical companies will have to go through the new CDF process. Having a new drug approved via the CDF, given the uncertainty associated with the data collection and budget control mechanisms, will be unappealing to industry and is difficult to see why they would engage in it.
10. One way it could potentially work is to increase access to cancer drugs by ensuring companies increase a discount/PAS instead of going through the CDF system. This would increase a full “yes” first time round, rather than having to go through a lengthy and uncertain process.
11. In the treatment of rare and less common cancers, drugs are often assessed in combinations and we are increasingly seeing situations where drugs are brought to market in single arm studies and in earlier phase trials. It is unclear to Cancer52 how the new CDF operating model will apply to these types of drug.

## Conclusions and next steps

- Given the lack of information and clarity on whether the new CDF operating will lead to improved access to cancer drugs, Cancer52 will be monitoring the application of the new CDF in detail to assess the impact it is going to have. It will be a number of years before the opportunity arises to see whether the data collection systems have collected robust-enough information to assist NICE decision-making.
- On its own, the CDF will not dramatically improve access to cancer drugs. Our hope is that moving forward, the Government will address reasons why NICE say “no” in the first place and derive long-term and sensible solutions to ensure patients are able to access innovative new treatments on the NHS.
- The Accelerated Access Review (AAR) is designed to look at these system-wide issues, however, given recent political developments following the EU referendum, it is unclear how this is going to be taken forward and by whom. We strongly hope that further information is issued on the status of the AAR as soon as possible and also other policy initiatives that will be put in place to ensure that drugs move smoothly through the development process through to patients.
- In the meantime, we hope the new NICE operated CDF is successful and will not lead to a situation where a new drug is added onto the CDF and then removed two-years later with little more information on how well it works in clinical practice.

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