Which way now for the Cancer Drugs Fund?

The government has extended the Cancer Drugs Fund for a further two years and increased its budget. **Andrew Jack** explains how it works and why it is controversial

From left: Funding most cancer drugs which NICE rejects, such as Kadcyla, does not make sense, says Andrew Dillon. But the policy seems to have public and political backing

What is the Cancer Drugs Fund?

The Cancer Drugs Fund was created in 2010 by the coalition government to pay for new cancer drugs that the NHS would otherwise not have provided because the National Institute for Health and Care Excellence (NICE) considered they were not cost effective. A budget of £200m (€250m; $330m) a year was set for four years using money the government initially said had been saved by the NHS "through our pledge to stop the rise in employer National Insurance contributions from April 2011."[1]

Oncologists can apply to the fund on a case by case basis, and they usually do this after a drug has been rejected by NICE. Committees of medical specialists decide whether to approve a drug for NHS use based on a 12 point scale for clinical effectiveness. Since it was created, the fund has approved about 43 drugs for 80 different indications,[2] allowing an estimated 55 000 patients to receive treatment. Around 20 drugs (for 31 indications) have been refused.

Why was it set up?

NICE was rejecting a growing number of new cancer therapies because it considered them too expensive for their modest benefits (usually only a few months of extended life expectancy). It was attacked by patient groups and parts of the media, which highlighted cases of patients being refused treatment, criticised the agency's methods, and pointed out the UK's overall poor performance in successfully treating cancer compared with other countries.[1] There was also argument over patients willing to pay out of their own pockets for drugs not recommended by NICE, and the obligations the NHS would have for their continued care.

Isn't the fund a way of bypassing NICE?

Yes—critics say the creation of the fund was poor policy because it represents "onco-exceptionalism," ignoring the cost effectiveness criteria by which most other drugs are assessed for reimbursement by the NHS and thus creating an inefficient allocation of scarce NHS resources not justified by evidence. NICE's chief executive, Andrew Dillon, argues that it does not make sense that when NICE rejects a drug for routine use, "in most cases the Cancer Drugs Fund then says yes to the treatments we have said no to."[3]

The fund also takes away the incentive created by NICE for drug companies to reduce the prices of their new drugs for the NHS. Drug companies normally continue to apply to NICE for scrutiny of new cancer drugs and may offer discounts through "patient access programmes" if the initially proposed prices are judged too high. But if their products are rejected, they have recourse not available for other medicines: they can still seek approval from the Cancer Drugs Fund at the price rejected by NICE.

Why has the fund just been given additional resources and extended for two years?

As the fund has approved new, better drugs, none of the less effective products have been removed from its list and the number of patients on funded drugs has steadily risen. That has helped swell total demand, breaking the annual £200m budget originally agreed. In late August, it was expanded to £280m a year for an extra two years, 2014-16. On the current trajectory, it is set to spend up to £1.2bn in total.

Peter Clark: public attitudes support a more favourable assessment for cancer treatments

Head of the Cancer Drugs Fund, Peter Clark, defends the body's approach to **Andrew Jack**

He may be an oncologist, but when Peter Clark sat on the National Institute for Health and Care Excellence's technology appraisal committee for a decade, he was suspicious of special pleading for cancer medicines. "Cancer patients got two special deals," he recalls: both NICE's end of life rules and cost effectiveness threshold were more generous than for many other types of drugs. "At the time I thought, 'Why should cancer patients get a better deal?'"

Yet he now runs the Cancer Drugs Fund, which critics argue undermines NICE by paying for drugs that have been rejected as providing insufficiently good value for money for the NHS—in the process removing resources from patients with other diseases who could benefit more. He expresses some bemusement over the approach but suggests that public attitudes and reactions support a more favourable assessment for treatments for cancer relative to other conditions.

"[The NICE approach] was never challenged," he says. "That told me it was in the psyche of English people, and those rules tapped into that understanding. David Cameron tapped into that again [with the launch of the fund in 2010]. The relative peace and quiet from other patient groups reflects the fact that cancer has a special meaning in what they are prepared to pay for. I wouldn't have agreed with it five years ago, but I have to say experience has proved that I was wrong. I can understand enviousness, but it reflects something that most people agree with."

He stresses that the fund has a different approach to drug assessment, examining effectiveness from a broader range of data than NICE, which is initially restricted in its appraisals to the "relatively immature" data from clinical trials. "They have enough to say whether a drug works but not how well or what effect it has on the patient pathway."

He adds that the fund will only review drugs for which drug companies have already provided the data to NICE for examination, and it reimburses the medicines only at the lowest price the producers ultimately proposed for use in the NHS. Precise costs are difficult to know, since it respects the commercial

Presumably that makes drug companies and patients very happy?

Not all of them. Roche, which produces many cancer drugs (including trastuzumab emtansine for breast cancer, which was rejected by NICE in August at £90 000 a treatment) has been a prime beneficiary. Others are less content. Under the terms of the most recent Pharmaceutical Price Regulation System agreed between the Department of Health and industry[4] any increase this year in the total NHS medicines bill must be absorbed by companies. That means if the fund pays for more cancer drugs, the producers of drugs for other conditions must absorb the difference by reducing their prices.

Similarly, although cancer patients may be thrilled to have access to potentially life extending drugs, and politicians have stressed that the cancer fund's annual budget does not displace other NHS spending, some clinicians have expressed concerns that the fund squeezed out money from other areas, especially at a time of intense cost cutting. Even some cancer specialists argue that better outcomes might have come from channelling additional funds into prevention, early diagnosis, radiotherapy, and surgery rather than expensive new treatments with limited effect. "It is inevitable if you choose to spend money on one thing you can't spend it on something else," says Dillon. "If you allocate more money to one condition, other conditions are getting less."

Can NICE and the fund continue in their current form?

As part of its recent 40% funding increase, the Cancer Drug Fund has agreed to remove drugs from its list that are overpriced or produce little clinical benefit and try to align its assessment process more closely with that of NICE.[5] The fund has also agreed to accelerate the process of gathering better data on the effects of supported cancer drugs in clinical practice. Currently the data collected are minimal. Better data would allow both a better assessment of the fund's value and provide information to clinicians to help cancer patients more broadly. An evaluation of the fund's performance suggested it had boosted use of drugs rejected by NICE but did not accelerate the uptake of treatments still under review by NICE that were subsequently approved.[6] Uptake of some of these approved drugs was more rapid in neighbouring Wales (where the fund is not operating) than in England.

Andrew Dillon argues that the fund should be brought under the remit of NICE,[3] but Stephen Whitehead, chief executive of the Association of British Pharmaceutical Industry, has argued that NICE's process for assessing value needs urgent reform.[5]

Reform of the CDF is an early test for Simon Stevens as head of NHS England, who has chosen personally to lead the negotiation with patient groups, researchers, and NICE as part of new scrutiny to ensure clinically effective drugs are made available cost effectively—capping any further expansion of the NHS drugs bill. NICE continues to review its methods, and the latest statements suggest there is at the very least likely to be tighter collaboration.[7] But scrapping the earmarked CDF now it has been created will prove politically sensitive.

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confidentiality of "patient access programmes" and other approaches that allow manufacturers to offer additional discounts to the NHS.

Clark, who was a NHS trust director, rejects concerns that the fund has diverted money from other parts of the NHS, stressing the government's pledge that there was additional "ring-fenced" funding for cancer treatments. "It was very definitely new money that was not in the system before."

But he concedes some past failings. Until its reorganisation into a single national fund in 2013, different practices by the 10 regional funds led to variations in the financing of cancer medicines around the country. There were twice as many applications from southern hospitals as from northern hospitals, for example. "Since the CDF [Cancer Drugs Fund] went national, regional variation has in effect been abolished," he says.

He also regrets the slow collection and publication of outcomes data from cancer treatments it has funded—a potentially powerful tool in pointing the way to improved treatment in the future. He pledges that from next year, that will change, combining fund information with broader data on cancer treatments collected by the NHS's systemic anti-cancer therapy teams.

"I'm disappointed it has taken as long as it has," he says. "It was a casualty of NHS reorganisation. But early next year, we'll begin to publish robust outcomes of at least some of the cancer drugs over the last 1-3 years." Since April 2014, hospitals have been required to collect data on outcomes in cancer patients. "The wealth of these data once mature and checked will be immense," he says.

Public attitudes and reactions support a more favourable assessment for treatments for cancer

Finally, he welcomes a new approach unveiled at the end of August which will give the fund, in conjunction with NICE, NHS England, patient groups, and doctors, greater ability to study costs. "In the last 1-2 years, the prices of some of these [cancer] drugs have risen very rapidly," he says. "Some companies have seen the CDF as an easy route to funding. They don't play NICE very seriously because they know they don't have to drop the price to get CDF approval."

In the future, he sees a purge of some of the less effective drugs currently reimbursed by the fund, allowing better and newer ones to be funded instead. This is the first chance for a purge since his organisation merged 10 different lists of drugs into a single group when it began to operate nationally.

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Now we will be able to re-evaluate drugs. We were in this unusual position of turning new ones away but not looking at what was already inside."

"We can make [the system] much more joined up and rational, take away lots of uncertainty, and say openly if [a drug] makes a bigger difference. We'll be working going forwards much better with NHS England and NICE."

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Peter Clark was appointed chair of the Cancer Drugs Fund in April last year. He was medical director at Clatterbridge Cancer Centre, Liverpool, from 1994 to 2000, where he currently practises as an oncologist. He was chair of the NICE technology appraisal committee from 2009 to 2013.

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