Despite a range of reforms planned for July, the Cancer Drugs Fund remains controversial, as Seamus Ward discovers

a bitter pill

There are few topics in healthcare that are more emotive than the availability of cancer drugs. Many members of the public believe treatments or drugs that ease pain or prolong lives – even by a few months – are a worthwhile use of NHS resources. But a publicly funded healthcare system has to be sure it is getting value from its drugs spending. This is the sharp end of NHS finance, where cost-effectiveness must be balanced with the understandable desire of patients to get the drug that they and their clinicians believe will help.

It's also a political issue. The prime minister set up the Cancer Drugs Fund (CDF) in 2010 to ensure patients could access new cancer drugs as well as medicines for less common cancers. It is thought to have supported around 72,000 patients. It was initially conceived as a short-term fix while reforms to the National Institute for Health and Care Excellence (NICE) processes and a new value-based pricing system for all branded medicines were developed. But delays and lack of agreement meant that the CDF was extended to March 2016. As *Healthcare Finance* went to press, a new CDF was announced, beginning in July.

Cost is a key factor in any discussion of the CDF and its reform. The NHS spends about £1.3bn on cancer drugs through routine commissioning, including high-cost drugs, which are paid for in addition to the tariff. The CDF supplements this routine funding.

The CDF has a single national list of drugs and indications (particular conditions or cancer stages) where the drug will be funded. In February 2016, there were 32 drugs on the list, covering about 40 indications, although NHS England will consider requests from individual patients for rarer cancers, including those affecting children.

Its budget was a relatively modest £200m in 2011/12, but it has grown and for the past two years it has overspent. NHS England controls the budget as part of its direct commissioning duties and an overspend in the CDF has become almost a standard element of its monthly financial updates. The cost of the fund grew from £175m in 2012/13 to £416m in 2014/15 – the latter a £136m overspend. And, despite increasing funding to £340m this year and two culls of drugs on the CDF list (with a third possible soon), NHS England still expects to overspend by between £70m and £90m. The new fund budget will be fixed at £340m.

Provider finance managers have told *Healthcare Finance* that the CDF is not a big issue for them, though it can sometimes lead to disputes with commissioners. Sometimes cancer drugs can be used for a number of different indications, some of which may not be on the CDF list. NHS England may argue, for example, that a drug was not used for the indication on the CDF list and should be funded through tariff or (if a high-cost drug) via pass-through arrangements.

There are three ways a licensed cancer drug can get onto the CDF list – it hasn't been appraised by NICE; it is being appraised by NICE;

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or it has not been recommended for routine use by NICE because it has failed to meet its clinical or cost-effectiveness thresholds. Many of the drugs prescribed under the CDF are for common cancers – for example, between April 2013 and March 2015, 59% of patients supported were being treated for three of the four most common cancers: colorectal, prostate and breast cancers. Half the patients were receiving drugs that had been rejected by NICE on clinical or cost-effectiveness grounds.

When assessing cost effectiveness, NICE uses a measure called the quality adjusted life year (QALY). In broad terms, drugs that cost less than £30,000 per QALY gained are deemed to be cost-effective. However, for drugs used towards the end of life this is adjusted, allowing NICE to consider life-extending drugs that cost more. The end of life criteria include treatments that are indicated for patients with a short life expectancy (normally less than 24 months); there is sufficient evidence to show the treatment offers patients at least an additional three months; or it is indicated for a population of not more than 7,000.

Payment controversy

The fact that the NHS is paying for drugs rejected by NICE has been criticised in some quarters. A York University study last year claimed the threshold should be reduced to £13,000 and that for every year of life gained under the CDF, five QALYs will be lost in other NHS patients. But others have argued that the fund is the only way patients can get access to innovative – and therefore usually expensive – treatments.

Last month, the Commons Public Accounts Committee weighed in with a critical report on the CDF. The committee said the Department of Health and NHS England were not using their buying power effectively and pointed out that when NHS England proposed removing some drugs from the CDF to control costs, pharmaceutical companies reduced their prices to help keep the drugs on the list.

The committee added that the Department and NHS England had no way of determining the impact of the fund on patient outcomes. Routine collection of outcomes was not mandated until April 2014 and even then there were significant gaps in the data – 93% of records did not have an outcomes summary, for example.

Commenting on the report, PAC chair Meg Hillier said: 'A vital step in addressing the financial challenges must be to properly evaluate the health benefits of drugs provided through the fund. If cancer patients seeking its support are to get the best possible treatment, there must be confidence that public money is being spent on the right medication, and at a fair price.'

While the access given to thousands of patients was welcome, it was clear that the CDF requires 'significant and urgent' reform if it is to be sustainable, she added.

That reform is imminent. It is proposed that the new Cancer Drugs Fund will be a managed access fund, providing time-limited funding while a promising drug proves its worth. Under the proposals, the process for funding a new cancer drug or indication will start around the time it receives a licence.

Before a cancer drug receives a licence, NICE will issue draft guidance. This will have one of three outcomes – the drug is rejected on clinical and cost-effectiveness grounds; it is approved for routine use; or it is recommended that it is funded by the CDF for a period of up to two years while evidence is gathered about its effectiveness.

A drug approved for routine use will be funded under the CDF until it receives a final verdict from NICE. This would normally be within 90 days of a cancer drug receiving a licence.

A joint NICE/NHS England committee will decide whether a drug recommended for the CDF will be funded. This decision will be based on the commercial access agreement – the financial arrangements that determine the cost to the NHS, which are agreed between the manufacturer and NHS England – and arrangements for data collection. The manufacturer will be responsible for funding the data collection and analysis. An NHS England spokesperson says that after a maximum of two years, NICE will undertake a short appraisal of the drug using the new evidence – at this point, it will only be able to recommend the drug be approved for routine use (and funded from baseline commissioning allocations) or that it not be recommended for routine use.

The end of life criteria would be amended under the proposals – removing the restriction on patient population (currently 7,000), while appraisal committees will be reminded of the discretion available to them when assessing a drug that extends life. A number of charities, including Sarcoma UK, have asked for clarification on how this will work. The fact that the NICE appraisal remains largely untouched is the elephant in the room as far as cancer patient groups and drugs companies are concerned.

Paul Catchpole, Association of the British Pharmaceutical Industry (ABPI) value and access director, says significant changes are needed in the appraisal process, particularly in the £30,000 per QALY value threshold. 'The proposal is to use a threshold that hasn't changed in the 16 years since NICE was set up. In that time investment in healthcare has changed dramatically and the cost of production has changed. It seems unreasonable to expect drugs to be assessed against the threshold when everything else has changed. If the QALY was adjusted in terms of inflation it would look very different.'

"The proposals require drugs to meet or have the potential to meet the cost effectiveness threshold and that's just not achievable sometimes"
Sally Greenbrook, Breast Cancer Now

He acknowledges the introduction of the end of life criteria in 2009 allowed patients access to life-extending drugs and says it effectively raised the threshold to £50,000 per QALY.

Sally Greenbrook policy manager at charity Breast Cancer Now, does not believe the proposals will lead to patients getting more effective breast cancer drugs. 'The QALY threshold is certainly part of the problem as we haven't seen it change for many years,' she says.

The charity would like greater flexibility around pricing. 'The proposals require drugs to meet or have the potential to meet the cost effectiveness threshold and that's just not achievable sometimes.'

The money allocated to the CDF will be fixed and cost control mechanisms have been proposed to ensure it remains within budget. Each drug in the new CDF will be allocated funds based on the number of patients needed to collect sufficient data and the cost-effective price implied by the initial NICE appraisal – these will be factored into the commercial access agreement. A contingency provision and cost cap will

Other funding mechanisms

As well as the Cancer Drugs Fund, patients and their oncologists have other funding routes to access expensive, new or innovative medicines.

Patients who believe they could benefit from a drug rejected by NICE or not on the CDF list can make individual funding requests. Clinicians make the request on their patient's behalf, making the case for 'clinical exceptionality' – where the patient is different to others with the same condition or might benefit in a different way.

Clinical urgency is a further reason for a request. This is where NICE has not completed an appraisal and the patient's condition would get worse without any prospect of recovery. As well as clinical evidence, in this case the clinician must demonstrate that the treatment offers value for money. If a review panel agrees to the request, the clinical commissioning group will provide the funding.

The Early Access to Medicines scheme started a year ago to give access to drugs that are not yet given a licence by NICE. There may be some uncertainty about their safety, effectiveness or side effects and the scheme can only be used where patients have a life-threatening or seriously disabling condition. The CDF can also fund drugs without a licence.

Manufacturers cannot charge for drugs under the early access scheme, but in return they can gather 'real world' information about its use, cost-effectiveness and value that could be used as evidence in a NICE technology appraisal, for example.

Drugs used in chemotherapy are defined as high-cost drugs in the NHS in England. The cost of these and other high-cost drugs is reimbursed according to locally set prices, additional to the national tariff.

Drugs can be added to the high-cost list if they are new and not captured in national prices; if currency design has not been developed or adjusted for their use; or if the treatment or intervention is carried out by a small number of providers and represents a disproportionate cost.

be introduced for each drug. Under the provision, a percentage of the amount due under the commercial access agreement will be retained until the end of the year. If the CDF has remained within budget, the contingency will be released and paid to manufacturers in proportion to the payments already made during the year. If the fund has overspent, the contingency will be used to balance the budget and if any funds remain, they will be released. However, if the overspend exceeds the amount held as a contingency, the shortfall will be recouped by an across-the-board reduction in prices for each drug on the list.

Pharma risk

The proposals represent a shift of risk to the pharmaceutical companies. Not only would they have to fund data collection and analysis, but they would also have to pay for any spending over and above the fixed sum. These proposals concern both the companies and patients' representatives.

Dr Catchpole argues against a fixed pot, believing better horizon scanning should be introduced to inform operational and financial planning. This would mean the amount allocated to the fixed sum would change each year – up or down – depending on the cancer drugs coming forward for licence as well as those exiting the CDF.

'We know very well what medicines are going to be coming out three to four years at least before they get a licence. We have good information on what to expect and we share it with budget holders in the NHS. We have got to try to integrate that information better into NHS financial and service planning,' he says.

'Our feedback from companies is that these [cost control] mechanisms are not going to be viable in some cases,' he adds. Companies are already taking a considerable financial hit as they are rebating significant sums on branded medicines through the Pharmaceutical Pricing Regulation Scheme (PPRS), he insists, and they have also negotiated lower prices on some drugs in the CDF.

'Under the proposals, 100% of an overspend would be paid for by the industry and the UK companies will have to seek permission from their parent companies to offer commercial arrangements that may be more harsh than in other comparable countries. That could be a step too far.'

Drugs currently on the list will be appraised during 2016/17 and NHS England has confirmed that patients receiving a treatment on 31 March 2016 will continue to receive it until the patient and their consultant agree it is no longer appropriate.

However, there is concern that some currently on the list will not pass the cost-effectiveness test, making them unavailable to new patients from July. Ms Greenbrook says Breast Cancer Now is worried about the future of two CDF medicines used for breast cancer patients – trastuzumab emtansine (Kadcyla) and pertuzumab (Perjeta). Both extend life, but she believes that despite the changes in the end of life adjustments, they would struggle to meet the criteria.

'They are hugely effective,' she says. 'One extends life by 16 months, which is unheard of in secondary cancers. But unless there is substantial negotiation on price, there is no way they will go into the new system. That would be a backward step for the treatment of breast cancer.'

An announcement on the new CDF is expected soon, but although it attempts to maintain access and protect the public purse, questions will remain about whether the new scheme has struck the right balance.

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Paul Catchpole, ABPI

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