



National Audit Office

Report

by the Comptroller
and Auditor General

Department of Health and NHS England

Investigation into the Cancer Drugs Fund

Our vision is to help the nation spend wisely.

Our public audit perspective helps Parliament hold government to account and improve public services.

The National Audit Office scrutinises public spending for Parliament and is independent of government. The Comptroller and Auditor General (C&AG), Sir Amyas Morse KCB, is an Officer of the House of Commons and leads the NAO, which employs some 810 people. The C&AG certifies the accounts of all government departments and many other public sector bodies. He has statutory authority to examine and report to Parliament on whether departments and the bodies they fund have used their resources efficiently, effectively, and with economy. Our studies evaluate the value for money of public spending, nationally and locally. Our recommendations and reports on good practice help government improve public services, and our work led to audited savings of £1.15 billion in 2014.



National Audit Office

Department of Health and NHS England

Investigation into the Cancer Drugs Fund

Report by the Comptroller and Auditor General

Ordered by the House of Commons
to be printed on 16 September 2015

This report has been prepared under Section 6 of the
National Audit Act 1983 for presentation to the House of
Commons in accordance with Section 9 of the Act

Sir Amyas Morse KCB
Comptroller and Auditor General
National Audit Office

15 September 2015

In January 2015, we reported on progress in improving cancer services and outcomes. During the work for the report, we identified a range of questions about the Cancer Drugs Fund. This investigation sets out the facts relating to the Fund to inform consideration of what the Fund has achieved and the debate about its future.

Investigations

We conduct investigations to establish the underlying facts in circumstances where concerns have been raised with us, or in response to intelligence that we have gathered through our wider work.

© National Audit Office 2015

The material featured in this document is subject to National Audit Office (NAO) copyright. The material may be copied or reproduced for non-commercial purposes only, namely reproduction for research, private study or for limited internal circulation within an organisation for the purpose of review.

Copying for non-commercial purposes is subject to the material being accompanied by a sufficient acknowledgement, reproduced accurately, and not being used in a misleading context. To reproduce NAO copyright material for any other use, you must contact copyright@nao.gsi.gov.uk. Please tell us who you are, the organisation you represent (if any) and how and why you wish to use our material. Please include your full contact details: name, address, telephone number and email.

Please note that the material featured in this document may not be reproduced for commercial gain without the NAO's express and direct permission and that the NAO reserves its right to pursue copyright infringement proceedings against individuals or companies who reproduce material for commercial gain without our permission.

Links to external websites were valid at the time of publication of this report. The National Audit Office is not responsible for the future validity of the links.

Contents

Key facts 4

**What this investigation
is about** 5

Key findings 6

Part One

Why was the Fund set up? 9

Part Two

How does the Fund relate to routine NHS
commissioning of cancer drugs? 11

Part Three

What impact has the Fund had on
patient access to cancer drugs? 16

Part Four

What impact has the Fund had on
patient outcomes? 26

Part Five

How much has the Fund cost? 28

Part Six

What is the future of the Fund? 33

Appendix One

Our investigative approach 35

The National Audit Office study team
consisted of:

Leon Bardot and David Xu, under
the direction of Laura Brackwell, with
assistance from Emily Charlton and
Payal Patel.

This report can be found on the
National Audit Office website at
www.nao.org.uk

For further information about the
National Audit Office please contact:

National Audit Office
Press Office
157–197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Tel: 020 7798 7400

Enquiries: www.nao.org.uk/contact-us

Website: www.nao.org.uk

Twitter: @NAOorguk

Key facts

£968m	74,380	48%
total cost of the Fund, October 2010 to March 2015	patients were approved to receive cancer drugs through the Fund, October 2010 to March 2015	overspend on the allocated budget for the Fund for 2014-15

- 39** cancer drugs that could treat 67 cancer conditions (indications) were available through the Fund in April 2015
- 19** cancer drug indications were removed from the Fund's national list in March 2015
- 51%** of patients supported by the Fund have received drugs previously appraised but not recommended by the National Institute for Health and Care Excellence
- 19%** of patients supported by the Fund were approved to access one drug, Avastin, between April 2013 and March 2015
- £416 million** total cost of the Fund in 2014-15

What this investigation is about

1 More than 1 in 3 people in England will now develop cancer in their lifetime. The most recent data indicate that in 2012 around 280,000 people were diagnosed with cancer and an estimated 133,000 died from cancer.

2 The government set up the Cancer Drugs Fund (the Fund) in October 2010 to improve access to cancer drugs that are not routinely available on the NHS. The Fund was initially expected to run until March 2014, with a total budget of £650 million. In 2013, the government extended the Fund until March 2016. The Fund now has a total lifetime budget of £1.27 billion.

3 The Fund is unique in that no other condition has a dedicated fund to provide access to drugs not routinely available on the NHS. During the work for our report on progress in improving cancer services and outcomes, published in January 2015, we identified a range of questions about the Fund.¹ These were about the rationale for the Fund and how it relates to mainstream NHS processes. We also heard concerns about the Fund's impact and whether it is sustainable in its current form. These issues were also covered by the Committee of Public Accounts report on cancer services and outcomes, published in March 2015.²

4 This investigation sets out the facts relating to the Fund to inform consideration of what it has achieved and the debate about its future beyond 2016. It covers:

- Why was the Fund set up?
- How does the Fund relate to routine NHS commissioning of cancer drugs?
- What impact has the Fund had on patients' access to cancer drugs?
- What impact has the Fund had on patient outcomes?
- How much has the Fund cost?
- What is the future of the Fund?

5 Our work was not designed to assess the value for money of the Fund. Our methods are set out in Appendix One.

¹ Comptroller and Auditor General, *Progress in improving cancer services and outcomes*, Session 2014-15, HC 949, National Audit Office, January 2015.

² HC Committee of Public Accounts, *Progress in improving cancer services and outcomes in England*, Forty-fifth Report of Session 2014-15, HC 894, March 2015.

Key findings

Why was the Fund set up?

6 The government set up the Cancer Drugs Fund (the Fund) in October 2010 to allow people access to cancer drugs that would not otherwise be routinely available on the NHS. A report in July 2010 had found that use of new cancer drugs in the UK was low compared with similar countries. There had also been campaigns by cancer charities to improve access to cancer drugs and individual cases regularly attracted media coverage. The Fund was intended as an interim measure, to run until March 2014, while a long-term pricing mechanism was worked out that would allow patients access to the drugs and treatments that their doctors thought would help them.

How does the Fund relate to routine NHS commissioning of cancer drugs?

7 The Fund provides access to a number of cancer drugs that have not been appraised by the National Institute for Health and Care Excellence (NICE), are still being appraised by NICE, or have not been recommended by NICE because they do not meet its clinical and/or cost-effectiveness thresholds. Since April 2013 the Fund has been managed by NHS England. It introduced a national list of drugs that would be available through the Fund. Nearly all approved applications are for drugs on the national list, although patients can also apply individually for drugs not on the list.

What impact has the Fund had on patient access to cancer drugs?

8 The Fund has improved access to cancer drugs not routinely available on the NHS. From October 2010 to March 2015, more than 74,000 patients were approved to receive drugs through the Fund.³ The Fund has become part of mainstream cancer services – in 2014-15, it supported almost 1 in 5 of the patients starting a new chemotherapy treatment. Data indicate that between 2009 and 2013 use of new cancer drugs (those launched in the previous 5 years) increased in the UK relative to the average in other comparable high-income countries, although it remained below this average.

³ All the patient numbers (and percentages) in this report refer to the number of patients approved to receive drugs through the Fund. These numbers may not represent the actual number of patients treated as some patients may not take up their treatment.

9 Around half of the cancer drugs accessed through the Fund have previously been appraised but not recommended by NICE. 51% of the patients supported between April 2013 and March 2015 accessed drugs that were appraised by NICE but not recommended for routine NHS commissioning because they did not meet its clinical and/or cost-effectiveness thresholds. The remaining patients accessed drugs that were in the process of being appraised, or had not been appraised, by NICE.

10 A small number of drugs account for most of the patients supported by the Fund. Although more than 40 cancer drugs were available through the Fund at some point during 2013-14 and 2014-15, the 10 most common drugs accounted for 71% of the patients supported by the Fund and one drug (Avastin) that can treat a range of cancer conditions (indications) accounted for almost one fifth of patients.

11 Geographic variations in access to drugs through the Fund have reduced since 2013. Between October 2010 and March 2013, the Fund was managed regionally by the 10 strategic health authorities, which had different access arrangements. Since April 2013, when NHS England introduced a national list of available drugs, variations in access across England have reduced.

What impact has the Fund had on patient outcomes?

12 Data on patient outcomes to evaluate the impact of the Fund are not available. The Department of Health (the Department) recognised the importance of outcomes data when it set up the Fund. However, hospital trusts were not mandated to submit data to the national chemotherapy dataset until April 2014 and there are still significant gaps in the data. The dataset has not been able to distinguish treatments paid for by the Fund from those paid for through routine NHS commissioning but, in July 2015, NHS England and Public Health England established a data-sharing agreement, which should enable the outcomes of patients supported by the Fund to be tracked. In addition, the data submitted by trusts are not complete; for example, in 2014-15 only 7% of records had an outcome summary.

How much has the Fund cost?

13 The total cost of the Fund from October 2010 to March 2015 was £968 million – slightly above the allocated budget (Figure 1 overleaf). In the early years of the Fund, the 10 strategic health authorities, on behalf of the Department, underspent the available budget by 28% in total. Taking 2013-14 and 2014-15 together, however, NHS England overspent the allocated budget for the Fund by 35%. The overspend meant that less money was available for other services.

Figure 1
Cost of the Cancer Drugs Fund

	2010-11	2011-12	2012-13	2013-14	2014-15	Total
Cost (£m)	38	108	175	231	416	968
Budget (£m)	50	200	200	200	280	930
Cost as a percentage of allocated budget (%)	77	54	88	115	148	104

Notes

- 1 Costs are rounded to the nearest £ million.
- 2 Data for 2010-11 represent in-year funding provided by the Department of Health in October 2010.

Source: National Audit Office analysis of Department of Health data and NHS England data

14 In the two years to March 2015, the cost of the Fund rose by £241 million – an increase of 138%. More than half of this increase was accounted for by an increase in the average cost per patient and the remainder by an increase in the number of patients supported by the Fund. In 2014-15, the average cost per patient was £16,700, although the cost ranged from less than £10,000 to more than £100,000.

15 NHS England has taken action to control the rapid growth in the cost of the Fund, including removing drugs on the grounds of cost for the first time.

In March 2015, NHS England removed a number of drugs from the national list following a review of clinical effectiveness and cost. From the outset, a mechanism was in place to remove drugs from the Fund in order to control costs, but this was the first time that either the Department or NHS England had used this mechanism. NHS England also secured discounts from some pharmaceutical companies. It estimated that these actions would generate savings of £80 million in the projected cost of the Fund in 2015-16, but actual savings are likely to be lower. In July 2015, NHS England forecast that the cost of the Fund would be £70 million over budget in 2015-16, and in September 2015 it announced that it was proposing to remove more drugs from the national list.

What is the future of the Fund?

16 All parties agree that the Fund is not sustainable in its current form and NHS England is developing proposals for reform. The Fund was intended as a temporary measure until the government put in place a new pricing system when the existing Pharmaceutical Price Regulation Scheme expired in 2013. However, no new pricing mechanism has been introduced. In July 2015, NHS England proposed that the Fund should become a ‘managed access’ fund that would pay for promising new drugs for a set period before NICE decides whether the drugs should be recommended for routine commissioning. The implication of NHS England’s proposals is that the Fund would no longer support the provision of drugs that have been appraised but not recommended by NICE. NHS England plans to consult on its proposals in autumn 2015, with the aim of implementing the new arrangements from April 2016.

Part One

Why was the Fund set up?

1.1 In May 2010, the new government outlined its commitment to create a fund to enable cancer patients to be treated with the cancer drugs their doctors thought would help them. In July 2010, the Secretary of State for Health announced that £50 million would be available to help patients access innovative new cancer drugs from October 2010 to March 2011, ahead of the creation of the Cancer Drugs Fund (the Fund) in April 2011. The announcement followed a report by the Department of Health's (the Department's) National Clinical Director for Cancer which found that use of new cancer drugs in the UK was low compared with other countries.⁴ The review found that, for cancer drugs launched within the previous 5 years, the UK's usage was about 45% of the average in 13 similar countries. There had also been campaigns by cancer charities to improve access to cancer drugs, particularly for rarer cancers, and individual cases regularly attracted media coverage.

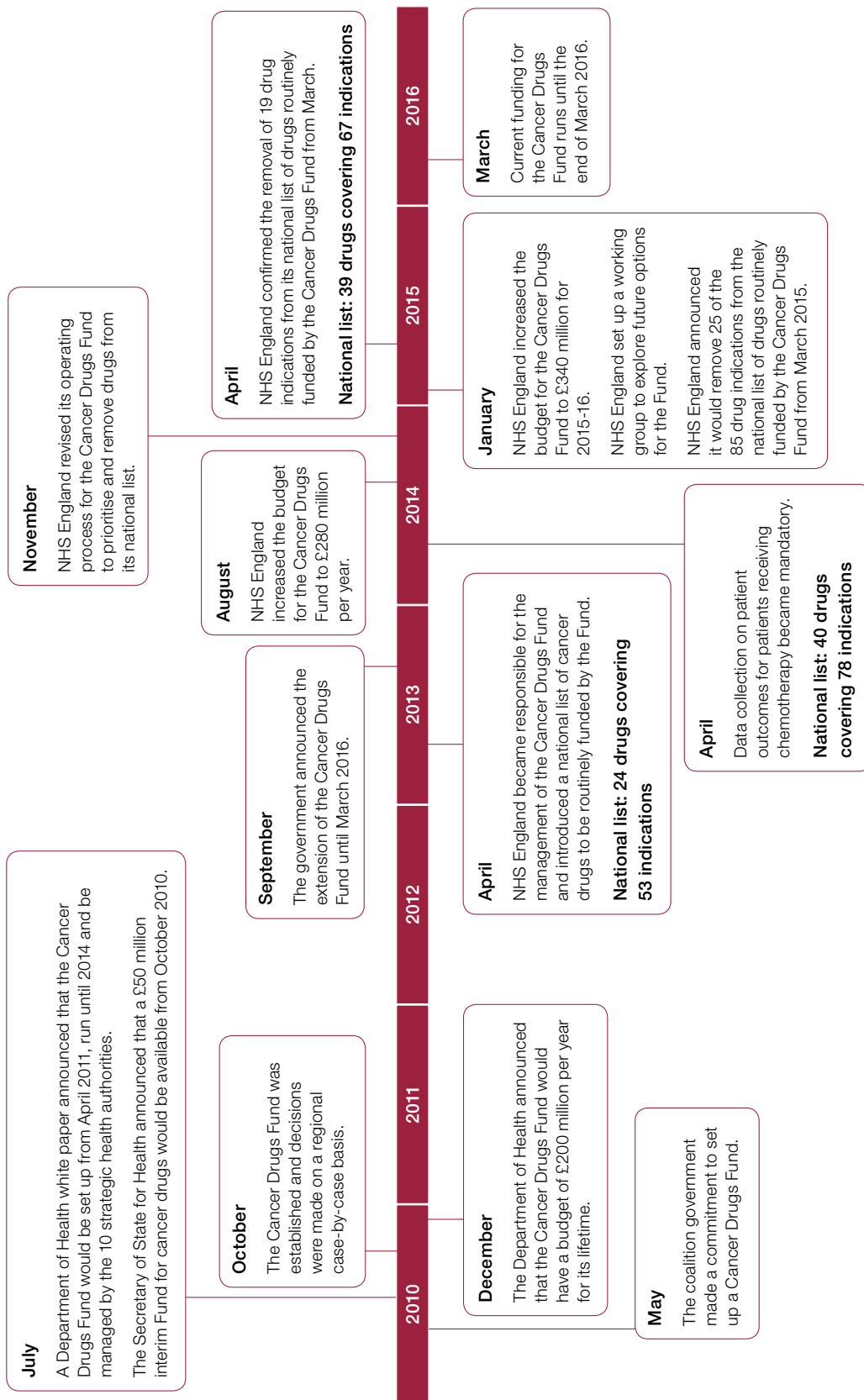
1.2 In October 2010, the Department published *The Cancer Drugs Fund – a consultation*, which set out proposals for establishing the Fund.⁵ The consultation noted that the National Institute for Health and Care Excellence (NICE) had recently introduced more flexibility in its appraisal of drugs for less common, end-of-life conditions. However, there remained cancer drugs that NICE had not felt able to recommend because pharmaceutical companies had been unwilling or unable to price the drugs at a level NICE would regard as cost-effective. The consultation also noted that NICE did not provide guidance on all new cancer drugs and that current arrangements might not always adequately reflect the value society placed on ensuring that patients nearing the end of their lives had access to drugs that could help them.

1.3 **Figure 2** overleaf shows how the Cancer Drugs Fund has developed over time. When it was set up, the Fund was expected to run until March 2014 with an annual budget of £200 million. In September 2013, the government announced that the Fund would be extended until March 2016 and NHS England increased the annual budget.

⁴ Professor Sir Mike Richards CBE, *Extent and causes of international variations in drugs usage: A report for the Secretary of State for Health*, July 2010. The other countries were broadly comparable to the UK in terms of economic development and had similar gross domestic product (GDP) levels and proportion of GDP spent on healthcare. The countries are listed in Figure 6.

⁵ Department of Health, *The Cancer Drugs Fund – A consultation*, October 2010.

Figure 2
Development of the Cancer Drugs Fund



Note

1 NHS England periodically reviews the national list of cancer drugs routinely funded by the Fund, adding new drugs or drug indications to the list and/or removing drug indications from the list when the indications have been recommended by NICE for routine commissioning.

Source: National Audit Office

Part Two

How does the Fund relate to routine NHS commissioning of cancer drugs?

2.1 All medicines, including cancer drugs, must receive a marketing authorisation from the European Medicines Agency (Europe-wide licence) or the Medicines and Healthcare products Regulatory Agency (UK licence), confirming quality, safety and medical effectiveness, before the medicine can be placed on the market for potential routine use in the NHS.⁶ A cancer drug may be licensed to treat a specific type of cancer or several different types of cancer, and/or different stages of the disease. The different licensed uses of a cancer drug are referred to as 'indications'.

Access to cancer drugs through routine NHS commissioning

2.2 NICE appraises new cancer drugs referred by Ministers to assess whether they should be available on the NHS. It uses a 'technology appraisal' to assess clinical and cost-effectiveness by reviewing the available clinical and economic evidence. This appraisal compares the drug with other treatments currently used in the NHS and assesses how well it might work for all patients. Once NICE has recommended a drug, NHS commissioners must then fund it.

2.3 NICE usually recommends a drug if its cost-effectiveness ratio is between £20,000 and £30,000 or less per 'quality-adjusted life year gained'. In 2009, NICE introduced greater flexibility for patients with a life expectancy of fewer than 24 months through its 'end-of-life criteria'. For these patients, if a drug extends life by more than 3 months and the affected patient population is small, NICE may recommend drugs with a cost-effectiveness ratio of up to £50,000. Of the 39 cancer drug indications recommended between 2009 and 2014, 14 (38%) were recommended using the end-of-life criteria.

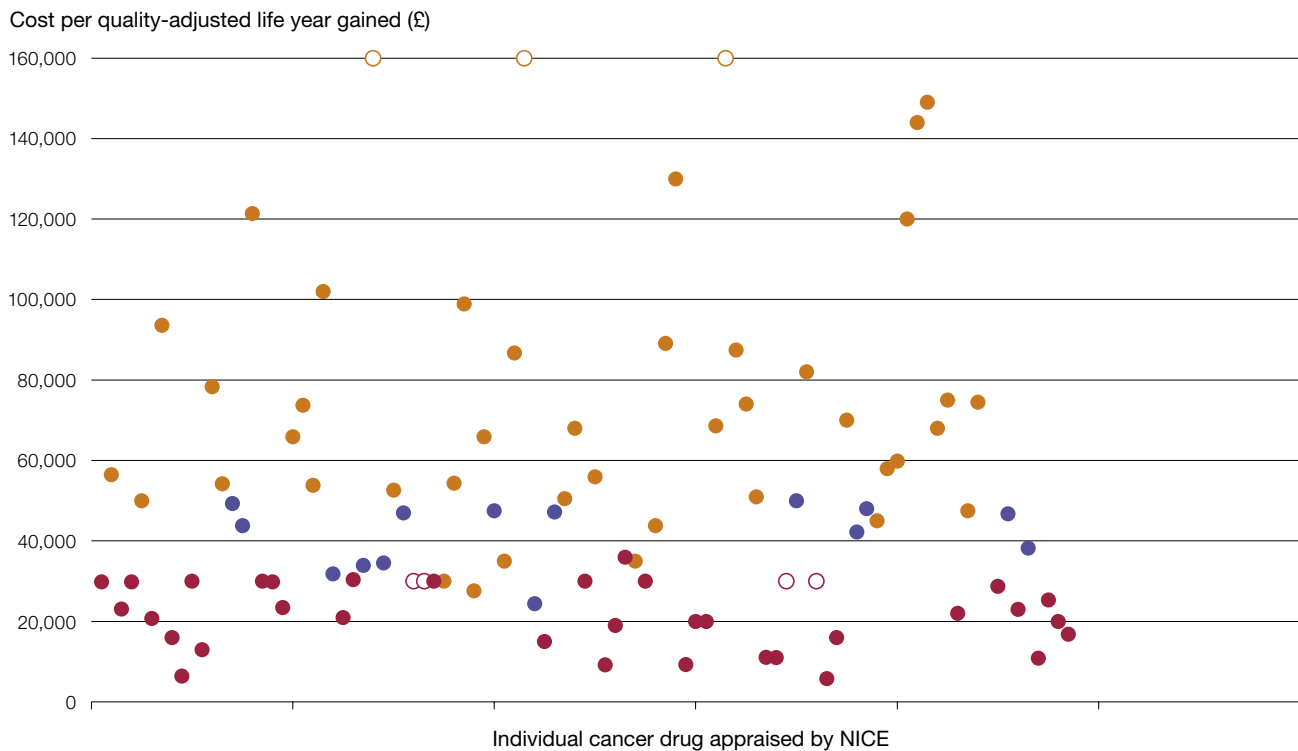
⁶ Before a marketing authorisation is granted, patients can sometimes opt to access a new cancer drug through clinical trials. Medicines taken as part of a clinical trial are usually supplied without charge to the NHS or patients. In addition, since 2014, the Medicines and Healthcare products Regulatory Agency has offered a scheme (the Early Access to Medicines Scheme) that enables patients to access certain promising new drugs, including some cancer drugs, at no cost to the NHS or themselves, before the drugs receive a marketing authorisation from the European Medicines Agency. Clinicians can also prescribe unlicensed medicines in other circumstances, but there would usually be a charge for the medicine and the clinician bears the liability if anything goes wrong.

2.4 In total, between 2007 and 2014, NICE appraised 102 cancer drug indications and recommended or partially recommended 47. This positive recommendation rate (46%) was lower than the rate for other drugs (81%). **Figure 3** shows the cost-effectiveness ratio for the cancer drugs appraised. Of the drugs that NICE recommended for routine NHS commissioning, 71% had an estimated cost per quality-adjusted life year gained of £30,000 or less and 29% had an estimated cost per quality-adjusted life year gained of more than £30,000.

Figure 3

Estimated cost per quality-adjusted life year gained for cancer drugs appraised by NICE, 2007 to 2014

29% of cancer drugs recommended by NICE had a cost per quality-adjusted life year above £30,000



- Recommended or partially recommended (with a specific estimated cost per quality-adjusted life year gained)
- Recommended or partially recommended (with an estimated cost per quality-adjusted life year gained of less than £30,000)
- Not recommended (with a specific estimated cost per quality-adjusted life year gained)
- Not recommended (with a specific estimated cost per quality-adjusted life year gained of more than £160,000)
- Recommended under end-of-life criteria (with a specific estimated cost per quality-adjusted life year gained)

Note

1 The cost per quality-adjusted life year gained used here is NICE's most credible estimate. There may be more than one cost per quality-adjusted life year gained estimate for a drug within a single drug appraisal.

2.5 Pharmaceutical companies may on occasion offer a discount on the list price of drugs through a Patient Access Scheme, or other arrangements (for example, a per patient cap on the cost of use or free stock), to reduce the overall cost and bring the drugs within NICE's cost-effectiveness thresholds. By the end of July 2015, NICE had published 28 pieces of guidance recommending cancer drugs with a Patient Access Scheme.

2.6 While some cancer drugs are not recommended by NICE because of their high cost, others are not recommended because of poor or unclear clinical effectiveness. NICE may also decide not to recommend drugs because of a lack of evidence or uncertainties in the available evidence. For example, between 2009 and 2014, NICE cited a lack of robust data as one of the reasons for not recommending 18 of the 52 cancer drugs considered under its end-of-life criteria. In some cases the lack of data may reflect early licensing by regulatory bodies, which reduces the time available to develop robust evidence on effectiveness. Also, more targeted therapies usually have a more limited evidence base because of the smaller number of people being treated.

2.7 Some cancer charities and pharmaceutical companies told us that they think NICE's cost-effectiveness thresholds do not adequately reflect the value society places on treating cancer patients, and that the thresholds hinder improving or extending end-of-life care for people with terminal conditions. A 2013 survey of 2,000 adults in Great Britain indicated that 64% of people considered cancer to be the condition they were most concerned about and 70% agreed that the NHS should pay for treatments for patients with all conditions including those with terminal illness. However, only 20% of people thought that the NHS should give terminally ill patients priority over other patients.⁷

Access to cancer drugs through the Fund

2.8 The Fund was set up to provide patients with access to cancer drugs not available through routine NHS commissioning, because the drugs have not been appraised, are in the process of being appraised, or have been appraised but not recommended by NICE. The number of drugs that potentially could be accessed through the Fund is therefore affected by the number of cancer drugs that NICE appraises, the time NICE takes to appraise cancer drugs, and whether NICE recommends cancer drugs for routine NHS commissioning.

2.9 The Fund was initially managed for the Department by the then 10 strategic health authorities. Applications for support from the Fund were made by clinicians on behalf of their patients and decisions were taken by regional clinically led panels.

2.10 In April 2013, following the abolition of strategic health authorities as part of the reforms to the health system, NHS England took over responsibility for managing the Fund, as part of its role of commissioning specialised health services. Day-to-day administration of the Fund is carried out by NHS England's 4 regional teams.⁸

⁷ Novartis, Roche Products Ltd and Sanofi, *Attitudes to Cancer Survey*, 2013, published by ComRes. Available at: http://comres.co.uk/wp-content/themes/comres/poll/Novartis,_Roche_Products_Ltd_and_Sanofi__NHS_Priority_Survey.pdf

⁸ London, Midlands and East of England, North of England and South of England.

2.11 NHS England changed the way the Fund works by creating a single national system. It introduced a national list of 28 drugs – which could treat approximately 70 cancer conditions (drug indications) – that would be routinely available through the Fund. Drug indications included on the list applied to at least 20 cancer patients nationally. Before NHS England introduced the national list, 167 drug indications were available across the 10 regions. Of the drug indications not included in the national list, 55 were made available to patients through routine NHS commissioning.

2.12 The Fund panel decides which drug indications should be available through the national list. The panel is part of the Clinical Reference Group for Chemotherapy, a statutory advisory body to NHS England. The 12-member panel is chaired by a practising oncologist and made up of oncologists, pharmacists, specialists in public health and patient representatives. A member of the Association of the British Pharmaceutical Industry sat on the panel until the end of 2014.

2.13 Between April 2013 and December 2014, the panel evaluated 65 applications for cancer drug indications to be included on the national list, of which 26 (40%) were approved. The panel's decisions were based on an assessment of the drug's clinical benefit.⁹ At the end of 2014, 85 indications were available through the national list.

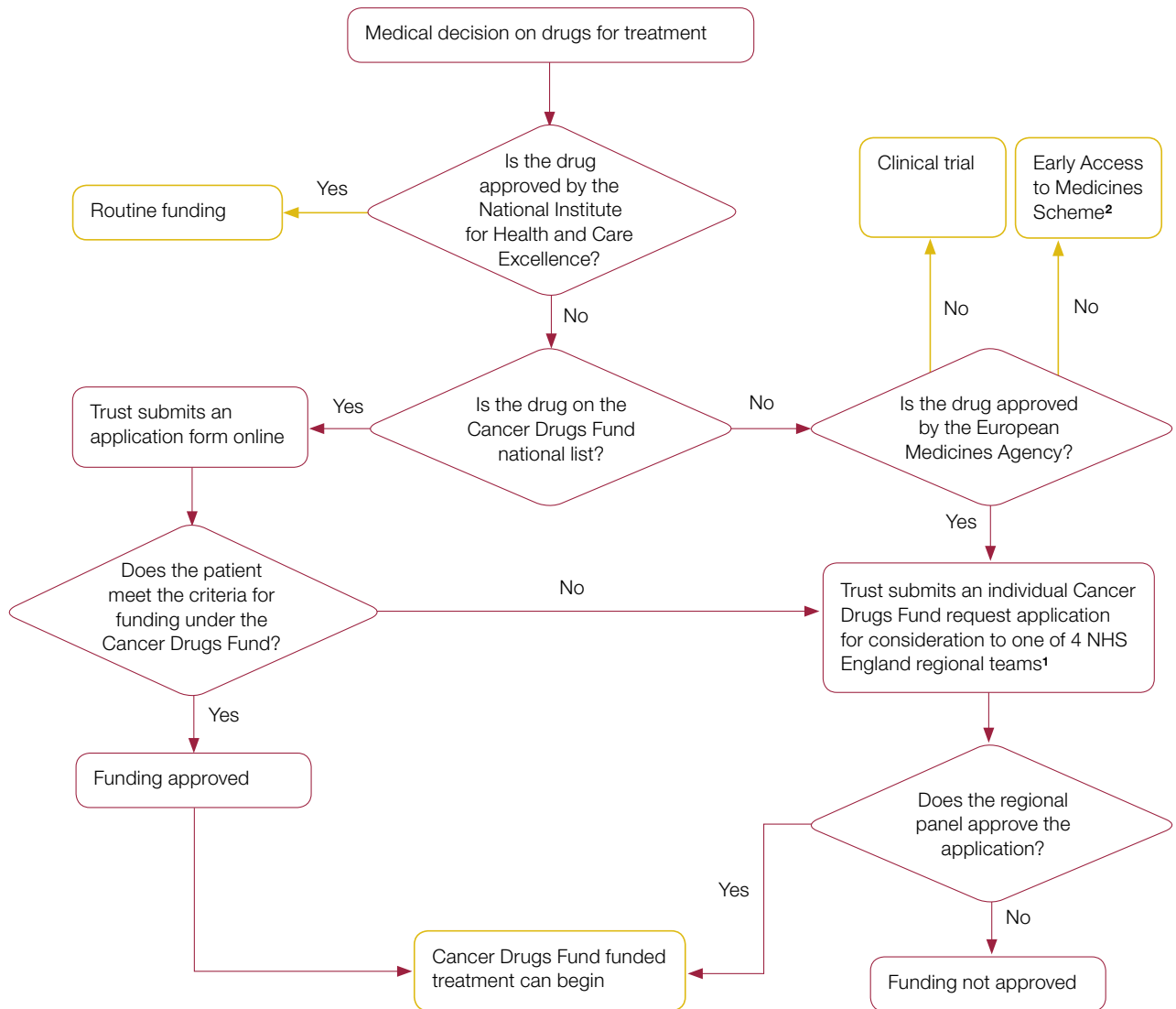
2.14 If a cancer drug that a clinician wants to prescribe for their patient is not available through routine NHS commissioning, the clinician can apply to the Fund panel for their region (**Figure 4**). Patients can access funding via two routes:

- If the drug applied for is on the national list, the application will be approved automatically if the patient meets the relevant clinical criteria. This route accounts for nearly all the patients supported by the Fund (99.5% of approved applications in 2014-15).
- If the drug applied for is not on the national list, the regional clinically led panel will decide whether to approve the application.¹⁰ If the panel decides not to pay for a drug, it provides an explanation for its decision. In 2014-15, 115 of the 540 applications made through this route (21%) were approved, accounting for just 0.5% of the patients supported.

9 The panel assessed the clinical benefit of each drug using: a scoring system that evaluated the drug's impact on median progression-free survival, median overall survival, quality of life, toxicity and unmet need; and the panel's experience and judgement.

10 Panel members are consultant oncologists and haemato-oncology specialists from trusts within the region, and patient or lay representatives.

Figure 4
How patients access drugs through the Cancer Drugs Fund



Notes

- 1 If more than 20 cases in a year have been requested by this route, this is regarded as a potential cohort and a request can be made to consider the drug for the national list.
- 2 In 2014, the Department established a mechanism to allow access to promising drugs before their licence is approved. This scheme is run by the Medicines and Healthcare products Regulatory Agency.
- 3 If the drug applied for is on the national list, the clinician should receive a decision within 2 working days; if the drug applied for is not on the national list, the clinician should receive a decision within 10 working days.
- 4 Trusts may appeal if they think due process was not followed. If upheld, the request is returned to the regional panel. A response should be received within 5 working days.
- 5 Different options for patients in England to access cancer drugs are shown in yellow.

Source: National Audit Office

Part Three

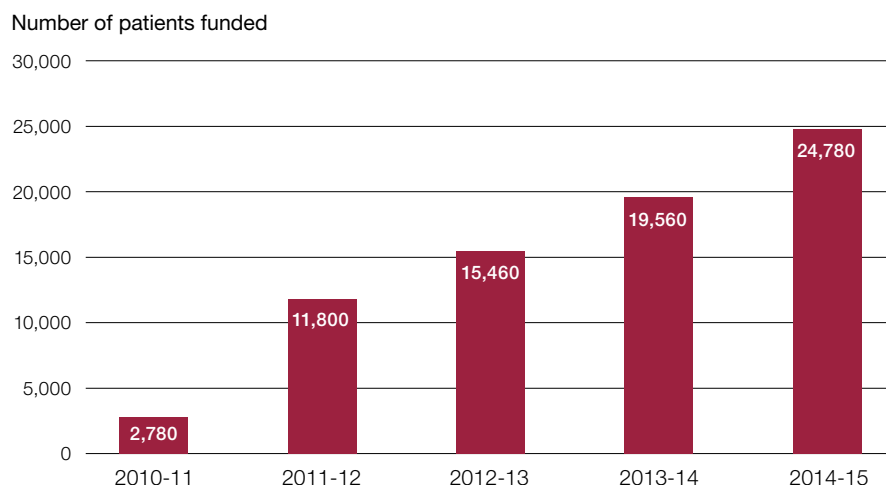
What impact has the Fund had on patient access to cancer drugs?

3.1 By the end of March 2015, 74,380 cancer patients had been approved to receive cancer drugs paid for by the Fund (**Figure 5**). The number of cancer patients approved for funding increased by about 30% each year between 2011-12 and 2014-15. Although the Fund was introduced as a temporary measure, it has become part of mainstream cancer services. In 2014-15, the number of patients approved for funding was about 19% of all cancer patients who started a new chemotherapy treatment.

Figure 5

Number of people approved to receive cancer drugs through the Fund, 2010-11 to 2014-15

The number of cancer patients approved for funding increased by about 30% each year between 2011-12 and 2014-15



Notes

- 1 An interim fund was available from October 2010 so the data for 2010-11 cover 6 months only.
- 2 Patient numbers have been rounded to the nearest 10.

Source: Department of Health data and NHS England data

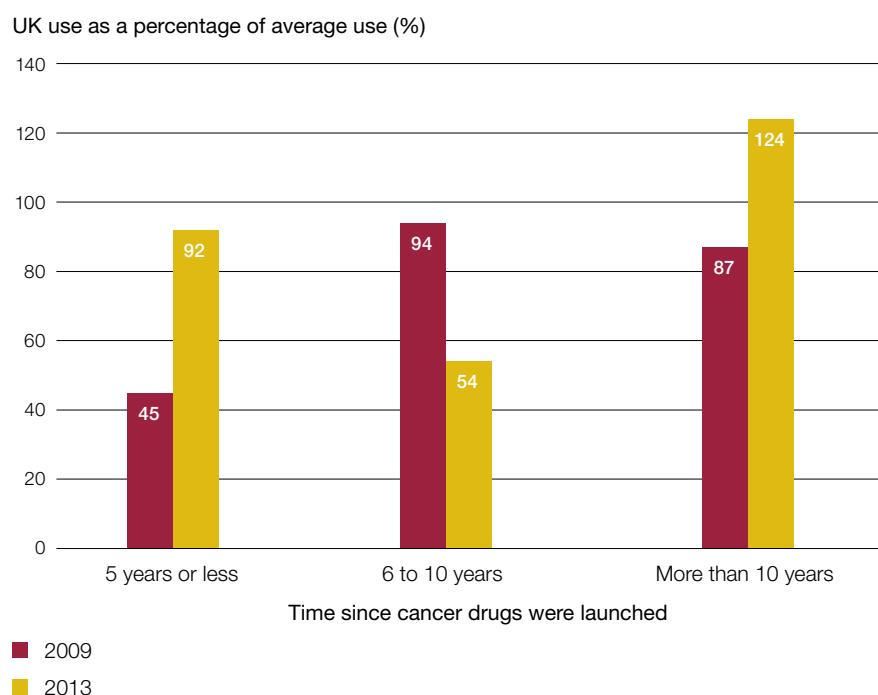
3.2 One of the reasons for introducing the Fund was that use of new cancer drugs in the UK was low compared with similar countries (see paragraph 1.1). **Figure 6** indicates that between 2009 and 2013:

- use of cancer drugs launched in the previous 5 years increased in the UK relative to the international average, but was still below this average;
- use of cancer drugs launched between 6 and 10 years ago decreased in the UK relative to the international average; and
- use of cancer drugs launched more than 10 years ago increased in the UK to above the international average.

Figure 6

The UK's use of cancer drugs compared with 13 other countries, 2009 and 2013

Use of cancer drugs launched in the previous 5 years increased in the UK between 2009 and 2013 relative to the international average, but was still below this average



Notes

- 1 The 13 other countries are: Australia, Austria, Canada, Denmark, France, Germany, Italy, New Zealand, Norway, Spain, Sweden, Switzerland and the USA. Denmark was excluded from the 2013 analysis because data were not available.
- 2 Data are not available for England alone.

Source: National Audit Office analysis of data presented in Professor Sir Mike Richards CBE, *Extent and causes of international variations in drug usage: A report to the Secretary of State for Health*, July 2010 and the Office of Health Economics, *International Comparison of Medicines Usage: Quantitative analysis*, Association of the British Pharmaceutical Industry, November 2014

3.3 Although there is no direct evidence, it is likely that the Fund has contributed significantly to the improvement in the UK's relative position in providing access to newer cancer drugs. In 2014-15, some 60% of patients supported by the Fund were accessing drugs that had been licensed during the previous 5 years. All of the organisations we spoke to during the course of our work, including cancer charities and pharmaceutical companies, thought the Fund had been successful in bridging the gap between a drug being licensed and its recommendation by NICE. They told us that the Fund had enabled patients to access medicines earlier and provided access to new cancer drugs where previously there was no national arrangement.

Variations in access

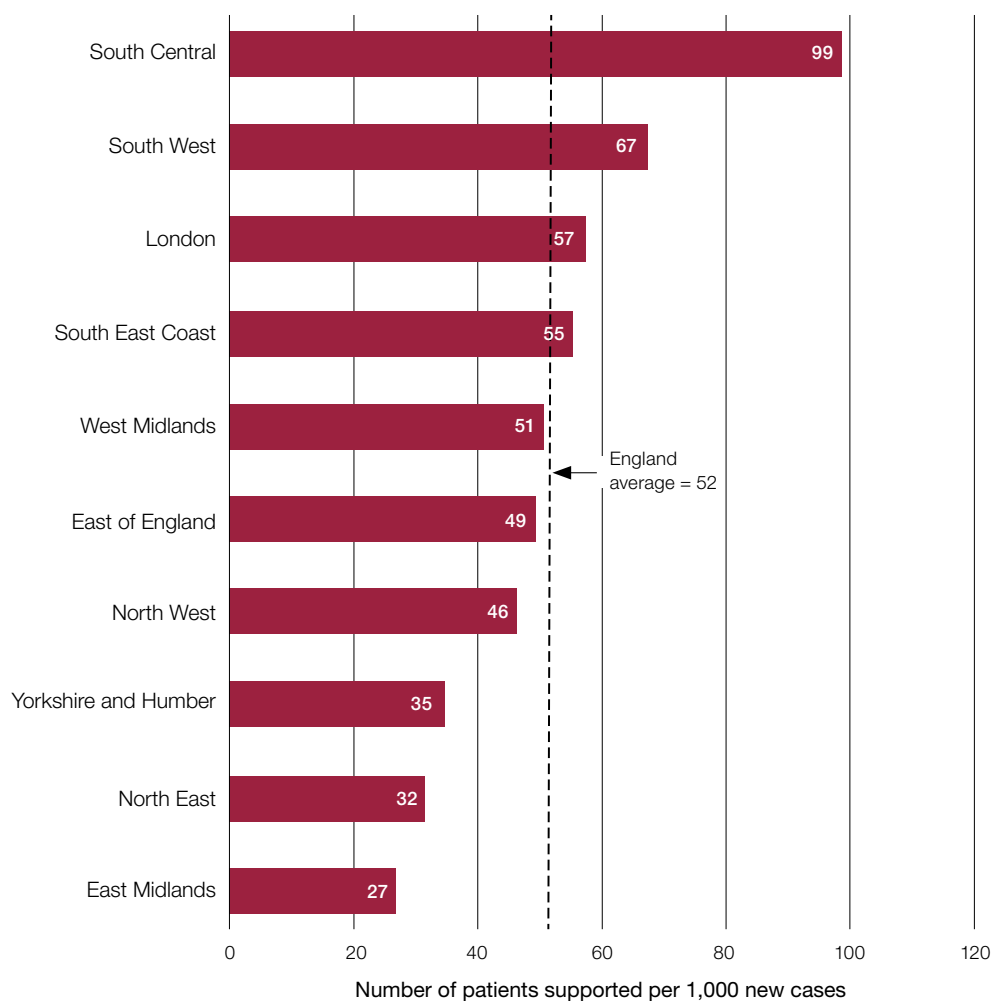
3.4 Between October 2010 and March 2013, there was significant geographical variation in access to the Fund. Regions in the south of England supported more patients per 1,000 new cancer cases than those in the north (**Figure 7**). The variation was partly due to the fact that some of the drugs accessed through the Fund in some regions were already available through routine commissioning in other regions. However, the variation also reflected the fact that each of the then 10 strategic health authorities, which managed the Fund during this period, had its own list of cancer drugs to be prioritised and access arrangements differed from one region to another. The Department's allocation of the Fund to each region took account of levels of need, and those regions with a lower level of access generally spent less of their allocated budget.

3.5 In 2013, NHS England created a single national system (see paragraph 2.11) with the aim of reducing variations in access to the Fund. Data for the 4 NHS England regions that run the national system show that access has generally increased and regional variations have reduced significantly since 2013 (**Figure 8** on page 20), although the proportion of patients supported by the Fund in the London region is substantially higher than in the other regions. This is likely to reflect a change in the way the data are reported in that the number of patients supported is now reported by the location of the treatment hospital rather than the area where the patient lives. London has a high number of teaching hospitals and specialist treatment centres, and a significant proportion of treatments carried out by hospitals in London involve patients from other parts of the country.

Figure 7

Number of patients supported by the Fund per 1,000 new cancer cases, by strategic health authority, 2012-13

There was significant geographical variation in access to the Fund in 2012-13

**Note**

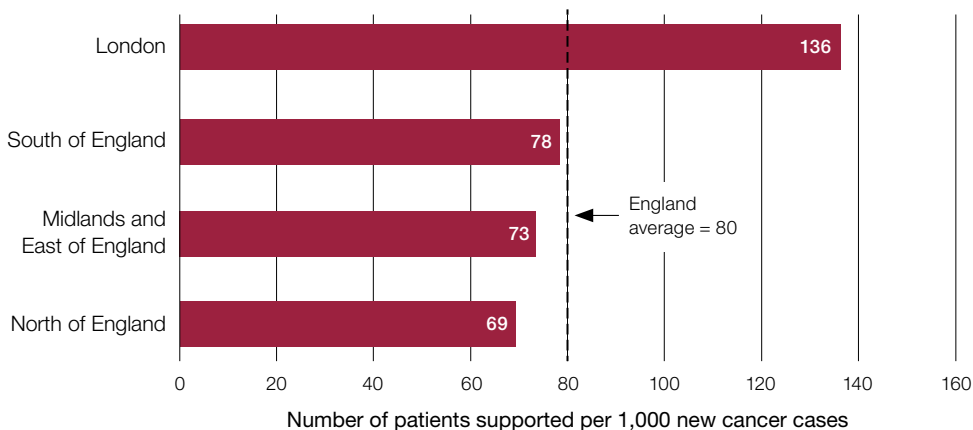
1 The number of new cancer cases by strategic health authority was estimated using the 3-year average (2008 to 2010) from the Cancer Commissioning Toolkit.

Source: National Audit Office analysis of Department of Health data and Public Health England data

Figure 8

Number of patients supported by the Fund per 1,000 new cancer cases, by NHS England region, 2013-14 and 2014-15

There was relatively little variation in access to the Fund across three regions in 2013-14 and 2014-15

**Notes**

- 1 Since April 2013, the number of approvals has been reported by the location of the treatment hospital, rather than by the location of their respective local commissioners.
- 2 The number of new cancer cases by clinical commissioning group was estimated using the 3-year average (2010 to 2012) from the Cancer Commissioning Toolkit.

Source: National Audit Office analysis of NHS England data and Public Health England data

Types of drug available and being accessed

3.6 **Figure 9** shows that in 2013-14 and 2014-15:

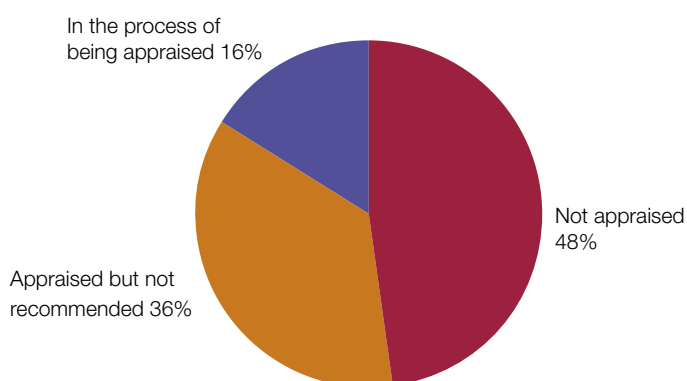
- almost half (48%) of the drug indications available through the Fund had not been appraised by NICE, although these indications accounted for only 17% of the patients supported by the Fund;
- 16% of the drug indications available through the Fund and 32% of the patients supported by the Fund involved drug indications that were in the process of being appraised by NICE; and
- 36% of the drug indications available through the Fund had not been recommended by NICE because it did not consider them to be an appropriate use of NHS funds based on the data available. These indications accounted for 51% of the patients supported by the Fund.

Figure 9

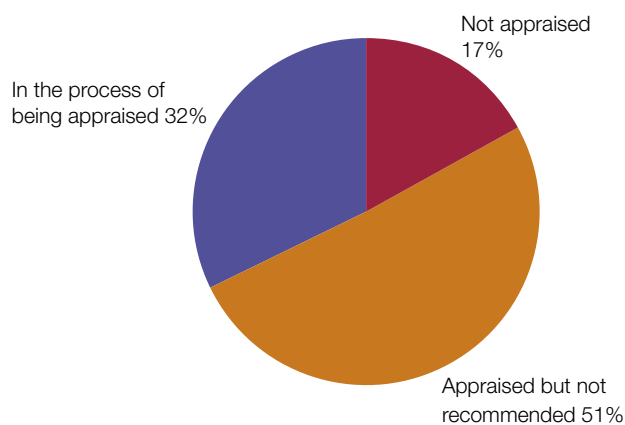
Drug indications available through the Fund and patients supported by the Fund, by NICE decision, 2013-14 and 2014-15

More than one third of the drug indications available through the Fund had been appraised but not recommended by NICE, accounting for just over half of the patients supported by the Fund

By drug indication



By patient

**Notes**

- 1 'Not appraised' includes applications that were terminated during the NICE appraisal process and drugs being used for indications that were not covered by the original licence.
- 2 'In the process of being appraised' includes drugs that have been recommended by NICE but are not yet available through local NHS commissioners. Following a NICE recommendation, local NHS commissioners have 3 months to start commissioning the drug.

Source: National Audit Office analysis of NHS England data

3.7 In 2013, the government noted that one of the Fund's objectives was to give patients with rare cancers access to lifesaving treatments.¹¹ Drugs for less common and, in particular, rare cancers are less likely to be appraised by NICE because of the relatively small number of people affected. They are therefore less likely to be available through routine NHS commissioning. In 2014-15, more than 70% of the drug indications available through the Fund (82 of 111 indications) were for less common and rare cancers.¹²

3.8 In practice, however, most of the patients supported by the Fund had common types of cancer. In 2013-14 and 2014-15, 26,000 of the patients supported (59% of the total) were being treated for colorectal, prostate and breast cancer, 3 of the 4 most common types of cancer (**Figure 10**). For patients with these 3 types of cancer, more than half were accessing drugs that had not been recommended by NICE.

3.9 Although more than 40 individual drugs were available through the Fund at some point during 2013-14 and 2014-15, 10 drugs accounted for more than 70% of the patients supported by the Fund during this period (**Figure 11** on page 24).¹³ The most common, Avastin (Bevacizumab), accounted for almost one fifth of the patients supported by the Fund over the two years. In 2014-15, Avastin was approved for 4,520 patients, nearly two-thirds of whom had colorectal cancer. Previously, NICE had not recommended Avastin for a range of cancer indications, including breast, colorectal and ovarian cancer, on the grounds of a lack of robust data or the high cost per quality-adjusted life year gained. Avastin was not eligible for consideration under NICE's end-of-life criteria, across a range of cancer indications, due to the large number of patients affected. The affected patient population must be small for drugs to meet the end-of-life criteria (see paragraph 2.3).

3.10 In 2013-14 and 2014-15, 20 pharmaceutical companies supplied the cancer drugs available through the Fund (**Figure 12** on page 25). Ten companies supplied the drugs for 84% of the patients supported by the Fund; one company, Roche, supplied the drugs for 24% of the patients supported, reflecting the fact that it manufactures Avastin (Bevacizumab), the most commonly supplied drug.

11 Department of Health and Prime Minister's Office, *Thousands of patients to benefit from £400 million cancer package*, September 2013.

12 Less common and rare cancers include all cancers except the 4 most common types of cancer (breast, prostate, lung and colorectal), which account for 54% of all new cancer cases.

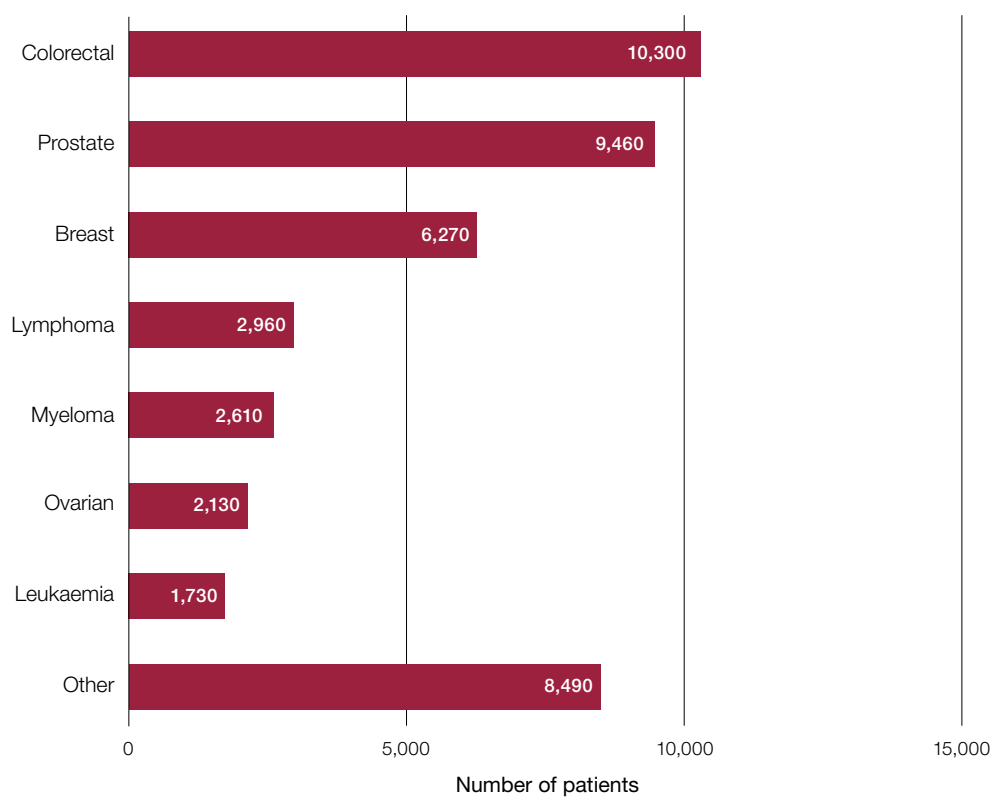
13 Individual drugs may be used for more than one cancer indication.

Figure 10

Number of patients supported by the Fund, by cancer type, 2013-14 and 2014-15

Most patients supported by the Fund had common types of cancer

Type of cancer

**Notes**

- 1 Numbers of patients are rounded to the nearest 10.
- 2 Data used in this figure do not include cancer patients approved through individual funding requests.

Source: National Audit Office analysis of NHS England data

Figure 11

The 10 drugs most commonly accessed through the Fund, 2013-14 and 2014-15

Cancer drug	Company	Cancer indications	NICE decisions across the cancer indications	Number of patients approved since April 2013	Percentage of patients approved (%)
Bevacizumab	Roche	Breast, cervical, colorectal, gliomas and ovarian	Not appraised, in process of being appraised or appraised but not recommended	8,520	19
Abiraterone	Janssen-Cilag	Prostate	In process of being appraised	4,940	11
Bendamustine ¹	Generic	Leukaemia, lymphoma and myeloma	Not appraised or in process of being appraised	3,370	8
Cetuximab	Merck Serono	Colorectal and skin	Not appraised or appraised but not recommended	3,330	8
Enzalutamide	Astellas	Prostate	In process of being appraised	2,630	6
Everolimus ²	Novartis	Breast, pancreatic and renal	Not appraised or appraised but not recommended	2,310	5
Eribulin	Eisai	Breast	Appraised but not recommended	1,840	4
Aflibercept	Sanofi	Colorectal	Appraised but not recommended	1,580	4
Pemetrexed	Lily	Lung	Not appraised or appraised but not recommended	1,300	3
Cabazitaxel	Sanofi	Prostate	Appraised but not recommended	1,270	3
Total				31,090	71

Notes

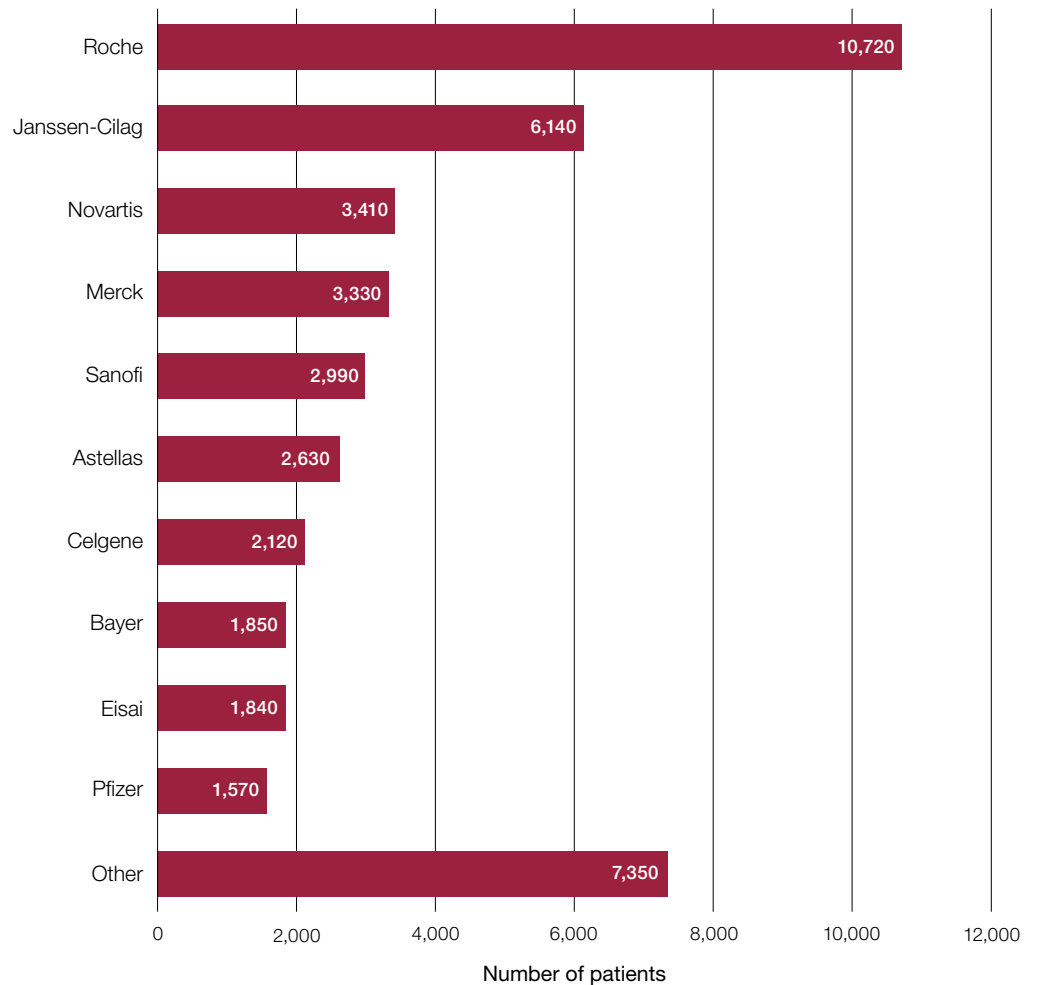
- 1 NICE has recommended Bendamustine for treating certain types of leukaemia.
- 2 At the time of our work, NICE was considering whether to appraise Everolimus for pancreatic neuroendocrine tumours.
- 3 Number of patients rounded to the nearest 10.
- 4 For a particular drug, NICE makes individual recommendations by cancer type and for subgroups of patients with the same type of cancer.

Source: National Audit Office analysis of NHS England data

Figure 12

Number of patients supported by the Fund by pharmaceutical company, 2013-14 and 2014-15

10 companies supplied the drugs for 36,600 patients (84% of patients) supported by the Fund between April 2013 and March 2015



Notes

- 1 Numbers of patients are rounded to the nearest 10.
- 2 Other includes generic drugs paid for by the Fund and drugs supplied by other pharmaceutical companies, for example GSK (1,300), Amgen (50) and Astra Zeneca (40).

Source: National Audit Office analysis of NHS England data

Part Four

What impact has the Fund had on patient outcomes?

4.1 Due to a lack of data, it is not possible to evaluate the impact the Fund has had on patient outcomes such as survival. The Fund pays for drugs that have been assessed as clinically effective in extending patients' lives, based on evidence from clinical trials. In setting up the Fund, the Department noted the importance of collecting data, including clinical audit data, to gain assurance on the use of the funding made available through the Fund. In particular, it recognised that collecting data would help provide evidence on how the drugs concerned performed in clinical practice.¹⁴

4.2 The Department had planned to collect clinical audit data on treatments paid for by the Fund (for example, on the duration of treatment and patient outcomes such as mortality following the treatment) from April 2012, through the national chemotherapy dataset.¹⁵ Although some data have been collected on the use of drugs paid for by the Fund, hospital trusts were not mandated to collect these data until April 2014. Public Health England estimates that, in 2013-14, approximately half of the patients receiving drugs paid for by the Fund were not recorded within the national chemotherapy dataset.

4.3 In January 2015, we reported that these gaps in data made it difficult to evaluate in a meaningful way the money spent through the Fund.¹⁶ By the end of March 2015, all hospital trusts providing chemotherapy treatment were reporting data to the national chemotherapy dataset. However, the dataset has not been able to distinguish treatments paid for by the Fund from those paid for in other ways, such as routine NHS commissioning or clinical trial. In July 2015, NHS England and Public Health England established a data-sharing agreement, which should enable the treatments and outcomes of patients supported by the Fund to be tracked.

¹⁴ Department of Health, *The Cancer Drugs Fund – Government response to consultation*, April 2011.

¹⁵ Department of Health, *The Cancer Drugs Fund – Guidance to support operation of the Cancer Drugs Fund in 2011-12*, March 2011.

¹⁶ Comptroller and Auditor General, *Progress in improving cancer services and outcomes in England*, Session 2014-15 HC 949, National Audit Office, January 2015.

4.4 In addition, it is not clear whether trusts are submitting data for all the patients they are treating and the completeness of the data that are submitted is poor. For example, in 2014-15:

- only 45% of patient records included information on the patient's general health status at the start of treatment; and
- although all patient records had a treatment start date and a primary diagnosis, many records lacked important data: 70% were missing a final treatment date; 47% did not include the cell type; 52% did not include the stage of disease at the start of treatment; and 93% did not have an outcome summary.

4.5 In March 2015, the Committee of Public Accounts recommended that NHS England should set out how it would use the new data (for 2014-15 patients) to evaluate the Fund's impact on patient outcomes. In response, the government said that NHS England, the Department and Public Health England were working with cancer charities, the pharmaceutical industry and NICE to improve the evaluation of the effectiveness of cancer drugs. The response did not address explicitly the Committee's point about evaluating the impact of the Fund.

4.6 Recent academic research has sought to assess the Fund's impact on patient outcomes. The research suggested that for 2013-14 some 3,000 quality-adjusted life years may have been gained through the Fund, based on an assumption that on average the drugs extended patients' lives by 3 months. The research also highlighted that had the funding been used for other NHS services, the impact could have been 5 times greater.¹⁷ The Department had itself recognised in 2010 that, while the Fund would provide much needed access to some cancer drugs, it might gain better value if the money was spent on other conditions.¹⁸

¹⁷ Claxton KP et al., *Methods for the Estimation of the NICE Cost Effectiveness Threshold*, Centre for Health Economics Research Paper 81, November 2013; Presentation at Science Media Centre press briefing, February 2015; Claxton KP et al., *Methods for the estimation of the NICE cost-effectiveness threshold*, Health Technology Assessment, Volume 19, Issue 14, February 2015.

¹⁸ Department of Health, *Impact Assessment of Proposal for a Cancer Drug Fund*, October 2010.

Part Five

How much has the Fund cost?

5.1 The government set an initial budget for the Fund of £650 million to March 2014. Following the government's decision to extend the Fund to March 2016, NHS England increased the annual budget from £200 million to £280 million for 2014-15 and 2015-16. In January 2015, it increased the budget for 2015-16 again to £340 million. This means that the Fund now has an expected total lifetime budget of £1.27 billion.

5.2 The total cost of the Fund from October 2010 to March 2015 was £968 million, compared with the budget of £930 million:

- Between October 2010 and March 2013, the 10 strategic health authorities, on behalf of the Department, underspent the budget by 28% in total (£128 million). The Chair of the Fund told us that underspending of this kind was common in the early stages of a new programme and that it reflected the variable take-up across the 10 strategic health authorities that managed the Fund (see Figure 7, page 19).
- In 2013-14 and 2014-15, NHS England overspent the allocated budget for the Fund by 15% (£31 million) and 48% (£136 million) respectively (**Figure 13**). The overspend was partly offset by NHS England underspending against other budgets but also meant the deferral of some planned spending on primary care services.

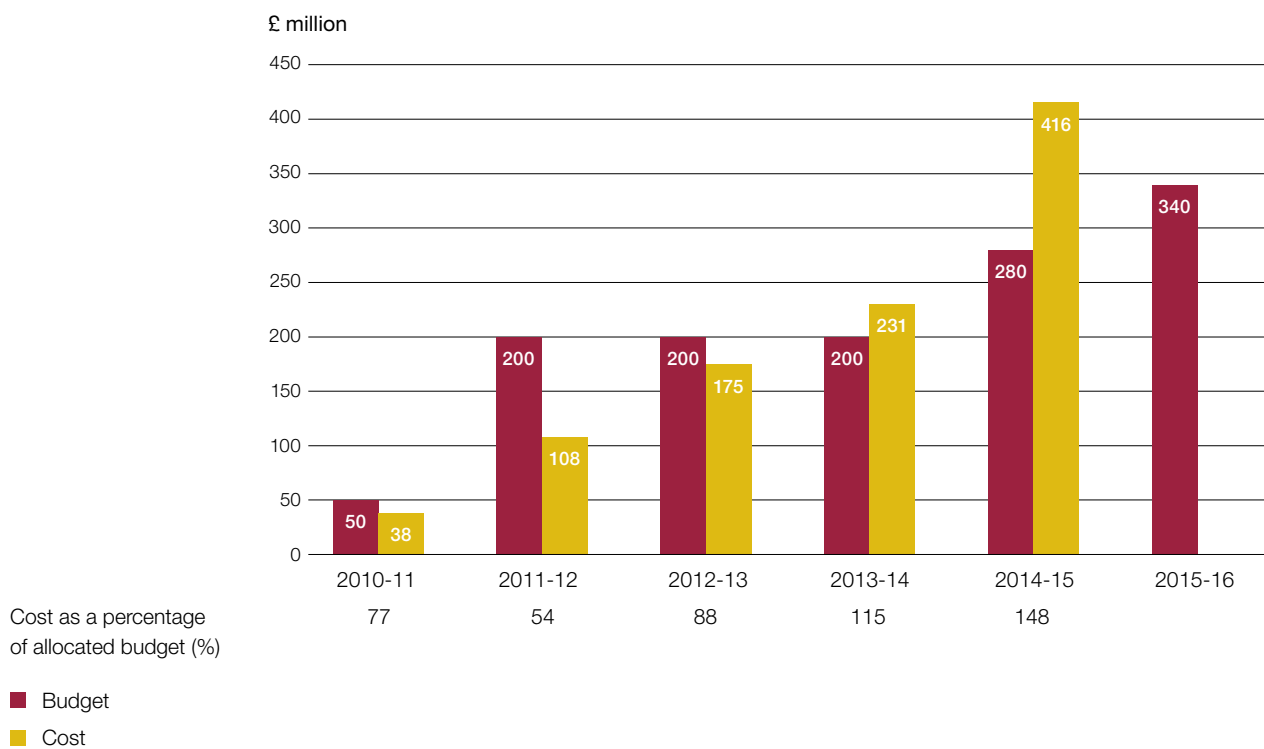
5.3 The Fund is demand-led and, over the two years to March 2015, the cost increased by £241 million:

- 44% of the increase in cost was accounted for by an increase of 9,320 (60%) in the number of patients supported by the Fund.
- 56% of the increase in cost was accounted for by an increase in the average cost per patient (**Figure 14** on page 30). The average cost is driven by the price of the drug in question and the duration of treatment. Between 2012-13 and 2014-15, the estimated average cost per patient supported by the Fund increased by £5,430 – a rise of 48%. In 2014-15, the estimated cost per patient ranged from less than £10,000 to more than £100,000 per drug.

Figure 13

Budget and cost of the Cancer Drugs Fund, 2010-11 to 2015-16

The budget of the Fund was overspent in 2013-14 and 2014-15

**Notes**

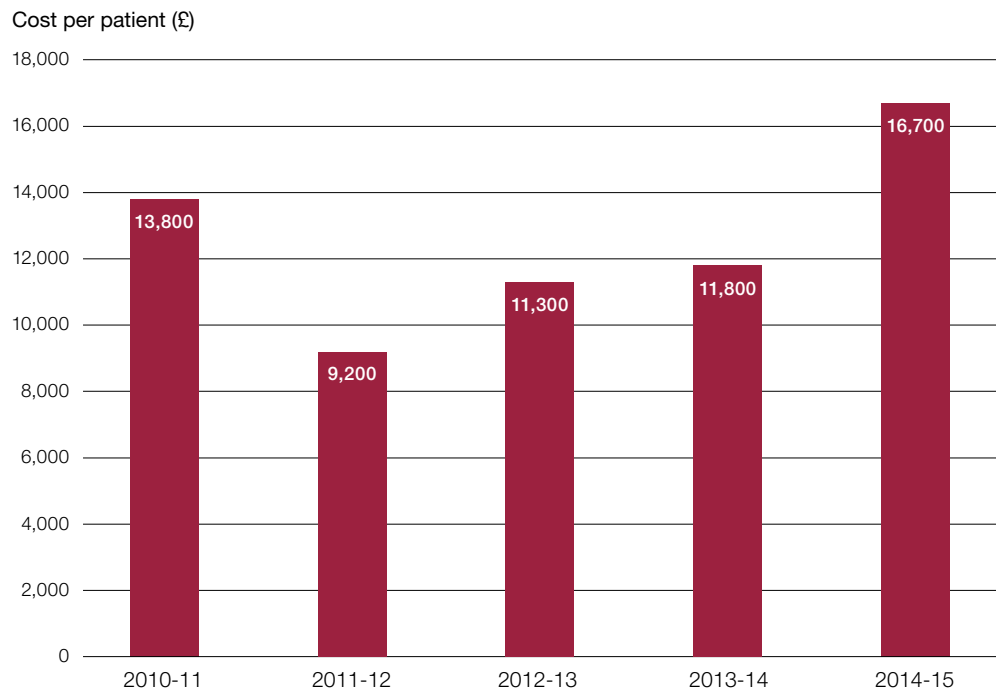
- 1 Data for 2010-11 represent in-year funding provided by the Department of Health in October 2010.
- 2 Costs are rounded to the nearest £ million.

Source: National Audit Office analysis of Department of Health data and NHS England data

Figure 14

Average cost per patient supported by the Fund, 2010-11 to 2014-15

The average cost per patient rose each year from 2011-12 to 2014-15



Note

1 Cost per patient is rounded to the nearest £100.

Source: National Audit Office analysis of Department of Health data and NHS England data

Action taken to control cost

5.4 In 2014-15, the Fund accounted for over a quarter of total NHS spending on cancer drugs (estimated by NHS England to be approximately £1.5 billion). In light of the rapid growth in the cost of the Fund, in autumn 2014 NHS England decided to take action to control the cost. It noted that some drugs available through the Fund “offer at best a modest or no impact on survival” and often “on price terms represented poor value”.¹⁹

5.5 In November 2014, NHS England published a revised operating procedure for the Fund following a consultation in October 2014.²⁰ The new guidance enabled NHS England to prioritise and remove drugs from its national list, based on a scoring system that considered both clinical effectiveness, such as impact on survival and toxicity, and cost. From the outset, a mechanism was in place to remove drugs from the Fund in order to control costs, but this was the first time that either the Department or NHS England had used the mechanism and taken action to manage the total cost of the Fund.

5.6 In December 2014, the Fund panel reviewed 45 drug indications with the lowest scores on the national list, along with 10 new drug indications. Pharmaceutical companies whose drugs were re-evaluated had the opportunity to provide new evidence on clinical benefits. For drugs with sufficient clinical benefits but high costs, pharmaceutical companies could offer a discount to the Fund, through a confidential process, to improve the overall score in order for their drugs to remain on the national list.

5.7 In January 2015, NHS England announced that it would remove 25 indications across 16 drugs from the national list from 12 March 2015. Patients who were already receiving these drugs could continue to receive them. Drugs removed from the national list could also still be available through individual funding requests to the Fund’s regional panels (see paragraph 2.14).

5.8 NHS England initially estimated that, through a combination of removing drugs from the national list and discounts offered by pharmaceutical companies, forecast spending for the Fund in 2015-16 would be £80 million less than it had previously projected: £340 million compared with £420 million without the re-evaluation exercise. Up to 90% of the estimated savings were expected to be generated by removing drugs from the national list. However, NHS England now expects that the actual savings will be less than the estimate of £80 million for a number of reasons. For example, appeals by pharmaceutical companies caused a delay in removing some drugs from the national list and there was a rise in applications for some drug indications before they were removed from the list.

¹⁹ Letter from the Chair of the Cancer Drugs Fund to the Chief Executive of NHS England on 26 August 2014 and the response from the Chief Executive of NHS England on 27 August 2014.

²⁰ NHS England, *Standard Operating Procedures: The Cancer Drugs Fund (CDF). Guidance to support operation of the CDF in 2014-15*, November 2014.

5.9 In July 2015, NHS England forecast that, in the absence of further prioritisation, the cost of the Fund in 2015-16 would be £410 million, £70 million more than the budget. In September 2015, as we finalised this report, NHS England announced that it was proposing to remove a further 23 indications from the national list from 4 November 2015. It noted that, while these actions would reduce costs further, it did not expect the cost of the Fund to be within budget in 2015-16.

5.10 Most organisations that we spoke to, including cancer charities and pharmaceutical companies, recognised that NHS England needed to take action to control the cost of the Fund. However, some raised concerns about the way NHS England had carried out the review process. A number of organisations felt the consultation on the proposed changes to the operating procedure was skewed because more than half of the individuals or organisations that responded to the consultation were NHS providers or commissioners, which meant the results were dominated by views from the NHS. For example, although 58% of respondents supported the proposal that the re-evaluation scoring system should take account of both clinical effectiveness and cost, only 14 of 48 pharmaceutical companies and cancer charities responding to the consultation agreed (29%). In contrast, 80 of 107 NHS organisations (75%) supported the proposal.²¹

5.11 A number of organisations, including cancer charities and pharmaceutical companies, told us that NHS England's scoring of individual drugs was not always transparent and that data on clinical effectiveness to support decision-making were not robust. They also raised concerns that the re-evaluation was done in isolation of NICE and duplicated work undertaken by NICE in its technology appraisals.

21 NHS England, *Operation of the Cancer Drugs Fund 2014-15 Consultation Report*, November 2014.

Part Six

What is the future of the Fund?

6.1 During the course of our work, we sought views about the future of the Fund. The organisations that we spoke to regularly highlighted that, for the Fund to be sustainable and to continue to improve access to effective cancer drugs, there needed to be greater consistency between the Fund, NICE appraisal processes and wider pharmaceutical pricing regulations.

6.2 In 2010, the government's intention was for the Fund to be a temporary measure until it put in place a 'value-based pricing' system when the existing Pharmaceutical Price Regulation Scheme (**Figure 15**) expired at the end of 2013. Under a value-based pricing system, prices for branded drugs would be set according to the drug's clinical and wider societal benefits, taking account of the severity of the condition being treated, compared with the benefits from other treatments used in the NHS. However, a value-based pricing system has not been introduced, and in 2013 the Department and the pharmaceutical industry agreed a revised Pharmaceutical Price Regulation Scheme that runs from 2014 to 2018.²²

Figure 15

The Pharmaceutical Price Regulation Scheme

- Has regulated the prices for branded drugs in the UK since 1957.
- Aims to provide a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry.
- Controls the prices of branded medicines and the level of profits the pharmaceutical industry can make on its sales to the NHS while allowing the industry freedom to set prices for new drugs.
- Is a voluntary scheme that the Department and the pharmaceutical industry usually renegotiate every 5 years.
- The current scheme runs from 2014 to 2018 and limits overall NHS spending on a subset of branded drugs. The baseline spending in 2013 was approximately £8 billion, and growth for the 5 years is limited to 0%, 0%, 1.8%, 1.8% and 1.9% respectively.
- The pharmaceutical industry makes payments to the Department to cover any spending above the limit. For the period from January 2014 to June 2015, the industry returned a total of £727 million.

Source: National Audit Office review of documents from the Department of Health

6.3 The extent to which the sale of cancer drugs available through the Fund is covered by the current Pharmaceutical Price Regulation Scheme has been disputed. In August 2015, the Department reached an agreement with the Association of the British Pharmaceutical Industry to clarify the way in which spending on the Fund is treated by the current Pharmaceutical Price Regulation Scheme, following a dispute. As a result, the Department published an addendum to the Scheme. In essence, this means that any spending on the Fund above an agreed amount each year is outside the growth limit for the Scheme and so the pharmaceutical industry would not repay that amount to the Department.

6.4 NHS England recognises that the re-evaluation process that it applied in November 2014 did not address wider issues relating to access to cancer drugs.²³ In January 2015, it established a working group to develop proposals to improve how new cancer drugs are appraised and commissioned. The group is chaired by the National Clinical Director for Cancer and consists of the Department, NHS England, NICE, cancer charities, the Ethical Medicines Industry Group and the Association of the British Pharmaceutical Industry. In July 2015, NHS England announced that the work of the group would be “paused” while it considered how the work should progress.

6.5 Also in July 2015, the Independent Cancer Taskforce recommended reform of the Fund.²⁴ It noted that because the Fund had “enabled some pharmaceutical companies to bypass NICE cost-effectiveness assessments, it was widely acknowledged that it is no longer sustainable or desirable for the Fund to continue in its current form”.²⁵ The Taskforce advocated a solution that allowed access to new cancer drugs while managing within a defined budget and aligning with NICE appraisal processes.

6.6 NHS England accepted this recommendation and proposed that the Fund should become a ‘managed access’ fund with clear entry and exit criteria. This would pay for promising new drugs for a set period before NICE decides whether or not the drugs should be recommended for routine commissioning. NHS England considers that this would provide time for further ‘real world’ evidence to be collected to support a more informed NICE appraisal process. The implication of NHS England’s proposals is that the Fund would no longer provide access to drugs that have been appraised but not recommended by NICE. NHS England plans to consult on its proposals in autumn 2015. It aims to implement the new arrangements from April 2016.

6.7 More widely, in March 2015, the government announced it had set up a review to explore opportunities to give NHS patients quicker access to innovative medicines and medical technology. The review plans to consider how schemes like the Fund, NICE technology appraisals, the Pharmaceutical Price Regulation Scheme and value-based pricing might fit into an integrated specialist commissioning system. In July 2015, the Chair of the review said the review would examine whether the principle of the Fund could be applied to non-cancer treatments.

23 Letter from the Chief Executive of NHS England to the Chair of the Cancer Drugs Fund, 27 August 2014.

24 The taskforce was set up by NHS England in January 2015 to develop a five-year action plan for cancer services, with the aim of improving survival rates.

25 Independent Cancer Taskforce, *Achieving world-class cancer outcomes – a strategy for England 2015–2020*, July 2015.

Appendix One

Our investigative approach

Scope

1 Between July and October 2014, we collected evidence for our report *Progress in improving cancer services and outcomes*, published in January 2015. During this process, we identified a range of questions about the Cancer Drugs Fund (the Fund). These were about the rationale for the Fund and how it relates to mainstream NHS processes. We also heard concerns about the Fund's impact and whether it is sustainable in its current form. These issues were also covered by the Committee of Public Accounts report on cancer services and outcomes, published in March 2015.

2 This investigation sets out the facts relating to the Fund to inform consideration of what it has achieved and the debate about its future beyond 2016. It covers:

- Why was the Fund set up?
- How does the Fund relate to routine NHS commissioning of cancer drugs?
- What impact has the Fund had on patients' access to cancer drugs?
- What impact has the Fund had on patient outcomes?
- How much has the Fund cost?
- What is the future of the Fund?

3 We carried out the investigation between March and July 2015. Our work was not designed to assess the value for money of the Fund.

Methods

4 We interviewed relevant officials from the Department of Health and NHS England (including the Chair of the Fund), who have a role in administering or overseeing the Fund. The interviews covered the Fund's development, its impact and cost, and whether it is sustainable in its current form. We also spoke to a number of people who had been clinical directors at the former strategic health authorities to establish how the Fund was set up and managed.

5 We interviewed officials from Public Health England who manage the national chemotherapy dataset about the data that are available on the impact of the Fund. We also interviewed officials from the National Institute for Health and Care Excellence about its processes for appraising new drugs, how the Fund relates to routine commissioning of cancer drugs, and the Fund's future.

6 We interviewed relevant staff from a range of organisations to seek their views on the effectiveness of the Fund and whether it is sustainable in its current form, and to identify research and analysis carried out on the topic. The organisations that we spoke to, or that provided written evidence, were:

- cancer charities: Cancer Research UK; Macmillan Cancer Support; the Rarer Cancers Foundation; and Breakthrough Breast Cancer;
- pharmaceutical industry: the Association of the British Pharmaceutical Industry; Amgen; Celgene Ltd; Janssen-Cilag; Pfizer Inc.; and Roche Products Ltd; and
- the King's Fund.

7 We reviewed relevant policy documents and announcements, operational guidance, reports and meeting minutes from the Department of Health, NHS England, Public Health England and the National Institute for Health and Care Excellence. We also reviewed reports and analysis from cancer charities, think tanks and the pharmaceutical industry.

8 We reviewed data analysis, or carried out our own analysis of data, received from the Department of Health, NHS England, Public Health England, the National Institute for Health and Care Excellence, the Office of Health Economics and the Centre for Health Economics at York University. The data and analysis covered trends in NICE recommendations, access to and costs of the Fund, and outcomes for patients receiving cancer drug treatments.

This report has been printed on Evolution Digital Satin and contains material sourced from responsibly managed and sustainable forests certified in accordance with the FSC (Forest Stewardship Council).

The wood pulp is totally recyclable and acid-free. Our printers also have full ISO 14001 environmental accreditation, which ensures that they have effective procedures in place to manage waste and practices that may affect the environment.



National Audit Office

Design and Production by NAO Communications
DP Ref: 10812-001

£10.00

ISBN 978-1-78604-004-6



9 781786 040046
