The Cancer Drugs Fund

Guidance to support operation of the Cancer Drugs Fund in 2011-12

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The Cancer Drugs Fund

Guidance to support operation of the Cancer Drugs Fund in 2011-12

Prepared by the Department of Health

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Section A - Background

1. Introduction

1.1 The purpose of this document is to provide guidance to the NHS in support of the operation of the Cancer Drugs Fund in 2011-12. It has been developed by the Department of Health in collaboration with NHS colleagues. A regional model based around Strategic Health Authority (SHA) established clinically-led panels is being adopted for the Cancer Drugs Fund in 2011-12, as set out in the consultation on the proposals for the Fund. The guidance is therefore intended primarily for SHAs and their clinically-led panels.

1.2 The guidance builds on experience in 2010-11 of operating the regional arrangements for providing additional cancer drugs and is issued following feedback to the Department of Health as a result of consultation between 27 October 2010 and 19 January 2011 on the proposals for the Cancer Drugs Fund.

1.3 Arrangements from 1 April 2012 and beyond will be the subject of discussions between the Department of Health and the shadow NHS Commissioning Board.

1.4 This guidance comes into force on 1 April 2011. It does not apply retrospectively. It will be kept under review and updated as appropriate during 2011-12.

1.5 The Cancer Drugs Fund applies in England only.

2. Context

Background to the Cancer Drugs Fund

2.1 The Coalition: our programme for government[1] confirmed the Government's commitment to the establishment of a Cancer Drugs Fund from April 2011:

> "We will create a Cancer Drugs Fund to enable patients to access the cancer drugs their doctors think will help them"

This was reaffirmed in the White Paper, Equity and excellence – Liberating the NHS.[2]

2.2 The Fund provides a means of improving patient access to cancer drugs prior to the anticipated reform of arrangements for branded drug pricing on expiry of the current Pharmaceutical Price Regulation Scheme (PPRS)[3] at the end of 2013.

[1] The Coalition: our programme for government, May 2010
[2] Equity and excellence – Liberating the NHS, July 2010
[3] Pharmaceutical Price Regulation Scheme (PPRS) 2009, December 2008

2.3 A consultation on the Government's proposals for the establishment of the Fund took place between October 2010 and January 2011.[4] The key objectives for the Fund, as outlined in the consultation, were that it should:

- provide maximum support to NHS patients
- put clinicians and cancer specialists at the heart of decision-making, consistent with the Government's wider policy of empowering health professionals and enabling them to use their professional judgement about what is right for patients
- act as an effective bridge to the Government's aim of introducing a value-based pricing system for branded drugs in 2014

Arrangements in 2010-11

2.4 In July 2010 in response to the publication of a report by Professor Sir Mike Richards, National Cancer Director, on the Extent and Causes of International Variations in Drug Usage,[5] the Government announced that £50 million additional funding had been identified in-year to support improved access to cancer drugs.

2.5 SHAs were tasked with working with their Cancer Networks and PCTs to ensure that appropriate arrangements were in place by October 2010 to manage this funding. These arrangements included the establishment of clinically-led panels to make decisions on the most appropriate use of resources and to approve funding requests.

2.6 Implementation of the arrangements in 2010-11 has provided useful experience to build on in 2011-12, complementing the consultation on the Cancer Drugs Fund proposals.

Funding for 2011-12

2.7 As set out in the NHS Operating Framework,[6] £200 million is being made available in each of the next three years for the Cancer Drugs Fund and SHAs should plan on this basis.

2.8 SHA shares of the £200 million have been calculated using the national weighted capitation formula.[7] It is expected that each SHA Cancer Drugs Fund will put in place a plan to fund cancer treatments using their appropriate weighted capitation share of the total £200 million fund.

2.9 Further information on the financial arrangements for 2011-12 is contained in Sir Bruce Keogh's letter of 1 March 2011 to Medical Directors and Directors of Finance in Strategic Health Authorities in England.[8]

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[4] The Cancer Drugs Fund – a consultation, 27 October 2010, Gateway reference 14909
[5] Extent and Causes of International Variations in Drug Usage, July 2010
[6] The Operating Framework for the NHS in England 2011-12, Gateway reference 15216
[7] The national weighted capitation formula takes account of such factors as the age distribution of the population and additional need in determining the appropriate allocation of funding
[8] http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_124791

Section B - Guidance

3. Format of SHA Arrangements for allocating the funding

3.1 Each SHA should put in place a transparent, published process for allocating the funding. This process should build on the arrangements put in place in 2010-11 to manage allocation of the additional £50 million funding for cancer drugs. As in 2010-11, applications for funding from the Cancer Drugs Fund should be made by clinicians on behalf of their patients and decisions on the appropriate use of resources should be taken by a clinically-led panel. The clinically-led panels should take into account this guidance in coming to their decisions.

3.2 It is imperative that decisions affecting individuals' treatment are made in a timely fashion. SHAs should ensure that the process put in place supports timely decision-making, bearing in mind the 31-day cancer treatment standard.[9] Evidence from operation of the arrangements in 2010-11 suggests that decision-making can routinely be much quicker than this. In recognition of this, clinically-led panels are encouraged to set more challenging timescales for decision-making under the Cancer Drugs Fund.

3.3 SHA clinically-led panels must provide both reasons for refusal to fund and the opportunity to have cases reconsidered in the light of new evidence or if relevant information was missed (see section 5.6). The SHA should have a clear process in place for considering appeals against funding decisions. SHAs should ensure that these processes support timely consideration.

3.4 Feedback to consultation has supported the involvement of a lay perspective in the operation of the Cancer Drugs Fund and it is felt this would help support patient confidence in the process. SHAs should therefore consider the best way of securing a lay perspective as part of the decision-making process.

4. Scope of the Funding

4.1 The Cancer Drugs Fund should be used to fund drug treatments, including radiopharmaceuticals[10] for patients who have been unable to access a drug recommended by their oncologist. This may include:

- drug / indication combinations appraised by NICE and not recommended on the basis of cost effectiveness, or where the recommendations materially restrict access to the treatment to a smaller group of patients than the specifications set out in the marketing authorisation (an 'optimised' recommendation)

[9] Cancer waiting time standards were introduced in the NHS Cancer Plan (2000) and the Cancer Reform Strategy (2007). The standards include: a maximum one month wait from date of decision to treat to first treatment for all cancers and a maximum 31-day wait for subsequent treatment where the treatment is an anti-cancer drug regimen

[10] Radiopharmaceutical: Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose, Directive 2001/83/EC of the European Parliament

- drug / indication combinations on which NICE has not, or not yet, issued appraisal guidance (this may include drugs that are not licensed for the clinical indication of interest where the clinician considers such a treatment to be the most appropriate based on clinical need)

4.2 The panels should take a sufficiently broad view of "cancer" in determining the drugs that are eligible for consideration from the Fund, for example to include pre-cancerous conditions where they consider this appropriate.

4.3 The Fund is intended to pay for the purchase of medicines. Primary Care Trusts are expected to meet the associated service costs related to provision of these medicines. The Fund may be used for molecular diagnostic testing which is necessary to help optimally target the use of drugs for patients who are most likely to benefit.

4.4 Panels may reasonably decide not to fund drugs where there has been no NICE appraisal as a result of the manufacturer refusing to cooperate with the NICE appraisal process.

4.5 It is in patients' interests that the Fund operates effectively and that it contributes to clinical audit, both regionally and nationally. SHAs may use up to 1% of the funding on audit and management costs but this will need to be managed within the SHA's overall administration cost limits.

5. Operation of the clinically-led panels

5.1 The criteria for access to the fund should be based primarily on evidence of clinical effectiveness and anticipated delivery of measurable outcomes such as improved overall survival, progression-free survival or improved quality of life. Panels should also consider cost effectiveness if there is robust data to support decision-making. Where treatments are similarly clinically effective or where ranking scores of clinical effectiveness do not differentiate between different therapies, panels should consider cost effectiveness in order to maximise the number of patients treated from the available funding.

5.2 Panels should be aware of rarity when assessing the evidence base and make appropriate allowances for potential limitations in the evidence base on treatments for rarer cancers, obtaining expert input where appropriate. For example, in cases where the treatment relates to a very rare tumour, the panels may wish to obtain specialist clinical input to support them in making an informed decision.

5.3 SHA clinically-led panels may wish to collaborate on evidence assessment and share expertise, particularly in cases where the published evidence may be limited. However, the responsibility for decision-making will remain with the respective SHA clinically-led panels.

5.4 The level of annual funding available will remain constant at £200 million over the three-year life of the Fund. Clinically-led panels will need to manage the funding in a way that enables them to respond to the changing profile of available treatments and potential fluctuations in the numbers of patients presenting for specific treatments. For example,

a positive recommendation from NICE will mean that funding for that drug in its respective indication will transfer from the Fund to the patient's PCT.

5.5 Panels are encouraged to take a population based approach to decision-making for defined patient groups given the benefits of taking this approach identified by SHAs in 2010-11. Such an approach should provide transparency, equity and speed of decision-making; reduce the burden on clinicians and managers and support SHAs in forward planning use of the funding. Where SHAs took this approach to allocation of the in-year funding, decisions affecting individual patients were frequently taken within days of a completed application to the SHA.

5.6 A population-based approach generates lists of drugs (a “priority list”) that will routinely be made available through the Fund. Experience from 2010-11 has demonstrated the importance of keeping these lists dynamic. They should not be viewed as restrictive and should be kept under regular review to take account of NICE appraisal recommendations, other new evidence, availability of new treatments, fluctuations in the numbers of patients presenting for treatment and local priorities. Given the dynamic nature of the Cancer Drugs Fund, review of such lists is recommended on at least a quarterly basis and there should be a facility for consideration of applications for additional candidate drugs in between scheduled review points. Local clinicians should be able to make representations for the inclusion of specific treatments on any such lists.

5.7 Where a drug has been removed from a priority list following its recommendation by NICE or the agreement of a local PCT funding policy, treatment should be available on the NHS, subject to any clinical criteria set out by NICE. In these cases, PCTs would normally be expected to assume responsibility for patients whose treatment had previously been supported by the Fund. Where the drug has been removed from a priority list as a result of new developments or new evidence, any patients currently receiving the treatment under the Fund should normally have the option to continue treatment until they and their clinician consider it appropriate to stop.

5.8 Where a clinically-led panel decides not to prioritise a drug for routine funding from the Cancer Drugs Fund or to remove a drug from a priority list, it should be clear that these decisions are open to review in response to new developments or new evidence.

Transitional Arrangements

5.9 The clinically-led panels will need to agree appropriate transitional arrangements for patients who are currently receiving treatment as a result of the additional £50 million funding for cancer drugs provided in 2010-11. The expectation is that these patients will continue to receive treatment for as long as is clinically appropriate.

6. Links to existing processes

6.1 The Cancer Drugs Fund complements existing PCT processes for funding drugs and does not replace the PCT Individual Funding Request (IFR) process, which should continue to consider individual, exceptional funding requests that come within the scope of these PCT processes.

6.2 As set out in the NHS Constitution, patients have a right to expect local decisions on funding of drugs and treatments to be made rationally following a proper consideration of the evidence. PCTs should ensure that they have robust, transparent processes in place to make such decisions, including decisions on exceptional funding, and in doing so, should have regard to the following guidance published by the Department of Health and the National Prescribing Centre:

- Defining guiding principles for processes supporting local decision-making about medicines[11]
- Handbook of good practice guidance supporting rational local decision-making about medicines[12]

6.3 Treating clinicians, working with local NHS managers, should fully explore all reasonable avenues for securing NHS funding before using the Cancer Drugs Fund. In these situations, clinicians should consider:

i. whether NICE has issued a positive technology appraisal for the treatment of the relevant indication. If so, such treatment must be made available on the NHS in line with NICE's recommendations

ii. if not, whether the relevant Primary Care Trust has a local policy on funding of the treatment,[13] perhaps based on collaboration with other PCTs, advice from a cancer network or through regional specialised commissioning arrangements

   a. If the PCT policy is to fund the treatment, it should be made available on the NHS; or

   b. If the PCT policy is not to fund the treatment the clinician should consider whether there are specific aspects of the patient's case which justify an application to the PCT for exceptional funding (refer to the PCT Individual Funding Request policy).

iii. If NICE has not issued positive guidance and the PCT has made a policy or IFR based decision not to fund the treatment, the clinician might consider making an application to the Cancer Drugs Fund. Depending on the arrangements that have been put in place locally, this may be considered by the clinically-led panel on an individual basis or in the context of a population-based decision (see section 5.5).

6.4 It should be emphasised that in most cases consideration of these options by a treating clinician will not involve any significant additional effort or delay, as steps (i) and (ii) would be normal good practice in the absence of the Cancer Drugs Fund.

[11] Defining guiding principles for processes supporting local decision-making about medicines, Department of Health and the National Prescribing Centre, January 2009, Gateway reference 11101

[12] Supporting rational local decision-making about medicines (and treatments): A handbook of good practice guidance, National Prescribing Centre, February 2009

[13] It is good practice for PCTs to have commissioning policies to cover decisions on the majority of medicines. If the PCT has no policy in place for the treatment, an Individual Funding Request (IFR) should be made to the PCT. If the clinical circumstance is so rare that it is unlikely that other patients will require the intervention, the PCT will consider the application on an individual basis. If a PCT receives an IFR that would apply to a population of patients, it should trigger the development of a new policy by the PCT

6.5 As outlined in section 5.5, the clinically-led panels may speed the consideration process by identifying lists of drugs and indications that will be funded routinely from the Cancer Drugs Fund. The drugs included on such lists would not normally be available through existing PCT processes for indications covered by the Fund, as:

i. the indication will be one that has either not been appraised by NICE or has not been recommended following appraisal; and

ii. the PCT will have a local policy in place not to fund the drug for the indication, as this will have been established by the panel before deciding to prioritise it for the Cancer Drugs Fund; and

iii. the drug will be prioritised by the panel for use in specific clinical circumstances and therefore appropriate to a defined patient group.

6.6 Regional policies need to ensure they set out clearly how the Cancer Drugs Fund and local drug funding arrangements interrelate. Patients should be supported in seeking funding through the most appropriate mechanism.

7. Monitoring and Audit

7.1 SHAs should audit and monitor use of the funding that has been made available for the Cancer Drugs Fund and ensure that appropriate clinical audit arrangements are in place. This will:

- support SHAs in managing allocation of the funding;
- provide assurance that the funding is being used in accordance with agreed regional arrangements
- help improve the available evidence on how these drugs perform in real-world clinical practice

7.2 SHAs might consider setting a clear expectation that clinicians should provide some basic clinical audit data on patients whose treatment is supported by the Fund. This should be made clear to treating clinicians as part of the application process.

7.3 Collection of this information anticipates the National Systemic Anti-Cancer Therapy Dataset, which is currently being piloted and will be mandatory from April 2012. Suggested basic minimum audit requirements for the Cancer Drugs Fund, consistent with the dataset, are as follows:

- NHS number
- Primary diagnosis
- Drug name
- Regimen
- Date treatment started
- Date treatment stopped
- Date of death

7.4 SHAs will be required to provide basic financial monitoring information to the Department of Health on a monthly basis to support effective management of the total resource available.

8. Information provision

8.1 Patients will need appropriate information on the available options to support them in making informed decisions. Clinicians and other treating health professionals should have open discussions with patients about the relative merits of drug treatment options, palliative care and end of life care. Written information on the likely benefits and possible side effects of treatments should be made available to the patient. The clinician should confirm that this has happened, and that informed patient consent to treatment has been obtained.

8.2 Improving Outcomes: A Strategy for Cancer[14] states that one of our priorities moving forward will be to enhance the information available to patients on the benefits and toxicities of treatment. The National Cancer Director will work with cancer charities and the pharmaceutical industry to support the availability of such information. The National Cancer Patient Information Pathway programme has developed tumour specific cancer information pathways, which can be found at www.cancerinfo.nhs.uk. Work is also continuing to develop the use of information prescriptions[15] throughout the cancer pathway.

8.3 Appropriate mechanisms should be put in place to ensure patients and clinicians can access up-to-date information on their local SHA's Cancer Drugs Fund policy. SHAs should ensure that clinicians have clear information on the process they need to follow to make applications for funding on behalf of their patients. Detailed information on the arrangements that have been put in place should be readily available and accessible via the internet, and clinicians should help to support patients who are unable to access this information themselves. Where panels use a prioritisation process to identify drugs that will be funded routinely from the Cancer Drugs Fund then details of these drugs should be readily available.

8.4 It is recommended that SHAs make appropriate Cancer Drugs Fund activity data available on their websites. Activity data may include such items as the number of applications, approvals by drugs and indication. SHAs are recommended to update this information regularly, for example monthly.

8.5 It is recommended that SHAs make information on expenditure against the Fund available on their websites. SHAs are recommended to update this information periodically, for example on a quarterly basis.

[14] Improving Outcomes: A Strategy for Cancer, Department of Health, January 2011, Gateway 15109

[15] Information prescriptions guide people to relevant and reliable sources of information to allow them to feel more in control, better able to manage their condition and maintain their independence (www.informationprescription.info)