A new vision for the Cancer Drugs Fund

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A new vision for (the) Cancer (Drugs Fund) and Specialised Commissioning

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National Cancer Strategy

Aim: To improve cancer services across the entire patient pathway by 2020

- Fewer people getting preventable cancers
- More people surviving for longer after a diagnosis
- More people having a positive experience of care
- More people having a better, long-term quality of life

Six strategic priorities

<table>
<thead>
<tr>
<th>Priority</th>
<th>Focus</th>
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<tr>
<td>Spearhead a radical upgrade in prevention and public health</td>
<td>Transform our approach to support people living with and beyond cancer</td>
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<td>Drive a national ambition to achieve earlier diagnosis</td>
<td>Make the necessary investments required to deliver a modern, high-quality service</td>
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<td>Establish patient experience on a par with clinical effectiveness and safety</td>
<td>Overhaul processes of commissioning, accountability and provision</td>
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The scale of the challenge

Survival in England continues to lag behind countries of similar wealth

Cancer prevalence is set to rise to 3.4 million by 2030

Data: Independent Cancer Taskforce
Introduction: The Cancer Taskforce

The scale of the challenge

- In 2013, **280,000** new diagnoses
- **80,000** additional cases in 2030
- **130,000** people still die from cancer each year

Data: Independent Cancer Taskforce
**Vision:** Future specialised services embedded in the delivery of the Five Year Forward View

- The Five Year Forward View set out ambitions for the NHS of a more engaged relationship with patients, carers and citizens to promote wellbeing and prevent ill-health. Our ambitions for specialised services are no different, and fully integrated with the triple aims:

  **Health and Well Being Gap:** To ensure specialised services are continuously improving health for all relevant populations, by focusing on the outcomes that matter most to patients, ensuring a stronger focus on prevention and connecting the commissioning of specialised services more strongly to prevention, precision and personalised medicine.

  **Care Quality Gap:** To integrate specialised services within the pathway, by unlocking new models of provision and enabling more flexibility in how different models can be adapted to local needs, while at the same time addressing unwarranted variation between areas and meeting national outcomes standards.

  **Finance and Efficiency Gap:** To maintain financial sustainability, by in the immediate term maintaining a tight grip on the national spend and maintaining the focus on efficiency programmes, but also by accelerating and supporting transformation to new models of commissioning and provision that can deliver better outcomes for less including stopping treatments and processes no longer of value. Each clinician and patient needs to understand the need to drive value: ensuring we enhance and maintain outcomes and experience whilst mindful of the cost.
Strategic Framework: Place-based care, enabled by national level support and strong financial control

- Achieving the ambitions for specialised services will require collaboration at a local level to agree priorities and deliver service change, but will also need national level support and financial control that enables change. The strategic framework set out **eight priorities as a focus for testing and engagement**.

**Sustainability and Transformation Programmes**

Delivering place & population based care

- 1. Person, population and place focus
- 2. Provider configuration
- 3. Collaborative commissioning and new commissioning models

Providing national level support

- 4. National clinical leadership
- 5. Better information
- 6. Mainstreaming treatments
- 7. Proactive management of pipeline for innovation and research

Ensuring financial sustainability and value for money

- 8. Maintaining financial control
Ensuring best value: Sustainable service provider configurations delivering highest quality outcomes

Source: NHSE 2014-15 Provider and Commissioner agree contract values
Strategic Framework: Place-based care, enabled by national level support and strong financial control

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Delivering place & population based care

Providing national level support

Ensuring financial sustainability and value for money
Implementation: Targeted

- Modern radiotherapy services
- Molecular diagnostics
- Targeted therapy/minimal access surgery

- Measuring and improving patient experience
- New emphasis on quality of life
- Holistic Needs Assessment (HNA)

- Stratified pathways
- Earlier diagnosis
- Reducing duplication and waste
Whole Patient Pathway

Prevention
- Tobacco control
- Alcohol review
- Obesity strategy

Screening
- Introduce HPV testing
- New simpler bowel testing (FIT)

Diagnosis
- National diagnosis capacity fund
- 28 days faster diagnosis standard
- Multidisciplinary diagnostic centres

Treatment
- Modernising technology (Linacs)
- Accelerating personalised medicine (molecular diagnostics)
- Creating a sustainable cancer workforce

Living with and beyond cancer
- New quality of life metric
- Holistic Needs Assessment (HNA)
- Stratified pathways

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Implementation: Integrated

16 Cancer Alliances and 3 Cancer Vanguard Partnerships

North
1. North East and Cumbria
2. Lancashire and South Cumbria
3. Cheshire and Merseyside
4. West Yorkshire
5. Humber, Coast and Vale
6. South Yorkshire and Bassetlaw

South
10. Thames Valley
11. Kent & Medway
12. Surrey & Sussex
13. Somerset, Wiltshire, Avon & Gloucestershire
14. Peninsula
15. Wessex

Midlands & East
7. West Midlands
8. East Midlands
9. East of England

London
16. South East London

2. National Cancer Vanguard: North West and South West London
Cancer Alliances

Local leadership
Planning and leading the delivery of the transformation required to implement the Cancer Taskforce strategy locally, taking a whole-pathway and cross-organisational approach.

Improved outcomes
Reducing variation in outcomes and access to high-quality, evidence-based interventions across whole pathways of care and for the Alliance’s whole population.

Devolved responsibility
Exploring the potential to take on devolved responsibilities for outcomes and funding across pathways for their local populations, based on learning from the National Cancer Vanguard.
National Cancer Vanguard

New commissioning model
Transforming system architecture via sector wide single cancer budgets and lead provider models

Pathway transformation
Working across the entire patient pathway with new levers and responsibilities for implementing best practice.

Creating value
Creating value for patients and the NHS by shifting from the treatment of late stage cancer to prevention and early diagnosis
Strategic Framework: Place-based care, enabled by national level support and strong financial control

- Delivering place & population based care
  - 1. Person, population and place focus
  - 2. Provider configuration
  - 3. Collaborative commissioning and new commissioning models

- Providing national level support
  - 4. National clinical leadership
  - 5. Better information
  - 6. Mainstreaming treatments
  - 7. Proactive management of pipeline for innovation and research

- Ensuring financial sustainability and value for money
  - 8. Maintaining financial control
Implementation: Informed

Integrated cancer dashboard “a single version of the truth”

Patient centric – equal emphasis on clinical outcomes and patient experience

Measureable and quantifiable – with renewed focus on early diagnosis and quality of life
Integrated Cancer Dashboard

- **Key metrics**
  - Incidence rate
  - One-year survival
  - Overall experience of care
  - Cancers diagnosed at stage 1 and 2
  - Cancers diagnosed through emergency presentation

- **New metrics**
  - 28 day faster diagnosis standard
  - Quality of life metric

- Available by Cancer Alliance, CCG, Provider
A working example – London Cancer Alliance Metrics

- In 2012, London Cancer Alliance trusts were recording stage for only 48% of stageable cancers.

- Use of scorecards, and working across the alliance, led to improvements over the next 2 years, reaching 74% stage recorded by the end of 2014.
Implications: What does Specialised Commissioning look like in 2020?

- **Improving population health**: Clearly differentiated levels of commissioning for Specialised Services, and a much greater role for local health economy leadership in how the ‘Spec Com £’ is spent.

- **High quality care system**: National service standards, but greater flexibility in local delivery to put in place most appropriate service model to meet those standards minimising unwarranted outcome variation.

- **Maximising Value**: New service models (both in the contracting model, and in how providers configure themselves) to ensure value: quality service sustainability within available resources.
Overview of CDF

1. An urgent need for reform

2. What do the changes mean?

3. How we got here

4. Overview of the new arrangements:
   a) Start of the process- NICE appraisal
   b) Early access- provision of interim funding
   c) Resolving uncertainty- the new ‘CDF’
   d) Financial control

5. Off-label Cancer Drug Indication Management

6. Transition Arrangements

7. Evaluation
1. An urgent need for reform (1)

- Established by the Government in April 2011 only ever as a temporary solution to support clinicians and their patients gain access to cancer drugs not routinely available on the NHS.

- Originally due to end in 2014, having acted as a bridge to a new system of Value Based Pricing. VBP not pursued and CDF extended further to March 2016.

- Despite benefitting over 95,000 patients, the lack of clear criteria for how and when drugs should exit the fund placed it under unsustainable financial pressure.

- Annual Budget was increased from £200m in 2011/12 to £340m in 2015/16. Despite this, the CDF exceeded its allocated budget each year since 2013/14.

- Even though two re-prioritisation (delisting) exercises undertaken, the final outturn position for 2015/16 was £466m - an overspend of £126m (37%)
1. An urgent need for reform (2)

**Independent Cancer Taskforce Report (July 2015)**

**Recommendation 31:** NHS England should work with NICE, the Government, the pharmaceutical industry and cancer charities to define a sustainable solution for access to new cancer drugs. This updated process should enable NHS England to confirm clinical utility, whilst managing within a defined budget, and should be aligned with NICE appraisal processes. The new process should be published for consultation in summer 2015, with a view to implementation from April 2016. The solution should set out reforms to NICE processes to make them more flexible for cancer drugs.

**Public Accounts Committee Report (Jan 2016)**

**Recommendation 1:** In putting in place arrangements for the new Fund to be established from April 2016, NHS England should set out clear objectives for what the Fund is seeking to achieve, and be prepared to take tough decisions to ensure that the Fund does not overspend.
2. What do the changes mean?

Three key objectives:

• Firstly, patients have faster access to the most promising new cancer treatments.

• Secondly, taxpayers get better value for money in drug expenditure.

• Thirdly, pharmaceutical companies that are willing to price their products responsibly can access a new, fast-track route to NHS funding for the best and most promising drugs.
4. **Overview of new process**

- **a) Start of the process - NICE Appraisal**
- **b) Early Access – Provision of interim funding**
- **c) Resolving Uncertainty – the new ‘CDF’**
- **d) Financial Control**

All new cancer drugs / indications expected to receive a marketing authorisation referred to NICE by DH Ministers.
a) Start of the process – NICE appraisal

- From now on, all new cancer drugs/indications expected to receive a marketing authorisation will be appraised by NICE.

- A modified appraisal process, introduced on 1st April 2016, allows NICE to make one of three recommendations:
  - Recommended for routine commissioning – ‘yes’
  - Not recommended – ‘no’
  - Recommended for use within the CDF – this is new

- The new recommendation can be used when NICE considers there to be plausible potential for a drug to satisfy the criteria for routine commissioning, but where there is significant remaining clinical uncertainty.

- The new appraisal process starts much earlier, with the aim of publishing draft guidance prior to marketing authorisation and Final Guidance within 90 days of marketing authorisation.
b) Early Access- interim funding (1)

- We want patients to benefit from new cancer drugs as quickly as possible.

- Therefore, pharmaceutical companies now have the option of accessing interim funding from the point of marketing authorisation for those drugs that have received either:
  - a draft recommendation for routine commissioning; or
  - a draft recommendation for use within the CDF

- Provision of interim funding will be met out of the fixed CDF budget (£340m) and will be conditional on the pharmaceutical company agreeing to the expenditure control mechanism described later.

- Where a company signs up to receive interim funding, that drug can be made immediately available to all eligible patients. **So far, 10 Interim Funding Agreements in place (100%)**

- Where a company does **not** wish to access interim funding, the drug in question cannot be made available to patients at that point in time.
b) Early Access- interim funding (2)

- For drugs/indications receiving a **positive draft recommendation** – reimbursement will be set at 100% of the price that generated that recommendation.

- Funding will then switch permanently to baseline commissioning budgets 90 days after NICE Final Guidance (30 days if an EAMS drug).

- For drugs/indications **recommended for use within in the CDF** – reimbursement will be at the price that is subsequently agreed as part of the CDF Managed Access Agreement (MAA).

- However, because this price will not be known at the point of marketing authorisation, the price submitted to NICE for the appraisal will be temporarily used with the pharmaceutical company then rebating the CDF budget the difference once the MAA price has been set.
c) Resolving uncertainty – the CDF

- For those drugs/indications that receive a recommendation for use within the CDF – a Managed Access Agreement (MAA) will need to be agreed between the pharmaceutical company and NHS England.

- The purpose of the ‘managed access’ period will be to resolve the significant remaining clinical uncertainty highlighted by NICE, and will comprise of:
  
  - A CDF Commercial Agreement; and,
  
  - A Data Collection Arrangement

- The aim will be to have the MAA in place as close to publication of the NICE Final Appraisal Determination as possible.

- At the end of the managed access period, NICE will re-appraise the drug with a view to deciding whether or not it can be recommended for routine commissioning.
d) Financial control

- The CDF budget is fixed at £340m and will have to cover the costs of:
  - Interim Funding Agreements
  - CDF Managed Access Agreements
  - Existing CDF drug indications pending NICE appraisal / reconsideration
  - Existing Individual Funding Request commitments
  - Any off label indication commitments agreed as part of the clinical policy development process
  - CDF administration

- An expenditure control mechanism is needed to ensure the CDF budget does not overspend. The ABPI has previously agreed with the Department of Health that only CDF expenditure up to £320m will count towards the agreed voluntary PPRS rebate scheme.
5. Off label cancer drugs

- Off label drugs will have similar opportunities for gaining access to CDF funding as licensed drugs, if deemed to be clinically promising. The process for considering off label indications will be integrated with NHS England’s specialised commissioning policy development process with NICE, in time, providing all the necessary underpinning evidence reviews.

- Applications will be made by clinicians, with endorsement from NHSE’s Chemotherapy Clinical Reference Group. Once endorsed, NHS England will include them in its policy development work programme and, ultimately, make one of three recommendations:
  - Progress as a routine commissioning proposal for consideration in the annual prioritisation round
  - Progress as a not routinely commissioned proposal for consideration as an in year decision
  - Progress within the CDF for further data evaluation to inform a commissioning position

- The CDF budget will provide a funding bridge for any off-label indications that are recommended for routine commissioning until annual prioritisation decisions are made.
6. Transition Arrangements

- All licensed drugs/indications on the previous CDF as of 31\textsuperscript{st} March 2016 (with just one exception) will be reconsidered or appraised by NICE over the next 18 months.

- These drugs are continuing to receive funding from the CDF budget at current commercial terms until such point that NICE is able to provide a commissioning recommendation.

- All funding is, however, subject to the new expenditure control mechanism as required.

- If NICE does not recommend an existing CDF drug for routine commissioning or the new CDF, the drug/indication will cease to be available to new patients but will continue to be available for existing patients.
7. Evaluation

- NHS England will keep the operational arrangements for the new CDF under continuous review.

- The single, national list of approved drugs will be updated regularly and published on the NHS England website, along with activity data, at [www.england.nhs.uk/ourwork/cdf/](http://www.england.nhs.uk/ourwork/cdf/)

- We will conduct a formal evaluation of the overall operation of the new scheme, for completion no later than autumn 2017 and plan to involve all of our stakeholders in that process.
New cancer drugs 2016 onwards

• Cancer drugs are being increasingly licensed on ever earlier outcome data ie longer term effectiveness is unknown with certainty; this trend will accelerate

• Unprecedented pipeline of drugs and technologies

• Targeted and immunotherapies of lung cancer, kidney cancer, bladder cancer, head and neck cancer

• Targeted treatments in breast cancer and thyroid cancer

• New drugs in leukaemia, lymphoma and myeloma

• Increased molecular profiling of tumours with increased targeted therapies: more opportunities

• Chimeric antigen receptor T cell therapy - CAR T cell therapy: genetic engineering of receptors on T cells to recognise tumour cells – ‘a living drug’
Summary

Aim of Cancer Programme:
- Fewer people getting preventable cancers
- More people surviving for longer after a diagnosis
- More people having a positive experience of care
- More people having a better, long-term quality of life

New CDF
- Faster access to the most promising new cancer treatments.
- Better value for money in drug expenditure.
- Pharmaceutical companies that are willing to price their products responsibly can access a new, fast-track route to NHS funding for the best and most promising drugs.

Specialised Commissioning
- Aligned to Five Year Forward View challenges
- Delivering Place and Population based Care
- Providing National level support and leadership
- Maintaining Financial sustainability and Value for Money

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