Consultation on the new Cancer Drugs Fund model  
– Breast Cancer Care’s consultation guide

December 2015

Introduction

The Cancer Drugs Fund (CDF or Fund) is the scheme which allows cancer patients in England to access drugs that are not currently available routinely through the NHS.

The CDF was launched in 2010 and is due to come to an end in its current format on 31 March 2016. In November 2015, NHS England, who manages the Fund, launched a consultation into the future of the CDF. This proposes changes to the way the CDF works, which will have an impact on people living with breast cancer, particularly those who have been diagnosed with secondary breast cancer.

Breast Cancer Care will be submitting a formal response to the consultation on the CDF, which looks at the process for the new system. To help inform this, we want to hear from people living with breast cancer about what you want to see from the new system.

This guide provides a simplified version of the main points in the consultation document and is specific to breast cancer. Once you’ve read this, you can take part in the following ways.

• Take our survey – (www.surveymonkey.co.uk/r/WTLMCWF) the answers from which may be used as part of our submission. Our survey closes on 20 January 2016.
• Send us your thoughts to campaigns@breastcancercare.org.uk

How the Cancer Drugs Fund currently works

Before a cancer drug can be routinely available on the NHS in England, it must have market authorisation (a licence) and be recommended by NICE (the National Institute for Health and Care Excellence). NICE will look at evidence on a drug’s clinical-effectiveness (how well it works) and cost-effectiveness. This is called a ‘technology appraisal’. The outcome of the technology appraisal will be one of two options.

a) Recommend the drug for routine use on the NHS.
b) Not recommend the drug routine use on the NHS.

As a result of this technology appraisal, NICE will issue guidance which outlines their decision. The NHS is legally obliged to fund and resource drugs recommended by NICE’s technology appraisals. Drugs which are not recommended will not be routinely available on the NHS, but patients may be able to access them through a successful Individual Funding Request1.

There’s an additional set of criteria used by NICE when they assess drugs, for drugs used at the end of life. The end of life criteria allows NICE to consider a higher cost for drugs that are life-extending rather than life-saving.

There have been a number of drugs, in particular for secondary breast cancer, which have not been recommended by NICE because they were deemed to be too expensive to provide routinely.

To go some way in addressing this problem, the Cancer Drugs Fund was created to give patients in England access to some of the more expensive cancer drugs not recommended by NICE for routine use. It was originally intended to be a temporary way for people to access cancer drugs while a longer-term solution to the problems of accessing expensive drugs, including reforming NICE’s processes, could be found.

1 An individual funding request allows some patients to access treatments that are not available routinely. For more information see NHS England’s guide for patients https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/06/indiv-fund-reqts-info-pats.pdf
To date, approximately 74,000 people have received cancer drugs through the Fund. Of these, 51% have been for drugs that were not recommended for routine use on the NHS by NICE. The remaining drugs were in the process of being appraised, or had not yet been appraised, by NICE.

The total cost of the CDF so far has been £968m. The budget has been increased; in 2015-2016, the total budget is £340m. However, the CDF has been overspent over the past few years. In 2014-2015, the Fund was overspent by 48%.

In January 2015, NHS England began the process of removing drugs from the Fund in order to better manage spending on the CDF. So far, there have been two rounds of removals from the Fund.

### Drugs for secondary breast cancer, as of November 2015

<table>
<thead>
<tr>
<th>Available through the CDF</th>
<th>Removed from the CDF</th>
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<tbody>
<tr>
<td>Eribulin (Halaven)</td>
<td>Bevacizumab (Avastin)</td>
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<tr>
<td>Pertuzumab (Perjeta)</td>
<td>Lapatinib (Tyverb)</td>
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<td>Everolimus (Afinitor)</td>
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<tr>
<td>Trastuzumab emtansine (Kadcyla/TDM-1)</td>
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### Current Cancer Drugs Fund system

New cancer drug awaiting marketing authorisation (licence).

Drug receives marketing authorisation (licence).

Assessment (‘technology appraisal’) by NICE and guidance is issued.

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**Yes**

Recommended for routine use. Drug is available for patients on the NHS in England.

**No**

Not recommended for routine use. Drug is not routinely available for patients on the NHS in England. Drug may still be available through the Cancer Drugs Fund or a successful Individual Funding Request (IFR).

Early Access to Medicines Scheme (EAMS)*

Introduced in March 2015, the EAMS gives patients access to promising drugs before they have received marketing authorisation (a licence).

*It is not clear from the consultation document how the EAMS will fit in with the new proposals.

Cancer Drugs Fund

**Budget for 2015/16 = £340m**

Some cancer drugs are made available to patients in England via the Cancer Drugs Fund. This may be because:

* the drug is in the process of being assessed by NICE
* the drug has been assessed by NICE but has not been recommended
* the drug will not be assessed by NICE.

There is no time limit on how long a drug can stay on the CDF, but drugs may be removed from the CDF in order to manage the cost of the Fund.
How will the new system operate?

NHS England and NICE are proposing that the Cancer Drugs Fund becomes a ‘managed access’ fund. The ‘managed access’ fund will be for new cancer drugs that appear promising but do not yet meet NICE’s criteria to receive a firm ‘yes’ (recommended for routine use) decision. If NICE decide that a drug has the potential to meet their criteria, but more evidence is needed to make a firm decision, the new model would allow such drugs to be available for a set period. During this time, additional evidence would be collected, so that a final decision, in a quicker timeframe, can then be made as to whether the drug should be routinely available on the NHS.

The proposed process can be broken down as follows.

1. Before a new cancer drug receives marketing authorisation (a licence), NICE will normally issue draft guidance on whether or not it would recommend the drug for routine use.

2. Once the drug receives marketing authorisation (a licence), but before it has been appraised by NICE, a drug which has received a draft recommendation (a ‘yes’) or a draft recommendation for use with the Cancer Drugs Fund (a ‘maybe’) will be made available to patients through temporary funding through the CDF. This arrangement will apply only until the final guidance is issued by NICE, at which time the final decision replaces it.

3. NICE will aim to produce final guidance within 90 days once a drug receives marketing authorisation (a licence). NICE can decide to either:
   a. recommend the drug for routine use on the NHS
   b. not recommend the drug for routine use on the NHS
   c. recommend the drug for use within the Cancer Drugs Fund.

4. If option (c) is recommended, the drug will be available through the Fund for a defined time of up to around two years. During this time, further evidence is collected to enable NICE to make a final decision.

5. Once this evidence has been collected, NICE will conduct a short re-assessment of the drug, using the new evidence, and decide either to:
   a. recommend the drug for routine use on the NHS
   b. not recommend the drug for routine use on the NHS.
New cancer drug awaiting marketing authorisation (licence)

Initial assessment (‘technology appraisal’) of drug by NICE and draft guidance is issued:
- **YES** - Recommended for routine use
- **NO** - Not recommended for routine use
- **MAYBE** - Recommended for use within the Cancer Drugs Fund

Drug receives marketing authorisation (licence)

Final assessment (‘technology appraisal’) by NICE and guidance is issued within 90 days of marketing authorisation.

Cancer Drugs Fund
The CDF becomes a ‘managed access’ fund.
- Drugs with a draft ‘yes’ or ‘maybe’ will be funded from the point of marketing authorisation (licence) until a final decision is made by NICE.
- If more evidence is needed on a drug for NICE to make a final decision, these may be funded for patients to access while further evidence is collected (usually up to 24 months).
- Once this evidence is collected the drug will be re-assessed by NICE.

The CDF becomes a transitional Fund. Drugs will stay on the Fund for a limited period of time.

Drug is assessed by NICE through a shortened technology appraisal process.

- **Yes** - Recommended for routine use.
  - Drug is available for patients on the NHS in England.

- **No** - Not recommended for routine use.
  - Drug is not routinely available for patients on the NHS in England.
  - Drug may still be available through a successful Individual Funding Request (IFR).

- **Maybe** - Recommended for use within the Cancer Drugs Fund.
  - The drug has the potential to meet the criteria set out by NICE to receive a recommendation, but more evidence is needed to make a firm decision.

Drugs that received a draft ‘Yes’ or ‘Maybe’ at the initial assessment will receive interim funding through the CDF, making it immediately available to patients. This arrangement will apply until the final guidance is issued by NICE, at which time the final decision replaces it.
The criteria NICE uses for assessing drugs will remain the same, apart from one change to the end-of-life criteria. Currently, NICE will consider a higher cost for drugs which meet the following criteria:

1. the treatment is for patients with a short life expectancy, normally less than 24 months
2. the treatment offers an extension to life, normally of at least three additional months, compared with current NHS treatments
3. the treatment is for small patient populations, normally not exceeding a total of 7000 for all its uses (often called ‘licensed indications’) in England.

The consultation document proposes removing criteria number 3, so only the first two criteria will be considered. NICE and NHS England suggest that the benefits of the new system will be that promising drugs will made available sooner. At the same time, the NHS will be able to better manage the budget for the Fund by ensuring only those drugs that present real promise are available through the new model, and for a limited period of time. If, following a period on the new CDF, a drug is then recommended for routine use on the NHS, it will no longer be funded through the Fund but instead through the usual NHS medicines budget. If the drug is not recommended for routine use on the NHS after being on the CDF, it will be removed for new patients. If this happens, existing recipients of the drug will continue to have access to it until it is no longer clinically appropriate for them to do so. ‘Rejected’ drugs (those that aren’t available on the NHS or in the new CDF) will only be available privately or through successful individual funding requests.

Money matters
The consultation also proposes a number of measures to help the CDF stay in budget, including:

- a contingency fund which can be used to balance the budget at the end of each year if it is exceeded
- capping the amount (£) paid for a drug through the CDF
- a new CDF Investment Group (a joint committee of NHS England and NICE). This group will be responsible for ensuring that the CDF stays within its budget.

What does this mean for breast cancer patients?
The Cancer Drugs Fund is an England-only scheme, so any changes will only affect people living in England. Just like other cancer patients, people living with breast cancer will be able to receive drugs that are available through the new CDF system where it’s clinically appropriate for them to do so. It’s understood that the current list of breast cancer drugs available on the Fund will be reassessed under the new system during the course of 2016/2017. Unfortunately, there is little information given in the consultation document on how this transitional period will take place, and this is something we will be highlighting in our consultation response. If you’re already receiving breast cancer drugs, or will do, under the current system (up until 31 March 2016), you will continue to be able to do so following the changeover, as long as it remains clinically appropriate for you.

From 1 April 2016, any new drugs that a pharmaceutical company begins to manufacture will then be subject to a decision making process regarding its availability which involves the new CDF system.

Have your say
This document is a simplified summary of the main parts of the consultation document. You can read the full consultation document from NHS England and NICE, which explains the proposals in more detail. Get involved with Breast Cancer Care’s response to the consultation on the new system for the Cancer Drugs Fund. Have your say on what you think about the principles of the new system and these could be included in our submission.

You can
- complete our survey (www.surveymonkey.co.uk/r/WTLMCWF). This survey includes further background information and context to the CDF consultation, to help give your feedback.
- or send your views about the proposed new model to campaigns@breastcancercare.org.uk

You can also respond directly to the consultation as a patient using NHS England’s survey.