

Breast Cancer Care's response to the Cancer Drugs Fund consultation

February 2016

Breast Cancer Care is the only UK-wide charity providing specialist support and tailored information for anyone affected by breast cancer.

Our clinical expertise and emotional support network help many thousands of people find a way to live with, through and beyond breast cancer.

Below is our response to the questions set out by NICE and NHS England in their consultation 'Consultation on proposals for a new Cancer Drugs Fund (CDF) operating model from 1st April 2016'.

1. Do you agree with the proposal that the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria?

➤ **Unsure**

Please provide comments to support your response

As the only UK-wide breast cancer support charity, Breast Cancer Care supports thousands of people affected by breast cancer each year. We know that access to drugs is an important issue for many people, especially those living with secondary (metastatic) breast cancer. Breast Cancer Care has for some time called for a more sustainable system for making effective cancer drugs available to patients in England. This call formed part of our recent Bucket List campaign, which aims to improve levels of care and support for people living with secondary breast cancer. It is vital that we get this new system right.

It is difficult to provide a definitive answer on the question of whether the CDF should become a 'managed access' fund, as so much of the detail required to make a fully informed decision is lacking from the consultation document.

Looking overall at what is presented in the consultation document, it is not clear to us that breast cancer patients (or indeed, cancer patients more widely) will have better access to drugs under the proposed new system than the current CDF.

We have significant concerns that the four drugs currently available for secondary (metastatic) breast cancer, as well as new drugs in the future, will not be made available under the proposed new system. Our concern is based on a number of related factors:

- The changes do not address the wider NICE appraisal system
- It's not clear how increased data collection will increase the likelihood that effective but expensive drugs will be accepted under a new CDF model
- It is not clear how pharmaceutical companies will react to the proposed changes. Our concern is the impact this may have on patient access to drugs (either on the CDF or through routine commissioning).

If the current drugs become unavailable, the new system would be a damaging step backwards in terms of breast cancer treatment, especially for those living with incurable, secondary breast cancer.

To support people affected by breast cancer to get involved in the consultation, we produced our own summary guide to the consultation proposals. Alongside this guide we conducted a survey of people affected by breast cancer between 10/12/2015 and 20/01/2016, to inform our response to this consultation. The survey provided some context to the proposals, and mirrored the consultation questions. We had 83 responses.

In our survey, we asked what people thought of the move to a 'managed access scheme'. Responses were mixed:

- 28% thought it could be a good change
- 36% thought it could be a bad change
- 36% were unsure

Specifically on the timeframe given for additional data collection through the CDF ('normally lasting no longer than 24 months'), we have concerns that this would not be enough time to collect sufficiently robust data. For example, the average efficacy of many drugs might be

three to six months of additional life; in some cases, such treatment may be more effective and give people years extra to live. Within such a small window, this effect cannot be measured.

This is something that has been echoed by patients who fed in to this response via our survey. Comments included:

'I think additional evidence about the drugs needs to be collected over time e.g. the length of 'extra time' given to incurable cancer sufferers, which can only be assessed over time. Not so sure a time limit of 2 years will be sufficient to get a full picture.'

'I get the impression that in many cases it would take more than 2 years to make a decision.'

'Will final decisions be clinically or austerity driven?'

Additionally, it is not clear from the consultation document:

- a) **What the additional data will look like.** We would welcome clarification around this point. We would especially welcome clarification about whether there will be greater consideration of patient experience and quality of life data in any additional data collection. Also, whether and/or how additional data collected (outside what is anticipated) may be considered by NICE.

And

- b) **How this additional data will be collected.** Looking at the failure so far for any outcomes data to be collected through the Systemic Anti-Cancer Therapy (SACT) dataset on the outcomes of drugs accessed via the CDF (as reported in the National Audit Office's report into the Cancer Drugs Fund), we have concerns about the possibility of this happening effectively going forward. As one respondent to our survey said:

'I think that the collection of data on effectiveness is vital to any new CDF process and indeed to cancer research generally. We should have been collecting data from the start and it is criminal that we haven't been to date. In business, if you make a large investment in a new venture where the outcome is in question or risky you always collect data to test whether to keep investing - this situation is no different to me'

2. Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

➤ Unsure

Please provide comments to support your response

In theory, we welcome all drugs being referred to NICE, provided that NICE have sufficient resources to take on this additional workload. We would hope that, as stated in the consultation document, this would lead to quicker and more efficient scheduling of drugs for appraisal.

However, our more pressing concern is that in order for the appraisal system to be truly effective, we would also want to see a wider reform of NICE's technology appraisal methods, to ensure that the system truly works for cancer drugs, both in the short term and in the future. In the last five years, eight secondary breast cancer treatments have been rejected by NICE for routine use on the NHS in England.

The new Cancer Strategy for England, which is quoted in the introduction to the consultation document, recommends that 'The solution [the new CDF] should set out reforms to NICE processes to make them more flexible for cancer drugs'. We do not feel that the proposals adequately meet this recommendation. Given that the original purpose of the CDF when it was set up in 2010 was to allow time and space for reform to take place, it is disappointing that another opportunity appears to have been missed in this regard.

We would specifically like to see:

- Greater weight given to patient experience and quality of life in NICE Technology Appraisals (TAs)
- Greater patient involvement in the TA process itself
- Greater flexibility for NICE committees in making decisions, especially around the QALY thresholds, and in considering how some drugs may have increased efficacy when prescribed together.

People affected by breast cancer who responded to our survey were unsure about this change. 48% said they were unsure if it would be a good or bad change. A number of people raised concerns about the CDF being integrated into NICE's processes:

'Will NICE be able to give sufficient time and effort to investigating every drug? Also, taking the decisions away from the NHS, who represents the patients? Will the process be too far divorced from the people dealing with the disease on a daily basis?'

3. Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?

➤ **Unsure**

Please provide comments to support your response

We have assumed that this question relates to points 19-21 in the consultation document.

Similarly to our answer to question two, we would in theory agree with this change, provided that NICE have sufficient resources to undertake this additional workload. As in our answer to question two, we would like to see this change alongside wider reform of NICE's technology appraisal methods.

The proposed changes would also put additional pressure on pharmaceutical companies to meet quite tight timescales. For the proposals to work, both NICE and pharmaceutical companies will need to be sure they can take on this additional workload, so that patient access is not adversely affected.

4. Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee's evaluation would be a set of recommendations falling into one of the following three categories:

- **Recommended for routine use;**

- **Recommended for use within the Cancer Drugs Fund;**
- **Not recommended.**

➤ **Unsure**

Please provide comments to support your response

As a stand alone proposal, we welcome the additional flexibility that a third option would give to NICE when appraising cancer drugs.

However, for it to be effective in improving access to treatments, the new CDF model needs to work. This is where we have key concerns, as we will set out in our response to subsequent questions.

Thinking beyond cancer, if the new model of three recommendation outcomes for NICE appraisals proves beneficial, we feel that the idea could be extended to other diseases and conditions.

5. Do you agree with the proposal that “patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation” be removed from the criteria for the higher cost effectiveness threshold to apply?

➤ **Agree**

Please provide comments to support your response

We agree with the proposal to remove the 7,000 patient population cap from the End of Life (EoL) criteria.

However, we would have liked to have seen a wider review of the EoL criteria. The consultation document states that there will be ‘amendments to emphasise the discretion that exists for NICE Appraisal Committees to interpret the uncertainty criteria when considering a drug for inclusion in the Cancer Drugs Fund’. We would like more clarity around what this might mean in practice.

The EoL criteria does not currently work for drugs for people living with secondary (metastatic) breast cancer, who can often live for longer than two years. Our view is that it would be beneficial for the EoL criteria to be explicitly more flexible.

6. Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

➤ **Agree**

Please provide comments to support your response

We agree with this proposal, provided that NICE has the capacity to ensure this happens consistently for all cancer drugs, where this is within their control.

7. Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?

➤ **Unsure**

Please provide comments to support your response:

We don't have any specific comments on this, as the impact will primarily be on the pharmaceutical companies and NICE in terms of increased workload and time pressures. Our key point would be that any changes should not have a negative knock-on effect on patient access (for example because of delays). We would welcome written assurance that, if there are delays on the part of NICE, patients would not be negatively affected.

8. Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?

➤ **Agree**

Please provide comments to support your response

We think this is a positive aspect of the proposals. People affected by breast cancer who responded to our consultation survey were overwhelmingly in favour of this, with 93% saying they think this would be a good change. One respondent said:

‘One thing patients with secondary breast cancer don’t have is time, therefore anything that gives you access to a promising drug as early as possible is only a good thing’.

One concern with this proposal is that there could be a scenario where a drug is later made unavailable if it eventually gets rejected by NICE – either at the initial Technology Appraisal stage or at the shortened appraisal post-CDF. It is vital that, if this happens, the decision is communicated in a sensitive and transparent manner to patients. It is vital that current patients receiving the treatment are made aware that they will continue to have access to the treatment; time and again, we hear from patients that this is a major worry.

9. What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?

We are unclear as to why a draft recommendation would not be produced. This question seems to imply that it is anticipated that NICE will not be able to assess all drugs at this draft stage. Without further information, it is difficult to comment in much detail.

Our overall feeling is that this alternative scenario would not be the best use of CDF funds, given that it would detract funds from the set CDF budget, which could be used in a better way for patients.

10. Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?

We would welcome further information about this before commenting in great detail.

If there is a strong evidence-base for an off-label use of an existing drug, we would want there to be appropriate hooks and levers in the system to allow it to be made available via normal commissioning routes.

However, we feel that this is one of many issues that should be considered as part of a wider reform of NICE's Technology Appraisal process.

11. Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in this consultation document?

➤ **Unsure**

Please provide comments to support your response:

We understand the desire for the CDF budget to be more effectively managed, to ensure that it delivers the best outcome for patients, at a cost the NHS can afford. Our overriding principle is that people affected by breast cancer must have access to the best treatment and care.

In terms of the specific recommendations in the consultation document, our views are as follows:

Fixing the annual budget allocation

The consultation states that the 2015/16 budget of £340 million will not be affected by the arrangements proposed in this consultation. However, we could find no detail in the consultation on what the budget will look like for 2016/17 or in subsequent years. Having a fixed annual budget seems too restrictive, and may not allow for ebbs and flows in new cancer drugs coming to market.

It has not been made clear in the proposals, or in the additional FAQs document published on 27 January, what the arrangements will be if the budget is exceeded during the financial year. It is not clear if this would mean that no more drugs could be admitted to the Fund during that year, or that a drug could only go on the Fund once another had completed its two-year period on the Fund (a 'one in, one out' approach). This seems a worrying potential consequence of the proposals.

Prospective Contingency Provision

We have questions about how this contingency provision will work. For example, will all companies which have drugs on the Fund pay an equal share to the contingency provision? If so, would this not introduce an advantage to bigger pharmaceutical companies, who would be more able to take on this additional financial risk? It may disincentivise smaller companies from entering the CDF, who may have innovative new drugs in development. Perhaps the contingency provision should be managed on a sliding scale, depending on the size of each company/their annual turnover?

Capping the cost of the drug aligned to prospective maximum patient numbers needed for data collection

We have significant concerns about an aspect of this proposal.

Based on our understanding of the proposals as set out in the consultation document, we were of the belief that access for patients would not be restricted by the number of patients required for data collection:

'Access to the drug by eligible patients will not be restricted to the number of patients considered necessary for data collection, but any costs for treatment over and above this number will be paid for by the company.' (Point 46 in the consultation document)

This seems to indicate that it will be a condition of acceptance onto the CDF that the company will cover the costs of any additional patients above the number needed for data collection.

However, from subsequent discussions and from looking at the consultation FAQs document published on 27 January this does not appear to be the case:

'Whether that means there is no access for them [to the drug] would depend on the specific arrangements made [with the company] in the commercial access agreement.'

Consultation on proposals for a new Cancer Drugs Fund (CDF) operating model: Q&A

If this is the case, this is not an improvement on the current system, and unacceptably unfair for those patients who happen to fall out of the required number for data collection.

CDF Investment Group

We welcome proposals to have a CDF Investment Group, but are disappointed that no patient involvement mechanism for the group has been put forward. It is vital that the voices of those affected are represented throughout the new process.

Overall comments

Overall, those who took part in our survey were keen that all parties work together to find a solution. A few comments are included below:

'I agree that pharmaceutical companies should lower their prices but budgets should be realistic and not detrimental to any patient requiring expensive drugs'

'I understand that there are budgetary constraints to be managed and think that there should be better cooperation between the drug companies and NHS & NICE'

'If the pharmaceutical companies will agree to this additional responsibility then this is a good thing. If there is any question over this then I would be anxious about the change'

12. Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the

budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

➤ **Unsure**

Please provide comments to support your response:

As noted for question 11, we are disappointed not to see any patient involvement mechanism built in to the CDF Investment Group. Including patients in the CDF Investment Group would help to improve transparency in the new CDF model.

Furthermore, we hope that the investment control arrangements will be reviewed regularly, to ensure that they do not have unintended consequences.

13. Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?

There are a number of additional points we would like to raise:

The consultation process

The consultation document states that NHSE are 'particularly keen to hear from as many patients, carers and patient representatives as possible to inform decisions on proposals concerning the Fund'.

Despite this, no patient-friendly guide to the proposals has been made available. Breast Cancer Care produced our own guide to the proposals in lieu of this. However, this is specifically tailored for those affected by breast cancer, and has probably not had the reach that a NHSE or NICE guide could have achieved.

The consultation document itself is not accessible to most people, creating a barrier to gaining meaningful patient feedback on the proposals. Only 22% of those who took our survey said that the official consultation document was easy to understand. One person told us:

'I would have liked to make a personal reply to the official consultation document, but did not find it accessible enough.'

Breast Cancer Care was willing to provide assistance in this and had been prepared to allow our own guide to be adapted for this use. It is simply not good enough that patient-friendly materials were not available from the outset of the consultation period. Involving those who could be affected by the changes to the CDF should have been a priority for this consultation.

Timeframe for consultation

We have significant concerns over the level of impact that consultation responses can have on the proposed new system. The consultation closes on 11 February 2016, with the changes due to come into effect from 1 April 2016. This leaves just 7 weeks for NHSE and NICE to take on board comments received and make changes as appropriate. We know that some steps have been taken already to prepare for the new system, which suggests that there is little scope for significant change as a result of the consultation.

The end of the current Cancer Drugs Fund has been known since the Fund was renewed in 2013. Repeated delays to the consultation have meant that the timeframe for consultation has been increasingly shortened.

Potential inconsistency in care

We feel that it is important to consider the impact of the proposals in relation to the consistency of care offered to patients. The proposed new system could still result in access to cancer drugs being removed at certain points, meaning that patient A may not have access to a drug, while patient B does solely because they applied for the drug a week earlier before it was removed from the CDF.

Lack of information about transitional arrangements

We have been assured at events held by NHSE/NICE that current CDF drugs which are being re-assessed under the new CDF will continue to be available to patients while this takes place. However, this has not been confirmed in writing. Given the huge anxiety this uncertainty can cause patients, this should have been included in the consultation document.

We are also unclear as to the status of drugs which have been recently de-listed from the current CDF (i.e. whether they will also be re-assessed under the new CDF or if they will simply cease to be available). It would be helpful to know if there is flexibility here.

Patient involvement in the new model

We are aware that in initial versions of the new system, there was a lot more patient involvement built into each stage along the pathway.

This has not translated into the proposals contained in the consultation document. Meaningful patient involvement should constitute a key aspect of any future arrangements. The NHS Constitution sets out patients' rights in detail: "You have the right to be involved, directly or through representatives, in the planning of healthcare services commissioned by NHS bodies, the development and consideration of proposals for changes in the way those services are provided, and in decisions to be made affecting the operation of those services."

Patients who took our survey also thought this was an issue that should be addressed:

"... it is really disappointing that it is unclear as to how patients will be involved in the new system - this is surely our democratic and moral right."

"... recipients (end users), need more of a voice in the process on an ongoing basis."

Individual Funding Requests as an alternative

In the proposals set out in the consultation document, Individual Funding Requests (IFRs) are suggested as an alternative route for patients to access drugs which are unsuccessful after going through the new CDF system.

We feel that this suggestion is hugely misleading, offering false hope to patients, due to the stricter criteria that has to be met to secure funding via this process (clinical exceptionality criteria).

Impact on devolved nations

As the only UK-wide breast cancer support charity, we support patients across England, Scotland, Wales and Northern Ireland. We feel it is important that discussions are had about:

- How data collected in the proposed new CDF could be used to inform decision-making in the devolved nations
- Impacts that a new CDF model could have on access in the devolved nations
- The impact of a continued post-code lottery

Ultimately, we want every patient in the UK to have access to the best possible treatment and care.

Survey responses

We would be happy to provide further details of the results of our survey of people affected by breast cancer, to help inform any new system for patients. Please contact campaigns@breastcancercare.org.uk.

14. Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?

➤ Disagree

Please provide comments to support your response:

We are aware of the issues with the current Cancer Drugs Fund, notably that the fund is a temporary attempt to enable patient access to drugs, that it is unsustainable in its current form and that it is hugely overspent. However, we feel that we cannot say with confidence that the proposals as set out in the consultation will be an improvement on the current system.

We acknowledge that there are potential positives to the proposals including:

- A more integrated approach
- Increased data collection on the effectiveness of drugs
- Clear entry and exit criteria

However, we feel that an opportunity has been missed to really address and reform the way that we assess and pay for cancer drugs in England. Under the current system, eight

secondary (metastatic) breast cancer drugs have been turned down for routine use on the NHS in England in the last five years.

The timeframes for the end to the current CDF have not been a surprise, yet, the consultation and the proposals have felt rushed.

The Cancer Drugs Fund has helped thousands of patients to access cancer drugs which would otherwise have been unavailable to them. However, it was only meant as a transitional arrangement, until a new, more sustainable system was developed. We believe that proposals in the consultation are effectively ‘tinkering around the edges’. They do not deal with the problems which have necessitated the need for a Cancer Drugs Fund in the first place. As such, we do not feel the proposals offer a sustainable solution.

People affected by secondary breast cancer tell us that they are concerned about what will happen in the coming months. One person told us:

‘I have secondary breast cancer and am pleased to be currently well. I am concerned that if these changes are implemented I may not receive the most appropriate drugs when I need them in the future.’

For this person and all those affected by breast cancer, it is vital that we get this new system right. We need a fair, sustainable system that enables effective cancer drugs to be available for patients in England. To avoid going backwards, we need to ensure we can improve levels of care and support for people with breast cancer.

Contact us

For queries relating to this consultation response, please contact campaigns@breastcancercare.org.uk