Briefing note: A new Cancer Drugs Fund (CDF) operating model

Suggested health oral PQ (deadline 12.30pm on 16 March)

What assessment he has made of the potential impact of the new Cancer Drugs Fund operating model on patient access to effective cancer drugs.

Suggested written PQs

To ask the Secretary of State for Health, what consideration NHS England and NICE have given to drug appraisal systems abroad, when developing proposals for a new Cancer Drugs Fund operating model.

To ask the Secretary of State for Health, if he will commit to undertaking an evaluation of the new Cancer Drugs Fund operating model within a year of it being implemented, in order to assess the impact that it has had on cancer patients.

To ask the Secretary of State for Health, what plans NHS England and NICE have to publish an impact assessment of the new Cancer Drugs Fund operating model, including consideration of impact on patients and their access to effective cancer drugs.

To ask the Secretary of State for Health, if he will ask NHS England’s Specialised Services Commissioning Committee to give due consideration to flexible pricing approaches when they develop the Standard Operating Procedures for a new Cancer Drugs Fund operating model.

To ask the Secretary of State for Health, what assurances he can give that all patients, who are eligible for a particular drug indication approved for use on the new Cancer Drugs Fund operating model, will be able to access it.

Consultation on a new CDF operating model

- In November 2015, NHS England and the National Institute for Health and Care Excellence (NICE) joined forces to propose changes to the way that the CDF operates, and to integrate the CDF into NICE’s current processes – the current CDF will cease to operate from 1 April 2016.

- The biggest change is that NICE will now have three options when appraising a new drug for routine use on the NHS:
  - Recommended for routine use
  - Not recommended for routine use
  - Recommended for use within the CDF
The third option is new to NICE and is intended for drugs where the evidence of clinical benefit is unclear. If NICE makes this recommendation, the drug will be made available on the NHS in England for up to two years while further data is collected on the clinical effectiveness of the drug.

After this two year period, NICE will re-assess the drug using the new evidence and will make a final decision about whether a drug should be made available for routine use on the NHS.

If a drug is recommended for use it will be removed from the CDF and will be funded through routine NHS budgets. If a drug is not recommended for use it will be removed from the CDF and will no longer be available on the NHS in England, although patients already taking the drug are likely to be able to continue taking it.

Impact on breast cancer patients

There is a real danger that the new system will reduce access to breast cancer medicines – we do not think that the current drug appraisal process has changed sufficiently to guarantee access to breast cancer drugs. The last six breast cancer drugs have been rejected by NICE, despite some of these being clinically effective. This is because NICE bases its final decision on strict cost-effectiveness criteria, which new medicines for cancer have had great difficulty in meeting.

There needs to be much wider reform of the drug appraisal process – NICE and NHS England do not have the flexibility to negotiate on price, so many of the clinically effective drugs currently available at discounted prices to the CDF may no longer be available on the new system. We believe that a wider review of the drug appraisal and decision process is needed to assess how flexible pricing could better ensure access to innovative medicines for patients. We know that successful systems exist in many other European countries and would like these to be taken into account when designing a drug appraisal system fit for the future.

Patient involvement needs to be meaningful – Breast Cancer Now represents the interests of breast cancer patients. We would like NICE to provide further clarity on how patient involvement in a drug’s appraisal process can influence the outcome of whether it is made available on the NHS.

End of life criteria – currently, for treatments to qualify for NICE’s end of life criteria the patient population has to be small. This has meant that breast cancer drugs were not eligible to be included. Under the new system this requirement is expected to be removed, which is very good news.
What do those affected by breast cancer think?
In January 2016, we launched a survey to find out what those directly affected by breast cancer thought of NHS England’s and NICE’s proposals. We received 704 responses in just under a month, showing both the strength of feeling and concern on this issue. This is what they had to say:

“It [the CDF] feels like a safety net that the new proposals will probably take from me. I feel depressed that drugs my oncologist will want to try won’t be available”

“It is morally abhorrent that drugs that are proven to help patients can be suddenly withdrawn so that new patients can’t access them. How can you tell someone who is fighting this awful disease that they are ‘too late’ for a drug that could help them?”

“My medical team saw me as a prime candidate for Perjeta and applied to the CDF...My disease has stabilised and I have been able to enjoy a normal life as a mother of 3 young children and a teacher with minimal side effects and disruption for nearly 3 years. This drug has been a lifesaver.”

“It is a crime to know that there are drugs that can make a huge difference to someone’s life are available but inaccessible.”

“At this moment in time I am on a CDF drug that’s working well but I know the next drug I’d be moved to is Kadcyla, which has been in debate for a while now...I worry every day that I’m going to be stripped of drugs that could give me YEARS of life.”
Next steps

On 25 February 2016, the NHS England Board approved proposals for a new system to replace the CDF. Specifically, they agreed:

- To implement a new managed access fund, with clear entry and exit criteria
- That the new scheme should go live from 1 July 2016 (rather than 1 April 2016, as originally proposed) to allow for further work on the operational detail
- That drugs on the old CDF should continue to receive transitional funding, subject to certain conditions, from 1 April 2016 until the point that NICE is able to complete their appraisal or reconsideration of these drugs
- That the overall budget of the CDF should be fixed at £340m

You can read our response to NHS England’s announcement below:

**Baroness Delyth Morgan, Chief Executive at Breast Cancer Now, said:**

"The current CDF proposals unfortunately represent a major relapse for patient access to breast cancer drugs in the UK. It is indefensible that the CDF’s long-awaited successor may actually result in fewer – rather than more – drugs being made available to patients.

“These proposals do not offer sufficient reform on the existing NICE appraisal process. With the last six breast cancer drugs to be assessed by NICE being rejected, and with key issues left unaddressed, we’re concerned that clinically-proven drugs will continue to struggle for approval on the new Fund.

“This delayed start offers a final opportunity to discuss what changes can be made to future-proof patient access to cancer drugs. We would now like to see due consideration given to flexible pricing approaches, used very successfully elsewhere in Europe, to enable effective negotiation and ensure that the system finally results in better access for patients."

We remain concerned that the new system will reduce access to effective breast cancer drugs. Help us raise this issue in Parliament by tabling one of the suggested PQs at the start of this briefing note.

Further information
We have written a series of blogs on the proposals for a new system to replace the CDF. If you would like further information, you might find it useful to follow the links below:

- [Cancer Drugs Fund consultation, 8 January 2016](#)
- [Transition of drugs to the CDF, 22 January 2016](#)
- [Cancer Drugs Fund consultation closes, 12 February 2016](#)

If you have any additional questions, please contact Amelia Chong, Acting Senior Officer, Public Affairs at Breast Cancer Now, on 020 7749 4102 or [amelia.chong@breastcancernow.org](mailto:amelia.chong@breastcancernow.org)