HOUSE OF COMMONS LIBRARY

DEBATE PACK

Number CDP 2017/0029, 23 January 2017

Access to Kadcyla and other breast cancer drugs

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Summary

This Debate Pack has been prepared ahead of the debate on access to Kadcyla and other breast cancer drugs, to be held on Thursday 26 January.

The subject for the debate has been chosen by the Backbench Business Committee, following a representation by Siobhain McDonagh.

The motion to be debate is:

That this House notes the provisional decision not to provide the breast cancer drug Kadcyla for use in the NHS on 29 December 2016; and calls on the National Institute for Health and Care Excellence (NICE) and pharmaceutical company Roche to come together and re-assess this decision to ensure Kadcyla is kept available for patients, and consider how access to both innovative new breast cancer drugs and off-patent drugs used for breast cancer, such as bisphosphonates, can be improved."

1. Background

1.1 Assessment and availability of cancer drugs in the UK

The process for the assessment of drugs' clinical effectiveness and value for money varies in different parts of the UK. In England and Wales, the National Institute of Health and Care Excellence (NICE) produces guidance about which drugs should be available on the NHS. They look at how effective a drug is and how much it costs through a process called Technology Appraisal. Local health bodies in England and Wales must make arrangements to fund drugs that have been recommended by NICE. The Department of Health, Social Services and Public Safety in Northern Ireland also uses guidance issued by NICE in helping to determine its funding decisions.

In Scotland, the Scottish Medicines Consortium (SMC) advises NHS boards about new drugs. Like NICE, they look at how effective a drug is and how much it costs. A sub-group of the SMC called the New Drugs Committee assesses all the evidence around a newly licensed drug to help the SMC make a decision about whether or not to recommend it. NHS Quality Improvement Scotland may also review NICE guidance and decide if it should apply in Scotland.

England is the only part of the UK that has a specific fund to pay for cancer drugs (the Cancer Drugs Fund) that have not yet been reviewed for use in the NHS. However, cancer drugs may also be funded by the Scottish Government's New Medicines Fund, set up to expand and replace the Rare Conditions Medicines Fund.

Further information about how each part of the UK decides which drugs to fund can be found on the Cancer Research UK website.

1.2 Kadcyla (trastuzumab emtansine)

Kadcyla is the brand name of a drug combining trastuzumab with another substance, emtansine. It is licensed to treat HER2-positive breast cancer which has spread to other parts of the body, cannot be surgically removed and has stopped responding to initial treatment.

The drug costs around £90,000 per patient at its full list price and recent data shows that people taking Kadcyla could live up to 9 months longer than those taking the alternative, lapatinib plus capecitabine.

In August 2014 NICE decided not to recommend funding for Kadcyla, finding that the price per patient set by the manufacturer Roche is too expensive. The SMC reached a similar decision in October 2014.

Kadcyla has been available on the Cancer Drugs Fund (CDF) in England but is not currently available in Wales, Scotland and Northern Ireland. Following changes to the Cancer Drugs Fund that took place in July 2016 NICE has reconsidered its advice on drugs previously available through the Fund. Once NICE publishes final guidance on re-assessed cancer drugs they will cease to be available through the CDF.

Around 700 patients in England access Kadcyla through the CDF in 2015/16, and it has been estimated that around 1,200 people with HER2-positive, unresectable, metastatic breast cancer would be eligible to receive Kadcyla if it were routinely funded by the NHS.

On 29 December 2016 NICE published draft guidance, confirming its original recommendation that Kadcyla should not be routinely funded on the NHS. Consultation on the draft guidance was open until 20 January 2017 and NICE is expected to take a final decision in March 2017. Kadcyla will continue to be available through the CDF while the NICE appraisal is ongoing:

https://www.nice.org.uk/news/article/kadcyla-too-expensive-for-routine-funding-on-nhs

If the final NICE guidance remains negative, patients already receiving the drug via the CDF will continue to receive it until the patient and their prescribing physician consider it appropriate to discontinue treatment. From 90 days after the publication of the final guidance no new patients will be able to receive Kadcyla from the CDF.

Breast cancer patients and charities have raised concerns about the potential withdrawal of access to Kadcyla. See Sections 2 and 3 of this briefing pack for further information.

1.3 General background on breast cancer treatment

There are many different breast cancer drugs and treatments, depending on how advanced and quickly developing the cancer is, whether it is recurring after first treatment and whether it has spread to other parts of the body. If breast cancer has spread to other parts of the body, such as the liver or bones, this is known as secondary breast cancer (also known as metastatic breast cancer or stage 4 breast cancer).

The staging system normally used in breast cancer is called TNM, which stands for tumour, node, and metastasis. TNM staging takes into account the size of the tumour, whether the cancer has spread to nearby lymph nodes, and whether it has spread to other parts of the body (metastasis). Information on the stage and grade of the cancer is

important because it helps determine the best treatment for the individual patient.

Breast cancer drugs are typically used in conjunction with other treatments, such as surgery and radiotherapy. As well as the staging of the cancer, the drug treatment recommended might depend on what other treatment had already been carried out and a number of other factors including a patients, general health, whether they have had the menopause (oestrogen can stimulate some breast cancer cells to grow so some treatments aim to stop the ovaries making oestrogen). Drugs can also have a number of different effects depending on an individual's circumstances, for example a drug might be used to reduce the size of a tumour before surgery, to prevent cancer from coming back after treatment, or to control or slow cancer growth. Broadly, cancer drugs, include chemotherapies, hormone therapies and biological therapies.

- Chemotherapy; there are a number of different chemotherapy drugs used for breast cancer of often patients will receive a combination of 3 chemotherapy drugs together.
- Hormone Therapy; hormone treatments for breast cancer typically lower the levels of oestrogen and progesterone in the body, or block their effects.
- Biological therapy, such as trastuzumab (Herceptin), treats cancer using substances that change cell processes.

Further background on breast cancer treatment can be found on the Cancer Research UK website:

http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/treatment/

Details of NICE technology appraisals (and other guidance) relating to breast cancer treatment are available. It is also important to note that that not all new drugs are assessed by NICE:

https://www.nice.org.uk/guidance/conditions-and-diseases/cancer/breast-cancer

1.4 The Cancer Drugs Fund (England)

The UK Government established the CDF in 2010 to help improve access to cancer drugs in England and its budget has been increased a number of times to meet demand; the CDF budget in 2016-17 is £340 million. Since July 2016 the aim of the Cancer Drugs Fund (CDF) is to cover treatment costs for patients for drugs that have not yet been assessed by NICE. Before July 2016 the CDF was used to fund cancer drugs that were not routinely funded by the NHS in England, whether or not they had been assessed by NICE.

The new arrangements for the CDF, introduced on 29 July 2016, are aimed to ensure that promising and innovative medicines get to patients as quickly as possible. Under the new model, the CDF

becomes a transitional fund that will pay for new drugs in advance of NICE carrying out a full assessment of whether the drugs should be recommended for routine commissioning. After assessment, the drug will either be approved by NICE for routine commissioning on the NHS, or be removed from the CDF. Further information on the current CDF and NICE operating model for cancer drugs can be found here:

https://www.england.nhs.uk/ourwork/cancer/cdf/

https://www.england.nhs.uk/2016/07/open-for-business/

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/cancer-drugs-fund

The most recent version of the national CDF list is available here: https://www.england.nhs.uk/ourwork/cancer/cdf/list/

The drugs that remain on the list from the previous CDF (drugs that had previous negative NICE recommendations in final guidance) have been planned into the NICE work programme for a rapid reconsideration, to be concluded by end of 2017.

Following the changes to the CDF in July 2016 all Individual Funding Requests relating to cancer drugs will now be considered using NHS England's single, national IFR system. Please see the specialised services key documents page for full details of the NHS England IFR system, and how clinicians can apply on behalf of patients.

2. Press articles

BBC, 16 January 2017

Breast cancer patients' distress at withdrawal of Kadcyla

Terminal breast cancer patients have spoken of their distress after learning that a life-extending drug they had been told would be available to them looks set to be withdrawn.

PharmaTimes, 3 January 2017

NICE backs Roche's Perjeta, but bars Kadcyla

Patients with certain forms of breast cancer should be able to get routine NHS access to Roche's Perjeta in England and Wales in the next three months following a recent final nod from cost regulators.

Guardian, 29 December 2016

Breast cancer drug rejected for NHS use on cost-benefit grounds

Charities angered by guidance on Kadcyla, which costs £90,000 per year per patient and gives extra nine months on average.

Telegraph, 29 December 2016

Breast cancer sufferers to be denied revolutionary life-extending drug due to cost

Women with breast cancer will be denied life-extending drugs following a rationing decision which charities say will leave desperate patients "reeling."

Independent, 28 December 2016

Breast cancer charity condemns 'disastrous' recommendation to block pioneering treatment

The recommendation from the National Institute for Health and Care Excellence to reject Kadcyla is 'disastrous', Breast Cancer Now says.

3. Press releases

NICE, 29 December 2016

Kadcyla too expensive for routine funding on NHS

Kadcyla (also called trastuzumab emtansine and made by Roche) is currently being funded through the Cancer Drugs Fund. NICE is looking again at its 2015 guidance on the drug to see whether it should be funded routinely on the NHS.

Breast Cancer Now, 29 December 2016

Breast Cancer Now launches urgent petition following NICE decision to reject Kadcyla for routine use on the NHS

The National Institute for Health and Care Excellence (NICE) has today announced that it is not recommending advanced breast cancer drug trastuzumab emtansine (Kadcyla) for routine use on the NHS, in new draft guidance following its reappraisal.

Breast Cancer Care, 29 December 2016

Kadcyla not approved for NHS routine funding

"Over the Christmas Holidays, more than a thousand women with incurable breast cancer and their loved ones will be left reeling by this decision. Their hopes for a longer life are pinned on Kadcyla, so this is totally unacceptable."

4. Parliamentary questions

Trastuzumab Emtansine

Asked by: Johnson, Diana

To ask the Secretary of State for Health, if he will make it his policy to ensure that Kadcyla trastuzumab emanstine remains available on the NHS to breast cancer patients.

Answering member: Nicola Blackwood | **Department:** Department of Health

The National Institute for Health and Care Excellence (NICE) is the independent body that provides guidance on the prevention and treatment of ill health and the promotion of good health and social care.

NICE is currently appraising trastuzumab emtansine (Kadcyla) for the treatment of HER2-positive unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane. NICE's final guidance to the National Health Service on whether the drug should continue to be routinely available on the NHS is expected in March 2017.

18 Jan 2017 | Written questions | House of Commons | 59932

Trastuzumab Emtansine

Asked by: Johnson, Diana

To ask the Secretary of State for Health, how many women received the drug Kadcyla trastuzumab emanstine through the Cancer Drugs Fund from 2014 to 2016.

Answering member: Nicola Blackwood | **Department:** Department of Health

The number of women who have had funding approved for trastuzumab emtansine (Kadcyla) for the treatment of HER2-positive unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane through the Cancer Drugs Fund in each year since 2014/15 are shown in the table.

Year Number of patients

2014/15778

2015/16683

Source: NHS England

18 Jan 2017 | Written questions | House of Commons | 59931

Breast Cancer: Drugs

Asked by: Gwynne, Andrew

To ask the Secretary of State for Health, what discussions his Department has had with (a) the National Institute for Health and Care Excellence and (b) Roche on draft guidance on Kadcyla (trastuzumab emtansine) during the consultation period.

Answering member: Nicola Blackwood | **Department:** Department of Health

Neither Ministers nor officials have had any such discussions with the National Institute for Health and Care Excellence (NICE). Officials have had contact with Roche about its patient access scheme proposals for trastuzumab emtansine since the consultation on NICE's draft guidance opened on 20 December 2016.

18 Jan 2017 | Written questions | House of Commons | 59317

Breast Cancer: Drugs

Asked by: Gwynne, Andrew

To ask the Secretary of State for Health, what estimate he has made of the number of patients who would potentially be ineligible each year for treatment with Kadcyla trastuzumab entansine if draft guidance published by NICE on 28 December 2016 were implemented.

Answering member: Nicola Blackwood | **Department:** Department of Health

We have made no such estimate. Evidence submitted by Roche, as part of the National Institute for Health and Care Excellence's technology appraisal of Kadcyla, estimated that around 1,200 people with HER2-positive, unresectable, metastatic breast cancer would be eligible each year to receive Kadcyla if it were to be recommended.

18 Jan 2017 | Written questions | House of Commons | 59291

Breast Cancer: Drugs

Asked by: Allin-Khan, Dr Rosena

To ask the Secretary of State for Health, whether the National Institute for Health and Care Excellence (a) has met since 29 December 2016 or (b) plans to meet Roche during the consultation period for the Kadcyla form of trastuzumab emtansine.

Answering member: Nicola Blackwood | **Department:** Department of Health

The National Institute for Health and Care Excellence has advised that there have been no such meetings since 29 December 2016 and that a meeting with Roche is in the process of being arranged.

17 Jan 2017 | Written questions | House of Commons | 59131

Breast Cancer: Drugs

Asked by: McDonagh, Siobhain

To ask the Secretary of State for Health, when his Department plans that patients will lose access to Kadcyla (trastuzumab emtansine) if NICE does not recommend that drug in its final appraisal determination; what estimate his Department has made of the number of patients who are eligible for the drug Tyverb (lapatinib); and what estimate his Department has made of the number of patients who are receiving the drug Tyverb (lapatinib) on the NHS.

Answering member: Nicola Blackwood | **Department:** Department of Health

No patients will lose access to trastuzumab emtansine (Kadcyla) for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane on publication of the National Institute for Health and Care Excellence's (NICE) draft final appraisal determination as this is not NICE's final guidance, which is expected in March 2017.

Under the new arrangements for the appraisal and funding of cancer drugs that came into effect from July 2016, where final guidance from NICE does not recommend a drug that is currently available through the Cancer Drugs Fund (CDF), no further routine funding will be available for patients to be prescribed the drug. Any patients who have been prescribed the drug during the time in which the drug was in the Fund will continue to receive the drug at the pharmaceutical company's cost until the patient and their prescribing physician consider it appropriate to discontinue treatment.

Lapatinib (Tyverb) is no longer routinely commissioned for the treatment of locally advanced or metastatic breast cancer through the CDF. Applications for its use can be made through NHS England's individual funding request process and no estimate has been made of the number of patients eligible to receive it through that route.

NHS England has advised that there may be a very small number of patients who accessed lapatinib when it was on the CDF and who are continuing their treatment until they and their clinician agree an appropriate time to stop.

16 Jan 2017 | Written questions | House of Commons | 58987

Breast Cancer: Medical Treatments

Asked by: Durkan, Mark

To ask the Secretary of State for Health, what treatment options are available for patients with HER2-positive metastatic breast cancer who stop responding to Herceptin (trastuzumab).

Answering member: Nicola Blackwood | **Department:** Department of Health

The available treatment option for patients with HER2-positive metastatic breast cancer who stop responding to trastuzumab (Herceptin) is trastuzumab emtansine (Kadcyla).

Trastuzumab emtansine is currently only available through the Cancer Drugs Fund (CDF) in England. However, on 29 December 2016 the National Institute for Health and Care Excellence (NICE) published draft guidance that did not recommend its use in the National Health Service in England. If the final NICE guidance remains negative, from 90 days after the publication of the final guidance, patients already receiving the drug via the CDF will continue to receive it until the patient and their prescribing physician consider it appropriate to discontinue treatment. However, no new patients will be able to receive it from that point and the treatment options for those patients will still be standard cytotoxic chemotherapy.

16 Jan 2017 | Written questions | House of Commons | 58939

5. Further reading

The Library has also prepared a briefing packs for the following debates:

The Cancer Strategy one year on

Debate pack: http://researchbriefings.intranet.parliament.uk/ResearchBriefing/Summary/CDP-2016-0239

Debate: HC Deb 8 December 2016 cc440-71

Availability of cancer drugs (October 2015)

Debate pack: http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CDP-2015-0076

Debate: HC Deb 20 October 2015 cc265-88WH

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