

Cancer Drugs Fund

Managed Access Agreement

**Abemaciclib with fulvestrant for treating
advanced hormone-receptor positive, HER2-
negative breast cancer after endocrine therapy
[TA579]**

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Cancer Drugs Fund – Data Collection Arrangement

**Abemaciclib with fulvestrant for treating advanced
hormone-receptor positive, HER2-negative breast cancer
after endocrine therapy [TA579]**

Company name: Eli Lilly and Company Limited

Primary source of data collection: Ongoing clinical study, MONARCH 2

Secondary source of data collection: Public Health England routine population-wide cancer data sets, including Systemic Anti-Cancer Therapy data set

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Public Health England Agreement Manager	Rebecca Smittenaar
Eli Lilly and Company Limited Agreement Manager	[REDACTED]

1 Purpose of data collection arrangement

1.1 The purpose of the agreement is to describe the arrangements and responsibilities for further data collection for abemaciclib with fulvestrant for treating advanced hormone-receptor positive, HER2-negative breast cancer after endocrine therapy [TA579]. A positive recommendation within the context of a managed access agreement has been decided by the appraisal committee.

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2 Commencement and period of agreement

- 2.1 This data collection arrangement shall take effect on publication of the managed access agreement. The data collection period is anticipated to conclude in December 2021 (see section 5.1). The process for exiting the Cancer Drugs Fund will begin at this point and the review of the NICE guidance will start.
- 2.2 As part of the managed access agreement, the technology will continue to be available through the Cancer Drugs Fund after the data collection period has ended and while the guidance is being reviewed. This assumes that the data collection period ends as planned and the review of guidance follows the standard timelines described in the [addendum](#) to NICE's methods and processes when appraising cancer technologies.

3 Patient eligibility

- 3.1 Abemaciclib with fulvestrant is recommended for use within the Cancer Drugs Fund as an option for treating locally advanced or metastatic, hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in people who have had endocrine therapy if they might otherwise be considered for exemestane plus everolimus
- 3.2 Key patient eligibility criteria for the use of abemaciclib in the Cancer Drugs Fund include:
- Application for abemaciclib in combination with fulvestrant is made by and the first cycle of abemaciclib plus fulvestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.
 - Patient has histologically or cytologically documented oestrogen receptor positive and HER-2 negative breast cancer.

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- Patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment
- Patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment
- Patient has an ECOG performance status of 0 or 1 or 2.
- Patient has received previous therapy according to one of the three populations as set out below as these are the only groups for which there was evidence submitted to NICE for the use of abemaciclib plus fulvestrant.
 - has progressive disease whilst still receiving adjuvant or neoadjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression or
 - has progressive disease within 12 or less months of completing adjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression or
 - has progressive disease on 1st line therapy for advanced/metastatic breast cancer with no subsequent endocrine therapy received following disease progression.
- Patient has had no prior treatment with a CDK 4/6 inhibitor unless either abemaciclib has been received as part of any compassionate use scheme for the combination of abemaciclib plus fulvestrant and the patient meets all the other criteria set out here
- Patient has had no prior treatment with fulvestrant
- Patient has had no prior treatment with everolimus

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- Abemaciclib will only be given in combination with a fulvestrant.
- Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner
- Treatment breaks of up to 6 weeks are allowed, but solely to allow toxicities to settle
- Abemaciclib and fulvestrant will be otherwise used as set out in its Summary of Product Characteristics (SPC)

3.3

[REDACTED]

3.4 The estimated patient numbers per year are shown in the table below. These are the estimated patient numbers expected to be treated within the Cancer Drugs Fund during the managed access arrangement period. These estimates include assumptions of uptake and market share.

Table 1: Number of people in England expected to start treatment of abemaciclib with fulvestrant

	Company estimate (NHS Year)
Year 1	[REDACTED]

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Year 2		■
Year 3		■

3.5 Mean time on treatment is ■ months (modelled). Median time on treatment is ■ months (modelled). Duration of therapy from the study was ■ months. Overall survival estimates (using economic model) were mean ■ months and median ■ months (Company submission table 67, page 168).

4 Area(s) of clinical uncertainty

4.1 The key clinical uncertainties identified by the appraisal committee are:

- Immaturity of the survival data from MONARCH 2: The committee considered that the survival data were immature impacted on the uncertainty of the survival extrapolations in the economic model. The committee were aware of the ongoing clinical trial (MONARCH 2) and considered that further data cut might provide greater clarity in this long term outcome.
- Estimate of time-on-treatment: The committee agreed that the time to treatment discontinuation was uncertain. The committee considered that more data might be collected on time on treatment

5 Source(s) of data collection

Phase III trial: MONARCH 2

5.1 It is anticipated that the clinical uncertainty concerning the immaturity of the survival data from MONARCH 2 will be addressed through the publication of OS data from the phase III clinical trial (MONARCH 2). ■

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Other data

- 5.2 NHS England's Blueteq database captures the CDF population. NHS England shares Blueteq data with Public Health England for the CDF evaluation purposes. That sharing is governed by a data sharing agreement between NHS England and Public Health England.
- 5.3 Public Health England identifies, collects, collates, quality-assures and analyses large population-level datasets for specific diseases and conditions, including cancer. These datasets include the Systemic Anti-cancer Therapy (SACT) dataset, which is a mandated dataset as part of the Health and Social Care Information Standards. Public Health England will use the routinely-captured data collected during the period of the data collection arrangement to provide analyses as defined in sections 6.2 and 7.2.
- 5.4 Public Health England will collect data, including via the SACT dataset, alongside the primary source of data collection.

6 Outcome data

Clinical trial

- 6.1 Overall survival is the outcome of interest and is a reported outcome from the MONARCH 2 trial. The final data cut will provide further evidence of overall survival in the trial population.

Other data, including SACT

- 6.2 During the managed access agreement period, Public Health England will collect data to provide information on overall survival and duration of therapy unless it is determined by the SACT Operational Group that no meaningful data will be captured in during the period of data collection.

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7 Data analysis plan

Clinical trials

MONARCH 2 [REDACTED]
[REDACTED]
[REDACTED].

The final analysis will follow the analysis plan outlined in the trial protocol.

Other data

- 7.1 At the end of the data collection period Public Health England will provide a final report for NHS England based on routinely collected population-wide data, including that collected via SACT. The report will present depersonalised summary data, including the total number of patients starting treatment, overall survival and treatment duration. The necessary controls will be put in place to ensure that patient confidentiality is not put at risk. The report will be shared with Eli Lilly and Company Limited in advance of the planned review of guidance.
- 7.2 Completeness of SACT dataset reporting will be shared with NHS England and Eli Lilly and Company Limited at regular intervals during the data collection period. Public Health England will provide summary results for treatment duration and overall survival to NHS England and Eli Lilly and Company Limited on an annual basis, to check the continuing validity of the period of the data collection arrangement.

8 Ownership of the data

- 8.1 For all clinical trial data listed above, Eli Lilly and Company Limited will be the owner]
- 8.2 The data analysed by Public Health England is derived from patient-level information collected by the NHS, as part of the care and support of cancer patients. The data is collated, maintained, quality-assured and analysed by

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the National Cancer Registration and Analysis Service, which is part of Public Health England. Access to the data was facilitated by the Public Health England Office for Data Release. Eli Lilly and Company Limited will not have access to the Public Health England patient data, but will receive de-personalised summary data, with appropriate controls in place to cover this. Public Health England will provide a report to NHS England and Eli Lilly and Company Limited at the end of the managed access period.

8.3 The SACT dataset is a mandated dataset as part of the Health and Social Care Information Standards. All necessary governance arrangements through SACT, and other datasets brought together by Public Health England, have been established with NHS Trusts and NHS England.

8.4 Blueteq's CDF system data is owned by NHS England. NHS England is responsible for implementing Blueteq data collection and generally for analysis of these data. NHS England, however, shares Blueteq data with Public Health England for CDF evaluation purposes. That sharing is governed by a data sharing agreement between NHS England and Public Health England.

9 Publication

9.1 The details/authorship of any proposed publications arising from these studies will be planned with the publication of the final study results.

9.2 Publication of the analysis results of data collected by Public Health England, including through SACT and the data from Blueteq's CDF system, will be planned and implemented by Public Health England.

10 Data protection

10.1 The terms of clause 7 (data protection) of the managed access agreement, as apply between NHS England and Eli Lilly and Company Limited, shall

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also apply between the parties to this data collection arrangement in relation to the performance of their obligations under this data collection arrangement

11 Equality considerations

11.1 Do you think there are any equality issues raised in data collection?

Yes **No**

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Commercial Access Agreement

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