

National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Palbociclib in combination with fulvestrant for treating advanced, hormone-receptor positive, HER2-negative breast cancer after endocrine therapy

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	Breast Cancer Now and Breast Cancer Care	Yes this topic is appropriate for a NICE appraisal.	Thank you for your comment. No action needed.
	Pfizer	The wording is appropriate.	Thank you for your comment. No action needed.
Wording	Breast Cancer Now and Breast Cancer Care	Yes.	Thank you for your comment. No action needed.
	Pfizer	The wording is appropriate.	Thank you for your comment. No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
Timing Issues	Breast Cancer Now and Breast Cancer Care	We welcome NICE's intention to appraise this technology. This will be the third CDK 4/6 inhibitor in combination with fulvestrant that will be going through the NICE appraisal process. It is important that these appraisals are progressed quickly as trial results demonstrate that these technologies can improve progression-free survival and therefore could offer an important option for patients.	Thank you for your comment. No action needed.
	Pfizer	The timing of the appraisal is appropriate.	Thank you for your comment. No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Breast Cancer Now and Breast Cancer Care	No comments.	-
	Pfizer	The information is appropriate.	Thank you for your comment. No action needed.
The technology/ intervention	Breast Cancer Now and Breast Cancer Care	Yes to the best of our knowledge.	Thank you for your comment. No action needed.
	Pfizer	The description is accurate.	Thank you for your comment. No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
Population	Breast Cancer Now and Breast Cancer Care	Yes the population is defined appropriately.	Thank you for your comment. No action needed.
	Pfizer	The population for this appraisal is those who have become resistant to previous endocrine therapy. The wording in the draft scope is appropriate: "People with hormone receptor-positive HER2-negative, locally advanced or metastatic breast cancer who have had prior endocrine therapy".	Thank you for your comment. No action needed.
Comparators	Breast Cancer Now and Breast Cancer Care	The comparators are appropriate. However, while the CDK 4/6 inhibitor with fulvestrant has been compared to fulvestrant alone in the clinical trial, it should be noted that fulvestrant is not routinely available as a second line treatment on the NHS in England, although it is offered in some areas.	Thank you for your comments. A footnote was added to the table noting that during the scope consultation it was noted that fulvestrant is not routinely available as a second-line treatment.
	Pfizer	Palbociclib in combination with fulvestrant is licensed for use in the whole population who have become resistant to prior endocrine therapy. It should be noted that some of the comparators listed in the scope are not licensed for the whole of the endocrine resistant population but rather restricted based upon the specific type of prior endocrine therapy. These include: <ul style="list-style-type: none"> • Everolimus, which is licensed only after prior non-steroidal aromatase inhibitors and only in postmenopausal women. • Fulvestrant, which is licensed only after prior antioestrogen therapy. 	Thank you for your comments. No action needed.
Outcomes	Breast Cancer Now and Breast	Yes.	Thank you for your comment. No action

Section	Consultee/ Commentator	Comments [sic]	Action
	Cancer Care		needed.
	Pfizer	No comments.	-
Economic analysis	Breast Cancer Now and Breast Cancer Care	None.	Thank you for your comment. No action needed.
	Pfizer	No comments.	-
Equality and Diversity	Breast Cancer Now and Breast Cancer Care	We are not aware of any issues at this stage.	Thank you for your comment. No action needed.
	Pfizer	No comments.	-
Other considerations	Breast Cancer Now and Breast Cancer Care	None.	Thank you for your comment. No action needed.
	Pfizer	No comments.	-
Innovation	Breast Cancer Now and Breast Cancer Care	<p>The class of medicines to which palbociclib belongs (CDK 4/6 inhibitors) are considered to be innovative. They have demonstrated positive results in increasing progression free survival, when compared to fulvestrant alone.</p> <p>Palbociclib in combination with fulvestrant could therefore offer an important treatment option for people with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer who have received prior endocrine therapy, and may delay the time to needing chemotherapy.</p>	Thank you for your comments. Innovation will be considered in detail by the committee during the appraisal. No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
	Pfizer	No comments.	-
Questions for consultation	Breast Cancer Now and Breast Cancer Care	We are extremely concerned that there will be substantial difficulties in this appraisal due to the inherent issues around combination therapies often not being considered cost-effective by the NICE process. These difficulties could also be further compounded by the fact that two different companies are responsible for palbociclib and fulvestrant.	Comments noted. These issues, if raised during the appraisal process, will be considered by the committee. No action needed.
	Pfizer	No comments.	-
Additional comments on the draft scope	Pfizer	No comments.	-

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

None.