National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Abemaciclib with an aromatase inhibitor for untreated advanced hormone-receptor positive, HER2-negative breast cancer ID1227

Response to consultee and commentator comments on the draft remit and draft scope

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
Wording *Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?*	Breast Cancer Now	Yes	Comment noted. No action required.
	Eli Lilly	No comments	Comment noted. No action required.
	Novartis	Suggested wording: People with postmenopausal advanced hormone-receptor positive HER2-negative breast cancer that has not been previously treated in the advanced setting	Comment noted. The remit has been kept broad to ensure that it captures possible wording of the marketing authorisation from the European Medicines Agency.

Section	Consultee/ Commentator	Comments [sic]	Action
Timing Issues	Eli Lilly	Guidance close to marketing authorisation given an appropriate evidence base	Comment noted. The dates of the expected marketing authorisation were taken into account when the topic was planned into the work programme.
Additional comments on the draft remit	Eli Lilly	None	No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Breast Cancer Now	ONS cancer registration statistics for 2015 show that there were 9,626 deaths from breast cancer. The stats provided for 5 year survival rates for metastatic breast cancer and percentage people with early or locally advanced breast cancer progressing to metastatic breast cancer are local rather than national statistics, as the document suggests. Although fulvestrant is not recommended by NICE for use following endocrine therapy, it is routinely available in some local areas following confirmation that it was 'in tariff' when it was removed from the Cancer Drugs Fund.	Thank you for your comments. The background section has been updated in the final scope. Fulvestrant is included as a comparator in the scope for ID1339.
	Eli Lilly	No comments	No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
The technology/ intervention *Is the description of the technology or technologies accurate?*	Breast Cancer Now	To the best of our knowledge.	No action required.
	Eli Lilly	Yes	No action required.
Population *Is the population defined appropriately? Are there groups within this population that should be considered separately?*	Breast Cancer Now	Yes. We are not aware of any groups that should be considered separately.	Comment noted. No action required.
	Eli Lilly	Patients treated with abemaciclib in combination with endocrine therapy should be in a post-menopausal state- this should be made clear in the definition of the population.	Comment noted. The population has been kept broad to ensure that it captures possible wording of the marketing authorisation from the European Medicines Agency.
	Novartis	People with postmenopausal advanced hormone-receptor positive HER2-negative breast cancer that has not been previously treated in the advanced setting.	Comment noted. The population has been kept broad to ensure that it captures possible wording of the marketing authorisation from the European Medicines Agency.
Comparators	AstraZeneca	The correct use of palbociclib or ribociclib in this indication is in combination with an aromatase inhibitor.	Thank you for your comment. The list of

Section	Consultee/ Commentator	Comments [sic]	Action
Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?		The correct use of fulvestrant in this indication is as a monotherapy.	comparators has been updated in the final scope.
	Breast Cancer Now	Yes	No action required.
	Eli Lilly	We do not believe that tamoxifen should be included in the list of comparators. The draft scope states that tamoxifen is a comparator for patients for whom aromatase inhibitors (AIs) are contraindicated or not tolerated- in this population, abemaciclib is to be used in combination with an AI- therefore it is not logical that tamoxifen would be a comparator for an AI ineligible population. Furthermore, tamoxifen is not a comparator in the final scope for ribociclib and palbociclib and there should be consistency with those appraisals. The scope should state that the comparators palbociclib and ribociclib should be used in combination with an AI. As the draft scope notes, the appraisal for palbciclib, ribociclib and fulvestrant are still in process. Until these are complete and any subsequent guidance embedded in clinical practise, AIs represent best alternative care.	Thank you for your comments. The list of comparators has been updated in the final scope.
Outcomes *Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	Breast Cancer Now	Yes	No action required.
	Eli Lilly	We agree with the outcome measures stated.	No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Economic analysis	Eli Lilly	A lifetime horizon will require extrapolation of post-progression survival and the associated cost of post-progression treatments, but in principle, a lifetime horizon is appropriate.	Comment noted. No action required.
Equality and Diversity	Eli Lilly	No issues identified.	No action required.
Other considerations	Eli Lilly	No comments	No action required.
Innovation *Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?*	AstraZeneca	No. Abemaciclib is one of three CDK 4/6 inhibitors in this class of molecules.	Comment noted. No action required.
	Breast Cancer Now	The class of medicines to which abemaciclib belongs is considered to be innovative, significantly extending progression free survival (PFS) for patients when taken with an aromatase inhibitor, compared to an aromatase inhibitor alone.	Comment noted. The innovative nature of abemaciclib will be considered by the committee during the appraisal.
	Eli Lilly	Abemaciclib is anticipated to be the first CDK 4/6 inhibitor to allow continuous dosing. This may present advantages to patients with respect to compliance and ease of use of the treatment. This aspect may be captured in the time on treatment data available but aspects that are less easy to quantify, such as fewer missed doses due to the simpler dosing regimen should be considered.	Comment noted. The innovative nature of abemaciclib will be considered by the committee during the appraisal.
	AstraZeneca	Appropriateness of the cost comparison methodology to this topic.	Comment noted.

Section	Consultee/ Commentator	Comments [sic]	Action
Questions for consultation		Abemaciclib is the third member of this class of molecules (CDK 4/6 inhibitors) and is likely to be similar in its clinical efficacy and resource use to both ribociclib and palbociclib in this setting. The primary outcome measured in the study is still clinically relevant.	
	Eli Lilly	The question regarding sub-groups mentions pre- and post-menopausal women. We would like to re-iterate that the SPC is anticipated to state that women treated with abemaciclib in combination with endocrine therapy should be in a post-menopausal state. We expect abemaciclib to be an option where endocrine therapy is currently placed in the NICE pathway.	Comment noted. No subgroups are specified in the final scope.
Additional comments on the draft scope	AstraZeneca	The relevance of NICE TA423 to this appraisal is unclear given it relates to treatment following 2 or more chemotherapy regimens.	Comment noted. The related NICE guidance section has been updated in the final scope.
	Eli Lilly	No further comments	No action required.

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

Pfizer