National Institute for Health and Care Excellence

Health Technology Evaluation

Selpercatinib for treating advanced thyroid cancer with RET alterations (MA review of TA742) [ID6288]
Response to stakeholder organisation 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 and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Eli Lilly	No comments. Lilly agrees that the proposed single technology appraisal is the most appropriate evaluation route for selpercatinib.	Thank you for your comment. No action required.
	Ipsen	N/A	No action required.
Wording	Eli Lilly	No comments.	No action required.
	Ipsen	N/A	No action required.
Timing Issues	Eli Lilly	No comments.	No action required.
	Ipsen	N/A	No action required.
Additional comments on the draft remit	Eli Lilly	N/A - no additional comments.	No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Eli Lilly	No comments.	No action required.
	Ipsen	Ipsen would like to flag the sentence "NICE technology appraisal 516 recommends cabozantinib as an option for treating advanced MTC in adults." NICE technology appraisal 516 does recommend cabozantinib, however it should be clear that this is Cometriq (cabozantinib capsules) and NOT Cabometyx (cabozantinib tablets). Ipsen holds licenses in the thyroid cancer space for both brands of cabozantinib and we would just like to ensure this is understood by those reading the background information.	Thank you for your comments. Section 2 'Information about cabozantinib' of NICE Technology Appraisal 516 clearly specifies Cometriq as the brand of cabozantinib for treating MTC. No action required.
Population	Eli Lilly	The population wording included in the draft scope does not currently align with the populations appraised as part of TA742. Additionally, since TA742, the licensed indication for selpercatinib in the thyroid cancer (TC) population is anticipated to be updated to include [redacted]. For the TC population, the draft scope should specify: "**people 12 years and older** with advanced *RET* fusion-positive thyroid cancer who require systemic therapy **after sorafenib or lenvatinib**". For the medullary thyroid cancer (MTC) population, the draft scope should specify "people **12 years and older** with advanced *RET*-mutant medullary thyroid cancer who need systemic therapy **after cabozantinib or vandetanib**". The remaining populations of the licensed indications for selpercatinib are currently being evaluated as part of the ongoing appraisal of selpercatinib for untreated RET-positive advanced thyroid cancer (ID6132).	Thank you for your comments. The population in the final scope has been updated. To keep the scope population broad, the suggested wording '12 years and older' has not been added. For the TC population, 'after sorafenib or lenvatinib' has been added to reflect selpercatinib as a

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			second-line treatment following sorafenib or lenvatinib in this population. For the MTC population, 'after cabozantinib or vandetanib' has been added to reflect selpercatinib as a second-line treatment following cabozantinib in this population.
	Ipsen	Yes	No action required.
Subgroups	Eli Lilly	Lilly agree with the potential relevance of the proposed subgroups, except the 'line of treatment (position in pathway)' subgroup, as in this appraisal, selpercatinib is being appraised as a second-line treatment for patients who require systemic therapy after sorafenib or lenvatinib for TC, or after cabozantinib or vandetanib for MTC.	Thank you for your comments. The final scope has been updated by removing 'line of treatment (position in pathway)' as a subgroup.
Comparators	Eli Lilly	Lilly agree that best supportive care or palliative care represent comparators to selpercatinib in the MTC and TC populations.	Thank you for your comments. The final scope has been

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		However, Lilly do not anticipate lenvatinib or sorafenib being comparators to selpercatinib in the TC population. Lenvatinib and sorafenib are both licensed and recommended by NICE as first-line treatments for differentiated TC after radioactive iodine (TA535). As this appraisal is considering selpercatinib as a treatment following lenvatinib and sorafenib (i.e., a second-line treatment), neither lenvatinib or sorafenib are considered comparators to selpercatinib. In addition, Lilly do not anticipate cabozantinib being a comparator to selpercatinib in the MTC population. Cabozantinib is licensed and recommended by NICE as a first-line treatment for MTC. As this appraisal is considering selpercatinib as a treatment following cabozantinib (i.e., a second-line treatment), cabozantinib is not considered a comparator to selpercatinib. As such, the scope should be amended to remove sorafenib and lenvatinib from the TC population, and cabozantinib from the MTC population, leaving just best supportive care or palliative care as the only relevant comparators.	updated to reflect selpercatinib as a second-line treatment following lenvatinib or sorafenib in the TC population. 'Lenvatinib or sorafenib for differentiated thyroid cancer which did not respond to radioactive iodine (adults only)' has been removed as a comparator in this population. The final scope has also been updated to reflect selpercatinib as a second-line treatment following cabozantinib in the MTC population. 'cabozantinib (adults only)' has been removed as a comparator in this population.

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	Ipsen	Cabozantinib is a comparator in this technology appraisal, however we would like to draw attention to the fact that for the MTC indication this is cabozantinib (Cometriq) and NOT cabozantinib (Cabometyx). For differentiated thyroid cancer, this is cabozantinib (Cabometyx).	Thank you for your comments. Section 2 'Information about cabozantinib' of NICE Technology Appraisal 516 clearly specifies Cometriq as the brand of cabozantinib for treating MTC. No action required.
Outcomes	Eli Lilly	The draft scope is accurate. No amendments are required.	Thank you for your comment. No action required
	Ipsen	Yes.	No action required
Equality	Eli Lilly	No equality issues were identified.	Thank you for your comment. No action required
	Ipsen	Thyroid cancer European age standardised (AS) incidence rates for females and males combined increased by 175% in the UK between 1993-1995 and 2016-2018. The increase was of a similar size in females and males. Females are much more likely to be diagnosed with thyroid cancer making up 72% of thyroid cancer cases in the UK. The AS incidence for thyroid cancer in females is 8.7 and for male it is 3.6 per 100,000, respectively. It should also	

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		be noted that men with thyroid cancer tend to have a worse prognosis, therefore numbers of men and women with aggressive disease is similar.	
Other considerations	Eli Lilly	No comments.	No action required
	Ipsen	N/A	No action required
Questions for consultation	Eli Lilly	Where do you consider selpercatinib will fit into the existing care pathway for advanced thyroid cancer with RET alterations? In line with the original appraisal for selpercatinib in this indication (TA742), selpercatinib is positioned as a treatment for TC and MTC in patients who require systemic therapy following treatment with lenvatinib or sorafenib (TC), or cabozantinib or vandetanib (MTC). Do you consider that the use of selpercatinib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? As part of the original appraisal of selpercatinib in this indication (TA742), the committee agreed that selpercatinib would be associated with improvements in carer utilities for people aged between 12 and 17 in the MTC population, and that this could be an additional benefit not currently captured in the model. Since TA742, the licensed indication for selpercatinib in the TC population is anticipated to be updated to include [redacted], so this benefit to carers also applies to the TC population.	Thank you for your comment. No action required

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		As this will not be modelled explicitly, it is likely that this will represent a substantial health-related benefit that will not be captured within the health economic model.	
	Ipsen	N/A	No action required
Additional comments on the draft scope	Eli Lilly	N/A – no additional comments.	No action required