

National Institute for Health and Care Excellence

Health Technology Evaluation

Selpercatinib for untreated advanced thyroid cancer with RET alterations ID6132
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 (company)	No comments. Lilly agrees that the proposed single technology appraisal is the most appropriate evaluation route for selpercatinib.	Thank you for your comment.
	Association for Multiple Endocrine Neoplasia Disorders	Very appropriate.	Thank you for your comment.
Wording	Association for Multiple Endocrine Neoplasia Disorders	Could include stats in para 2 to highlight the relatively small number of people for whom this therapy may be appropriate, alongside stats for prevalence and survival.	Thank you for your comment. NICE is unaware of any reliable statistics for this population. The background section is intended to be a brief overview of the

Section	Stakeholder	Comments [sic]	Action
			condition. No change to scope required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Eli Lilly (company)	<p>The following statements are incorrect:</p> <p><i>“Selpercatinib (Retsevmo, Eli Lilly) does not currently have a marketing authorisation in the UK for treating people with untreated RET fusion-positive advanced thyroid cancer, or untreated RET mutation-positive advanced MTC.”</i></p> <p><i>“It also has a marketing authorisation for the treatment of adults and adolescents 12 years and older with advanced RET-mutant MTC who require systemic therapy following prior treatment with cabozantinib and/or vandetanib.</i></p> <p>The MTC marketing authorisation was updated in February 2023 to include patients with untreated <i>RET</i>-mutant medullary thyroid cancer (MTC). As such, within the MTC population, selpercatinib has a marketing authorisation for the treatment of adults and adolescents 12 years and older with advanced <i>RET</i>-mutant MTC (i.e., the current marketing authorisation already includes patients who have not received previous treatments). The description of the marketing authorisation of selpercatinib in the MTC population should be updated to reflect this.</p>	Thank you for your comment. The background information section has now been corrected to specify that selpercatinib currently has a marketing authorisation for people with <i>RET</i> -mutant medullary thyroid cancer who have not received previous treatments.

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	Association for Multiple Endocrine Neoplasia Disorders	Could include stats in para 2 to highlight the relatively small number of people for whom this therapy may be appropriate, alongside stats for prevalence and survival.	Thank you for your comment. NICE is unaware of any reliable statistics for this population. The background section is intended to be a brief overview of the condition. No change to scope required.
Population	Eli Lilly (company)	The draft scope is accurate, no amendments are required.	Thank you for your comment.
	Association for Multiple Endocrine Neoplasia Disorders	Yes, but see above [AMEND comment on background information section].	Thank you for your comment.
Subgroups	Eli Lilly (company)	No subgroups are expected to be relevant for separate consideration in this appraisal.	Thank you for your comment.
	Association for Multiple Endocrine Neoplasia Disorders	Already defined – RET alterations.	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
Comparators	Eli Lilly (company)	The draft scope is accurate, no amendments are required.	Thank you for your comment.
	Association for Multiple Endocrine Neoplasia Disorders	Yes [all relevant comparators have been included].	Thank you for your comment.
Outcomes	Eli Lilly (company)	The draft scope is accurate, no amendments are required.	Thank you for your comment.
	Association for Multiple Endocrine Neoplasia Disorders	Yes [the outcomes listed are appropriate].	Thank you for your comment.
Equality	Eli Lilly (company)	No equality issues were identified.	Thank you for your comment.
	Association for Multiple Endocrine Neoplasia Disorders	No changes needed.	Thank you for your comment.
Questions for consultation	Eli Lilly (company)	<i>What is best supportive care for adults with advanced RET fusion-positive thyroid cancer and advanced RET mutation-positive MTC? What is best</i>	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action																
		<p><i>supportive care for adolescents 12 years and older with advanced RET-mutant MTC (i.e. is it different to best supportive care for adults)?</i></p> <p>In UK clinical practice, best supportive care varies between patients but broadly consists of non-systemic treatment options, additional monitoring and palliative care. For example, as part of TA516, best supportive care was modelled to include the following:</p> <table border="1" data-bbox="712 560 1281 1098"> <thead> <tr> <th data-bbox="712 560 1077 639">Component</th> <th data-bbox="1077 560 1281 639">Rate/year PFS and PD</th> </tr> </thead> <tbody> <tr> <td data-bbox="712 639 1077 687">Consultant outpatient</td> <td data-bbox="1077 639 1281 687">6</td> </tr> <tr> <td data-bbox="712 687 1077 735">CT scans</td> <td data-bbox="1077 687 1281 735">2</td> </tr> <tr> <td data-bbox="712 735 1077 783">MRI scans</td> <td data-bbox="1077 735 1281 783">1</td> </tr> <tr> <td data-bbox="712 783 1077 863">Community palliative care support</td> <td data-bbox="1077 783 1281 863">12</td> </tr> <tr> <td data-bbox="712 863 1077 911">Palliative radiotherapy</td> <td data-bbox="1077 863 1281 911">2</td> </tr> <tr> <td data-bbox="712 911 1077 1054">Bisphosphonates for bone metastases (IV + outpatient visit – for 5% pt. only)</td> <td data-bbox="1077 911 1281 1054">0.6</td> </tr> <tr> <td data-bbox="712 1054 1077 1098">Palliative surgery</td> <td data-bbox="1077 1054 1281 1098">0.03</td> </tr> </tbody> </table> <p>Abbreviations: CT: computerised tomography; IV: intravenous; PD: progressed disease; PFS: progression-free survival; MRI: magnetic resonance imaging.</p> <p>In this appraisal, it is anticipated that best supportive care will be modelled in a similar way to prior NICE appraisals in advanced TC and/or MTC (such as</p>	Component	Rate/year PFS and PD	Consultant outpatient	6	CT scans	2	MRI scans	1	Community palliative care support	12	Palliative radiotherapy	2	Bisphosphonates for bone metastases (IV + outpatient visit – for 5% pt. only)	0.6	Palliative surgery	0.03	
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		<p>TA516), and informed by UK clinical experts who will be consulted as part of the development of this submission.</p> <p><i>Would selpercatinib be a candidate for managed access?</i></p> <p>The comparative efficacy data to be presented in this submission are anticipated to be suitably robust to allow selpercatinib to be considered for routine commissioning. Selpercatinib is expected to offer substantially improved efficacy and reduced toxicity compared to the multi-kinase inhibitors (MKIs), which currently represent the standard of care in this setting and are associated with a significant toxicity profile, and therefore it is important to ensure that patients are able to routinely access selpercatinib, a step change in the treatment pathway for RET altered TC and MTC, at the earliest possible opportunity.</p> <p>However, should NICE deem that a managed access agreement may be more appropriate for selpercatinib in this indication, future additional data for selpercatinib is anticipated to become available, although the timing of data availability is currently uncertain.</p> <p><i>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?</i></p> <p>As part of TA742, the committee agreed that selpercatinib could be associated with improvements in carer utilities for people aged between 12 and 18 in the MTC population, and that this could be an additional benefit not currently captured in the model.</p> <p>It is likely that selpercatinib will be associated with a similar benefit on carer utilities as part of this appraisal; while 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.</p>	

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

Royal College of Pathologists