National Institute for Health and Care Excellence

Health Technology Evaluation

Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer (Managed Access review of TA781) ID6287

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	Amgen	The proposed evaluation route is appropriate.	No action.
Wording	Amgen	The wording of the remit is appropriate and aligned with the licenced indication.	No action.
Timing Issues	Amgen	It is important that sotorasib is evaluated and moved into specialised commissioning as soon as possible.	No action.
Additional comments on the draft remit	Amgen	No comment	No action.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Amgen	The background section is accurate and complete.	No action.
Population	Amgen	The population is defined appropriately.	No action.
Subgroups	Amgen	Amgen is not aware of any subgroups in which sotorasib could be considered particularly clinically or cost effective.	No action.
Comparators	Amgen	Amgen is aware that at this stage of the evaluation, identifying comparators should be inclusive, but makes the following observations: 1. Adagrasib is currently being appraised [ID6339] by NICE and the expected publication of the decision is 02 July 2025, which is after the submission date for the sotorasib evidence dossier. Therefore, since adagrasib will NOT be a recommended treatment for eligible patients in this appraisal, it cannot be considered to be “in routine clinical practice” or a relevant a comparator. 2. Although docetaxel with nintedanib may be offered as a second-line treatment for patients considered in this appraisal, this treatment is rarely used in practice. Patients with adenocarcinoma who are eligible for docetaxel may also be eligible for docetaxel in combination with nintedanib, in line with NICE TA347. Clinical expert opinion obtained at the UK advisory board prior to the original appraisal (February 2021), indicated that use of docetaxel in combination with nintedanib was	As outlined in section 2.2.12 of NICE’s health technology evaluations manual (PMG36), identifying comparators at the scope stage should be inclusive. Therefore, no changes have been made to the scope.

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		variable across different regions in the UK. Furthermore, preliminary analysis of the Cancer Analysis System database shows that docetaxel with nintedanib is rarely used in current practice to treat advanced non-small cell lung cancer in these patients. Therefore, it cannot be considered routine clinical practice and should not be a comparator in this appraisal	
Outcomes	Amgen	Amgen considers that the outcomes listed in the draft scope are appropriate for capturing important health-related benefits (and harms) of sotorasib.	No action.
Equality	Amgen	Amgen is unaware of any potential impacts of the draft remit and scope on the equality of opportunity or discrimination against people with protected characteristics.	No action.
Other considerations	Amgen	None	No action.
	Amgen	**Have all the relevant comparators for sotorasib been included in the scope?** Yes. Please see responses above for more details **Is the KRAS G12C mutation tested for as part of routine practice in advanced or metastatic NSCLC care?** Yes. Amgen believes that routine testing for driver mutations prior to initiation of first-line therapy always includes tests for variants in KRAS, often as part of next-generation sequencing panels. Indeed, a positive test for the G12C mutation is required	Thank you. No action.

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		for access to sotorasib through the managed access arrangement with NHS England. **Have all the relevant subgroups for sotorasib been included in the scope?** Yes. Amgen is not aware of any subgroups in which sotorasib could be considered particularly clinically or cost effective. **Do you consider that the use of sotorasib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** Amgen believes that all substantial health-related benefits are likely to be captured in the QALY calculation. **Where do you consider sotorasib will fit into the existing care pathway for locally advanced or metastatic NSCLC?** Sotorasib will be used in agreement with it's marketing authorisation; in adult patients with locally advanced or metastatic KRAS p.G12C-mutated NSCLC whose disease has progressed after at least one prior line of systemic therapy. **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims.** **Amgen is not aware of any such issues.**	
Additional comments on the draft scope		Amgen notes that according to Section 6.25 of NICE's Guide to the Processes of Technology Appraisal (https://www.nice.org.uk/process/pmg19/chapter/reviews),	NICE's Guide to the Processes of Technology Appraisal (PMG19) was superseded by the NICE health

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		No changes to the scope of the appraisal will be considered." **Thus, the comparators for this appraisal should remain unchanged from the original appraisal [TA781], i.e. docetaxel monotherapy and docetaxel in combination with nintedanib.**	technology evaluations manual (PMG36), for appraisals published in 2022 onwards. Section 2.8 outlines the approach taken to scoping after a period of Managed Access. Specifically, 2.8.1 states: *"For technologies that were recommended with managed access, NICE will update the original scope. This is to make sure that the guidance update considers the care pathway and use of the technology in England at the time the guidance update starts. NICE can review any element in the scope, including changes that happened during the managed access period to the:* • *eligible patient population* • *treatment pathway* • *relevant health outcomes measures."* The scope identifies the potential comparators that are relevant at the time of the current appraisal.

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

Association of Respiratory Nurses