National Institute for Health and Care Excellence

Single Technology Evaluation

Tarlatamab for previously treated advanced small-cell lung cancer [ID6364]

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 need for an appraisal is appropriate and the Company agrees with the proposed evaluation route (STA).	Comment noted, no action required.
Wording	Amgen	The Company believes that the remit wording is appropriate.	Comment noted, no action required.
Timing issues	Amgen	Advanced SCLC is a disease with an extremely poor prognosis, limited options for treatment, and high unmet need. The Company therefore wishes to achieve reimbursement for tarlatamab as soon as possible.	Comment noted. NICE aims to publish guidance as soon as possible after the company receives the marketing authorisation and introduces the technology in the UK. NICE has

Section	Stakeholder	Comments [sic]	Action
			scheduled this topic into its work programme.
Additional comments on the draft remit	Amgen	N/A	-

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Amgen	The Company believes that the background information provided by NICE is accurate and complete.	Comment noted, no action required.
Population	Amgen	The Company agrees with the definition of the suggested population.	Comment noted, no action required.
Subgroups	Amgen	The population in our submission will be aligned with the population of DeLLphi-301. [redacted]	Comment noted. Tarlatamab will be appraised within its marketing authorisation or a population for whom the company provides evidence if this is narrower than the marketing authorisation. The company can submit relevant subgroup analyses in their submission which will

Section	Consultee/ Commentator	Comments [sic]	Action
			be considered by the Appraisal Committee.
Comparators	Amgen	The Company does not believe that lurbinectedin is an appropriate comparator as it has not been reimbursed in this patient population nor is it used in clinical practice. In addition, no usage of lurbinectedin was identified in analyses of the NHS Systemic Anti-Cancer Therapy (SACT) database performed by the Company. Further to this, the NICE appraisal for lurbinectedin in this patient population has been suspended as of 28th March 2023 (information accurate as of 5th February 2024). Amgen feels strongly that best supportive care (BSC) is not an appropriate comparator. The Company believes that patients who have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 are more likely to be candidates for systemic therapy, like tarlatamab, as per the inclusion criteria of DeLLphi-301, compared with patients with an ECOG performance status of >1, who are more likely to receive BSC alone. The Company agrees that the rest of the comparators listed are appropriate for inclusion.	Thank you for your comments. Based on anticipated appraisal timelines, lurbinectedin has been removed from the scope. BSC has been included because NICE aims to keep the comparators list inclusive. The rationale for excluding any comparators from the evidence submission will be considered by the Appraisal Committee.
Outcomes	Amgen	The outcomes listed are appropriate, although response rate is not modelled in the economic analysis, which focuses on overall survival (OS) and progression-free survival (PFS) for modelling of efficacy outcomes and health state occupancy.	Comment noted, no action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Equality	Amgen	It is not anticipated that there will be any equality or equity issues with the draft remit and scope.	Comment noted, no action required.
Other considerations	Amgen	N/A	-
Questions for consultation	Amgen	What treatments are established clinical management in the NHS for previously treated advanced small cell lung cancer? - An analysis of the NHS SACT database determined that the following treatments are used in this treatment setting: o CAV (cyclophosphamide + doxorubicin + vincristine) [redacted] o Topotecan [redacted] o Platinum-based chemotherapy [redacted] o Other treatments [redacted] Which combinations of chemotherapy are established clinical management in the NHS for previously treated advanced small cell lung cancer? - As above Where do you consider tarlatamab will fit into the existing care pathway for advanced small cell lung cancer? [redacted] Have all relevant comparators for tarlatamab been included in the scope? - Please see our response to the “Comparators” question above	Comments noted. The positioning of the technology in the treatment pathway will be considered by the committee during the appraisal.

Section	Consultee/ Commentator	Comments [sic]	Action
		Are the outcomes listed appropriate? - Please see our response to the “Outcomes” question above Are there any subgroups of people in whom tarlatamab is expected to be more clinically effective and cost effective or other groups that should be examined separately? - [redacted] Would Tarlatamab be a candidate for managed access? - [redacted] Do you consider that the use of tarlatamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? - No; the Company expects all benefits to be captured via quality-adjusted life years (QALYs) Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. - N/A 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. Please see our response to the “Equality” question above	

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

Oncogene-Driven Lung Cancer Patient Alliance UK (ODLC Patient Alliance) not participating