

National Institute for Health and Care Excellence

Health Technology Evaluation

Tarlatab for treating extensive-stage small-cell lung cancer that has progressed after platinum-based chemotherapy ID6617

Response to stakeholder organisation comments on the draft remit and draft scope

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Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Amgen UK Ltd	Amgen consider a single technology appraisal (STA) to be the appropriate evaluation route.	Comment noted. No action needed.
	Oncogene Cancer Research	<p>Oncogene Cancer Research strongly supports NICE's evaluation of tarlatamab. People with small-cell lung cancer (SCLC) who have already had platinum-based chemotherapy have very few treatment options and face some of the poorest outcomes in lung cancer. For these patients and their families, every additional option matters.</p> <p>Because SCLC is fast-moving and life-limiting, it is important that new treatments are assessed and made available as quickly as possible. We therefore support using the Single Technology Appraisal route. This approach is focused, efficient, and allows patients to benefit from new treatments without unnecessary delay.</p> <p>From listening to patients and families, we hear clearly how urgent the need is for a treatment that can offer more time and more hope. An evaluation of</p>	Comment noted. No action needed.

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		tarlatamab is not only appropriate but essential, and we welcome NICE's commitment to reviewing it.	
	British Thoracic Oncology Group	Yes. Appropriate. A significant unmet need in the patient population.	Comment noted. No action needed.
Wording	Amgen UK Ltd	Yes, Amgen consider the wording of the remit to be reflective of the decision problem being addressed in this submission.	Comment noted. No action needed.
	Oncogene Cancer Research	<p>Overall, we feel the wording of the remit reflects the key issues of clinical and cost effectiveness that NICE should consider for tarlatamab. It is clear that the evaluation will look at how well the treatment works, how it compares to what is currently available, and whether it offers value for the NHS.</p> <p>We would suggest one small improvement to strengthen the focus on real-life patient need. The remit could more clearly highlight the very limited treatment options for people whose small-cell lung cancer has progressed after platinum-based chemotherapy, and the urgent nature of this stage of the disease. This would ensure that the evaluation fully reflects the context in which patients and clinicians must make decisions.</p> <p>A possible alternative wording could be:</p> <p>“To evaluate the clinical and cost effectiveness of tarlatamab for people with small-cell lung cancer that have progressed after platinum-based chemotherapy – a setting where treatment options are extremely limited and the disease is fast-moving.”</p> <p>This small change would make the remit more reflective of the reality patients face and the importance of assessing a new option like tarlatamab.</p>	Thank you for your comment. The wording of the remit does not usually include information about the unmet needs.
	British Thoracic Oncology Group	Yes	Comment noted. No action needed.

Section	Stakeholder	Comments [sic]	Action
Additional comments on the draft remit	Amgen UK Ltd	N/A – Amgen have no additional comments on the draft remit.	No action needed.
	Oncogene Cancer Research	<p>We welcome the remit and offer a few additional points from a patient perspective.</p> <p>Access to clinical trials for relapsed small-cell lung cancer is often very limited. The fast-moving nature of the disease, strict eligibility criteria and uneven availability of trial centres mean that many people never have a realistic opportunity to join a study. This makes the availability of new NHS treatment options even more important.</p> <p>We also hear from patients and families that the lack of clear next-line treatments after platinum-based chemotherapy creates significant anxiety and uncertainty. As patients progress, the emotional impact is immediate and severe. This highlights the importance of evaluating a treatment like tarlatamab.</p> <p>It is also important to recognise the stigma linked to lung cancer. Many patients feel judged or blamed for their diagnosis, which can affect how they seek care and how supported they feel. Ensuring timely access to new treatments can help counter some of this stigma by showing that people with small-cell lung cancer deserve the same attention and investment as any other cancer community.</p> <p>Overall, we strongly support the remit and welcome NICE’s commitment to evaluating tarlatamab for people who urgently need more choices.</p>	Comment noted. No action needed.
	British Thoracic Oncology Group	No comments	No action needed.

Comment 2: the draft scope

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Consultation comments on the draft remit and draft scope for the technology appraisal of tarlatamab for treating small-cell lung cancer that has progressed after platinum-based chemotherapy ID6617

Issue date: February 2026

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Amgen UK Ltd	<p>Amgen consider the background information in the draft scope to be accurate. However, Amgen suggest that the inclusion of additional context, specific to the 2L indication of interest in this appraisal, would be helpful:</p> <ul style="list-style-type: none"> • The Blackhall et al. (2023) publication is cited, reporting a median survival of 8 to 13 months from diagnosis with extensive-stage SCLC (ES-SCLC).¹ Blackhall et al. (2023) also reports a median survival of 6.6 months following initiation of 2L treatment, irrespective of disease classification,¹ clearly showing the rapid deterioration in prognosis following disease relapse. Amgen propose adding this information in the draft scope, as it represents survival estimates most relevant to this appraisal, and provides important context for the high unmet need and urgency faced by patients in the population included in this draft scope. • Although chemotherapy treatments are recommended for patients with relapsed SCLC, NG122 states that patients “<i>should be advised that there is no evidence supporting benefit of chemotherapy treatment in the 2L</i>”.⁴ This highlights the extremely poor outcomes and limited hope for survival currently faced by patients with relapsed SCLC, and represents important background to the scope addressed in this appraisal. 	Thank you for your comment. We have added the proposed information to the background section of the scope.
	Oncogene Cancer Research	While we are not experts in this disease outside of the lived experience, the background information looks accurate. From a patient perspective it could better reflect the lived experience of people with relapsed small-cell lung cancer. Current treatment options after platinum-based chemotherapy are extremely limited, and many patients see little benefit in practice. SCLC progresses very quickly, meaning some patients become too unwell for further treatment or trial participation. The uncertainty about next-line options has a profound emotional impact, and stigma linked to lung cancer can affect how people seek care and the support they receive. Including these realities	Thank you for your comment. We have included additional information regarding the limited treatment options and poor prognosis for people starting second-line treatment. We have

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		would give a fuller picture of unmet need and the importance of evaluating tarlatamab.	also acknowledged the limited evidence supporting chemotherapy treatment as a second-line option. Please note that the purpose of the background information is to provide a brief overview of the condition and it is not intended to be exhaustive.
	British Thoracic Oncology Group	<p>Accurate. A couple of additional points.</p> <p>Prognosis is the lowest of all subtypes of lung cancer. Treatment advances have been limited in recent years.</p> <p>There are international limitations in supply / manufacture of oral topotecan</p>	Thank you for your comment. We have included additional information regarding the limited treatment options and poor prognosis for people starting second-line treatment. We have also acknowledged the limited evidence supporting chemotherapy treatment as a second-line option. Please note that the purpose of the

Section	Consultee/ Commentator	Comments [sic]	Action
			background information is to provide a brief overview of the condition and it is not intended to be exhaustive.
Population	Amgen UK Ltd	Amgen consider the population definition outlined in the draft scope to be broadly appropriate. However, Amgen expect tarlatamab to receive marketing authorisation as a 2L treatment for patients with ES-SCLC specifically, following progression on or after platinum-based chemotherapy. Amgen propose making this distinction explicit in the population defined in NICE's scope: <i>"People with extensive-stage small cell lung cancer that has progressed on or after platinum-based chemotherapy"</i>	Thank you for your comment. We have included the proposed amendment.
	Oncogene Cancer Research	Yes, the population appears to be defined appropriately. People whose small-cell lung cancer has progressed after platinum-based chemotherapy face some of the poorest outcomes in lung cancer, and the scope reflects this group correctly. It may be helpful to make clear that patients can decline very quickly at this stage, which makes timely access to any new treatment even more important.	Thank you for your comment. Please note that information about outcomes is not included in the population section of the scope.
	British Thoracic Oncology Group	Yes	Comment noted. No actioned needed.
Subgroups	Amgen UK Ltd	Subgroup analyses for the primary outcome of the DeLLphi-304 trial, overall survival (OS), have been conducted and are planned to be presented in the Company Evidence Submission for patient subgroups that are considered to be clinically relevant. As shown in Mountzios et al. (2025), ⁵ the treatment	Comment noted. No actioned needed.

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		<p>effect of tarlatamab is consistent across all patient subgroups tested in the DeLLphi-304 trial.</p> <p>Amgen are collecting feedback from clinicians experienced in the treatment of SCLC in NHS practice to identify which subgroups, if any, are clinically important to consider, and the submission will reflect this feedback accordingly.</p>	
	Oncogene Cancer Research	The scope defines limited-stage and extensive-stage SCLC. From a patient perspective the priority is ensuring that all people whose cancer has relapsed after platinum-based chemotherapy have fair access to tarlatamab. We feel the evaluation should focus on providing access to all eligible patients, reflecting the urgent need and limited options at this stage of the disease.	Comment noted. No actioned needed.
	British Thoracic Oncology Group	Not that I am aware of.	Comment noted. No actioned needed.
Comparators	Amgen UK Ltd	<p>Amgen agree that the chemotherapy comparators provided in the draft scope issued by NICE are an appropriate reflection of current NHS clinical practice. However, Amgen disagree with the inclusion of best supportive care (BSC) as a potential comparator. BSC is non-systemic and palliative in nature, and is not prescribed with the intent to alter the course of disease or prolong life. Therefore, BSC is used in patients unfit or unwilling to receive further systemic treatment, who would be ineligible for treatment with tarlatamab.</p> <p>Tarlatamab is intended to be used in a different patient population from BSC: in patients able and willing to receive further systemic treatments, who would currently receive chemotherapies listed in the draft scope.</p> <p>For this reason, BSC does not represent a relevant comparator to tarlatamab in this appraisal, and Amgen request its removal from the final scope.</p>	Thank you for your comment. The comparators listed in the scope aims to be inclusive. The rationale for excluding any comparators from the evidence submission will be considered by the appraisal committee.

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	Oncogene Cancer Research	We are not experts in all the comparators listed but these do appear to reflect the current NHS practice. It is important to note that these treatments are largely ineffective for patients after relapse, which reinforces the unmet need for new therapies such as tarlatamab.	Comment noted. No actioned needed.
	British Thoracic Oncology Group	Yes. It is worth noting that some patients will receive repeated re-challenges with platinum-based chemotherapy if they remain platinum-sensitive. The limited availability of oral topotecan has meant that single agent chemotherapy is sometimes used in its place	Comment noted. No actioned needed.
Outcomes	Amgen UK Ltd	Amgen agree that the outcomes listed in the draft scope issued by NICE are appropriate, and that they capture the most important health-related benefits of tarlatamab. All listed outcomes were collected in the pivotal DeLLphi-304 trial, and are planned for presentation in the company submission.	Comment noted. No actioned needed.
	Oncogene Cancer Research	The outcomes listed in the scope are appropriate. From a patient perspective, outcomes that capture symptom relief, ability to continue daily activities and time with family are especially important and should be given weight in the evaluation.	Comment noted. No actioned needed.
	British Thoracic Oncology Group	Yes	Comment noted. No actioned needed.
Equality	Amgen UK Ltd	No equality issues have been identified with regard to the introduction of tarlatamab for the treatment of ES-SCLC following first-line platinum-based chemotherapy.	Comment noted. No actioned needed.
	Oncogene Cancer Research	We do not see wording that would explicitly exclude any protected group, but there are important equality considerations. Small-cell lung cancer is strongly associated with a history of smoking and disproportionately affects people from more deprived communities. Stigma, lower health literacy, and financial challenges can make it harder for patients to seek care promptly, participate	Thank you for your comment. The committee will consider any relevant equalities

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		in clinical trials, or access treatment. Ensuring timely access to new treatments like tarlatamab could help reduce these inequalities and improve outcomes for people who are already disadvantaged. Offering tarlatamab as a standard-of-care treatment would provide this group with equitable access to an effective new therapy and help reduce existing health inequalities.	issues in its deliberations.
	British Thoracic Oncology Group	It is worth noting that small cell lung cancer is associated with a heavy smoking population – often co-associated with multiple co-morbidities, frailty and poorer performance status. This is not always represented well in clinical trials.	Thank you for your comment. The committee will consider any relevant equalities issues in its deliberations.
Other considerations	Amgen UK Ltd	No additional comments	No actioned needed.
	Oncogene Cancer Research	The evaluation should consider the emotional impact of having very few treatment options at relapse. Patients often describe this as one of the most distressing moments in their cancer experience. Even modest improvements in survival or quality of life can make a meaningful difference. It is also relevant that access to clinical trials in relapsed SCLC is limited, so NHS availability of new treatments is particularly important. The presence of related and emerging treatments underscores how few effective options currently exist and the urgency of evaluating tarlatamab.	Comment noted. No actioned needed.
	British Thoracic Oncology Group	No comments	No actioned needed.
Questions for consultation	Amgen UK Ltd	Where do you consider tarlatamab will fit into the existing care pathway for small-cell lung cancer?	Thank you for your comments. No further action needed.

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		<p>In this submission, tarlatamab is being positioned as a second-line treatment option for patients with ES-SCLC that has progressed on or after platinum-based chemotherapy. This is based on the anticipated license extension for tarlatamab, and the available safety and efficacy evidence from the DeLLphi-304 trial – the pivotal clinical trial comparing tarlatamab and SoC chemotherapy in the patient population relevant to this submission.⁵</p> <p>Would tarlatamab be used to treat only extensive-stage small-cell lung cancer or would it also be used to treat limited-stage small-cell lung cancer?</p> <p>In line with its anticipated marketing authorisation extension and the patient population enrolled in the DeLLphi-304 trial, tarlatamab is being positioned as a second-line treatment option for all patients with ES-SCLC following first-line platinum-based chemotherapy.^{5, 6}</p> <p>If tarlatamab would also be used to treat limited-stage small cell lung cancer, would durvalumab be a relevant comparator in this evaluation?</p> <p>Durvalumab is only recommended for patients with limited-stage SCLC (LS-SCLC) if their disease has not progressed following platinum-based chemotherapy [TA1099], whereas the patient population relevant to this evaluation is patients with ES-SCLC whose disease has progressed following first-line platinum-based chemotherapy.⁷ This means that patients with LS-SCLC for whom durvalumab is reimbursed represent a distinct patient population that is not relevant to this submission and for whom tarlatamab would not be used or reimbursed as a treatment option, if recommended by NICE. Therefore, durvalumab does not represent a relevant comparator to tarlatamab in this submission.</p> <p>Please select from the following, will tarlatamab be:</p>	

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		<p>A. Prescribed in primary care with routine follow-up in primary care</p> <p>B. Prescribed in secondary care with routine follow-up in primary care</p> <p>C. Prescribed in secondary care with routine follow-up in secondary care</p> <p>D. Other (please give details):</p> <p>Tarlatamab will be prescribed in secondary care with routine follow-up in secondary care.</p> <p>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</p> <p>It is expected that relevant comparators in this submission and subsequent treatments are prescribed in secondary care with routine follow-up in secondary care, similar to tarlatamab.</p> <p>Would tarlatamab be a candidate for managed access?</p> <p>No, Amgen do not expect tarlatamab to be a candidate for managed access. The latest available data from the DeLLphi-304 trial are planned to be presented within the submission. Given the aggressive nature of relapsed SCLC, these data are anticipated to be mature to a large degree, with median OS and progression-free survival (PFS) reached in both arms. Thus, it is not expected that further data collection would meaningfully resolve any remaining uncertainty sufficiently to warrant consideration for entry into managed access.</p>	

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		<p>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?</p> <p>In ES-SCLC, the health-related benefits of tarlatamab are expected to be primarily captured in QALY calculations through delaying disease progression and prolonging survival. Reduced treatment burden is expected to be reflected in adjustments to utility associated with side effects of treatments. However, patients and families may experience value beyond measured health states, such as psychological benefits – a sense of hope and empowerment – from access to a novel, targeted therapy in a difficult-to-treat setting, which HRQoL instruments may fail to capture. Additionally, NICE’s preferred EQ-5D instrument lacks cancer-specific sensitivity to short-term fluctuations in symptoms, meaning some clinically meaningful improvements may be undervalued.⁸</p> <p>Therefore, while QALYs will capture the core survival and quality-of-life effects relevant to relapsed SCLC, there is potential for some benefits to be uncaptured, such as those related to patient and caregiver experience, and nuanced symptom relief.</p> <p>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</p> <p>The DeLLphi-304 trial collected EQ-5D data, which are anticipated to form the basis for utility values in the Company submission. As noted above, existing HRQoL instruments may not fully capture aspects of treatment but which patients consider important, and literature evidence exists suggesting such benefits exist.^{8, 9} Therefore, use of the EQ-5D data may result in some benefits not being captured in the QALY calculations and Amgen encourage</p>	

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		<p>the Committee to consider both quantitative and qualitative evidence when considering uncaptured benefits in its decision-making.</p> <p>Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.</p> <p>The platinum rechallenge chemotherapy, whilst licensed for use in SCLC, is not specifically licensed for 2L SCLC, and is therefore understood to be used off-label in this indication. Amgen do not foresee this to be an issue, as we understand that all listed comparators are administered at the recommended doses in their respective Summary of Product Characteristics (SmPCs).</p>	
	Oncogene Cancer Research	No additional comments	No actioned needed.
	British Thoracic Oncology Group	<p>Pathway: Small cell lung cancer who has progressed on / after platinum doublet chemotherapy – post chemo-immunotherapy or if limited stage post chemo-RT.</p> <p>It would be only for those individuals who have progressed post-platinum-based chemotherapy. I would be guided by the trial inclusion / exclusion criteria and if this included limited stage who progressed after platinum-doublet with RT then they should also be included.</p>	Thank you for your comments. No further action needed.

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		<p>It would be prescribed with routine follow up in secondary care</p> <p>It would be a candidate for managed access.</p> <p>I do not consider other health-related benefit outside QALY</p>	
Additional comments on the draft scope	Amgen UK Ltd	Amgen note that the appraisal for durvalumab with etoposide and either carboplatin or cisplatin for untreated ES-SCLC [TA1041]10 is not included in the list of relevant technology appraisals.	Thank you for your comment. We have added TA1041 to the list of relevant technology appraisals.
	Oncogene Cancer Research	We strongly support the draft scope and welcome NICE's commitment to evaluating a treatment option in an area of urgent and longstanding unmet need. Ensuring that this evaluation progresses at pace is vital for patients who have very limited time and very few alternatives.	Comment noted. No actioned needed.
	British Thoracic Oncology Group	Resource implications for its administration in the NHS + There are some international centres utilising semi-ambulatory / long day administration of antibody-drug conjugates to reduce impact on health services.	Comment noted. No actioned needed.