National Institute for Health and Care Excellence

Health Technology Evaluation

Serplulimab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer [ID6346]
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	Accord Healthcare	The company agrees that NICE should consider this topic for appraisal. The single technology appraisal route is most appropriate for serplulimab.	Thank you for your comment. No action.
Wording	Accord Healthcare	The wording of the remit is accurate, and the company suggests no further changes.	Thank you for your comment. No action.
Timeliness	Accord Healthcare	The urgency of this evaluation to the NHS is high. Lung cancer causes a huge global burden and is the leading cause of cancer-related deaths worldwide (1). The most aggressive sub-type of lung cancer (presented in <15% of all lung cancer cases) is small cell lung cancer (SCLC), displaying rapid growth and early tendency to metastases, resulting in poor prognosis (2).	Thank you for your comment. No action needed.

Section	Stakeholder	Comments [sic]	Action
		Approximately 70% of SCLC patients present with extensive-stage disease (ES-SCLC) at diagnosis with a median overall survival of less than one year and a 5-year survival rate of >7% (3, 4). Serplulimab has demonstrated meaningful and consistent benefits over chemotherapy alone in improving overall survival and also demonstrated longer progression free survival in patients with previously untreated EC-SCLC when administered in combination with carboplatin and etoposide (5). It is therefore of high importance that this intervention be considered for approval by NICE.	
Additional comments on the draft remit	Accord Healthcare	No further comments.	No action.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Accord Healthcare	The background is defined appropriately.	Thank you for your comment. No action.
Population	Accord Healthcare	The population is defined appropriately.	Thank you for your comment. No action.
Subgroups	Accord Healthcare	There are no subgroups that should be considered separately. NICE should evaluate serplulimab for use in all patients with extensive-stage small-cell lung cancer.	Thank you for your comment. No action.

Section	Consultee/ Commentator	Comments [sic]	Action
Comparators	Accord Healthcare	The comparators are defined appropriately.	Thank you for your comment. No action.
Outcomes	Accord Healthcare	The outcomes are defined appropriately.	Thank you for your comment. No action.
Equality	Accord Healthcare	The company have identified no issues in the draft remit or scope pertaining to equality.	Thank you for your comment. No action.
Other considerations	Accord Healthcare	The company believes no other considerations need to be covered at this point in time.	Thank you for your comment. No action.
Questions for consultation		Where do you consider serplulimab will fit into the existing care pathway for extensive stage SCLC? Platinum-based chemotherapy is the current standard of care for 1L ES-SCLC, as per the NICE guidelines (6). Serplulimab will be offered as another option for previously untreated ES-SCLC patients. Please select from the following, will serplulimab be: • Prescribed in primary care with routine follow-up in primary care • Prescribed in secondary care with routine follow-up in primary care • Prescribed in secondary care with routine follow-up in secondary care • Other (please give details): It is believed that serplulimab will be prescribed in secondary care with routine follow-up in secondary care.	Thank you for your comments. No change to the scope needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		<u>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</u> It is expected that there should be no changes to the current setting for prescribing and routine follow-up for serplulimab compared to current therapies. <u>Would serplulimab be a candidate for managed access?</u> It is not expected that serplulimab would be recommended under a managed access scheme. <u>Do you consider that the use of serplulimab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</u> We don't believe there are any additional benefits that are uncaptured in the QALY calculation at this time. <u>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</u> • ASTRUM-005 is the pivotal phase III randomised control trial to be considered for the efficacy of serplulimab versus platinum-based chemotherapy. • There is also a network meta-analysis to compare the efficacy and safety of serplulimab with other treatments recommended by the European Society for Medical Oncology. • Efficacy for atezolizumab is informed by an indirect treatment comparison.	

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft scope	Accord Healthcare	No additional comments.	

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

None.