National Institute for Health and Care Excellence

Single Technology Appraisal

Durvalumab for treating limited-stage small-cell lung cancer after chemoradiation [ID5073]
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	AstraZeneca	The proposed route (single technology appraisal) is considered appropriate for this evaluation.	Thank you for your comment.
Wording	AstraZeneca	The wording of the remit reflects the issue(s) of clinical and cost effectiveness about this technology that NICE should consider.	Thank you for your comment.
Additional comments on the draft remit	AstraZeneca	No timing issues identified.	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AstraZeneca	The background information in the draft scope is accurate and aligned with AstraZeneca's understanding.	Thank you for your comment.
Population	AstraZeneca	The expected license wording is as follows: [redacted]	Thank you for your comment. The population has been amended to better reflect this.
Subgroups	AstraZeneca	There are no subgroups within the population that should be considered separately. Clinical data from the ADRIATIC trial demonstrates a consistent treatment effect for durvalumab across the trial population.[1] 1. David R. Spigel et al., ADRIATIC: Durvalumab (D) as consolidation treatment (tx) for patients (pts) with limited-stage small-cell lung cancer (LS-SCLC).. JCO 42, LBA5-LBA5(2024). DOI:10.1200/JCO.2024.42.17_suppl.LBA5	Thank you for your comment. The subgroups have been kept inclusive at this stage and type of chemoradiation has been added to allow committee to consider any relevant evidence identified.
Comparators	AstraZeneca	Following treatment with chemoradiotherapy, the established clinical management is active monitoring. AstraZeneca is therefore aligned with the draft scope in relation to the comparator.	Thank you for your comment.
Outcomes	AstraZeneca	Disease free survival (DFS) is not an appropriate outcome for this appraisal. This outcome is typically used in clinical trials of adjuvant therapies (therapies used after resection of a tumour). The ADRIATIC trial studied durvalumab in stage I-III, adult LS-SCLC patients whose disease has not progressed following chemoradiation therapy and did not collect DFS[2-4].	Thank you for your comment. The scope has been amended to reflect this.

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		AstraZeneca considers all other outcomes listed in the draft scope to be appropriate. 2. Food and Drug Administration (FDA). Clinical Trial Endpoints for the Approval of Lung Cancer Drugs and Biologics Guidance for Industry. Available from: https://www.fda.gov/media/71195/download. 2018. Last accessed: August 2024. 3. European Medicines Agency (EMA). Guideline on the evaluation of anticancer medicinal products in man. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-evaluation-anticancer-medicinal-products-man-revision-4_en.pdf. Last accessed: August 2024. 4. ClinicalTrials.gov. Study of Durvalumab + Tremelimumab, Durvalumab, and Placebo in Limited Stage Small-Cell Lung Cancer in Patients Who Have Not Progressed Following Concurrent Chemoradiation Therapy (ADRIATIC). Available from: https://clinicaltrials.gov/study/NCT03703297. Last accessed: August 2024.	
Equality	AstraZeneca	No equality issues have been identified.	Thank you for your comment.
Other considerations	AstraZeneca	No additional issues.	Thank you for your comment.
Questions for consultation	AstraZeneca	**Where do you consider durvalumab will fit into the existing care pathway for limited-stage SCLC?** Durvalumab is anticipated to be positioned following the treatment of chemoradiotherapy for patients with LS-SCLC. **Would durvalumab be a candidate for managed access?**	Thank you for your responses to the consultation questions. These have been

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		The available evidence for durvalumab in LS-SCLC is expected to be appropriate for routine commissioning decision making. **Do you consider that the use of durvalumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** QALY calculations are expected to include all substantial health-related benefits. **Are the outcomes suggested above complete and appropriate?** With the exception of DFS, all other suggested outcomes are deemed to be complete and appropriate. Progression-free survival (PFS) and overall survival (OS) are the most relevant outcomes and are dual-primary endpoints within the ADRIATIC trial. **Are the comparators suggested above complete and appropriate?** Yes, the comparator suggested (active monitoring) is complete and appropriate. There are currently no treatment options for LS-SCLC patients following chemoradiation therapy. Active monitoring involves physical examinations and radiographic imaging at regular intervals to facilitate earlier diagnosis and treatment in the case of disease progression. **Would topotecan as recommended in TA184 be used as a maintenance treatment after chemoradiotherapy in NHS clinical practice?** Topotecan would not be considered as maintenance treatment as it is used only in patients who have relapsed following chemotherapy. This patient population does not align with that of durvalumab from the ADRIATIC trial, with whom patients would receive treatment immediately following chemoradiotherapy.	considered while finalising the scope.

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		Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. **AstraZeneca would like the committee to consider clinical trial data from the ongoing ADRIATIC study (NCT03703297).**	
Additional comments on the draft scope	AstraZeneca	None	N/A

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

British Thoracic Oncology Group

Roy Castle Lung Cancer Foundation