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GmbH

Tarlatamab (IMDYLLTRA®) for the treatment of extensive-stage small cell lung cancer

Health Technology Assessment

Appendix

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Project Team

Project lead: Dr. Tatiana Marschik

AIHTA Appraisal Board Author Group:
Alba Colicchia, BSc MPH; Daniel Fabian, MSc; PharmDr. Eva Malíková, PhD
Dr. Tatiana Marschik; Michaela Riegelnegg, BSc MA; Dr. med. Eleen Rothschedl
Diana Szivakova, MA; Priv.-Doz. Dr. phil. Claudia Wild; Sarah Wolf, MSc

Project Support

Literature Search & Information Retrieval: Tarquin Mittermayr, BA(Hons), MA

Internal Review: Sarah Wolf MSc, Dr. MMag. Sabine Geiger-Gritsch

Correspondence: HTA-Austria Appraisal Board Team, bewertungsboard@aihta.at

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Dr. rer. soc. oec. Ingrid Zechmeister-Koss, MA, managing director

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List of abbreviations

AE..... Adverse Event
AIC ..... Akaike Information Criterion
ASP..... Average Sales Price
BIC ..... Bayesian Information Criterion
BNF..... British National Formulary
BSA..... Body Surface Area
BSC ..... Best Supportive Care
CAD ..... Canadian Dollar
CAS ..... Cancer Analysis Service
CAV..... Cyclophosphamide + Doxorubicin (Adriamycin) + Vincristine
CDA-AMC..... Canada's Drug Agency
CDF ..... Cancer Drugs Fund
CE..... Cost-Effectiveness
CHEC..... Consensus on Health Economic Criteria
CHEERS..... Consolidated Health Economic Evaluation Reporting Standards
CI..... Confidence Interval
CMS ..... Centers for Medicare & Medicaid Services
CRS ..... Cytokine Release Syndrome
CUA ..... Cost-Utility Analysis
DLL3..... Delta-Like Ligand 3
DSA..... Deterministic Sensitivity Analysis
EAG..... External Assessment Group
ECOG..... Eastern Cooperative Oncology Group
EQ-5D-3L ..... EuroQol 5-Dimension 3-Level (preference-based quality of life instrument)
EQ-5D-5L ..... EuroQol 5-Dimension 5-Level (preference-based quality of life instrument)
ES-SCLC ..... Extensive-Stage Small-Cell Lung Cancer
FDA..... Food and Drug Administration
GDP ..... Gross Domestic Product
HCUP ..... Healthcare Cost and Utilization Project
HR..... Hazard Ratio
HRQoL ..... Health-Related Quality of Life
ICANS..... Immune Effector Cell-Associated Neurotoxicity Syndrome
ICER ..... Incremental Cost-Effectiveness Ratio
ITC ..... Indirect Treatment Comparison
IV..... Intravenous
KM ..... Kaplan-Meier
LY..... Life-Year

MAIC ..... Matching-Adjusted Indirect Treatment Comparison
NCCN ..... National Comprehensive Cancer Network
NHS..... National Health Service
NIC..... Net Ingredient Cost
NICE..... National Institute for Health and Care Excellence
NRDL ..... National Reimbursement Drug List
ORR..... Objective Response Rate
OS ..... Overall Survival
PartSA..... Partitioned Survival Analysis (model)
PD ..... Progressive Disease
PD-L1 ..... Programmed Death-Ligand 1
PFS..... Progression-Free Survival
PSA..... Probabilistic Sensitivity Analysis
PSM..... Partitioned Survival Model
PSS ..... Personal Social Services
QALY..... Quality-Adjusted Life-Year
QoL ..... Quality of Life
RCT..... Randomised Controlled Trial
RDI..... Relative Dose Intensity
RMB ..... Renminbi (Chinese currency)
SCLC..... Small-Cell Lung Cancer
SMR ..... Standardised Mortality Ratio
TTD ..... Time to Treatment Discontinuation
UK..... United Kingdom
US / USA ..... United States (of America)
USD..... US Dollar
VAT..... Value-Added Tax
WTP ..... Willingness-To-Pay

1 Introduction

1.1 Disease background

No content.

1.2 Standard of care in Austria

No content.

1.3 Medicinal product under evaluation

No content.

2 Scope of assessment

2.1 Research questions

No content.

2.2 Inclusion criteria

No content.

3 Methods

Guiding questions [1]

Table 3-1: Health problems and current use

Element ID	Research question
A0001	For which health conditions, and for what purposes, is the technology used?
A0002	What is the disease or health condition in the scope of this assessment?
A0003	What are the known risk factors for the disease or health condition?
A0004	What is the natural course of the disease or health condition?
A0005	What is the burden of disease for patients with the disease or health condition?
A0006	What are the consequences of the disease or health condition for society?
A0024	How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025	How is the disease or health condition currently managed according to published guidelines and in practice?
A0007	What is the target population in this assessment?
A0023	How many people belong to the target population?

Table 3-2: Description of the technology

Element ID	Research question
B0001	What is the technology and the comparator(s)?
A0020	For which indications has the technology received marketing authorisation or CE marking?
B0002	What is the claimed benefit of the technology in relation to the comparators?
B0003	What is the phase of development and implementation of the technology and the comparator(s)?
B0004	Who administers the technology and the comparators, and in what context and level of care are they provided?
B0008	What kind of special premises are needed to use the technology and the comparator(s)?
B0009	What supplies are needed to use the technology and the comparator(s)?
A0018	What are the other typical or common alternatives to the current technology?
A0022	Who manufactures the technology?

Table 3-3: Economic aspects

Element ID	Research question
E0001	What types of resources are used when delivering the assessed technology and its comparators (resource-use identification)?
A0002	What amounts of resources are used when delivering the assessed technology and its comparators (resource-use measurement)?
E0009	What were the measured and/or estimated costs of the assessed technology and its comparator(s)?
G0007	What are the likely budget impacts of implementing the technologies being compared?
E0005	What is (are) the measured and/or estimated health-related outcome(s) of the assessed technology and its comparator(s) (outcome identification, measurement and valuation)?
E0006	What are the estimated differences in costs and outcomes between the technology and its comparator(s)?

Element ID	Research question
E0010	What are the uncertainties surrounding the costs and economic evaluation(s) of the technology and its comparator(s)?
E0013	What methodological assumptions were made in relation to the technology and its comparator(s)?
E0012	To what extent can the estimates of costs, outcomes, or economic evaluation(s) be considered as providing valid descriptions of the technology and its comparator(s)?

Table 3-4: Organisational, ethical and social aspects

Element ID	Research question
G001	How does the technology affect the current work processes?
G002	What kind of involvement has to be mobilised for patients/participants and important others and/or caregivers?
H0200	What are the experiences of living with the condition?
H0100	What expectations and wishes do patients have with regard to the technology, and what do they expect to gain from the technology?
H0002	What is the burden on caregivers?
H0202	How are treatment choices explained to patients?

4 Clinical effectiveness and safety

No content.

5 Price comparisons, treatment costs and budget impact

5.1 Pharmacoeconomic model(s)

5.1.1 Submitted pharmaco-economic model

No pharmaco-economic model was submitted by the MAH.

5.1.2 Economic evaluation based on pharmaco-economic models

Table 5-1: Economic evaluation of tarlatamab in adult patients with extensive-stage small-cell lung cancer

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
Canada's Drug Agency (CDA-AMC) 2025 [2]	Canada	**Tarlatamab** (IV: step-up dosing: 1 mg on day 1, 10 mg on day 8 and day 15, then 10 mg every 2 weeks in subsequent 28-day cycles until disease progression); submitted price: CAD $1,545/1 mg vial; CAD $15,450/10 mg vial	Adult patients with extensive-stage small-cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy (third-line or later setting)	Cost-utility analysis; outcomes reported as LYs, QALYs, and ICER (CAD$/QALY gained)	Partitioned survival model (PSM) with 3 health states: progression-free, post-progression, and death. All patients enter in the progression-free state. Proportion in each health state derived from area under non-mutually exclusive survival curves: PFS curve = proportion progression-free; OS minus PFS = proportion post-progression.	Canadian publicly funded healthcare payer perspective Lifetime time horizon of 20 years (weekly cycles)	**Sponsor submission:** Health state utilities derived from patient-level EQ-5D-5L data collected in the DeLLphi-301 trial (data cut-off: June 27, 2023), valued using Canadian tariffs: progression-free = 0.834; post-progression = 0.755 AE disutilities applied for grade ≥3 AEs occurring in >3% of patients, plus grade 1/2 CRS and ICANS (tarlatamab-specific)	Not applicable / not reported No severity modifier framework was applied in this Canadian CDA-AMC review	1.5% per annum applied to both costs and outcomes	**Key sponsor assumptions:** (1) Basket comparator regimen distribution sourced from an Albertan real-world cohort while efficacy was derived from the US Flatiron database, inconsistent sources for cost and efficacy inputs

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
		Basket comparator consisting of: topotecan; platinum agent + etoposide; cyclophosphamide + doxorubicin + vincristine (CAV); etoposide monotherapy; and irinotecan. Regimen distribution based on an Albertan retrospective cohort study.			Sponsor selected log-logistic distribution for OS and generalised gamma for PFS (both arms). CDA-AMC reanalysis applied Weibull for tarlatamab OS, gamma for basket comparator OS, and gamma for PFS in both arms. All analyses run probabilistically (5,000 iterations)		**CDA-AMC reanalysis:** Applied alternative utility values from published Canadian literature (Vellani et al.): progression-free = 0.720; post-progression = 0.520, on the grounds that the sponsor's values lacked face validity: the PFS utility (0.834) was near-equivalent to the Canadian age-matched general population norm (0.839), which is implausible given the severity and treatment burden of third-line ES-SCLC			Estimated drug acquisition cost: $27,740 for first cycle; $26,420 for subsequent cycles (based on 85.5% RDI). Estimated 28-day basket comparator cost: $2,216/patient (2) First 2 tarlatamab doses administered in inpatient setting (24-hour hospitalisation on day 1 and day 8 of cycle 1) (3) Disutilities and costs for grade 1/2 CRS and ICANS included, with CRS hospitalisation assumed to be 1 day (likely an underestimate) (4) A proportion of patients assumed to receive subsequent active treatment post-progression (5) Tarlatamab discontinued upon disease progression per product monograph

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
										(6) Drug wastage accounted for in both arms (7) RDI of 85.5%[1] applied to tarlatamab, biasing acquisition costs in favour of tarlatamab relative to most basket comparator agents (RDI 93%–100%)
National Institute for Health and Care Excellence (NICE), 2025 [3]	United Kingdom (England; NHS perspective)	**Tarlatamab** (IV; step-up dosing: 1 mg on day 1, 10 mg on day 8 and day 15, then 10 mg every 2 weeks thereafter in 28-day cycles until disease progression). List price: £955/1 mg vial; £9,550/10 mg vial (excluding VAT). A confidential commercial arrangement was in place	Adult patients with ES-SCLC with disease progression on or after at least 2 prior lines of therapy, including platinum-based chemotherapy, and with an ECOG performance status of 0 or 1. This reflects the marketing authorisation indication and the NHS England commissioning criteria.	Cost-utility analysis; outcomes reported as QALYs (with severity-weighted QALYs) and ICER (£/QALY gained). Both deterministic and probabilistic results presented; probabilistic results preferred for decision making	Partitioned survival model (PSM) with 3 health states: progression-free, progressed disease, and death. All patients enter in the progression-free state. Proportion in each health state derived from area under non-mutually exclusive survival curves (PFS and OS). Proportional hazards assumption did not hold for either PFS or OS; therefore, parametric curves fitted separately to each treatment arm.	UK NHS and Personal Social Services (PSS) payer perspective Time horizon not explicitly stated in the guidance text but consistent with a lifetime horizon as per NICE reference case	Health-state utility values derived from EQ-5D-5L data collected in the DeLLphi-301 trial, mapped to the EQ-5D-3L value set using the NICE reference case crosswalk **Committee's preferred values:** MAIC-adjusted population utility values (adjusted to reflect characteristics of the UK CAS study population), as these were considered to better represent patients receiving standard care	**Applied: severity weight of 1.7.** In both the company and EAG base cases, the proportional QALY shortfall was greater than 0.95, meeting the NICE threshold for the highest severity weight (1.7) per NICE's health technology evaluations manual.	Not explicitly stated in the guidance text; standard NICE reference case applies a discount rate of 3.5% per annum for both costs and health outcomes	**Key modelling assumptions:** (1) Basket of standard care chemotherapy as the only relevant comparator (best supportive care excluded) (2) Unanchored MAIC with UK CAS study used as the preferred ITC source for standard care efficacy (3) TTD used as a proxy for PFS in the standard care arm (UK CAS study did not collect PFS data)

[1] An RDI of 85.5% means that, on average, patients only received 85.5% of the total planned dose of tarlatamab, for example, due to dose delays, dose reductions, or treatment interruptions caused by toxicity such as CRS or ICANS.

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
		Basket of standard care chemotherapy treatments reflecting UK clinical practice, based on distribution from the UK Cancer Analysis Service (CAS) study: topotecan (42%), CAV (38%), and platinum-based chemotherapy with etoposide (20%). *Best supportive care was explicitly excluded as a comparator, as the committee concluded it was not relevant for patients well enough to receive tarlatamab (ECOG status 0 or 1)*	Clinical experts confirmed that tarlatamab would only be considered for patients with sufficient physiological reserve to tolerate its toxicity profile		**Preferred parametric distributions (committee's preferred assumptions):** OS: gamma distribution for both tarlatamab and standard care; PFS: log-normal for tarlatamab, TTD used as proxy for PFS in standard care arm (generalised gamma); TTD: generalised gamma for both arms Clinical data for tarlatamab from DeLLphi-301 (October 2023 data cut, MAIC-weighted and censored for post-progression use) Clinical data for standard care from the UK CAS study (via unanchored MAIC) Both company submission and EAG exploratory base case presented; committee preferred EAG assumptions where these differed		Pre-progression utility: unchanged from full trial population value Post-progression utility: slightly higher than full trial population value in the MAIC-adjusted population The committee acknowledged utility values may be higher than expected in real-world ES-SCLC practice (trial selection bias; inclusion of patients who continued tarlatamab post-progression in the progressed utility calculation), but preferred trial-based estimates over the EAG alternative (Chouaid et al. 2013, NSCLC utility values), which were considered less clinically relevant. AE costs modelled for grade ≥3 AEs occurring in >3% of patients in either arm, plus grade 1/2 CRS and ICANS	The committee concluded the 1.7 severity weight was appropriate and that unmet need was captured by this modifier. No additional uncaptured benefits were identified beyond those already reflected in the economic model and severity weighting		(4) Proportional hazards assumption did not hold: separate parametric curves fitted to each arm (5) Gamma distribution applied to OS for both arms; generalised gamma for TTD in both arms; log-normal for tarlatamab PFS (6) Post-progression tarlatamab use in DeLLphi-301 censored from OS and TTD analyses (7) Grade ≥3 AEs with >3% incidence in either arm included, plus grade 1/2 CRS and ICANS (8) One-off tocilizumab cost included for CRS management (9) Inpatient hospitalisation assumed for first 2 tarlatamab doses (10) Severity weight of 1.7 applied to QALYs

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
							EAG's weighted-average approach to AE costs preferred over company's use of most expensive healthcare resource group code			
Zheng H, Wen F, Wu B, 2026 [4]	United States	**Tarlatamab (**IV step-up dosing: 1 mg on day 1, 10 mg on days 8 and 15, then 10 mg every 2 weeks in 28-day cycles**)** Drug cost: $1,611.28/mg (range $1,289.02–$1,933.54), sourced from October 2025 Medicare Part B average sales price (CMS) and Drugs.com price guide Median treatment duration: 4.2 months	Adults (≥18 years) with ES-SCLC who experienced disease progression during or after first-line platinum-based chemotherapy (second-line setting)	Cost-utility analysis; primary outcome: ICER ($/QALY gained) Model outputs: total costs, incremental costs, QALYs, and incremental QALYs Reported in accordance with the CHEERS checklist	Partitioned survival model (PartSA) with 3 health states: PFS, progressive disease (PD), and death; all patients enter in the PFS state; transitions between mutually exclusive health states at each cycle Cycle length: 28 days; time horizon: 10 years KM curves digitised using WebPlot Digitizer; individual patient data reconstructed using the survHE package in R (version 4.2.3) Best-fitting parametric distributions selected based on AIC, BIC, and visual assessments: tarlatamab: log-normal for PFS (meanlog=1.414, sdlog=1.113); exponential for OS (rate=0.0487)	US healthcare payer perspective (direct medical costs only) Time horizon: 10 years (28-day cycles)	Utility values not available from the DeLLphi-304 trial and sourced from published literature based on EQ-5D-5L assessments: PFS = 0.70 (range 0.56–0.84; Vedadi et al. 2021 and Gan et al. 2023) PD = 0.60 (range 0.48–0.72; Yi et al. 2024)	Not applicable / not reported No severity modifier framework was applied; this is consistent with standard US pharmacoeconomic methodology, which does not employ a NICE-equivalent severity weighting system	3% per annum applied to both costs and health outcomes, per the recommendations of the Second Panel on Cost-Effectiveness in Health and Medicine (Sanders et al., JAMA, 2016)	**Key assumptions:** (1) Direct medical costs only included: drug acquisition, follow-up, BSC, AE management, and end-of-life care (2) **O**nly grade 3/4 AEs with >5% incidence in the clinical trial included; AE costs treated as one-time expenditures (3) **E**qual distribution assumed between IV and oral topotecan as the DeLLphi-304 trial did not report this split

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
		Chemotherapy basket consisting of topotecan (IV: $747.79/mg; oral: $519.28/mg) and lurbinectedin ($2,071.27/mg), reflecting the DeLLphi-304 trial control arm (185 patients received topotecan; 47 patients received lurbinectedin); **e**qual distribution assumed between IV and oral topotecan as the trial did not specify the split; **a**mrubicin excluded as it is not approved in the US Median chemotherapy treatment duration: 2.5 months			Chemotherapy: log-normal for PFS (meanlog=1.202, sdlog=0.843); log-logistic for OS (shape=1.507, scale=8.653) Gompertz distribution excluded from scenario analyses due to PFS/OS curve crossover inconsistent with clinical expectations		AE disutility decrements incorporated for grade ≥3 AEs with >5% incidence in either arm, sourced from published literature (Nafees et al. 2017; Yi et al. 2024): hyponatremia -0.09; pneumonia -0.07; fatigue -0.07; neutrophil count decrease -0.20; platelet count decrease -0.05; febrile neutropenia -0.20; thrombocytopenia -0.20; leukopenia -0.20; neutropenia -0.09; anaemia -0.07			(4) **P**ost-progression (third-line) treatment assumed to be nivolumab or pembrolizumab for patients receiving further anticancer therapy, based on CheckMate 032 and KEYNOTE-028/158 trial data; patients not receiving further treatment assumed to receive BSC (5) **A**verage body weight of 77.5 kg and BSA of 1.86 m^2 assumed for drug dosing calculations (6) **D**rug costs obtained from CMS Medicare Part B ASP (October 2025) and Drugs.com where CMS data unavailable**:** listed/retail prices may overestimate actual acquisition costs (7) **U**tility values borrowed from prior published studies as no QoL data were available from DeLLphi-304

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
Liu X, Wu Q, Li Q, Qin Y, 2026 [5]	United States and China	**Tarlatamab (**IV; step-up dosing: 1 mg on day 1, 10 mg on days 8 and 15, then 10 mg every 2 weeks in subsequent 28-day cycles**)** **Initial tarlatamab cycle capture 3 administrations (days 1, 8, 15) plus step-up intensive monitoring; subsequent cycles normalised to 2 administrations / month with routine outpatient monitoring** US drug cost: $1,567.49/mg (sourced from CMS Medicare Part B ASP files, October 2025) Chinese drug cost assumed at one-third of US price ($522.50/mg), reflecting pricing patterns of comparable imported immune-oncology agents (39-42% of US levels) and anticipated NRDL-driven discounts, as tarlatamab is not yet marketed in China	Adults with ES-SCLC who experienced disease progression during or after first-line platinum-based chemotherapy (second-line setting) **Subgroup analyses conducted for:** (1) Age (<65 vs. ≥65 years) (2) Sex (male/female) (3) Region (White/Asian) (4) Prior anti-PD-(L)1 exposure (yes/no) (5) Chemotherapy-free interval (<90 days; ≥90 days; ≥90 to <180 days; ≥180 days) (6) Brain metastases (yes/no) (7) Liver metastases (yes/no) (8) Chemotherapy type (topotecan/ amrubicin vs lurbinectedin)	Cost-utility analysis; primary outcomes: QALYs and ICER ($/QALY gained) Additional outputs: LYs, total costs, incremental costs Reported in accordance with CHEERS 2022 guidelines	Three-state Markov cohort model with health states: PFS (active treatment and ongoing monitoring), PD (palliative and supportive care), and death (absorbing state) PFS and OS KM curves digitised from DeLLphi-304 using WebPlotDigitizer; pseudo-individual patient data reconstructed following Hoyle and Henley (2011) Parametric survival models fitted (exponential, Weibull, Gompertz, log-logistic, log-normal, generalised gamma); model fit evaluated by AIC, BIC, and visual inspection Key methodological innovation: AIC-weighted Bayesian model averaging applied rather than a single parametric distribution, to account for structural uncertainty in extrapolation choice	Healthcare payer perspective for both the United States and China Lifetime time horizon (1-month cycles)	Health state utilities derived from a published real-world observational study specific to SCLC patients (Vedadi et al., 2021), given absence of QoL data in DeLLphi-304 Utility values assumed transferable across US and Chinese modelled cohorts given biological uniformity of ES-SCLC and universal symptom burden: PFS = 0.70; PD = 0.60; death = 0 Disutility decrements applied as one-time decrements in the first model cycle for grade ≥3 AEs with incidence ≥5% and all-grade CRS in the tarlatamab arm, sourced from published literature (Lee et al., 2015; Nafees et al., 2017; Yang et al., 2019) To address uncertainty in cross-national utility transfer, an exploratory sensitivity analysis varied baseline utility values by ±50%	Not applicable / not reported No severity modifier framework applied; consistent with US and Chinese pharmacoeconomic methodology, neither of which employs a NICE-equivalent severity weighting system	United States: 3% per annum for both costs and health outcomes (per Sanders et al./Second Panel on Cost-Effectiveness in Health and Medicine recommendations) China: 5% per annum for both costs and health outcomes (per Chinese pharmacoeconomic evaluation guidelines, Yue et al., 2021)	**Key assumptions:** (1) Direct medical costs only included: drug acquisition and administration, routine monitoring and follow-up, grade ≥3 AE management (incidence ≥5%) plus all-grade CRS for tarlatamab, subsequent systemic therapies post-progression, BSC, and end-of-life care (2) Chinese tarlatamab price assumed at one-third of US list price, consistent with pricing patterns for comparable imported immuno-oncology agents and anticipated NRDL-driven discounts (3) AIC-weighted Bayesian model averaging applied to account for structural uncertainty in survival extrapolation rather than single distribution selection

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
		Chemotherapy basket reflecting DeLLphi-304 control arm: topotecan (IV 1.5 mg/m^2 or oral 2.3 mg/m^2, days 1–5 every 3 weeks) and lurbinectedin (3.2 mg/m^2 IV, day 1 every 3 weeks) Post-progression (subsequent) treatment regimens modelled separately for the US and China to reflect local clinical practice guidelines, with proportions derived from DeLLphi-304 trial data; remaining patients assumed to receive BSC			Cycle-specific transition probabilities derived from fitted parametric survival functions in conjunction with background (age- and sex-matched) mortality data Transition from PFS to death set to background mortality rate to avoid double-counting cancer-related deaths Transition from PFS to PD computed as residual Transition within PD state derived algebraically to match target OS prevalence (OS – PFS) Price-simulation analyses conducted to identify tarlatamab per-mg threshold prices achieving cost-effectiveness at prespecified WTP thresholds in both countries					(4) **T**ransition from PFS to death set equal to background age- and sex-matched mortality rate to avoid double-counting cancer-related deaths (5) **P**ost-progression treatment regimens modelled separately for US and China to reflect local practice guidelines (6) **U**tility values assumed transferable from US-based observational SCLC cohort (Vedadi et al., 2021) to Chinese population (7) AE costs treated as one-time decrements in first model cycle (base case) (8) **S**ubgroup-specific chemotherapy survival assumed identical across subgroups with HR adjustments applied to OS and PFS

Author, year (REF)	Country	Intervention and comparator	Target population (base case)	Economic evaluation	Model	Perspective and time horizon	Utility values	Severity modifier	Discount rate	Model assumptions
										(9) Chinese costs converted at 2025 exchange rate ($1 = RMB 7.1371); all costs inflated to 2025 USD using medical-specific indices **(10)** Dosing assumptions based on average body weight and BSA values for US and Chinese populations respectively

Abbreviations: AE…Adverse Event, AIC…Akaike Information Criterion, ASP…Average Sales Price, BIC…Bayesian Information Criterion, BNF…British National Formulary, BSA…Body Surface Area, BSC…Best Supportive Care, CAD…Canadian Dollar, CAS…Cancer Analysis Service (UK CAS study), CAV…Cyclophosphamide + Doxorubicin + Vincristine, CDA-AMC…Canada's Drug Agency - Agence des médicaments du Canada, CDF…Cancer Drugs Fund, CHEERS…Consolidated Health Economic Evaluation Reporting Standards, CI…Confidence Interval, CMS…Centers for Medicare & Medicaid Services, CRS…Cytokine Release Syndrome, CUA…Cost-Utility Analysis, DLL3…Delta-Like Ligand 3, EAG…External Assessment Group, ECOG…Eastern Cooperative Oncology Group, EQ-5D-5L…EuroQol 5-Dimension 5-Level (preference-based quality of life instrument), ES-SCLC…Extensive-Stage Small-Cell Lung Cancer, FDA…Food and Drug Administration, GDP…Gross Domestic Product, HCUP…Healthcare Cost and Utilization Project, HR…Hazard Ratio, HRQoL…Health-Related Quality of Life, ICANS…Immune Effector Cell-Associated Neurotoxicity Syndrome, ICER…Incremental Cost-Effectiveness Ratio, ITC..Indirect Treatment Comparison, IV…Intravenous, KM…Kaplan-Meier, LY…Life-Year, MAIC…Matching-Adjusted Indirect Treatment Comparison, NCCN…National Comprehensive Cancer Network, NHS…National Health Service, NICE…National Institute for Health and Care Excellence, NRDL…National Reimbursement Drug List, ORR…Objective Response Rate, OS…Overall Survival, PartSA…Partitioned Survival Analysis, PD…Progressive Disease, PDL1…Programmed Death-Ligand 1, PFS…Progression-Free Survival, PSA…Probabilistic Sensitivity Analysis, PSM…Partitioned Survival Model, QALY…Quality-Adjusted Life Year, QoL…Quality of Life, RCT…Randomised Controlled Trial, RDI…Relative Dose Intensity, RMB…Renminbi (Chinese currency), SCLC…Small-Cell Lung Cancer, SMR…Standardised Mortality Ratio, TTD…Time to Treatment Discontinuation, USD…US Dollar, VAT…Value Added Tax, WTP…Willingness-To-Pay

Table 5-2: Main results of the included economic evaluations of tarlatamab in adult patients with extensive-stage small-cell lung cancer

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
Canada's Drug Agency (CDA-AMC) 2025 [2]	Canada	**Sponsor's base case:** Tarlatamab total cost: CAD $221,531 vs basket comparator: CAD $32,400 → incremental cost: CAD $189,132. Drug acquisition costs accounted for 91% of tarlatamab's total expected costs **CDA-AMC reanalysis base case:** Tarlatamab total cost: CAD $255,623 vs basket comparator: CAD $33,422 → incremental cost: CAD $222,201. Drug costs again comprised 91% of total tarlatamab costs. Tarlatamab was more costly than the basket comparator in all stepped reanalyses	**Sponsor's base case:** Tarlatamab: 1.93 QALYs vs basket comparator: 0.87 QALYs → incremental gain: 1.06 QALYs; incremental LY gain: 0.42. Of the incremental QALY benefit, 57% was derived from the extrapolated period beyond observed trial data. At end of 20-year horizon, 2.0% of tarlatamab patients and 0.3% of basket comparator patients remained alive. The key QALY driver was the utility value for the progression-free health state **CDA-AMC reanalysis base case:** Tarlatamab: 0.93 QALYs vs basket comparator: 0.53 QALYs → incremental gain: 0.40 QALYs; incremental LY gain: 0.65. Proportion of incremental QALYs derived from extrapolated period reduced to 30% (from 57% in sponsor's base case), reflecting the more conservative OS extrapolations applied by CDA-AMC.	**Sponsor's base case ICER:** CAD $178,286/QALY gained **CDA-AMC reanalysis base case ICER:** CAD $559,946/QALY gained CE threshold: CAD $50,000/QALY gained (Canadian publicly funded healthcare payer WTP threshold). At this threshold, the probability of tarlatamab being cost-effective = 0% in both the sponsor's and CDA-AMC's base cases. A price reduction of 68% (to CAD $494/1 mg vial) would be required based on the sponsor's base case, and 85.6% (to CAD $222/1 mg vial and $2,220/10 mg vial) based on the CDA-AMC reanalysis, to achieve cost-effectiveness at $50,000/QALY	**Sponsor's probabilistic scenario analyses:** ICERs ranged from $121,226/QALY (using oncology outcomes study data for basket comparator efficacy) to $215,756/QALY (using observed DeLLphi-301 treatment duration and OS without post-progression adjustment) Deterministic scenario analyses exploring alternative parametric functions for OS, PFS, and TTD extrapolation were largely aligned with the sponsor's base case. No scenario analysis was conducted from a non-payer perspective **CDA-AMC stepped reanalyses:** (1) Tarlatamab OS changed from log-logistic to Weibull → ICER $531,705/QALY, the single most impactful change, driving the ICER substantially upward (2) Basket comparator OS changed from log-logistic to gamma → ICER $152,305/QALY (3) Tarlatamab PFS changed from generalised gamma to gamma → ICER $190,049/QALY (4) Basket comparator PFS changed from generalised gamma to gamma → ICER $176,873/QALY (5) RDI set to 100% for all treatments → ICER $207,538/QALY (6) Health utilities revised to 0.720 (PFS) and 0.520 (PD) → ICER $219,962/QALY	**Key limitations identified by CDA-AMC:** (1) Absence of head-to-head comparative evidence, DeLLphi-301 was a single-arm phase II trial; indirect treatment comparison (ITC) with Flatiron external control cohort subject to significant risk of selection bias, reduced effective sample size, population heterogeneity, and inadequate confounding adjustment (2) Survival extrapolations (particularly OS for tarlatamab using log-logistic) were considered highly optimistic by clinical experts; sponsor predicted 5-year OS of 12.2% vs near-0% in Canadian real-world data (3) Sponsor's health utilities for progression-free state (0.834) lacked face validity, being near-identical to age-matched general population norms (4) More than half (57%) of incremental QALY gains in sponsor's base case derived from the extrapolated period beyond observed trial data (5) Tarlatamab requires specialised administration settings (inpatient monitoring for CRS/ICANS), which may limit eligible treatment sites (6) Uncertainty about whether patients would continue tarlatamab beyond progression in real-world practice, which could substantially increase costs

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
					(7) Full CDA-AMC base case (all changes combined) → ICER $559,946/QALY **CDA-AMC additional scenario analyses:** (a) Alternative RDI scenario in which both tarlatamab and basket comparator RDI lowered to 85.5% (b) Extended tarlatamab use beyond disease progression, with treatment duration reflecting actual DeLLphi-301 trial use, exploring the real-world possibility that clinicians may continue tarlatamab post-progression given the absence of other treatment options	**The sponsor's base-case ICER of $178,286/QALY is likely a significant underestimate**, driven by three key biases: (1) highly optimistic OS extrapolation using a log-logistic function predicting 5-year OS of 12.2%, compared to near-0% in Canadian real-world third-line ES-SCLC data; (2) health utilities for the progression-free state (0.834) near-equivalent to the Canadian age-matched general population norm (0.839), implausible in a heavily pretreated cancer population; and (3) systematic underestimation of tarlatamab drug costs through asymmetric application of RDI across arms
National Institute for Health and Care Excellence (NICE), 2025 [3]	United Kingdom (England; NHS perspective)	Specific incremental cost figures are not explicitly reported in the published guidance text, as the commercial arrangement between Amgen and NHS England is confidential and the exact discounted price was not disclosed A confidential commercial arrangement was in place that would have applied had tarlatamab been recommended. Drug acquisition costs comprised the key cost driver in both the company and EAG base cases	Specific incremental QALY figures are not explicitly reported in the published guidance text due to confidentiality of the commercial arrangement and associated modelling inputs Utility values applied were derived from EQ-5D-5L data from DeLLphi-301, mapped to EQ-5D-3L using the NICE reference case crosswalk Committee's preferred values were MAIC-adjusted population utilities (adjusted to reflect UK CAS study population characteristics)	**Company base case (post-consultation):** Deterministic ICER = £28,449/QALY gained Probabilistic ICER = £29,134/QALY gained (including confidential commercial arrangement and 1.7 severity weight) **EAG exploratory base case:** Deterministic ICER = £31,437/QALY gained Probabilistic ICER = £35,393/QALY gained (→ **committee's preferred ICER:** probabilistic, EAG base-case assumptions, including 1.7 severity weight and confidential commercial arrangement)	**Survival extrapolation scenarios:** (1) The committee considered multiple parametric distributions for OS, PFS, and TTD across both treatment arms - the ICER was not found to be sensitive to the choice of OS distribution for tarlatamab (company's exponential vs EAG's gamma), supporting the committee's preference for the gamma distribution (2) The choice of TTD extrapolation (exponential vs generalised gamma for tarlatamab) had a greater impact; the committee preferred the generalised gamma as it implied a decreasing risk of treatment discontinuation over time, consistent with the declining AE rate profile of tarlatamab	**Key limitations:** (1) DeLLphi-301 was a single-arm, open-label, uncontrolled phase II trial, no direct head-to-head comparison with chemotherapy (2) Unanchored MAIC subject to substantial systematic error, small effective sample size after matching indicates limited overlap between DeLLphi-301 and UK CAS populations, reducing confidence in relative treatment effect estimates (3) UK CAS study did not include data on prior PDL1 inhibitor use, potentially not reflecting current NHS practice where most patients receive atezolizumab at first line (4) OS and PFS data from DeLLphi-301 were immature at time of submission, with short follow-up, introducing additional extrapolation uncertainty

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
			The key QALY driver was the utility value for the progression-free health state, and more than 57% of incremental QALY benefit in the company's base case was derived from the extrapolated period beyond observed trial data	CE threshold: NICE's standard range of £20,000–£30,000/QALY gained; given the high degree of uncertainty, particularly from the unanchored MAIC, immature survival data, and potentially overestimated utility values, the committee determined that its preferred ICER threshold for decision making was around the middle of this range (i.e., approximately £25,000/QALY gained), applying greater caution than it would for a more certain ICER → the committee's preferred ICER of £35,393/QALY exceeded this threshold, and tarlatamab was therefore not recommended	**(3) TTD as proxy for PFS in standard care arm:** A scenario analysis applying the DeLLphi-301 TTD-to-PFS ratio to the standard care TTD curve was provided by the company at committee request - the EAG confirmed this had minimal impact on cost-effectiveness results; the committee accepted TTD as an acceptable PFS proxy for standard care **ITC scenarios:** The company provided an updated MAIC adjusting for both means and variances of continuous covariates (as requested by the committee at the first meeting); results were similar to the means-only adjustment, with minimal impact on cost-effectiveness. An alternative ITC using individual patient-level data from the US Flatiron database was also submitted; this was considered to introduce more uncertainty than the UK CAS MAIC and was not used for decision making **Utility value scenarios:** MAIC-adjusted utility values (reflecting UK CAS population characteristics) were provided at consultation; post-progression utility was slightly higher than the full DeLLphi-301 population value - impact on ICER was minimal; committee preferred MAIC-adjusted values; the EAG's alternative utility values from Chouaid et al. (2013, NSCLC population) were lower than trial-derived values but considered less clinically relevant.	(5) >57% of incremental QALY benefit in the company's base case derived from the extrapolated period beyond observed trial data (6) Utility values from DeLLphi-301 may overestimate real-world quality of life due to trial selection bias and inclusion of patients who continued tarlatamab post-progression (7) The application of the 1.7 severity modifier, while appropriate given the proportional QALY shortfall, also highlights an important methodological tension: the severity weighting substantially improves the ICER (without it, the ICER would be considerably higher), yet even this adjustment was insufficient to bring tarlatamab within the acceptable threshold under conditions of high evidential uncertainty

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
					AE cost scenarios: EAG replaced the company's use of the most expensive healthcare resource group code for each AE with a weighted average across all available severity levels, and matched febrile neutropenia costs to non-sepsis infection; the committee concluded the EAG approach was more appropriate and consistent with prior NICE appraisals **Post-progression tarlatamab use scenario:** CDA-AMC (in the parallel Canadian review) explored continued tarlatamab use beyond disease progression; the NICE committee similarly acknowledged this as a real-world possibility but the DeLLphi-301 post-progression data were censored in the base case per the product monograph	
Zheng H, Wen F, Wu B, 2026 [4]	United States	Tarlatamab total cost: $392,812.09 vs chemotherapy total cost: $189,479.81 → **incremental cost: $203,332.28** The cost of tarlatamab was the primary cost driver, identified as the most influential parameter Drug acquisition costs accounted for the dominant share of total costs in the tarlatamab arm	Tarlatamab: 1.08 QALYs vs chemotherapy: 0.79 QALYs → **incremental gain: 0.29 QALYs** Utility values applied: PFS = 0.70; PD = 0.60, sourced from published literature (Vedadi et al. 2021; Gan et al. 2023; Yi et al. 2024) as no QoL data were collected in the DeLLphi-304 trial AE disutility decrements incorporated for grade ≥3 AEs with >5% incidence in either arm	**Base-case ICER:** $701,145.79/QALY gained (tarlatamab vs chemotherapy) CE thresholds applied: $150,000/QALY and $200,000/QALY for the US The base-case ICER substantially exceeded both WTP thresholds, rendering tarlatamab not cost-effective at current pricing from the US payer perspective Based on the model, achieving cost-effectiveness at the $200,000/QALY threshold would require an approximately 56% price reduction for tarlatamab compared with standard chemotherapy	**One-way sensitivity analysis:** Parameters varied within ±20% of base-case values. The two most influential parameters were: (1) **C**ost of tarlatamab = the dominant driver (2) Utility of PFS in the tarlatamab arm, followed by utility of PFS in the chemotherapy arm, cost of PD in both arms, utility of PD, cost of chemotherapy, cost of AEs in both arms, and cost of routine follow-up (minimal impact) The ICER consistently exceeded both WTP thresholds across all parameter variations, confirming the robustness of the conclusions **PSA:** 10,000 Monte Carlo iterations conducted**:**	**Key limitations acknowledged by authors:** (1) **L**imited follow-up duration and absence of individual patient data from DeLLphi-304 introduces uncertainty in parametric OS and PFS extrapolations (2) Only grade ≥3 AEs with >5% incidence included, potentially underestimating real-world safety costs**,** though the one-way sensitivity analysis confirmed AE costs have minimal impact on conclusions (3) **D**rug prices from Drugs.com represent listed/retail prices and may overestimate actual acquisition costs (4) **U**tility values derived from prior studies rather than trial-specific data**,** sensitivity analysis confirmed ±20% variation did not alter conclusions

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
			The utility of PFS in the tarlatamab arm was identified as the second most influential parameter, after the cost of tarlatamab, followed by the utility of PFS in the chemotherapy arm		(1) At a WTP threshold of $150,000/QALY, the probability of tarlatamab being cost-effective was 0% (2) With increasing WTP thresholds, the probability of tarlatamab being cost-effective gradually increased, as shown in the cost-effectiveness acceptability curve **Survival extrapolation scenario analyses:** Alternative parametric distributions tested (exponential, Weibull, Gompertz, log-logistic, log-normal) The Gompertz function was excluded because it generated PFS/OS curve crossovers inconsistent with the clinical setting **The log-normal distribution yielded the most favourable ICER**, while the Weibull distribution yielded the highest ICER **Third-line treatment scenario analyses:** Two alternative third-line strategies were evaluated: (A) BSC alone → ICER increased to $744,498.14/QALY (B) Excluding subsequent treatment costs entirely → ICER increased to $733,938.48/QALY. Despite these increases, neither scenario altered the base-case conclusion of non-cost-effectiveness at either WTP threshold	(5) Assumed third-line treatment patterns (nivolumab/pembrolizumab) may not reflect heterogeneous real-world clinical practice (6) A 56% price reduction would be required for tarlatamab to achieve cost-effectiveness at the $200,000/QALY threshold

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
Liu X, Wu Q, Li Q, Qin Y, 2026 [5]	United States and China	**USA:** Tarlatamab total cost: $248,766.23 vs chemotherapy: $49,852.12 → **incremental cost: $198,914.10** **China:** Tarlatamab total cost: $72,393.49 vs chemotherapy: $10,514.90 → **incremental cost: $61,878.59** The unit price of tarlatamab was the dominant cost driver in both countries, accounting for the majority of total treatment costs in the tarlatamab arm The Chinese incremental cost was substantially lower than the US figure, reflecting the assumption that Chinese tarlatamab acquisition costs are set at one-third of the US list price	The incremental QALY gain was identical across both country analyses: 0.15 QALYs (tarlatamab: 0.99 QALYs vs chemotherapy: 0.84 QALYs), as the same clinical efficacy data from DeLLphi-304 and the same utility values were applied in both models Cumulative life-years were also identical: tarlatamab 1.54 LYs vs chemotherapy 1.39 LYs, yielding an incremental LY gain of 0.15 Utility values applied: PFS = 0.70; PD = 0.60; death = 0 (Vedadi et al., 2021); utility of PFS was identified as the single most influential parameter in the DSA in both countries, followed by the discount rate and the price of tarlatamab Disutility decrements applied for grade ≥3 AEs (incidence ≥5%) and all-grade CRS in the tarlatamab arm as one-time decrements in the first model cycle	**USA base-case ICER:** $1,306,254.68/QALY gained (tarlatamab vs chemotherapy) CE thresholds applied: USA: $150,000/QALY gained (Neumann et al., 2014) **China base-case ICER:** $406,352.26/QALY gained (tarlatamab vs chemotherapy, at one-third of US price) China: $40,247.01/QALY gained (three times 2024 per capita GDP, per Chinese pharmacoeconomic guidelines) Both ICERs substantially exceed their respective WTP thresholds: the US ICER exceeds the threshold by approximately 8.7-fold and the China ICER by approximately 10-fold, rendering tarlatamab not cost-effective in either setting at current prices	**Deterministic sensitivity analysis:** Parameters varied within reported 95% CIs or ±20% of base-case values where CIs unavailable; an exploratory analysis also varied parameters within ±50% The unit price of tarlatamab was excluded from the DSA as it was addressed separately via price-simulation analyses: In the US, tarlatamab is cost-effective only when priced below $349.19/mg (WTP $150,000/QALY) or $296.50/mg (WTP $100,000/QALY), requiring an approximately 80% price reduction from the base-case list price of $1,567.49/mg In both countries, the most influential parameters were: (1) utility of PFS, dominant driver in both models (2) discount rate (3) price of tarlatamab In the USA, the proportion and price of lurbinectedin in the chemotherapy arm, and AE costs, had moderate effects; other parameters had minor influence In China, cost of administration, proportion of BSC in both arms, and price of pembrolizumab had moderate effects In no scenario did any parameter variation reduce the ICER below the prespecified WTP threshold in either country	**Key limitations acknowledged by authors:** (1) Survival extrapolation beyond trial follow-up period introduces uncertainty: multiple distributions compared and best visual fit selected; proportional hazards assumption could not be formally tested due to reliance on published summary HRs rather than individual patient data (2) Most cost inputs and healthcare resource-use parameters drawn from published literature or other cancer types, potentially not fully reflecting real-world practice, sensitivity analyses confirmed robustness (3) Trial-based HRQoL data unavailable: utility values sourced from external observational study, limiting generalisability; varying utility values by ±50% did not alter ICER threshold conclusion (4) Post-progression treatment assumptions based on trial reports and guidelines, which may differ from actual clinical practice (5) Approximately 80% price reduction required in the US and 95% in China to achieve cost-effectiveness at respective WTP thresholds at current list prices

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
					In China, using a WTP of $40,247.01/QALY, cost-effectiveness requires a price below $88.57/mg (approximately 95% reduction from assumed Chinese price); using Beijing's higher WTP of $95,907.44/QALY (three times Beijing per capita GDP), cost-effectiveness requires a price below $154.54/mg (approximately 90% reduction) **PSA** (1,000 Monte Carlo iterations): The probability of tarlatamab being cost-effective increased with higher WTP thresholds but remained low at conventional thresholds, exceeding 50% only at substantially higher WTP values in both countries **Subgroup analyses:** ICERs closely tracked survival benefits across all subgroups (age, sex, region, prior anti-PDL1 exposure, chemotherapy-free interval, brain/liver metastases, chemotherapy type)**:** **L**ower ICERs were observed in women (US: $334,016/QALY; China: $99,917/QALY), **w**hite patients (US: $316,368/QALY; China: $99,155/QALY), and patients with brain metastases (US: $348,631/QALY; China: $104,085/QALY) Higher ICERs were observed in Asian patients (US: $570,991/QALY), patients with liver metastases (US: $604,297/QALY), and patients receiving lurbinectedin as chemotherapy (US: $754,776/QALY)	

Author, year (REF)	Country	Incremental costs (base case)	Incremental utilties (base case)	ICER (base-case) CE-threshold applied (base-case)	Sensitivity and scenario analyses	Reflection
					All subgroup ICERs exceeded WTP thresholds in both countries (CE probability 0% across all subgroups) **Scenario analyses:** Replacing AIC-weighted model averaging with individual parametric distributions showed significant ICER variability: log-normal yielded the most optimistic ICERs ($172,409/QALY for US; $52,137/QALY for China); Gompertz yielded the highest ICERs ($712,384/QALY for US; $222,080/QALY for China) Applying a standardised mortality ratio of 1.5 to the PFS state resulted in minimal baseline change, confirming robustness Incorporating recurrent AEs increased ICERs to approximately $1,290,000/QALY (US) and $402,307/QALY (China) **Including grade 1-2 CRS produced the least favourable safety scenario: ICERs rose to $1,340,000/QALY (US) and $435,227/QALY (China)** **R**estricting time horizon to 5 or 10 years substantially elevated ICERs in both countries No scenario achieved cost-effectiveness at prespecified WTP thresholds	

Abbreviations:AE…Adverse Event, AIC…Akaike Information Criterion, ASP…Average Sales Price, BIC…Bayesian Information Criterion, BNF…British National Formulary, BSA…Body Surface Area, BSC…Best Supportive Care, CAD…Canadian Dollar, CAS…Cancer Analysis Service (UK CAS study), CAV…Cyclophosphamide + Doxorubicin + Vincristine, CDA-AMC…Canada's Drug Agency - Agence des médicaments du Canada, CDF…Cancer Drugs Fund, CE…Cost-Effectiveness, CHEERS…Consolidated Health Economic Evaluation Reporting Standards, CI…Confidence Interval, CMS…Centers for Medicare & Medicaid Services, CRS…Cytokine Release Syndrome, CUA…Cost-Utility Analysis, DLL3…Delta-Like Ligand 3, DSA…Deterministic Sensitivity Analysis, EAG…External Assessment Group, ECOG…Eastern Cooperative Oncology Group, EQ-5D-3L/5L…EuroQol 5-Dimension 3/5-Level (preference-based quality of life instrument), ES-SCLC…Extensive-Stage Small-Cell Lung Cancer, FDA…Food and Drug Administration, GDP…Gross Domestic Product, HCUP…Healthcare Cost and Utilization Project, HR…Hazard Ratio, HRQoL…Health-Related Quality of Life, ICANS…Immune Effector Cell-Associated Neurotoxicity Syndrome, ICER…Incremental Cost-Effectiveness Ratio, ITC…Indirect Treatment Comparison, IV…Intravenous, LY…Life-Year, KM…Kaplan-Meier, MAIC…Matching-Adjusted Indirect Treatment Comparison, NCCN…National Comprehensive Cancer Network, NHS…National Health Service, NICE…National Institute for Health and Care Excellence, NRDL…National Reimbursement Drug List, ORR…Objective Response Rate, OS…Overall Survival, PartSA…Partitioned Survival Analysis, PD…Progressive Disease, PDL1…Programmed Death-Ligand 1, PFS…Progression-Free Survival, PSA…Probabilistic Sensitivity Analysis, PSM…Partitioned Survival Model, QALY…Quality-Adjusted Life Year, QoL…Quality of Life, RCT…Randomised Controlled Trial, RDI…Relative Dose Intensity, RMB…Renminbi (Chinese currency), SCLC…Small-Cell Lung Cancer, SMR…Standardised Mortality Ratio, TTD…Time to Treatment Discontinuation, USD…US Dollar, VAT…Value Added Tax, WTP…Willingness-To-Pay

5.1.3 Quality assessment of the included economic evaluation based on pharmaco-economic models

Table 5-3: Check of reporting standards – the CHEERS checklist [6]

#	Domain	Canada's Drug Agency (CDA-AMC) 2025 [2]	National Institute for Health and Care Excellence (NICE), 2025 [3]	Zheng H, Wen F, Wu B, 2026 [4]	Liu X, Wu Q, Li Q, Qin Y, 2026 [5]
TITLE					
1	Title	✅ Reported	✅ Reported	✅ Reported	✅ Reported
ABSTRACT					
2	Abstract	✅ Reported	✅ Reported	✅ Reported	✅ Reported
INTRODUCTION					
3	Background & objectives	✅ Reported	✅ Reported	✅ Reported	✅ Reported
METHODS					
4	Health economic analysis plan	❌ Not reported[2]			
5	Study population	✅ Reported	✅ Reported	✅ Reported	✅ Reported

[2] No prespecified or registered analytical plan referenced in either report.

#	Domain	Canada's Drug Agency (CDA-AMC) 2025 [2]	National Institute for Health and Care Excellence (NICE), 2025 [3]	Zheng H, Wen F, Wu B, 2026 [4]	Liu X, Wu Q, Li Q, Qin Y, 2026 [5]
6	Setting and location	✅ Reported	✅ Reported	✅ Reported	✅ Reported
7	Comparators	✅ Reported	✅ Reported	✅ Reported	✅ Reported
8	Perspective	⚠️ Partial[3]		✅ Reported	✅ Reported
9	Time horizon	✅ Reported	⚠️ Partial[4]	✅ Reported	✅ Reported
10	Discount rate	✅ Reported	⚠️ Partial[5]	✅ Reported	✅ Reported
11	Selection of outcomes	✅ Reported	✅ Reported	✅ Reported	✅ Reported
12	Measurement of outcomes	⚠️ Partial[6]		⚠️ Partial[7]	
13	Valuation of outcomes	⚠️ Partial[8]		⚠️ Partial[9]	
14	Measurement & valuation of resources and costs	✅ Reported	✅ Reported	✅ Reported	✅ Reported
15	Currency, price date & conversion	✅ Reported	✅ Reported	✅ Reported	✅ Reported
16	Rationale & description of model	✅ Reported	✅ Reported	✅ Reported	✅ Reported
17	Analytics & assumptions	✅ Reported	✅ Reported	✅ Reported	✅ Reported
18	Characterising heterogeneity	❌ Not reported[10]			✅ Reported
19	Characterising distributional effects	❌ Not reported[11]			
20	Characterising uncertainty	✅ Reported	✅ Reported	✅ Reported	✅ Reported

[3] Payer perspective stated but formal rationale for excluding societal perspective not provided.

[4] Lifetime (not explicitly stated in guidance text).

[5] 3.5% per NICE reference case (not stated in guidance text).

[6] CDA-AMC: EQ-5D-5L from DeLLphi-301 with Canadian tariffs; rejected on face validity grounds. NICE: EQ-5D-5L mapped to 3L from DeLLphi-301; MAIC-adjusted values preferred.

[7] Utilities from published literature, because no QoL data from the trial.

[8] CDA-AMC: Canadian tariffs stated. Both acknowledge utility values may not reflect real-world SCLC population. NICE: NICE reference case crosswalk applied.

[9] EQ-5D from published literature.

[10] No formal subgroup analyses by patient characteristics. CDA-AMC: no subgroup analyses conducted. NICE: ECOG 0–1 restriction noted.

[11] No equity or distributional analysis across patient subgroups reported.

#	Domain	Canada's Drug Agency (CDA-AMC) 2025 [2]	National Institute for Health and Care Excellence (NICE), 2025 [3]	Zheng H, Wen F, Wu B, 2026 [4]	Liu X, Wu Q, Li Q, Qin Y, 2026 [5]
21	Approach to engagement with patients and others	⚠ Partial[12]		❌ Not reported[13]	⚠ Partial[14]
RESULTS					
22	Study parameters	✅ Reported	⚠ Partial[15]	✅ Reported	✅ Reported
23	Summary of main results	✅ Reported	✅ Reported	✅ Reported	✅ Reported
24	Effect of uncertainty	✅ Reported	✅ Reported	✅ Reported	✅ Reported
25	Effect of engagement with patients and others	❌ Not reported[16]			
DISCUSSION					
26	Study findings, limitations, generalizability & current knowledge	✅ Reported	✅ Reported	✅ Reported	✅ Reported
OTHER					
27	Source of funding	✅ Reported	✅ Reported	✅ Reported	✅ Reported
28	Conflicts of interest	✅ Reported	✅ Reported	✅ Reported	✅ Reported
OVERALL		✅ **Reported: 15** ⚠ **Partial: 7** ❌ **Not reported: 6**	✅ **Reported: 14** ⚠ **Partial: 8** ❌ **Not reported: 6**	✅ **Reported: 17** ⚠ **Partial: 3** ❌ **Not reported: 5**	✅ **Reported: 18** ⚠ **Partial: 2** ❌ **Not reported: 5**

[12] CDA-AMC: patient and clinician input summarised but not integrated into modelling. NICE: patient organisation submission referenced; no formal engagement in model development.

[13] No patient involvement.

[14] Not reported.

[15] NICE: parameters described in committee discussion.

[16] Patient and clinician perspectives noted but their effect on model parameters or results not quantified.

Table 5-4: CHEC list quality assessment [7]

#	Item	Canada's Drug Agency (CDA-AMC) 2025 [2]	National Institute for Health and Care Excellence (NICE), 2025 [3]	Zheng H, Wen F, Wu B, 2026 [4]	Liu X, Wu Q, Li Q, Qin Y, 2026 [5]
1	Is the study population clearly described?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
2	Are competing alternatives clearly described?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
3	Is a well-defined research question posed in answerable form?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
4	Is the economic study design appropriate to the stated objective?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
5	Is the chosen time horizon appropriate in order to include relevant costs and consequences?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
6	Is the actual perspective chosen appropriate?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
7	Are all important and relevant costs for each alternative identified?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
8	Are the measurements of outcomes appropriate?	⚠️ Unclear[17]			
9	Is an incremental analysis of costs and outcomes performed?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
10	Are all future costs and consequences discounted appropriately?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
11	Are all important uncertain variables subjected to sensitivity analysis?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
12	Are the costs of the interventions described?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
13	Are all direct and indirect costs and consequences described?	⚠️ Unclear[18]			
14	Are the costs properly measured and valued?	✅ Yes	✅ Yes	✅ Yes	✅ Yes

[17] CDA-AMC: EQ-5D-5L data from the DeLLphi-301 with Canadian tarifs; NICE: utility data also from the DELLphi-301 (MAIC adjusted); Also for the other 2 studies.

[18] Only direct medical costs included; indirect costs (productivity loss, informal care) and non-medical direct costs excluded; this exclusion is not explicitly justified in the methods.

#	Item	Canada's Drug Agency (CDA-AMC) 2025 [2]	National Institute for Health and Care Excellence (NICE), 2025 [3]	Zheng H, Wen F, Wu B, 2026 [4]	Liu X, Wu Q, Li Q, Qin Y, 2026 [5]
15	Is the effectiveness established based on a systematic review?	❌ No[19]			
16	Is the model structure described?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
17	Do the conclusions follow from the data reported?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
18	Does the study discuss generalisability to other settings or patient groups?	⚠️ Unclear[20]		✅ Yes	⚠️ Unclear[21]
19	Does the article indicate no potential conflict of interest?	✅ Yes	✅ Yes	✅ Yes	✅ Yes
OVERALL		✅ **Yes: 15** ⚠️ **Unclear: 3** ❌ **No: 1**	✅ **Yes: 15** ⚠️ **Unclear: 3** ❌ **No: 1**	✅ **Yes: 16** ⚠️ **Unclear: 2** ❌ **No: 1**	✅ **Yes: 15** ⚠️ **Unclear: 3** ❌ **No: 1**

[19] Effectiveness data sourced solely from the IMforte Phase III RCT; no systematic review or network meta-analysis conducted to identify all relevant comparators or confirm best available evidence.

[20] Generalisability of the results is uncertain.

[21] Limited to US payer perspective, no discussion about generalisabilty to other health care systems.

6 Extended perspectives

6.1 Stakeholder perspectives

Table 6-1: Questions for clinical experts

Questions about the relevance of JCA-PICOs	
Question 1	Sind alle 7 PICOs aus österreichischer Versorgungsperspektive relevant, oder können einzelne PICOs als weniger relevant eingestuft werden?
Questions about the standard of care in Austria	
Question 2	Welche Leitlinien werden in Ihrer Einrichtung für diese Indikation angewendet (z.B. ESMO, S3)?
Question 3	Welche Therapieoptionen würden Sie aktuell als Standard- bzw. Vergleichstherapie für diese Indikation in Österreich betrachten?
Question 4	Erhalten Patient:innen mit ECOG PS2 in Österreich noch eine aktive systemische Zweitlinientherapie? Wenn ja, welche
Question 5	Nach welchen Kriterien wählen Sie primär in Ihrer klinischen Praxis zwischen den verfügbaren Zweitlinienoptionen?
Question 6	Wie verteilen sich die eingesetzten Zweitlinienoptionen in Ihrer klinischen Praxis?
Questions about the target population in Austria	
Question 7	Gibt es Subgruppen, die in der klinischen Versorgungspraxis tatsächlich nicht für die Therapie infrage kommen, obwohl sie formal von der Zulassung umfasst sind?
Question 8	Einschätzung der Zielpopulation?
Questions about resource use and organisational aspects	
Question 9	Sind für die sichere Anwendung von Tarlatamab zusätzliche organisatorische Maßnahmen, Infrastruktur (z.B. MRT, CT) oder Schulungen des medizinischen Personals erforderlich?
Questions about further relevant aspects	
Question 10	Ethische Aspekte: Gibt es aus Ihrer Sicht ethische Aspekte im Zusammenhang mit der Anwendung von Tarlatamab, die in der Bewertung berücksichtigt werden sollten?
Question 11	Falls bereits eigene klinische Erfahrungen mit Tarlatamab vorliegen: Gibt es weitere Aspekte der klinischen Anwendung oder Versorgungssituation, die aus Ihrer Sicht für die Bewertung relevant sind und bisher nicht angesprochen wurden?
Question 12	Register/Dokumentation: Welche Register gibt es (österreichweit)? Werden neue Therapien in Österreich erfasst? Neben z.B. LALUCA-Register
Question 13	Gibt es zusätzliche relevante Aspekte seitens der klinischen Expert:innen, die im Zuge der HTA-Erstellung berücksichtigt werden sollten?

Abbreviations: Abbreviations: CT …Computertomographie, ESMO …European Society for Medical Oncology, HTA …Health Technology Assessment, JCA …Joint Clinical Assessment, MRT …Magnetresonanztomographie, PICO …Population, Intervention, Komparator, Outcome, PS …Perdormance Status

6.2 Patient´s perspective

Table 6-2: Questions asked to patients, carers or members of patient organisations

Question 1	Rolle des Ausfüllenden (Einzelne(r) Patient(in)/Angehörige(r)/Andere).
Question 2	Nur für Angehörige/Vertreter:innen einer Patient:innenorganisation: Wie sind Sie an Informationen zu den Erfahrungen von Patient:innen gelangt?
Question 3	In welchem Land befindet sich Ihr Hauptwohnsitz?
Question 4	Sind Sie Mitglied einer Patient:innenorganisation? ■ 4a: Bei welcher Patient:innenorganisation sind Sie Mitglied? ■ 4b: Welche Erkrankung(en) werden von der Patient:innenorganisation vertreten? ■ 4c: Welche Rolle haben Sie in der Patient:innenorganisation?
Question 5	■ 5a: Wie lautet die Diagnose? Bitte geben Sie die Erkrankung an, an der Sie/Ihre Angehöriger/Ihr Angehöriger leiden/leidet. ■ 5b: In welchem Stadium Ihrer Erkrankung befindet befinden Sie sich? Wie würden Sie den Schweregrad aktuell einschätzen? ■ 5c: Welche Symptome haben Sie oder hat Ihre Angehörige/Ihr Angehöriger derzeit? ■ 5d: Krankheitsgeschichte: Seit wann leben Sie/Ihre Angehörige/Ihr Angehöriger mit der Erkrankung? Wann wurde sie diagnostiziert? ■ Welche Behandlungen wurden bisher durchgeführt? ■ 5e: Zusätzliche Informationen, die Ihrer Meinung nach für den HTA-Bericht hilfreich wären.
Question 6	Wie beeinflusst die Erkrankung Ihr tägliches Leben (bzw. das Leben eines Patienten/einer Patient:in)?
Question 7	Wie wirkt sich die Erkrankung auf Ihr familiäres und soziales Umfeld aus?
Question 8	Wie wirkt sich die Erkrankung auf das familiäre und soziale Umfeld der Patient:innen aus?
Question 9	Wie würden Sie die aktuelle Versorgungssituation in Österreich für Ihre Erkrankung beschreiben?
Question 10	Wie geht es Ihnen/Ihrer Angehörigen/Ihrem Angehörigen mit der derzeit angewandten Therapie? Falls keine spezifische Therapie zur Verfügung steht, geben Sie dies bitte an.
Question 11	Was würden Sie oder Ihre Angehörigen oder Ihr Angehöriger im Allgemeinen von einer neuen Therapie erwarten?
Question 12	Kennen Sie das Arzneimittel Tarlatmab (IMDYLLTRA®)?
Question 13	Welche Gedanken haben Sie zum neuen Arzneimittel?
Question 14	Für Personen, die Erfahrung mit IMDYLLTRA® im Rahmen klinischer Studien haben: Welche Auswirkungen hatte bzw. Was hat es auf Ihr Leben (positiv und negativ) ausgemacht?
Question 15	Was ist Ihrer Meinung nach noch wichtig? Gibt es weitere Aspekte, z.B. ethische oder soziale Aspekte, die noch nicht besprochen wur-den? Bitte erläutern Sie diese.

Abbreviations: HTA … Health Technology Assessment

7 Development costs and public contributions

7.1 Own development costs, aquisitions and licenses

No content.

7.2 Public constributions to drug development

Table 7-1: Financing/patent deals/licensing/funding rounds of all companies involved in the development of IMDYLLTRA®

Type of information	Details on collaboration, financing, and public funding	Year	Amount (in USD)	Funders/Investors/ Acquiror	Source
Amgen					
Patent	IMDYLLTRAB® and more specifically it's associated bifunctional polypep-tides are under patent protection with an expected expiration 8th of January 2036	2025	n.a.	n.a.	https://www.sec.gov/Archives/edgar/data/318154/000031815426000010/amgn-20251231.htm
Earliest mention	Earliest mention of AMG 757 (alternative name for tarlatamab) found in official Amgen SEC reportings.	2018	n.a.	n.a.	https://www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm
Clinical trial progress	In 2023, Amgen reported its results of the phase 2 trial for taralatamab, which led to the breakthrough designation by the FDA.	2023	n.a.	n.a.	https://www.sec.gov/Archives/edgar/data/318154/000031815424000011/amgn-20231231.htm
UNIVERSITY OF ALABAMA AT BIRMINGHAM					
Public funding	A Novel Approach to Enhance Therapeutic Efficacy of Tarlatamab for Small Cell Lung Cancer Treatment	2025, 2026	381,830	National Cancer Institute	https://reporter.nih.gov/search/oJR31ufNC0KKaHZ9yYS5Yw/project-details/11269230

Abbreviations: SEC…U.S. Securities and Exchange Commission, FDA…U.S. Food and Agricultura Administration

Table 7-2: Search terms used to identify the development history and public contributions of IMDYLLTRA®

Database/News outlet/ clinical trial registry/funding website	Search terms used	Additional search terms	Relevant information found (yes/no)	Search period	Type of information extracted
https://www.ema.europa.eu/en/medicines	IMDELLTRA Imdelltra IMDYLLTRA Imdylltra Tarlatamab-dlle AMG 757	n.a.	Yes	Earliest mention-07.2026	Active substance, Medical speciality, Pharmacotherapeutic group, Therapeutic area, Class, Orphan designation, Categorization, Additional monitoring, Conditional approval, Accelerated assessment, PRIME: priority medicines, Marketing authorisation issued
https://www.fda.gov/			Yes		
https://adisinsight.springer.com/			Yes		Alternative names/ Alternative Product identifiers
https://ihsi-horizonscandb.ecri.org/					
https://pubmed.ncbi.nlm.nih.gov/			Yes		Development history, Researchers
https://clinicaltrials.gov/			Yes		Clinical trials
https://euclinicaltrials.eu/			Yes		
https://trialsearch.who.int/			Yes		
https://eudract.ema.europa.eu/			No		
https://cordis.europa.eu/			No		
https://reporter.nih.gov/		BeOne Medicines	Yes		
https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm		Se-Hoon Lee, Samsung Medical Center (Responsible Party)	No		Basic research. Authors selected based on literature found on PubMed
https://www.sec.gov/		Asrar Alahmadi, Ohio State University Comprehensive Cancer Center (Responsible Party)	Yes		Collaborations, funding, financing, Series A-C funding, patent information, acquisitions, development history
https://competition-cases.ec.europa.eu/search			No		
https://www.ihi.europa.eu/			No		
https://eismea.ec.europa.eu/index_en			No		
https://eit.europa.eu/		Grupo Espanol de Tumores Neuroendocrinos	No		
https://eic.ec.europa.eu/index_en			No		
https://www.eib.org/en/index			No		

Database/News outlet/ clinical trial registry/funding website	Search terms used	Additional search terms	Relevant information found (yes/no)	Search period	Type of information extracted
https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls_en		Duke University AstraZeneca	No		
https://www.sbir.gov/		ETOP IBCSG Partners Foundation	No		
https://www.nsf.gov/		Gustave Roussy, Cancer Campus, Grand Paris	No		
https://www.ukri.org/		University of Arizona	No		
https://foerderportal.bund.de/		Fundación GECP	No		
https://www.health-holland.com/		Intergroupe Francophone de Cancerologie Thoracique	No		
https://www.bpifrance.com/		Centre Leon Berard	No		
https://www.inserm.fr/en/home/		Asrar Alahmadi	No		
https://innovationsfonden.dk/da		Jaume Capdevila	No		
https://www.ucc.ie/en/apc/		Laura Alder	Yes		
https://www.amractionfund.com/about		Maurice Pérol	No		
https://reporter.nih.gov/		Federico Capuzzo	No		
https://www.gatesfoundation.org/		Charles Hsu	No		
https://www.google.com/		Ricklie Julian	No		
https://www.forbes.com/		Mariano Provencio	No		
https://www.reuters.com/			No		
https://www.science.org/			No		
https://www.cafepharma.com/			No		
https://www.livescience.com/			No		
https://www.biospace.com/			No		
https://www.bioworld.com/			No		
https://www.biopharmadive.com/			No		
https://pharmaphorum.com/			No		
https://pharmatimes.com/			No		
https://pharmafile.com/			No		
https://www.fiercepharma.com/			No		
https://www.businesswire.com/			No		
https://www.businessinsider.com/			No		

Database/News outlet/ clinical trial registry/funding website	Search terms used	Additional search terms	Relevant information found (yes/no)	Search period	Type of information extracted
https://www.statnews.com/			no		

8 Landscape overview

No content.

9 Conclusion

No content.

10 References

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HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH