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Cost-Effectiveness of Ivonescimab Plus Chemotherapy Versus Chemotherapy Alone in EGFR-Mutant Non-Small Cell Lung Cancer After EGFR-TKI Failure: A Partitioned Survival Analysis of the HARMONi-A Randomized Clinical Trial

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Research Article

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Abstract

Background

In the HARMONi-A phase 3 trial, ivonescimab—a first-in-class PD-1/VEGF bispecific antibody—added to platinum-pemetrexed chemotherapy significantly improved progression-free survival compared with chemotherapy alone in patients with EGFR-mutant non-small cell lung cancer (NSCLC) whose disease had progressed on EGFR tyrosine kinase inhibitor therapy (hazard ratio 0.46; median 7.1 vs 4.8 months). Whether this efficacy gain represents high-value care from the Chinese healthcare system perspective is unknown.

Methods

We constructed a three-state partitioned survival model with a 21-day cycle length and a 10-year time horizon. Weibull parametric survival functions were fitted to published HARMONi-A landmark survival data and calibrated to reproduce the trial's reported median progression-free and overall survival to within 0.1 months. Drug costs reflected 2025 China National Reimbursement Drug List negotiated prices, including ivonescimab at $1,227 per 21-day cycle (¥736 per 100 mg vial). The willingness-to-pay threshold was set at $41,527 per quality-adjusted life-year (QALY)—three times China's 2025 gross domestic product per capita. We conducted one-way and probabilistic sensitivity analyses (1,000 Monte Carlo iterations).

Results

Ivonescimab plus chemotherapy produced 0.884 QALYs at a cost of $48,266, versus 0.724 QALYs at $29,094 for chemotherapy alone, yielding an incremental cost-effectiveness ratio (ICER) of $119,512 per QALY—188% above the willingness-to-pay threshold. Across 1,000 probabilistic iterations, the probability of cost-effectiveness at the Chinese threshold was below 1%. One-way sensitivity analysis identified the Weibull overall survival and progression-free survival scale parameters, ivonescimab acquisition cost, and progression-free survival utility as the most influential drivers. A reduction in the ivonescimab acquisition cost of approximately 79% (to roughly $260 per cycle) would be required to meet the conventional cost-effectiveness threshold.

Conclusions

Ivonescimab plus chemotherapy is not cost-effective for EGFR-mutant NSCLC after EGFR-TKI failure at current Chinese drug prices. The modest absolute survival gains in this heavily pretreated population, combined with the high acquisition cost of ivonescimab, produce an ICER nearly three times the conventional willingness-to-pay threshold.

Background

Lung cancer remains the leading cause of cancer mortality worldwide, with non-small cell lung cancer (NSCLC) accounting for approximately 85% of incident cases [1]. In East Asian populations, activating EGFR mutations are present in 40–50% of lung adenocarcinomas [2]. Although third-generation EGFR tyrosine kinase inhibitors (TKIs) such as osimertinib have substantially improved outcomes in the first-line setting, acquired resistance is nearly universal, and effective treatment options after TKI failure remain limited [3, 4].

Ivonescimab (AK112) is a first-in-class humanized tetravalent bispecific antibody targeting both programmed cell death protein 1 (PD-1) and vascular endothelial growth factor A (VEGF-A) [5]. On 24 May 2024, the China National Medical Products Administration approved ivonescimab in combination with pemetrexed and carboplatin for patients with EGFR-mutant NSCLC whose disease has progressed on EGFR-TKI therapy, on the basis of the HARMONi-A phase 3 trial [6, 7]. In HARMONi-A, ivonescimab plus chemotherapy reduced the risk of disease progression or death by 54% compared with chemotherapy alone (hazard ratio [HR] 0.46; 95% confidence interval [CI] 0.34–0.62; P < 0.001), with median progression-free survival (PFS) extended from 4.8 to 7.1 months [7]. The final overall survival (OS) analysis, first presented at the Society for Immunotherapy of Cancer 2025 Annual Meeting and subsequently published, confirmed an OS benefit (HR 0.74; 95% CI 0.58–0.95; P = 0.02), with a median OS of 16.8 versus 14.1 months [6].

The inclusion of ivonescimab in the 2024 China National Reimbursement Drug List (NRDL) at a negotiated price of ¥736 per 100 mg vial (approximately $1,227 per 21-day cycle for a 60 kg patient) raises an important economic question: does the magnitude of clinical benefit observed in HARMONi-A justify the incremental cost of adding ivonescimab to chemotherapy in the second-line setting [8]? To date, no cost-effectiveness analysis of this regimen has been published.

We conducted a partitioned survival analysis comparing ivonescimab plus platinum-pemetrexed chemotherapy with chemotherapy alone in EGFR-mutant NSCLC after TKI failure, drawing efficacy inputs from the HARMONi-A trial and cost data from the Chinese healthcare system. This study was reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS 2022) [9].

Methods

Model structure

A three-state partitioned survival model was developed in R (version 4.6.0) comprising progression-free survival (PFS), post-progression disease (PD), and death. All patients entered the model in the PFS state. A cycle length of 21 days was applied over a 10-year time horizon, which effectively captures the lifetime experience of this population given the short median OS (14–17 months). The analysis adopted the Chinese healthcare system perspective and applied a 5% annual discount rate, consistent with Chinese pharmacoeconomic guidelines [10]. The willingness-to-pay (WTP) threshold was set at $41,527 per QALY

—three times China's 2025 gross domestic product per capita ($13,842; ¥99,665, at an exchange rate of 7.2 CNY per USD) [11].

Clinical data and survival extrapolation

Efficacy data were obtained from the HARMONi-A trial (ClinicalTrials.gov: NCT05184712), a double-blind, placebo-controlled, randomized phase 3 study conducted at 55 sites in China [6, 7]. The trial enrolled 322 patients with EGFR-mutant advanced non-squamous NSCLC whose disease had progressed on EGFR-TKI therapy, randomized 1:1 to receive either ivonescimab (20 mg/kg) plus pemetrexed (500 mg/m²) and carboplatin (area under the curve 5) every 3 weeks for four cycles followed by ivonescimab plus pemetrexed maintenance, or placebo plus the same chemotherapy backbone.

Published landmark survival probabilities were extracted at monthly intervals from the HARMONi-A Kaplan-Meier curves [6, 7]. Weibull parametric survival functions were fitted independently to the PFS and OS data for each treatment arm. Parameters were calibrated such that the modelled median survival reproduced the published trial medians to within 0.1 months (Table 1). The logical consistency condition $S_{OS}(t) \geq S_{PFS}(t)$ was enforced by taking the maximum of the two survival functions; this constraint was never binding.

Table 1
Weibull survival parameters

Parameter	Ivonescimab + chemo	Chemotherapy
Progression-free survival		
Shape (κ)	1.10	1.00
Scale (λ, years)	0.83	0.58
Modelled median (months)	7.1	4.8
Published median (months) [7]	7.1	4.8
Overall survival		
Shape (κ)	1.20	1.10
Scale (λ, years)	1.90	1.64
Modelled median (months)	16.8	14.1
Published median (months) [6]	16.8	14.1
Cost inputs		

All drug costs were derived from the 2025 China NRDL negotiated prices (Table 2). The ivonescimab cost was based on the NRDL price of ¥736 per 100 mg vial, at a dose of 20 mg/kg every 3 weeks for a 60 kg reference patient (12 vials per cycle; $1,227 at 7.2 CNY per USD) [8]. Pemetrexed and carboplatin costs

were consistent with prior Chinese cost-effectiveness analyses [12, 13]. Non-drug costs were obtained from published Chinese health economic evaluations [12, 13]. All costs are reported in 2025 US dollars.

Table 2
Cost inputs (2025 USD)

Parameter	Base value	Distribution	Source
Ivonescimab 20 mg/kg, per cycle	1,227	Gamma(100, 12.27)	NRDL 2025 [8]
Pemetrexed 500 mg/m², per cycle	708	Gamma(100, 7.08)	NRDL 2025
Carboplatin AUC 5, per cycle	56	Gamma(100, 0.56)	NRDL 2025
IV administration, per cycle	139	Gamma(100, 1.39)	[12, 13]
CT and laboratory monitoring, per cycle	83	Gamma(100, 0.83)	[12]
Post-progression management, per cycle	1,111	Gamma(100, 11.11)	[12, 13]
Terminal care (one-time)	3,472	Gamma(50, 69.44)	[13]
AE management: ivonescimab + chemo	850	Gamma(25, 34.0)	[6, 12, 13]
AE management: chemotherapy	500	Gamma(25, 20.0)	[6, 12, 13]

AE, adverse event; AUC, area under the curve; CT, computed tomography; IV, intravenous; NRDL, National Reimbursement Drug List.

Adverse event (AE) costs reflect the grade ≥ 3 treatment-emergent adverse event rates reported in the final HARMONi-A analysis: 67.1% for ivonescimab plus chemotherapy and 54.7% for chemotherapy alone [6].

Health state utilities

Utility weights for PFS (0.804) and PD (0.321) were taken from the international EQ-5D-based study by Nafees et al. [14]. These values are widely cited in NSCLC cost-effectiveness analyses [12, 13, 15]. Beta distributions were used to represent parameter uncertainty in the probabilistic sensitivity analysis.

Sensitivity analyses

One-way deterministic sensitivity analysis varied ten parameters across plausible ranges. Probabilistic sensitivity analysis was conducted using second-order Monte Carlo simulation (1,000 iterations). Three scenario analyses were performed: (a) log-logistic parametric fits for both PFS and OS; (b) a 3% discount rate; and (c) the Chinese EQ-5D utility value (0.814) applied to both health states [16].

Results

Base case

Over the 10-year time horizon, ivonescimab plus chemotherapy generated 0.884 QALYs at a per-patient cost of $48,266, compared with 0.724 QALYs at $29,094 for chemotherapy alone (Table 3). The incremental QALY gain was 0.160 at an incremental cost of $19,172, producing an ICER of $119,512 per QALY—188% above the WTP threshold. The incremental net monetary benefit was −$12,510.

Table 3
Base case cost-effectiveness results

Outcome	Chemotherapy	Ivo + chemo	Difference
Total cost (2025 USD)	29,094	48,266	19,172
Total QALYs	0.724	0.884	0.160
ICER ($/QALY)\|—\|—\|119,512\|\|Netmonetarybenefit($)	963	−11,547	−12,510

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

Figure 1 displays the modelled partitioned survival curves. The modelled median PFS values matched the HARMONi-A reported medians to within 0.1 months. The modelled 24-month OS probability was 34.5% for ivonescimab plus chemotherapy and 28.8% for chemotherapy alone, closely matching the published 24-month rates of 35.3% and 28.8%, respectively. At 30 months, the model estimated 24.9% and 20.4%, compared with published rates of 29.1% and 18.4% [6], indicating that the Weibull fit slightly underestimates the combination arm's long-term survival and therefore provides a conservative estimate of the incremental OS benefit.

One-way sensitivity analysis

The Weibull OS and PFS scale parameters for the combination arm were the most influential parameters (ICER range $97,071–$219,399 and $94,271–$187,082 per QALY, respectively), followed by ivonescimab acquisition cost ($99,713–$139,312 per QALY) and PFS utility ($106,232–$138,234 per QALY) (Table 4, Fig. 2). Increasing the OS scale by 20% reduced the ICER to $97,071 per QALY—still 134% above the WTP threshold—whereas decreasing it by 20% increased the ICER to $219,399 per QALY. Under the most favorable scenario for ivonescimab cost ($982/cycle, a 20% reduction), the ICER remained $99,713 per QALY, still 140% above the WTP threshold.

Table 4
One-way sensitivity analysis

Parameter	Low value	ICER ($/QALY)| Highvalue |ICER(/QALY)	Range ($/QALY)		
OS scale, ivo + chemo arm	−20%	219,399	+ 20%	97,071	122,328
PFS scale, ivo + chemo arm	−20%	187,082	+ 20%	94,271	92,811
Ivonescimab cost per cycle	−20%	99,713	+ 20%	139,312	39,599
PFS utility	0.70	138,234	0.90	106,232	32,002
Pemetrexed cost per cycle	−20%	116,307	+ 20%	122,717	6,410
AE cost, ivo + chemo arm	−50%	116,863	+ 50%	122,162	5,299
PD utility	0.20	117,432	0.44	121,632	4,200
Discount rate	3%	118,387	8%	121,156	2,769

AE, adverse event; ICER, incremental cost-effectiveness ratio; OS, overall survival; PD, progressive disease; PFS, progression-free survival.

Probabilistic sensitivity analysis

Across 1,000 probabilistic iterations, the probability of cost-effectiveness at the Chinese WTP threshold was below 1% (Figs. 3 and 4). The 95% credible interval for the ICER was approximately $75,732 to $280,234 per QALY. The probability of cost-effectiveness reached 50% at approximately $125,000 per QALY.

Scenario analyses

Three scenario analyses examined the robustness of the base-case finding. Fitting log-logistic rather than Weibull distributions to the landmark survival data decreased the ICER to $109,873 per QALY, confirming that the conclusion is robust to the choice of parametric extrapolation. Applying a 3% annual discount rate reduced the ICER to $118,387 per QALY. Substituting the Chinese EQ-5D utility value increased the ICER to $127,028 per QALY. In every scenario, the ICER remained well above the WTP threshold.

Threshold analysis

A reduction in the ivonescimab acquisition cost of approximately 79% (to roughly $260 per cycle) would be required to meet the $41,527 per QALY threshold. At a zero ivonescimab price, the ICER would fall to $20,515 per QALY, below the threshold. In contrast, reductions in the cost of pemetrexed alone could not achieve cost-effectiveness, because pemetrexed is administered in both arms and the ICER remained $103,487 per QALY even at a zero pemetrexed price.

Discussion

This study provides the first cost-effectiveness analysis of ivonescimab plus platinum-pemetrexed chemotherapy in EGFR-mutant NSCLC after TKI failure. The base-case ICER of $119,512 per QALY exceeds the Chinese WTP threshold by 188%, and the probability of cost-effectiveness at current prices is below 1%. These findings indicate that the combination is unlikely to represent high-value care from the Chinese healthcare system perspective without substantial price reductions.

The economic challenge is driven by two factors. First, the absolute survival gains in this heavily pretreated population are modest. Although the PFS HR of 0.46 is among the largest relative benefits reported in the post-TKI setting, the absolute PFS gain of 2.3 months and the absolute OS gain of 2.7 months translate into an incremental QALY gain of only 0.16—approximately 1.9 quality-adjusted months. Second, ivonescimab is costly. At $1,227 per cycle, the drug acquisition cost alone accounts for approximately 83% of the incremental cost in the combination arm. Because ivonescimab is continued as maintenance therapy until progression or unacceptable toxicity, costs accumulate over a treatment duration that, although short in absolute terms, is prolonged relative to the control arm.

The one-way sensitivity analysis confirms that survival extrapolation, followed by ivonescimab pricing, is the dominant driver of cost-effectiveness. A 20% reduction in the ivonescimab cost produced an ICER of $99,713 per QALY—still more than 2.4 times the WTP threshold. Achieving cost-effectiveness would require an approximately 79% price reduction, a magnitude unlikely to be realized through routine NRDL renegotiation alone unless accompanied by competitive market entry of biosimilar or alternative bispecific antibodies.

These findings are consistent with international evidence showing that immunotherapy-based regimens, despite established efficacy, frequently exceed conventional cost-effectiveness thresholds. An international analysis of durvalumab in unresectable stage III NSCLC, for example, found that the regimen was not cost-effective in the United States, Brazil, Singapore, or Spain at country-specific WTP thresholds [17]. In the post-TKI EGFR-mutant setting, the combination of limited residual survival and the high cost of novel biologics presents a particularly challenging economic problem. For clinicians, these data support shared decision-making: the 54% reduction in the risk of disease progression is clinically meaningful, but patients and payers should be aware that this benefit comes at an incremental cost nearly three times the conventional threshold for value in China.

Several limitations warrant consideration. First, individual patient-level data were not available; survival extrapolation relied on digitized published curves and parametric fitting, which introduces uncertainty,

particularly in the OS tail. Second, the present analysis used the final HARMONi-A OS data recently published in JAMA (June 2026), which confirmed an OS benefit (HR 0.74; P = 0.02) after 32.5 months of median follow-up. However, the absolute OS gain was modest (2.7 months), with more pronounced separation of the survival curves at later time points (30-month OS 29.1% vs 18.4%). Longer-term survival data beyond 3 years are not yet available, and the Weibull extrapolation may under-estimate the late survival benefit of immunotherapy-based regimens. Third, health state utilities were derived from a non-Chinese population, although sensitivity analyses using Chinese values produced consistent results. Fourth, the model did not incorporate subsequent lines of therapy, which may differentially affect long-term costs and outcomes in both arms. Fifth, a societal perspective including productivity losses was not evaluated; given the short survival and advanced disease stage, however, the incremental societal benefit is likely to be limited.

Conclusions

Ivonescimab plus platinum-pemetrexed chemotherapy confers a statistically significant and clinically meaningful PFS benefit in EGFR-mutant NSCLC after TKI failure, yet from the Chinese healthcare system perspective it is not cost-effective at current NRDL prices. The base-case ICER of $119,512 per QALY exceeds the WTP threshold by 188%, with less than a 1% probability of cost-effectiveness at the current threshold. An approximately 79% reduction in the ivonescimab acquisition cost would be required to bring this regimen within conventional cost-effectiveness boundaries in China. These findings highlight the economic challenge of translating incremental efficacy gains from novel biologics into high-value care in heavily pretreated populations.

Abbreviations

AE
adverse event AUC:area under the curve CEAC:cost-effectiveness acceptability curve CEA:cost-effectiveness analysis CHEERS:Consolidated Health Economic Evaluation Reporting Standards CI:confidence interval CT:computed tomography EGFR:epidermal growth factor receptor GDP:gross domestic product HR:hazard ratio ICER:incremental cost-effectiveness ratio IV:intravenous NRDL:National Reimbursement Drug List NSCLC:non-small cell lung cancer OS:overall survival PD:progressive disease PFS:progression-free survival QALY:quality-adjusted life-year SE:standard error TKI:tyrosine kinase inhibitor WTP:willingness-to-pay

Declarations

Ethics approval and consent to participate

Not applicable. This study is a model-based economic evaluation using published aggregate trial data and did not involve human participants or identifiable data.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

K.C. conceptualized the study, developed the model, performed all analyses, and drafted the manuscript. D.D. supervised the study, critically revised the manuscript, and approved the final version. Both authors read and approved the final manuscript.

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Not applicable.

Data Availability

All data supporting the findings of this study are available within the paper .

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Figures

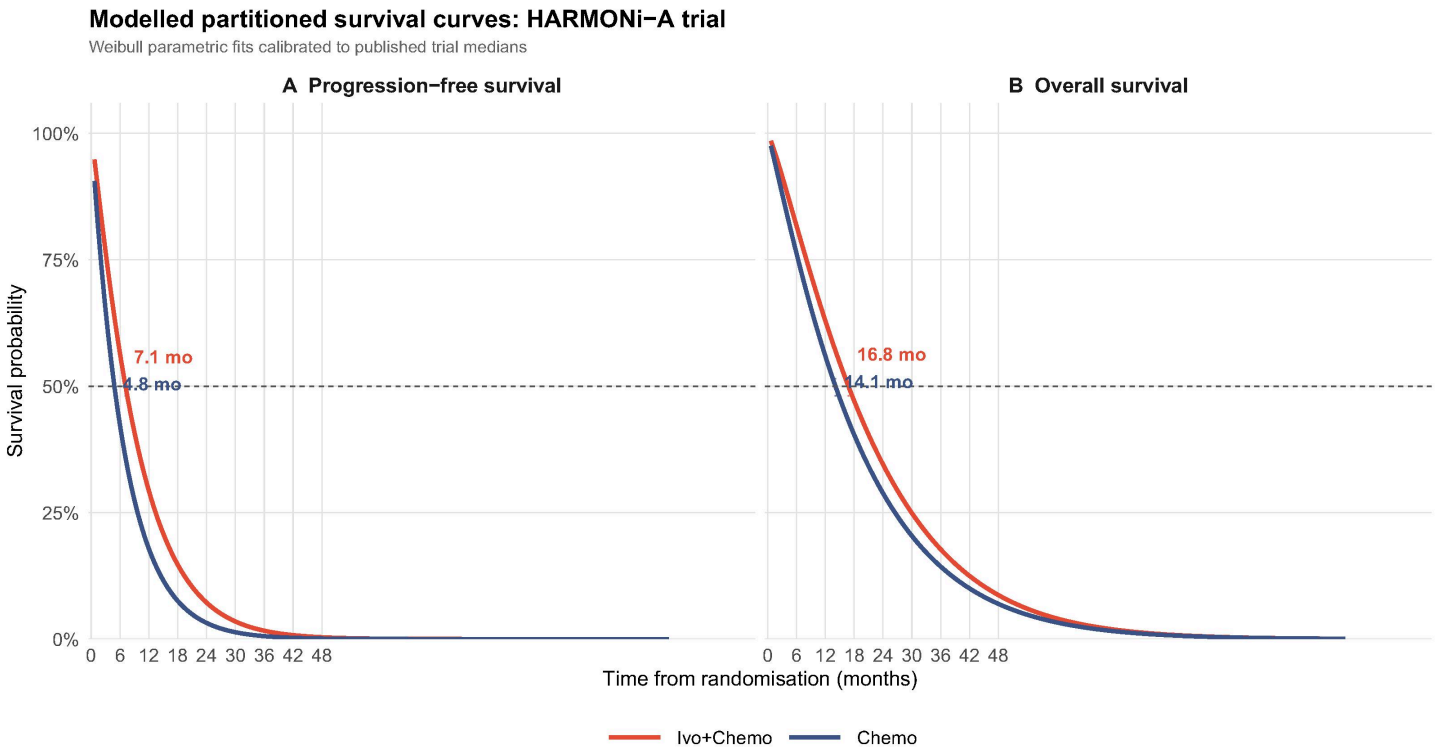


Figure 1

Modelled partitioned survival curves. Weibull parametric fits to the HARMONi-A landmark survival data, calibrated to the published trial medians. (A) Progression-free survival; (B) overall survival.

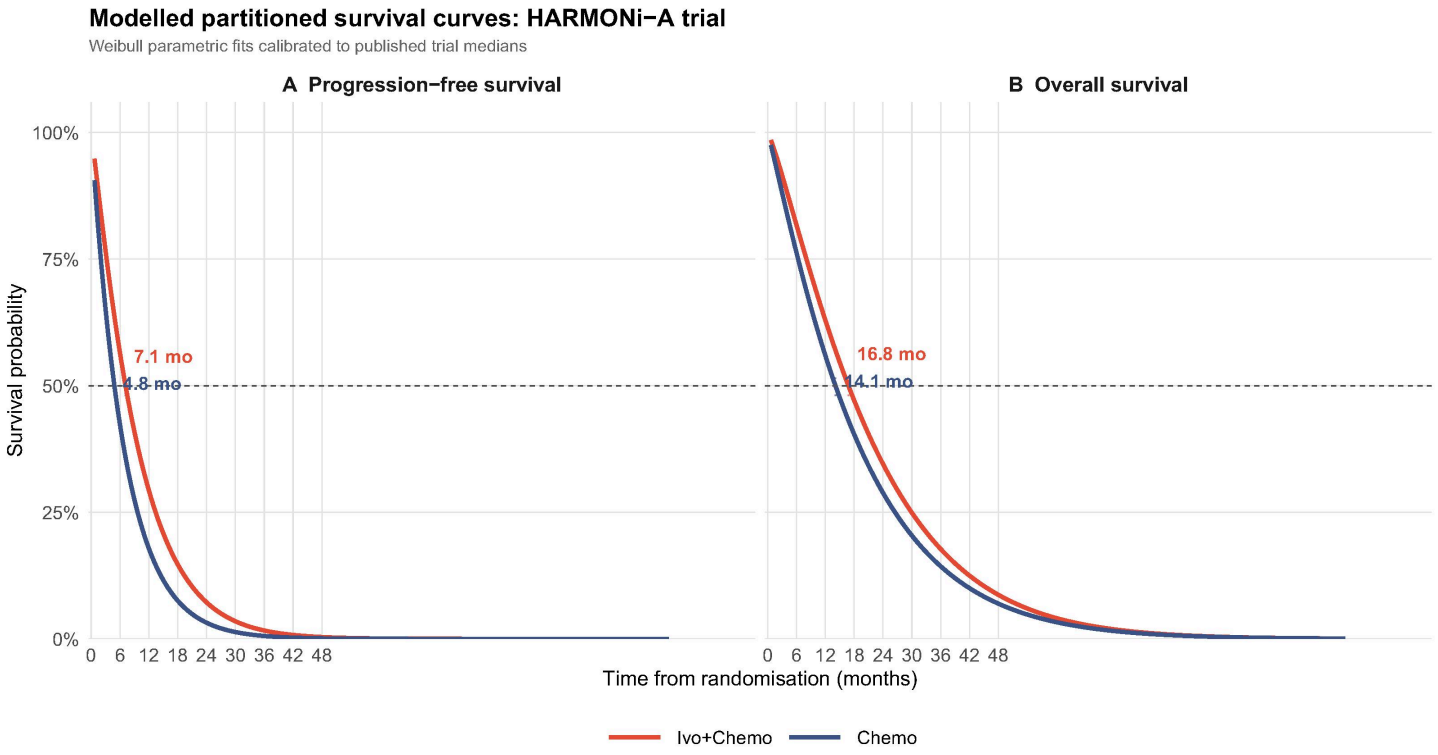


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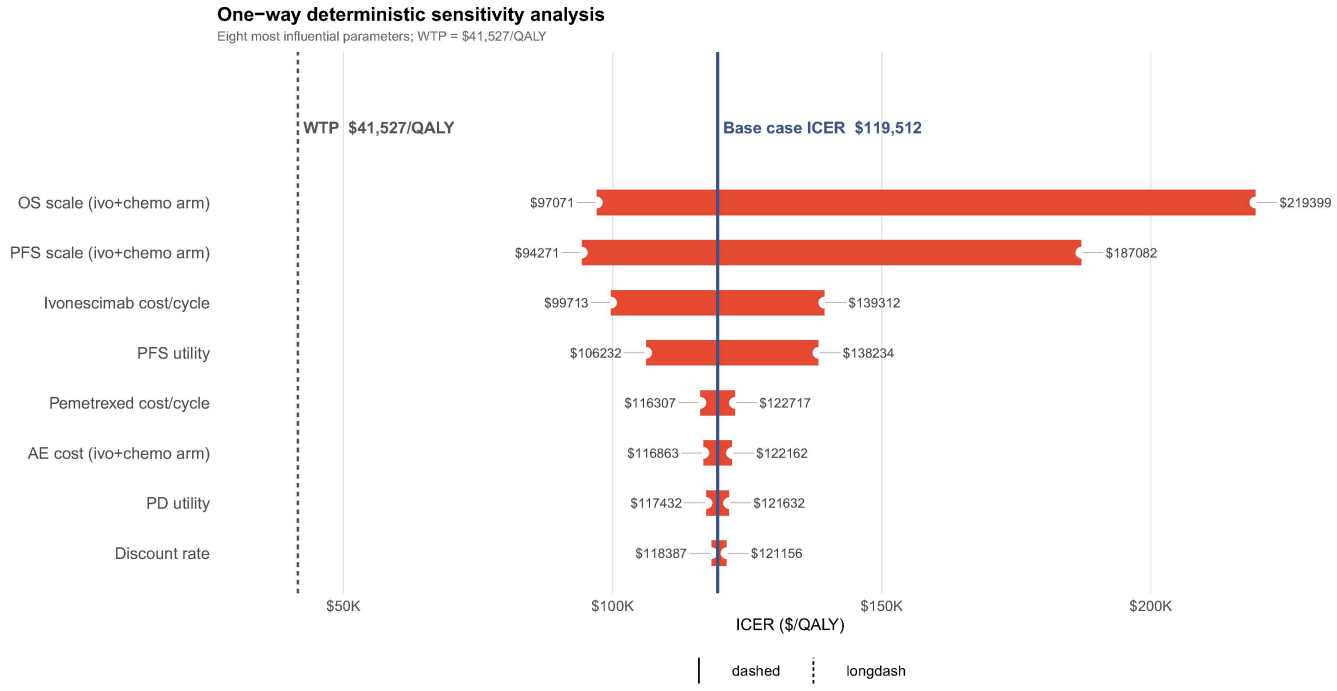


Figure 2

One-way deterministic sensitivity analysis. Tornado diagram showing the eight most influential parameters. The vertical dashed lines indicate the base-case ICER and the WTP threshold ($41,527 per QALY).

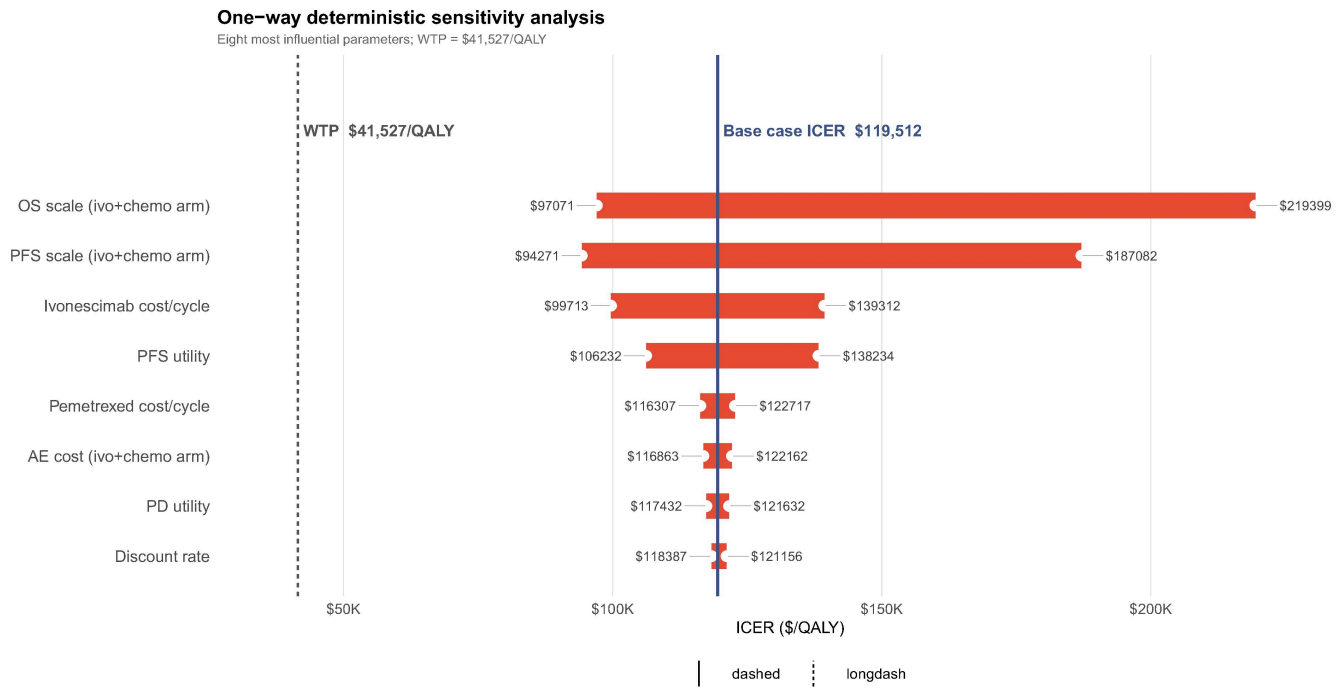


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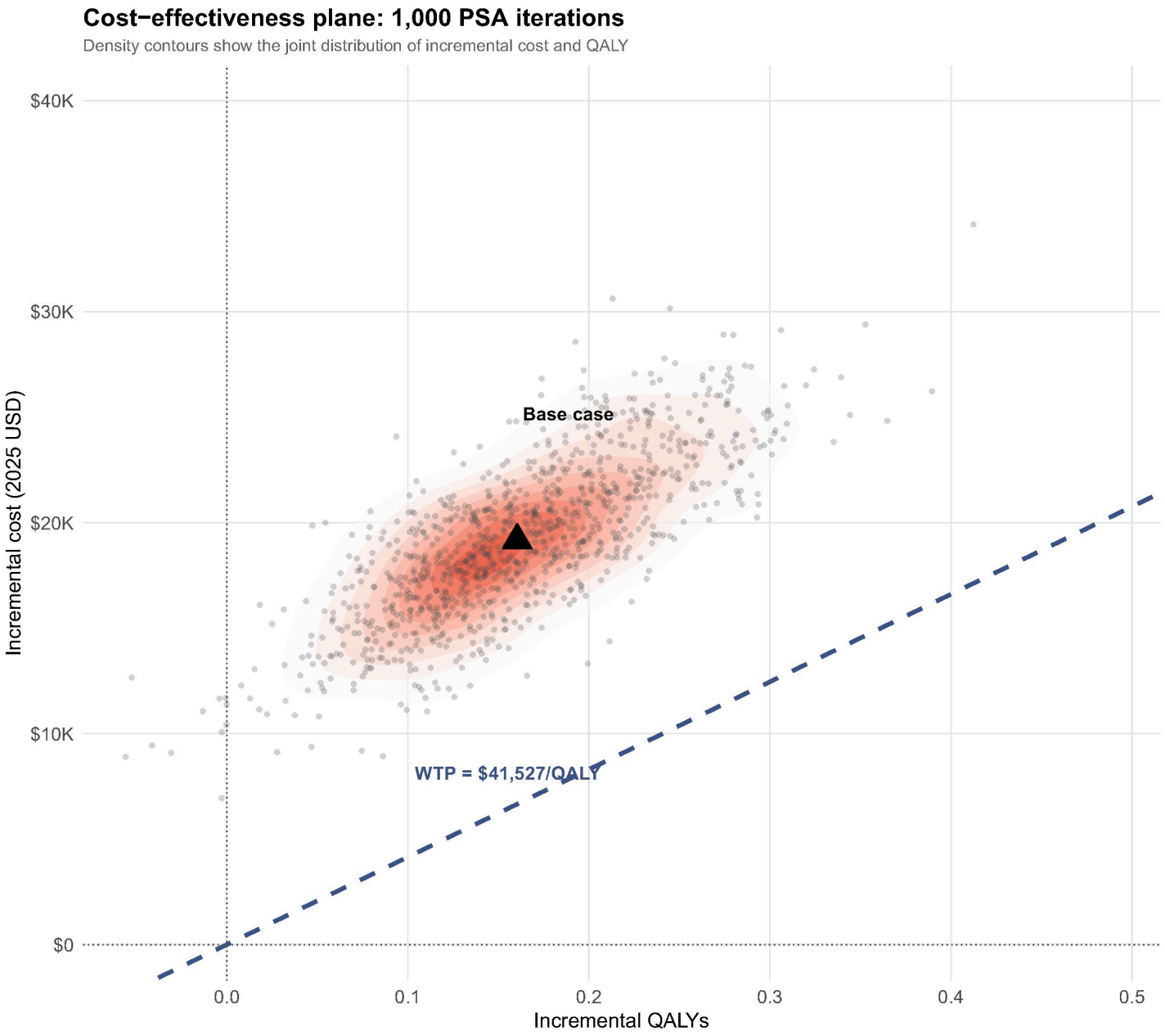


Figure 3

Cost-effectiveness plane. Scatter plot of incremental cost versus incremental QALY across 1,000 probabilistic iterations. Points below the WTP line are cost-effective.

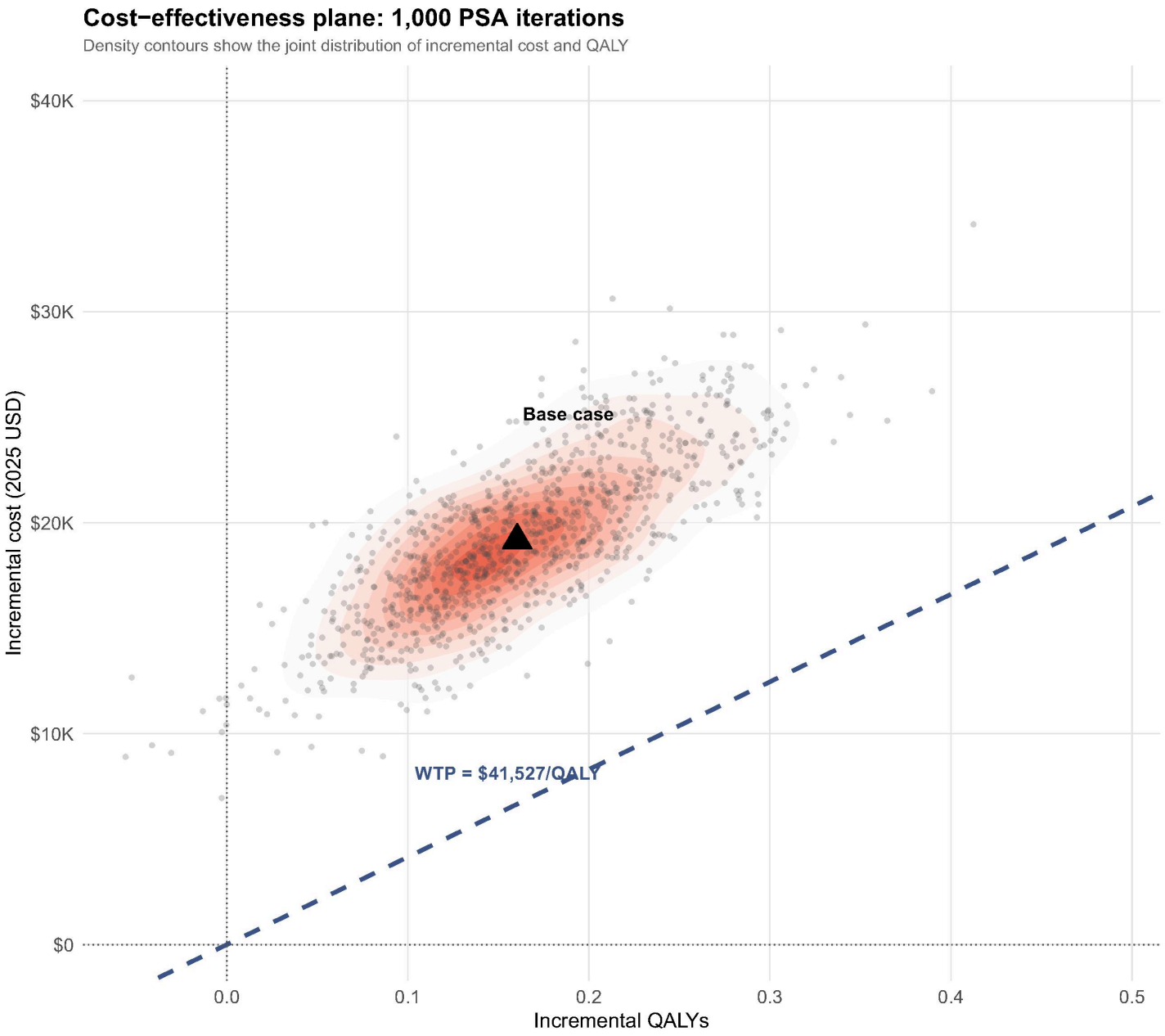


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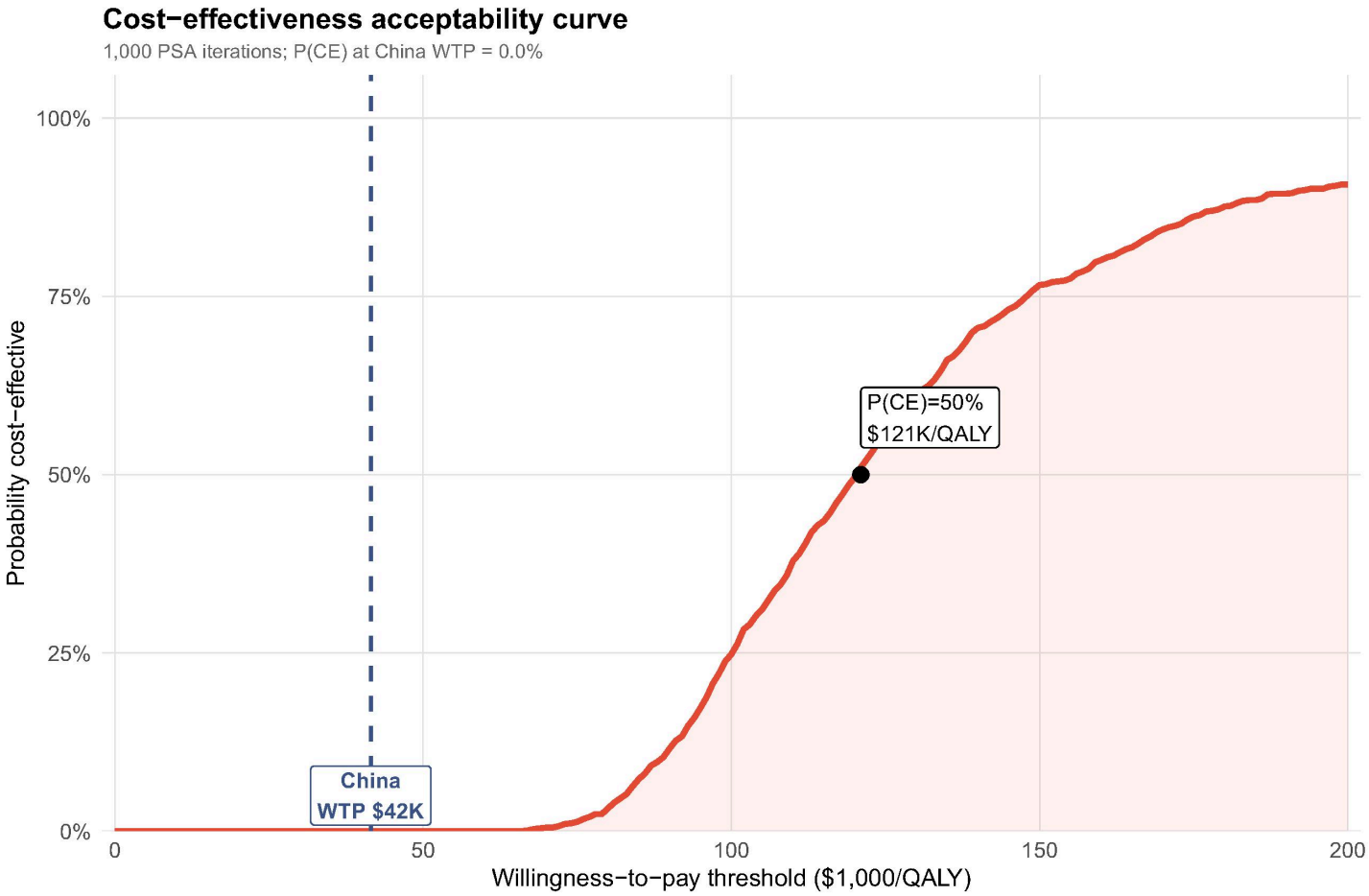


Figure 4

Cost-effectiveness acceptability curve. Probability that ivonescimab plus chemotherapy is cost-effective across a range of WTP thresholds. The dashed line indicates the Chinese WTP threshold of $41,527 per QALY.

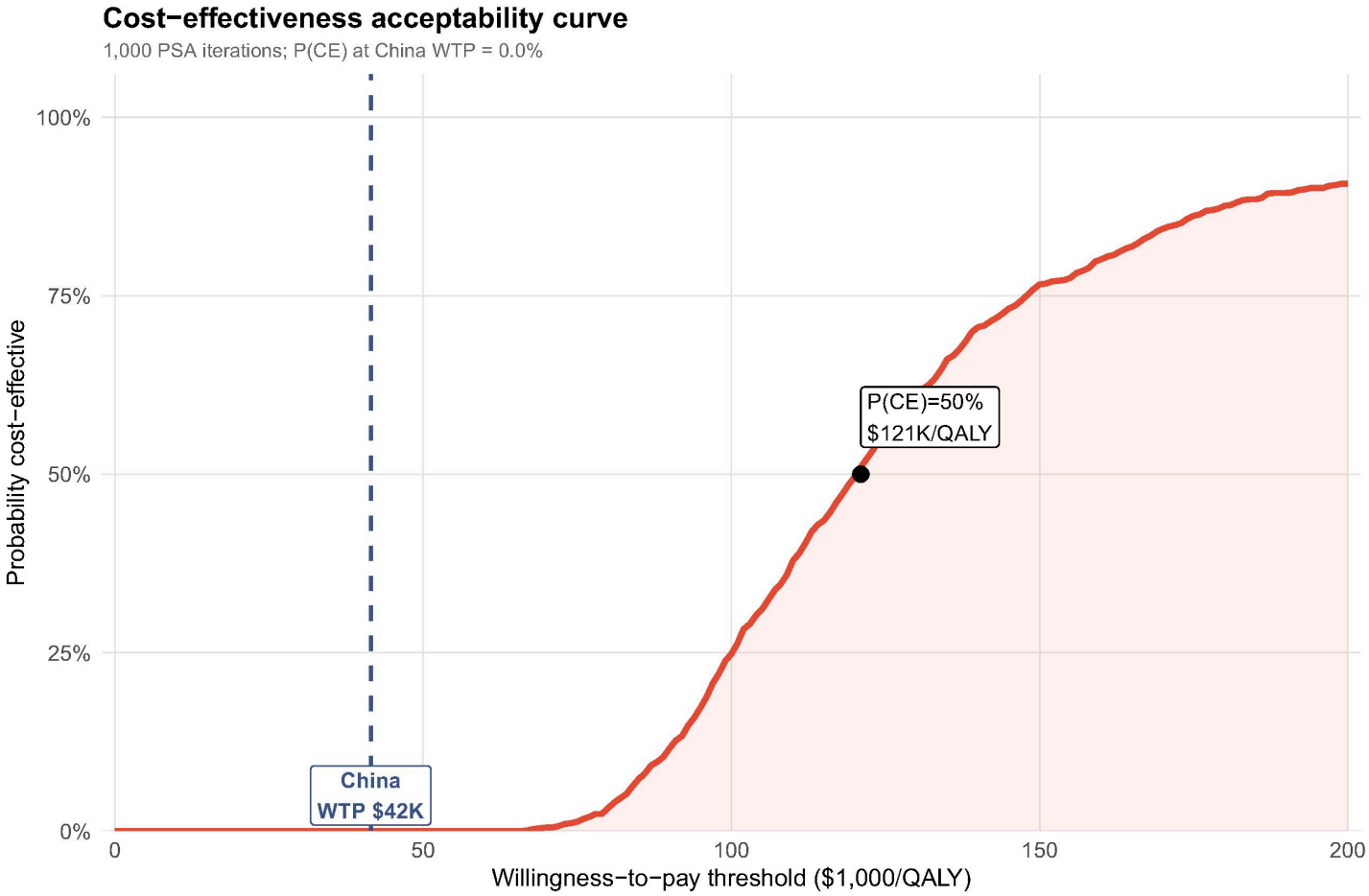


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