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Cost-effectiveness of datopotamab deruxtecan versus chemotherapy as a first-line treatment for patients with advanced triple-negative breast cancer

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Background: The phase III TROPION-Breast02 trial demonstrated improved progression-free and overall survival with datopotamab deruxtecan (Dato-DXd) versus chemotherapy in patients with previously untreated advanced triple-negative breast cancer who were ineligible for immunotherapy. This study evaluated the cost-effectiveness of Dato-DXd from the perspectives of the United States (U.S.) and Chinese healthcare systems.

Methods: A three-state partitioned survival model was developed using TROPION-Breast02 data, with a 10-year horizon and 21-day cycles. Costs and utilities were obtained from public databases and published literature. The primary outcome was the incremental cost-effectiveness ratio (ICER), expressed as cost per quality-adjusted life-year (QALY) gained. Willingness-to-pay thresholds were $150,000/QALY in the U.S. and $27,906/QALY in China. Sensitivity and scenario analyses assessed uncertainty and the robustness of the findings, and exploratory subgroup analyses were performed.

Results: Compared with chemotherapy, Dato-DXd increased costs by $565,572.29 and QALYs by 0.44 in the U.S., yielding an ICER of $1,287,001.65/QALY. In China, the corresponding increases were $39,052.50 and 0.42 QALYs, yielding an ICER of $92,640.82/QALY. Price reductions of approximately 62.43% in the U.S. and 28.83% in China were required to reach the respective cost-effectiveness thresholds. Progression-free survival utility and Dato-DXd price were the most influential parameters in one-way sensitivity analyses. In exploratory scenario analyses, limiting treatment duration to the reported median yielded cost-effective results in both countries. Assuming unchanged efficacy, a hypothetical reduction in the Dato-DXd dose from 6 to 4 mg/kg made it cost-effective in China but not in the U.S. Exploratory subgroup analyses yielded conclusions consistent with the base-case findings.

Conclusion: At the modeled prices and under the base-case assumptions, Dato-DXd was not cost-effective compared with chemotherapy in either country. Price reductions could improve its cost-effectiveness. Results were sensitive to

assumptions about treatment duration. The potential economic benefits of reduced-dose or fixed-duration strategies depend on clinical confirmation of maintained efficacy and acceptable safety.

KEYWORDS

cost-effectiveness, datopotamab deruxtecan, first-line treatment, partitioned survival model, triple-negative breast cancer

1 Introduction

Breast cancer ranks as the most common and fatal malignancy among women. In 2023, it was estimated that there were 2.3 million new cases and 764,000 deaths attributable to this disease, accounting for 24.1 million disability-adjusted life-years (DALYs) globally (Bhangdia et al., 2026). In the United States (U.S.) and China, the annual expenditures for breast cancer treatment are reported to be $29.8 billion and $3.8 billion, respectively (Zhou et al., 2024; Centers for Disease Control and Prevention, 2025). Triple-negative breast cancer (TNBC) is the most aggressive subtype of breast cancer, distinguished by its lack of expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2). This subtype is associated with a poor clinical prognosis and disproportionately affects younger women. Although TNBC constitutes approximately 15% of all breast cancer cases, it accounts for 35% of breast cancer-related mortality (Zhang et al., 2021). Although first-line standard therapies, including immune checkpoint inhibitors for programmed cell death ligand-1 (PD-L1)-positive disease and poly(ADP-ribose) polymerase (PARP) inhibitors for germline breast cancer susceptibility gene (gBRCA)-mutated tumors, are now available for advanced triple-negative breast cancer (TNBC), approximately 70% of TNBC patients do not benefit from immunotherapy (Punie et al., 2025), and the prevalence of gBRCA mutations in TNBC is less than 15% (Demarest et al., 2024).

The phase III TROPION-Breast02 trial assessed the efficacy of datopotamab deruxtecan (Dato-DXd), a trophoblast cell surface antigen 2 (TROP2)-targeted antibody-drug conjugate (ADC), compared to chemotherapy as a first-line treatment for patients with advanced TNBC who were not eligible for immunotherapy. At a median follow-up of 27.5 months, the median progression-free survival (PFS) was 10.8 months with Dato-DXd, compared to 5.6 months with chemotherapy (hazard ratio [HR] 0.57, 99% confidence interval [CI] 0.44–0.73; $P < 0.0001$). The median overall survival (OS) was 23.7 months with Dato-DXd versus 18.7 months with chemotherapy (HR 0.79; 95.01% CI 0.64–0.98; $P = 0.029$) (Dent et al., 2026). Based on these favorable outcomes, the U.S. Food and Drug Administration approved Dato-DXd on 22 May 2026, as a first-line treatment for this patient cohort. Furthermore, the National Comprehensive Cancer Network (NCCN) guidelines have endorsed Dato-DXd as the preferred first-line treatment option for these patients.

While Dato-DXd has shown substantial clinical efficacy, its high cost and limited accessibility may present significant barriers to widespread adoption. This study aimed to assess the cost-effectiveness of Dato-DXd versus chemotherapy as a first-line treatment for patients with advanced TNBC who were ineligible for immunotherapy, from the perspectives of the U.S. and Chinese healthcare systems. Cost-effectiveness analysis can help ascertain whether the survival benefits provided by Dato-DXd justify its associated expenses. Accordingly, our findings are expected to provide valuable economic evidence to support decision-making by reimbursement authorities, clinical oncologists, and pharmaceutical companies.

2 Methods

The study adhered to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines, as detailed in Supplementary Table S1.

2.1 Patients and interventions

The patient characteristics aligned with those observed in the TROPION-Breast02 trial. The cohort comprised individuals with locally recurrent inoperable or metastatic TNBC who had not received prior treatment and were deemed unsuitable for immunotherapy. Among the participants, 99.7% were female, 44.1% identified as White, and 43.8% identified as Asian. All subjects exhibited an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and presented with at least one measurable untreated lesion, as defined by the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Participants were randomly allocated in a 1:1 ratio to receive either 6 mg/kg Dato-DXd every 3 weeks or a chemotherapy regimen. Chemotherapy options included paclitaxel, nab-paclitaxel, carboplatin, eribulin mesylate, and capecitabine. Detailed information regarding the proportion of each chemotherapy regimen and specific administration protocols can be found in Supplementary Table S2. Treatment was continued until disease progression. The proportions of patients in the PD state who received subsequent anticancer treatment, as well as the specific regimens administered, were determined based on data from the TROPION-Breast02 trial, the NCCN guidelines, and the Chinese Society of Clinical Oncology (CSCO) guidelines. Notable subsequent agents included sacituzumab govitecan, trastuzumab deruxtecan, and various other chemotherapeutic agents, with additional details provided in Supplementary Table S3. It was assumed that patients continued to receive subsequent treatment until death.

2.2 Model structure

A partitioned survival model was developed using TreeAge Pro 2022. The model comprised three mutually exclusive health states: PFS, progressive disease (PD), and death. At any time t, the proportion of patients in each health state was defined using survival functions: $S_{PFS}(t)$ for the PFS state, $S_{OS}(t) - S_{PFS}(t)$ for the PD state, and $1 - S_{OS}(t)$ for the death state. These state probabilities remained non-negative and summed to 1 across the

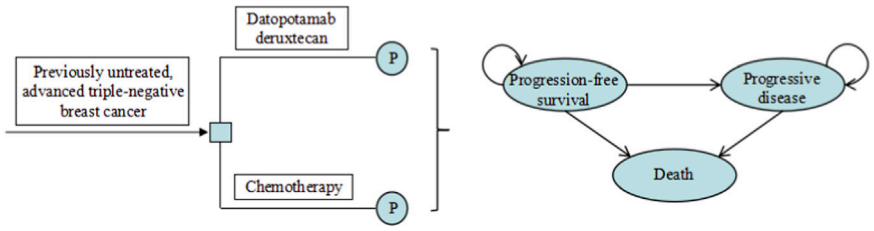

FIGURE 1
Model structure. P, partitioned survival model.

full model time horizon. Transitions were irreversible, with all patients starting in the PFS state. Patients could remain in PFS or transition to PD or death, while those in PD could either stay in PD or transition to death, as illustrated in Figure 1. In accordance with the patients' dosing regimen, the model established a cycle length of 21 days. The time horizon was set at 10 years. Primary outcomes included total costs, quality-adjusted life-years (QALYs), and the incremental cost-effectiveness ratio (ICER). A widely used willingness-to-pay (WTP) threshold of $150,000/QALY was adopted in the U.S. (Neumann et al., 2014; Neumann and Kim, 2023). As per the 2025 China Guidelines for Pharmacoeconomic Evaluations, a WTP threshold equivalent to twice the 2025 Gross Domestic Product (GDP) *per capita*, amounting to $27,906/QALY, was utilized in China (Wu and Liu, 2026). Furthermore, annual discount rates of 3% in the U.S. and 4.5% in China were applied (Sanders et al., 2016; Wu and Liu, 2026).

2.3 Clinical data

Survival data were extracted from the OS and PFS curves using WebPlotDigitizer. Subsequently, time-to-event data were derived utilizing the algorithm developed by Guyot et al. (Guyot et al., 2012), which was implemented in R with the survHE and flexsurv packages. The accuracy of the curve reconstruction was verified using the IPDfromKM package. The comparison of median survival data from the original and reconstructed survival curves is detailed in Supplementary Table S4. Given that the model's time horizon extended beyond the observation period of the TROPION-Breast02 trial, we employed multiple standard parametric models, including exponential, Weibull, gamma, log-normal, log-logistic, Gompertz, and generalized gamma distributions, in addition to three flexible modeling approaches: fractional polynomials (FP), restricted cubic splines (RCS), and Royston-Parmar (RP) models, to fit and extrapolate the survival curves. The selection of the optimal distribution was guided by lower Akaike Information Criterion (AIC) values and higher log-likelihood (LnL) values, supplemented by visual inspection and clinical plausibility. The fitting and extrapolation results are detailed in Supplementary Tables S5 and Supplementary Figures S1-S4. The optimal distributions for each survival curve and key parameters are presented in Supplementary Table S6.

2.4 Costs and utilities

This study was conducted from the perspectives of the U.S. and Chinese healthcare systems, focusing exclusively on direct medical costs, as shown in Table 1. These costs encompassed drug procurement, administration for intravenous infusion, imaging, follow-up, best supportive care (BSC), terminal care, and the management of severe adverse events (AEs). In the U. S., drug prices were derived from the databases of the Centers for Medicare & Medicaid Services (CMS), utilizing the Medicare Part B average sales price plus 6% (Centers for Medicare & Medicaid Services, 2026). Conversely, in China, drug prices were obtained from official bidding outcomes (Yaozhi Net, n.d.). Drug dosages were calculated using average body metrics for women: 160.65 cm height, 77.42 kg weight, and 1.87 m^2 body surface area in the U.S., based on data from National Center for Health Statistics (Centers for Disease Control and Prevention, n.d.); and 158 cm height, 59 kg weight, and 1.62 m^2 body surface area in China, according to 2020 Chinese Nutrition and Chronic Disease Report (National Health Commission of the People's Republic of China, 2021). Additional expenses were sourced from existing literature or local data. Pharmaceutical costs for both initial treatment in the chemotherapy group and subsequent treatment were calculated as the weighted sum of costs for each regimen, with weights set to the proportion of patients receiving the corresponding regimen during the respective treatment periods. Only grade 3–4 AEs with an incidence rate of 5% or higher in any group were considered. To adjust all costs to the 2025 price level, the U.S. Tom's inflation calculator (Halfhill, n.d.) and the Chinese Consumer Price Index were utilized. An exchange rate of 1 USD to 7.1429 RMB was employed to convert all costs into U.S. dollars.

Due to the lack of comprehensive quality-of-life data from the TROPION-Breast02 trial, the study derived utility values by referencing a prior study that utilized the standard gamble method to assess utility values for metastatic breast cancer (Lloyd et al., 2006). It was assumed that the transition from the stable state on treatment to the disease response results in an increase in utility value, which is calculated as the utility gained from the treatment response multiplied by the objective response rate (ORR) (Mudumba et al., 2024). PD utility was determined by subtracting disutility values associated with disease progression from the PFS utility (Lloyd et al., 2006; Wu and Ma, 2020; Zhu et al., 2026). Disutility values for AEs were also incorporated into the model to more accurately reflect changes in quality of life. All AEs were assumed to occur in the initial cycle. The total cost and disutility associated with AEs were calculated by multiplying the cost or disutility of each individual AE by its occurrence probability, with the resulting values applied in the first model cycle. For the chemotherapy group, calculations drew on the overall AE incidence rates reported in the TROPION-Breast02 trial.

TABLE 1 Key model inputs.

Parameter	Baseline value	Minimum	Maximum	Distribution	Source
Cost in U.S. ($)					
Dato-DXd per 1 mg	57.89	46.31	69.47	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Paclitaxel per 100 mg	16.52	13.21	19.82	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Nab-paclitaxel per 100 mg	676.41	541.13	811.69	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Carboplatin per 50 mg	3.30	2.64	3.96	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Eribulin mesylate per 1 mg	862.43	689.94	1,034.92	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Capecitabine per 500 mg	0.34	0.27	0.40	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Sacituzumab govitecan per 2.5 mg	39.01	31.21	46.81	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Trastuzumab deruxtecan per 1 mg	33.14	26.51	39.76	Gamma	(Centers for Medicare & Medicaid Services, 2026)
Tumour assessment per cycle	135.87	108.70	163.04	Gamma	(Xie et al., 2023)
Chemotherapy infusion					
First hour	138.38	110.70	166.06	Gamma	CPT code 96413, (Centers for Medicare & Medicaid Services, n.d.)
Additional hour	29.35	23.48	35.22	Gamma	CPT code 96415, (Centers for Medicare & Medicaid Services, n.d.)
Terminal care per patient	11,363.98	9,091.18	13,636.78	Gamma	(Xie et al., 2023)
Best supportive care per cycle	4,300.45	3,440.36	5,160.54	Gamma	(Lang et al., 2023)
Follow-up per cycle	1,068.12	854.50	1,281.74	Gamma	(Lang et al., 2023)
Cost of grade ≥3 AEs management				Gamma	
Stomatitis	10,391.33	8,313.06	12,469.60	Gamma	(Zhu et al., 2026)
Neutropenia	18,894.66	15,115.73	22,673.59	Gamma	(Zhu et al., 2026)
Amylase increased	7,573.32	6,058.66	9,087.98	Gamma	(Cai et al., 2021)
Body weight (kg)	77.93	62.34	93.52	Normal	(Centers for Disease Control and Prevention, n.d.)
Body surface area (m^2)	1.87	1.50	2.24	Normal	(Centers for Disease Control and Prevention, n.d.)
Discount rate (%)	3	0	8	Fixed	(Xie et al., 2023)
Cost in China ($)					
Dato-DXd per 1 mg	9.33	7.46	11.20	Gamma	(Yaozhi Net, n.d.)
Paclitaxel per 100 mg	43.77	35.02	52.52	Gamma	(Yaozhi Net, n.d.)
Nab-paclitaxel per 100 mg	50.43	40.34	60.52	Gamma	(Yaozhi Net, n.d.)
Carboplatin per 50 mg	6.39	5.11	7.67	Gamma	(Yaozhi Net, n.d.)
Eribulin mesylate per 1 mg	91.77	73.42	110.12	Gamma	(Yaozhi Net, n.d.)
Capecitabine per 500 mg	0.57	0.46	0.68	Gamma	(Yaozhi Net, n.d.)
Sacituzumab govitecan per 2.5 mg	16.33	13.06	19.60	Gamma	(Yaozhi Net, n.d.)
Trastuzumab deruxtecan per 1 mg	4.87	3.90	5.84	Gamma	(Yaozhi Net, n.d.)

(*Continued*)

TABLE 1 Continued

Parameter	Baseline value	Minimum	Maximum	Distribution	Source
Sacituzumab tirumotecan per 1 mg	3.37	2.70	4.04	Gamma	(Yaozhi Net, n.d.)
Tumour assessment per cycle	42.85	34.28	51.42	Gamma	(Shu et al., 2025)
Intravenous infusion per time	7.16	5.73	8.59	Gamma	(Shu et al., 2025)
Terminal care	2,481.55	1,985.24	2,977.86	Gamma	(Shu et al., 2026)
Best supportive care per cycle	361.87	289.50	434.24	Gamma	(Liu et al., 2025a)
Follow-up per cycle	499.86	399.89	599.83	Gamma	(Wang et al., 2024)
Cost of grade ≥3 AEs management					
Stomatitis	13.16	10.53	15.79	Gamma	(Zhu et al., 2026)
Neutropenia	417.18	333.74	500.62	Gamma	(Zhu et al., 2026)
Amylase increased	420	336.00	504.00	Gamma	Estimated
Body weight (kg)	59	47.20	70.80	Normal	(National Health Commission of the People's Republic of China, 2021)
Body surface area ($m^{2)}$	1.62	1.30	1.94	Normal	(National Health Commission of the People's Republic of China, 2021)
Discount rate (%)	4.5	0	5	Fixed	(Zhu et al., 2026)
Utility					
PFS	0.85	0.68	1.00	Beta	(Wu and Ma, 2020)
PD	0.52	0.42	0.62	Beta	(Wu and Ma, 2020)
Utility gained by treatment response	0.075	0.06	0.09	Beta	(Lloyd et al., 2006)
Disutility					
Stomatitis	0.15	0.12	0.18	Beta	(Lloyd et al., 2006)
Neutropenia	0.1	0.08	0.12	Beta	(Shu et al., 2026)
Amylase increased	0.09	0.07	0.11	Beta	(Critchlow et al., 2024)
Risks of grade ≥ 3 AEs in Dato-DXd group					
Stomatitis	0.08	0.06	0.10	Beta	(Dent et al., 2026)
Neutropenia	0.03	0.02	0.04	Beta	(Dent et al., 2026)
Amylase increased	0.06	0.05	0.07	Beta	(Dent et al., 2026)
Risks of grade ≥ 3 AEs in chemotherapy group					
Stomatitis	0	NA	NA	NA	(Dent et al., 2026)
Neutropenia	0.13	0.10	0.16	Beta	(Dent et al., 2026)
Amylase increased	0	NA	NA	NA	(Dent et al., 2026)
ORR in Dato-DXd group	0.63	0.50	0.76	Beta	(Dent et al., 2026)
ORR in chemotherapy group	0.29	0.23	0.35	Beta	(Dent et al., 2026)

AE, adverse event; Dato-DXd, datopotamab deruxtecan; PD, progressive disease; PFS, progression-free survival; ORR, objective response rate.

2.5 Sensitivity analyses

One-way sensitivity analysis was employed to assess the impact of changes in individual variables on the outcomes. Variables were adjusted by ±20% from their baseline values (Zhu et al., 2026). Subsequently, two-way sensitivity analysis was conducted on the two variables with the greatest impact on outcomes. Probabilistic sensitivity analysis was then performed by assigning appropriate distributions to each variable and executing 5,000 Monte Carlo simulations to evaluate the effects of concurrent changes across all variables. Specifically, gamma distributions were assigned to costs, beta distributions to utility and probability parameters, and normal distributions to body weight and surface area (with standard deviation set at 10% of the baseline value). The proportions of subsequent treatment regimens were incorporated into the sensitivity analysis to evaluate their influence on the model outcomes.

2.6 Price simulation

To inform the pricing strategy of Dato-DXd, a threshold analysis was conducted on its price.

2.7 Scenario analyses

A comprehensive series of scenario analyses was undertaken. Scenarios 1–3 evaluated the effects of establishing the time horizon at the observation duration of the TROPION-Breast02 trial (39 months), as well as at 5 years and 15 years, respectively. Scenarios 4–7 were formulated to explore uncertainties inherent in the model structure. In scenario 4, a suboptimal model was utilized wherein all curves were fitted and extrapolated with standard parametric distributions: the OS curves employed a log-logistic distribution, whereas the PFS curves employed a generalized gamma distribution. Key parameters are detailed in Supplementary Table S7. In scenarios 5 and 6, a proportional hazards (PH) model was utilized to address bias resulting from different parametric survival models between the two groups. However, the Schoenfeld residual test showed the PFS curve did not meet the PH assumption (Supplementary Figures S5, S6). Thus, scenario 5 assumed a constant HR for 39 months, then a linear approach to 1 over the period from 39 months to 10 years. Scenario 6 assumed a constant HR over 10 years to evaluate cost-effectiveness with optimal Dato-DXd efficacy. Scenario 7 adopted a four-state partitioned survival model consisting of four health states: PFS, first PD, second PD, and death. This model was developed based on recently published PFS2 data, which was defined as the duration from randomization to either the first documented disease progression during the subsequent line of therapy or death from any cause (Cescon et al., 2026), as depicted in Supplementary Figure S7. The proportion of patients in each health state was derived from survival functions: $S_{PFS}(t)$ corresponded to the PFS state, $S_{PFS2}(t) - S_{PFS}(t)$ to the first PD state, $S_{OS}(t) - S_{PFS2}(t)$ to the second PD state, and $1 - S_{OS}(t)$ to the death state. Due to the lack of specific utility data, utility values for first PD and second PD were not differentiated. Costs were categorized according to the stage of disease progression, with the assumption that patients in the first PD state receive the subsequent treatment outlined in the base-case analysis until further disease progression, after which they receive only BSC in the second PD state. All cost inputs, including drug prices, were aligned with those utilized in the base-case analysis. The extrapolation results for PFS2 are presented in Supplementary Table S5 and Supplementary Figures S8, S9, with the key parameters of the optimal distributions detailed in Supplementary Table S6. Scenarios 8–11 incorporated four additional sets of PFS and PD utility values derived from similar studies (Rui et al., 2020; Liu et al., 2025b). In scenario 12, the increase in utility arising from the transition from the stable state on treatment to disease response was not incorporated. In scenario 13, response-related utility was further adjusted according to the duration of response (DoR). In scenario 14, life-years (LYs) were utilized as the measure of effectiveness instead of QALYs. In scenario 15, the median treatment duration from the TROPION-Breast02 study was used to limit treatment cycles for Dato-DXd (12 cycles) and chemotherapy (6 cycles), assessing the impact of factors like AE intolerance and poor adherence on cost-effectiveness. In addition, we examined ICER changes with varying Dato-DXd treatment durations. Scenario 16 explored a hypothetical dose reduction of Dato-DXd from 6 mg/kg to 4 mg/kg for economic simulation purposes. Scenario 17 assumed that all patients received only BSC after disease progression. With another TROP2-ADC, sacituzumab tirumotecan, being included in the Chinese National Medical Insurance Drug List (NMIDL) for subsequent treatment of breast cancer, scenario 18 proposed replacing sacituzumab govitecan with sacituzumab tirumotecan in subsequent treatment regimens from a Chinese perspective. In the chemotherapy arm of scenario 19, patients with no prior taxane or prior (neo)adjuvant taxane and disease-free interval (DFI) > 12 months (82%) were assumed to receive nab-paclitaxel, while patients with prior taxane exposure and DFI ≤ 12 months (18%) were assumed to receive eribulin mesylate.

2.8 Subgroup analyses

To assess the cost-effectiveness of Dato-DXd across different patient subgroups, subgroup analyses were performed based on the following characteristics: age, ECOG performance status, HER2 expression, presence of brain metastases, presence of liver metastases, number of metastatic sites, DFI history, PD-L1 status, prior exposure to immunotherapy, and the pre-selected chemotherapy regimen. Owing to limited data, the ICER for each subgroup was estimated using the specific HR values for OS and PFS of each subgroup, under the PH assumption.

3 Results

3.1 Base-case analysis

Table 2 presents the results of the base-case analysis. From the U.S. perspective, the incremental cost was $565,572.29, the incremental QALYs were 0.44, and the ICER was $1,287,001.65/QALY. From the Chinese perspective, the incremental cost was $39,052.50, the incremental QALYs were 0.42, and the ICER was $92,640.82/QALY. In both countries, the ICERs exceeded the respective WTP thresholds, indicating that Dato-DXd was not cost-effective in either setting.

TABLE 2 The results of the base-case analysis.

Regimen	Cost ($)	Incremental cost ($)	QALYs	Incremental QALYs	ICER ($/QALY)
U.S. perspective					
Chemotherapy	385,841.58	NA	1.50	NA	NA
Dato-DXd	951,413.88	565,572.29	1.93	0.44	1,287,001.65
Chinese perspective					
Chemotherapy	96,501.79	NA	1.45	NA	NA
Dato-DXd	135,554.29	39,052.50	1.87	0.42	92,640.82

Dato-DXd, datopotamab deruxtecan; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

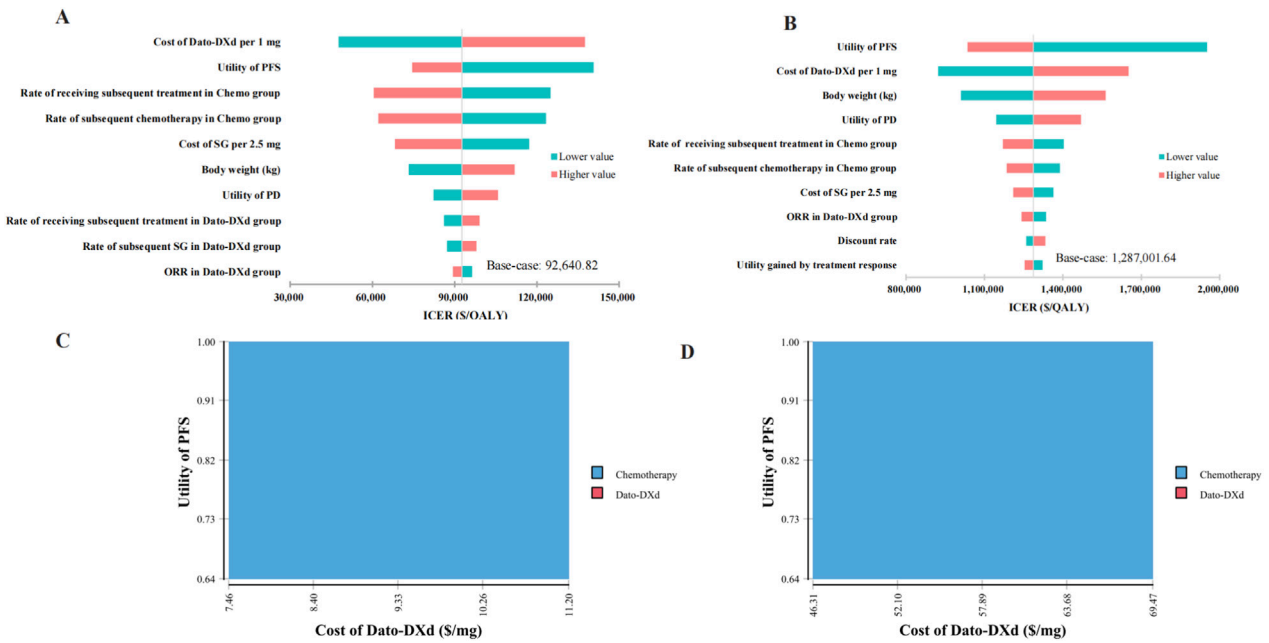

FIGURE 2
The one-way and two-way sensitivity analysis results in China **(A, C)** and U.S. **(B, D)**. Note: Red background indicates that the ICER for Dato-DXd versus Chemo is lower than the WTP threshold, while blue represents that the ICER is higher than the WTP threshold. Chemo, chemotherapy; Dato-DXd, datopotamab deruxtecan; PFS, progression-free survival; ORR, objective response rate; OS, overall survival; SG, sacituzumab govitecan.

3.2 Sensitivity analyses

The one-way sensitivity analysis, presented as a tornado plot in Figure 2, identified the top ten variables affecting the model outcomes, among which PFS utility and Dato-DXd price were the most influential variables in both the U.S. and China. Even so, variations in these variables did not make the ICER fall below the WTP threshold. Two-way sensitivity analysis of PFS utility and Dato-DXd price showed that Dato-DXd was not cost-effective within the tested ranges of these two variables (Figure 2). Figure 3 presents the results of the probabilistic sensitivity analysis, where the scatter plots indicated that under the WTP thresholds adopted in this study, Dato-DXd had a 0% probability of being cost-effective in the U.S., compared with 3.62% in China. The cost-effectiveness acceptability curves showed that the probability of Dato-DXd being cost-effective increased as the WTP threshold rose.

3.3 Price simulation

In the U.S., a price reduction exceeding 62.43% for Dato-DXd (to $21.75/mg) was necessary for the ICER to fall below the WTP threshold of $150,000/QALY. In China, a price reduction of more than 28.83% (to $6.64/mg) was required for the ICER to fall below the WTP threshold of $27,906/QALY, as illustrated in Figure 4.

3.4 Scenario analyses

The model's outcomes remained consistent across the majority of scenario analyses, as outlined in Supplementary Table S8. However, when treatment cycles were restricted based on the median duration of therapy, Dato-DXd demonstrated cost-effectiveness in both the U.S. and China, with ICERs of $108,468.19/QALY and −$52,521.71/QALY, respectively,

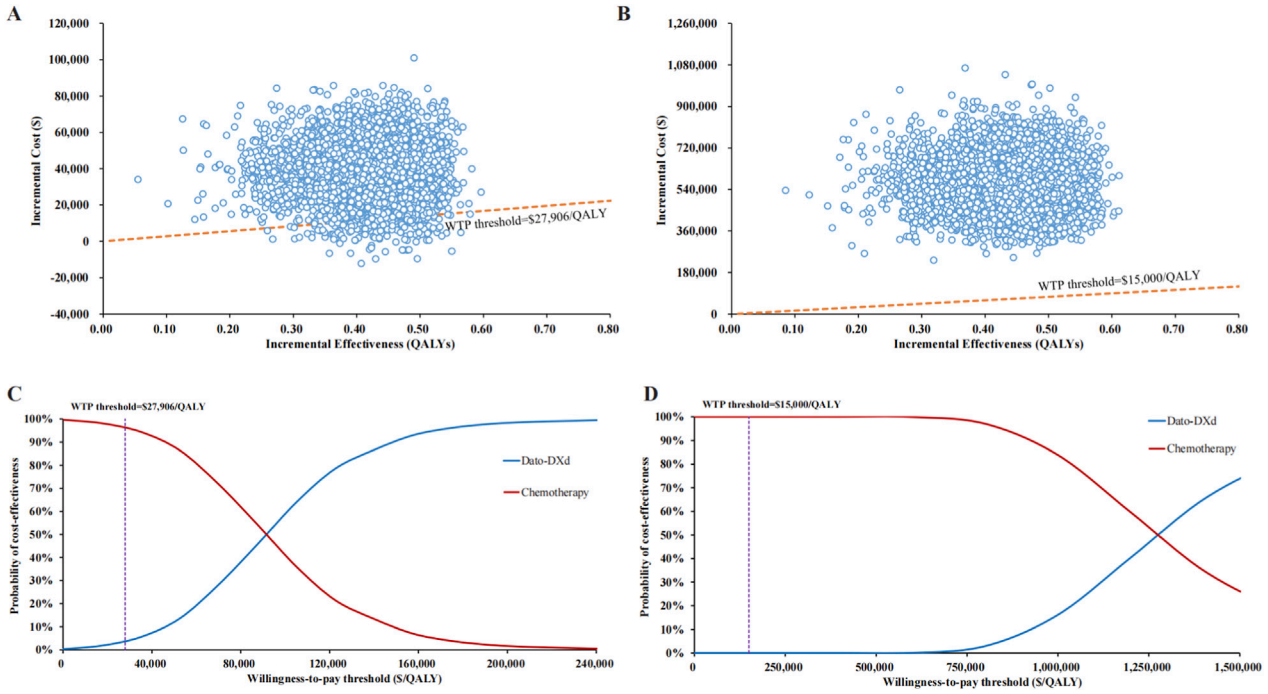

FIGURE 3
Incremental cost-effectiveness scatter plot and cost-effectiveness acceptability curve of probabilistic sensitivity analysis results in China **(A, C)** and U.S. **(B, D)**. Dato-DXd, datopotamab deruxtecan; QALY, quality-adjusted life-year; WTP, willingness-to-pay.

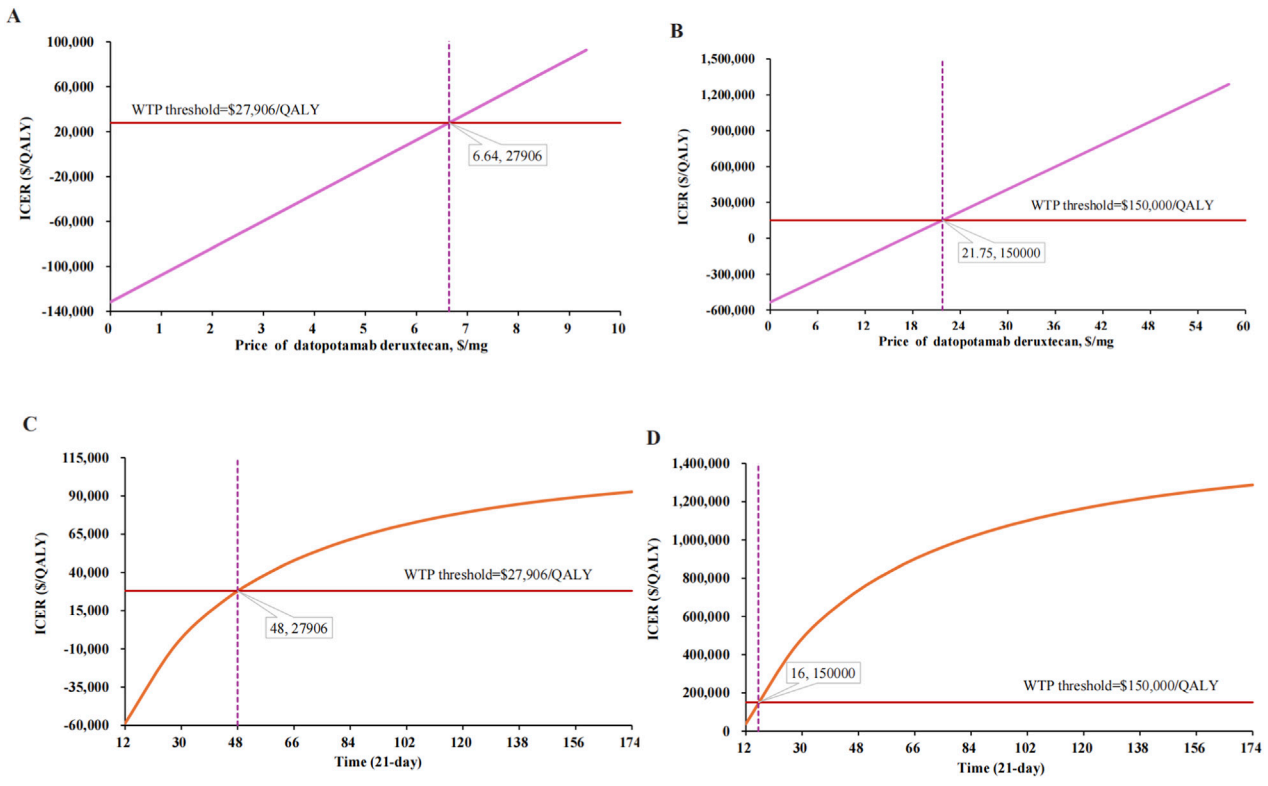

FIGURE 4
Dato-DXd price simulation and treatment duration simulation results. **(A)**, Price simulation in China. **(B)**, Price simulation in the U.S. **(C)**, Treatment duration simulation in China. **(D)**, Treatment duration simulation in the U.S. Dato-DXd, datopotamab deruxtecan; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; WTP, willingness-to-pay.

establishing it as the dominant option in China. Since median treatment duration reflects neither the mean treatment duration nor the maximum treatment duration, these findings should be interpreted with caution. Hypothetical simulations of Dato-DXd treatment duration suggested that restricting treatment to 16 cycles in the U.S. and 48 cycles in China could reduce the ICER to the corresponding WTP thresholds (Figure 4). When a hypothetical 4 mg/kg dose was modeled, the ICER in China decreased to $17,858.06/QALY, suggesting potential economic favorability under this assumption. However, the corresponding ICER for the U.S. remained above its WTP threshold.

3.5 Subgroup analyses

The cost-effectiveness outcomes across all subgroups were consistent with those of the base-case analysis, as summarized in Supplementary Table S9. However, this was only an exploratory analysis as the PH assumptions were not consistently satisfied.

4 Discussion

Compared to another TROP2 ADC, sacituzumab govitecan, which has demonstrated a significant improvement in PFS as a first-line monotherapy for metastatic TNBC in its Phase III trial and has recently received approval from the U.S. FDA for this indication, Dato-DXd currently emerges as the sole TROP2 ADC to exhibit a significant OS benefit. Moreover, Dato-DXd necessitates less frequent administration (once every 3 weeks as opposed to twice every 3 weeks) and is associated with lower incidences of severe hematologic toxicity. However, our model results indicated that the high costs limit the economic viability of Dato-DXd. Sensitivity analyses revealed that, aside from the utility of PFS, the cost of Dato-DXd was the most critical factor affecting cost-effectiveness. This finding aligned with another cost-effectiveness analysis comparing Dato-DXd to docetaxel for the treatment of advanced non-squamous non-small-cell lung cancer in the U.S. (Song, 2025). Based on pricing simulations, Dato-DXd would require a 62.43% price reduction to achieve cost-effectiveness in the U.S., versus 28.83% in China. U.S. drug prices have long been elevated. In 2022, average prices in the U.S. were 2.78 times those of other Organisation for Economic Co-operation and Development (OECD) countries, and branded originals reached 4.22 times higher (Mulcahy et al., 2024). In contrast, Europe uses a national health insurance system that acts as the sole or dominant purchaser and relies on Health Technology Assessment (HTA) to tightly control prices. For example, the United Kingdom uses cost-benefit analysis to limit new drug prices (Rodwin, 2021b), while France and Germany compare new drugs to existing ones, ensuring prices do not exceed those of current treatments unless additional benefits are offered (Rodwin, 2021a). The U.S. has only recently taken action, with the Inflation Reduction Act of 2022 authorizing CMS to negotiate prices. The first two negotiation rounds cut Medicare net prices by 22% and 44% (Rome and Kesselheim, 2026). Furthermore, a Most-Favored-Nation pricing model has been proposed for implementation in 2025 (Hwang et al., 2026). However, HTA is not yet mandatory for U.S. pricing decisions, making the 62.43% price reduction for Dato-DXd extremely challenging. In China, price negotiations have become a pivotal mechanism for managing the NMIDL. Each year, numerous innovative pharmaceuticals are incorporated into the list through these negotiations, whereby manufacturers gain reimbursement eligibility by accepting price reductions, thereby securing market share in public hospitals. As a result, enhanced drug accessibility and affordability have substantially improved equity in medication access nationwide. Price reductions for drugs successfully added to the NMIDL range from 24% to 72%, with health technology assessment (HTA) serving as a critical reference (Zhu et al., 2025). In this context, given the irreplaceable clinical value of Dato-DXd as first-line treatment for TNBC, our study provides important evidence for government agencies in setting reimbursement prices and for pharmaceutical companies in developing pricing strategies.

In the dose-escalation study for lung cancer, the conventional Dato-DXd dose was established at 6 mg/kg; however, no clinical evaluations of alternative dosages have been conducted in breast cancer patients (Tang et al., 2026). In the TROPION-Breast02 trial, 27% of patients receiving Dato-DXd required dose reductions, and 24% had treatment interruptions. The 4 mg/kg dose was the recommended first reduction level. Although the clinical efficacy of this dose has not been validated, real-world evidence suggests that reducing the ADC dose may not substantially affect outcomes in advanced breast cancer (Stabellini et al., 2026). This reduced-dose simulation suggested potential cost-effectiveness for Dato-DXd in the scenario analysis. Moreover, treatment duration was a critical factor affecting total drug exposure. Limiting treatment cycles is a strategy to optimize ADC administration and may mitigate chronic toxicities from prolonged dosing (Liao et al., 2021). Establishing upper limits of 16 cycles in the U.S. and 48 cycles in China would make Dato-DXd cost-effective at the established WTP thresholds. These hypothetical economic simulations suggest that cost-effectiveness might be improved if future clinical validation confirms maintained efficacy and safety with dose reduction or fixed-duration treatment. Such strategies remain hypothetical and would require prospective clinical evaluation before clinical implementation. Subgroup analyses demonstrated consistent cost-effectiveness across all subgroups. However, these findings should be interpreted with caution and not used to establish definitive treatment-selection recommendations, given that this was an exploratory analysis and the PH assumptions were not met for the PFS curves.

This study had several limitations. Firstly, extrapolation of survival curves introduced structural uncertainty that may bias the results. Although we employed both standard and flexible parametric models to capture the inflection points and tail patterns of the curves, and conducted scenario analyses (including a four-state model, PH models, and a suboptimal model) to assess this uncertainty, further validation using real-world long-term follow-up data remains essential. Secondly, utility values were sourced from existing literature and may differ from actual clinical data; however, one-way sensitivity analysis and scenario analyses confirmed the robustness of the results to these variations. Thirdly, the study exclusively considered disutility values and management costs associated with grade ≥ 3 AEs, and assumed that all AEs occur during the initial treatment cycle. This approach may not fully capture cumulative or delayed treatment-related toxicity. Nevertheless, tornado plot analysis demonstrated that AE-related variables exerted minimal impact on the model outputs. Fourthly, assumptions about subsequent treatment

regimens may not fully reflect real-world practice. To address this, we included the proportions of these regimens in sensitivity analyses and performed scenario analyses, including a model with BSC only after disease progression and a model replacing sacituzumab govitecan with sacituzumab tirumotecan in the Chinese setting. These analyses demonstrated that such variations did not materially affect the results. Future validation using real-world data would be highly beneficial. Finally, the probabilistic sensitivity analysis in this study did not incorporate uncertainty in survival model parameters. Because the OS and PFS models were fitted separately, independent parameter sampling may violate the structural constraints of the partitioned survival model. Although we assessed the uncertainty of survival extrapolation via scenario analyses using alternative survival models, the overall uncertainty may still be underestimated.

5 Conclusion

In both the U.S. and China, Dato-DXd was not considered cost-effective relative to chemotherapy as a first-line treatment for patients with advanced TNBC who are ineligible for immunotherapy. Lowering its price would improve economic viability, thereby allowing more patients to benefit from its clinical effects. Additionally, hypothetical economic simulations suggest that cost-effectiveness might be improved via dose optimization or fixed-duration strategies if supported by future clinical studies confirming maintained efficacy and safety. These remain investigational and not yet actionable as clinical strategies.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding authors.

Author contributions

ZX: Formal Analysis, Writing – original draft, Data curation, Conceptualization. QX: Writing – review and editing, Software. ZL: Methodology, Conceptualization, Writing – review and editing.

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Conflict of interest

The author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fphar.2026.1965457/full#supplementary-material

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