Incorporating Dynamic Drug Pricing in US Cost-Effectiveness Models: A Hypothetical Simulation Study

MSR10

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INTRODUCTION

- In the United States (US), cost-effectiveness analysis (CEA) is increasingly central to reimbursement and coverage decision-making, particularly as payers and policymakers seek to align drug expenditure with demonstrated clinical value[1]
- Conventional CEA models assume drug prices remain fixed over the analytic time horizon - an assumption that poorly reflects the US market reality, where net prices evolve through competition, Pharmacy Benefit Manager (PBM) rebate negotiations, and multi-year contracting arrangements[2]
- The Inflation Reduction Act (2022) and the expansion of outcomes-based agreements (OBAs) have further accelerated the shift toward price structures that are explicitly linked to real-world performance, rendering static pricing assumptions increasingly untenable in US health economic models[3]
- Dynamic Drug Pricing (DDP) frameworks operationalize this shift by allowing drug costs to be reassessed at predefined intervals based on observed outcomes - influencing the cost component of the CEA while leaving the effectiveness structure intact[4]
- Despite growing policy relevance, the methodological implications of incorporating DDP into Markov cohort models have not been formally evaluated - representing a structural gap in current US CEA practice

OBJECTIVE

- To assess the methodological and decision-analytic implications of incorporating a DDP framework into a Markov cohort cost-effectiveness model, using a hypothetical simulation study conducted from a US payer perspective over a 10-year time horizon

METHODS

- A three-state Markov cohort model was developed to evaluate a hypothetical novel therapy versus standard of care (SoC), comprising: Stable/Response, Progressive Disease, and Death
- A one-year model cycle was applied over a 10-year time horizon from a US third-party payer perspective; costs and outcomes were discounted at 3% annually per US Panel recommendations
- Health-state transition probabilities and utility values were sourced from published literature reflecting plausible disease trajectories for a hypothetical oncology-like indication
- Incremental quality-adjusted life years (QALYs) were derived from simulated longitudinal effectiveness data consistent with published real-world evidence ranges
- Under the static scenario, drug acquisition costs were held constant across the 10-year horizon
- Under the DDP scenario, drug prices were subject to biennial reassessment at years 2, 4, 6, and 8; price adjustments were triggered when cumulative QALY thresholds were not met, with a maximum permissible reduction of 20% per reassessment cycle
- Dynamic price adjustments influenced the cost component of the model only; effectiveness inputs remained unchanged across both scenarios

Figure 1: DDP biennial reassessment framework

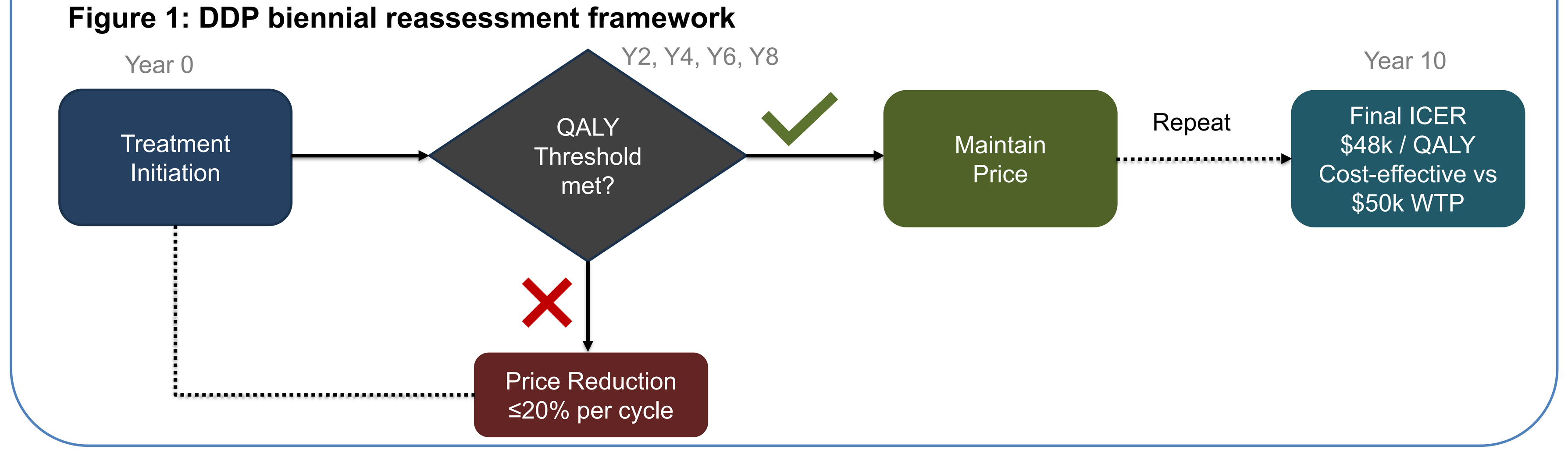
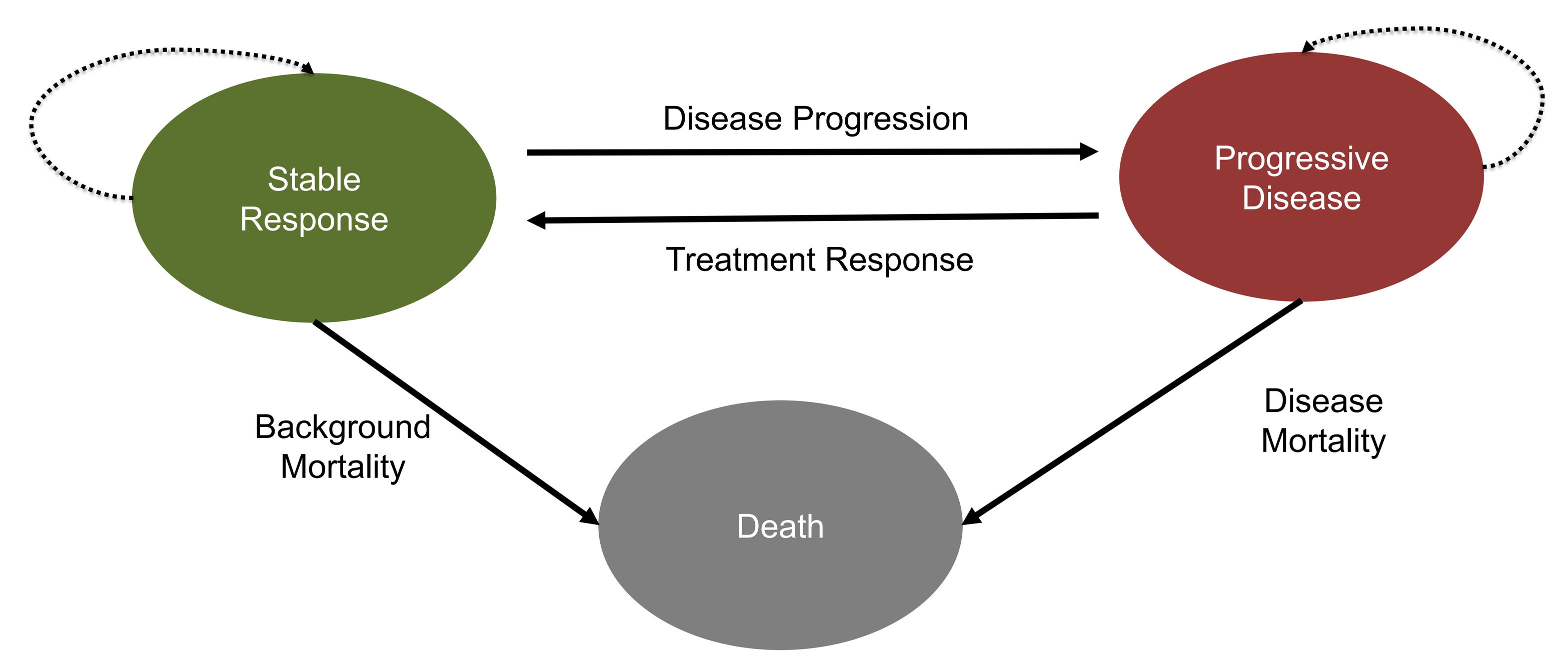


Figure 2: Markov cohort model structure



- Probabilistic sensitivity analysis (PSA) was conducted to estimate the probability of cost-effectiveness at a willingness-to-pay (WTP) threshold of USD 50,000/QALY
- The incremental cost-effectiveness ratio (ICER) and cost-effectiveness probability under static and DDP scenarios were compared to quantify the decision-analytic impact of dynamic pricing assumptions

Table 1: Structural assumptions distinguishing static and dynamic drug pricing scenarios

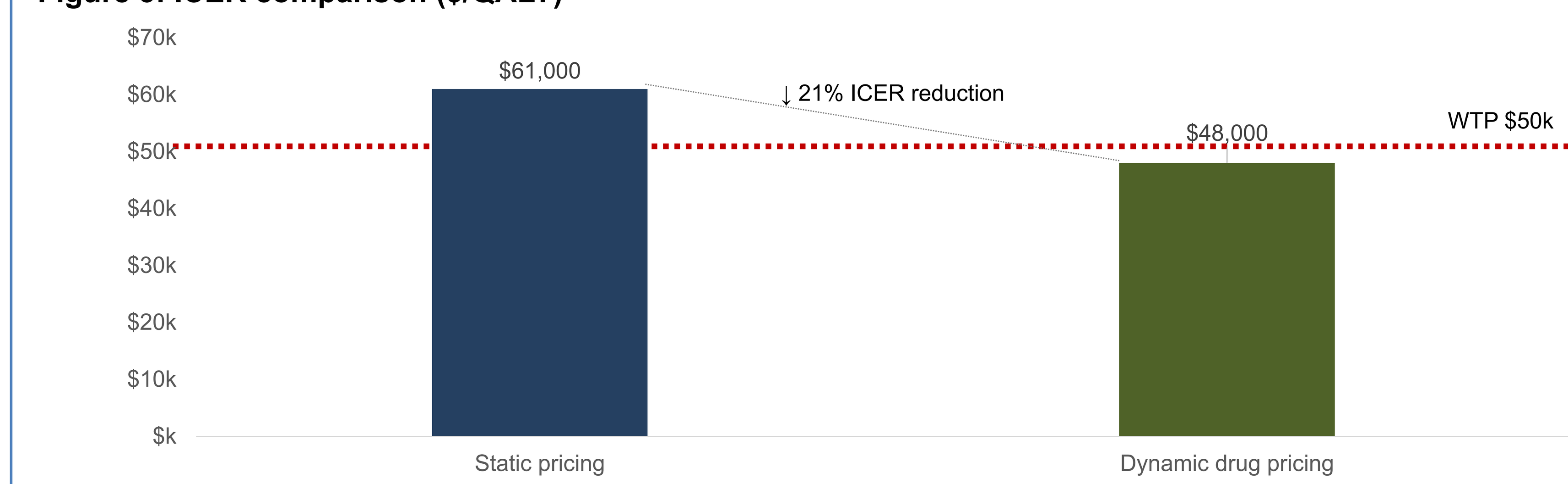
Parameter	Static pricing	Dynamic drug pricing
Drug cost assumption	Fixed throughout horizon	Time-varying
Price reassessment	None	Biennial (Y2, Y4, Y6, Y8)
Reassessment trigger	N/A	Cumulative QALY threshold
Max price adjustment	N/A	≤20% reduction per cycle
Effect on outcomes	—	None (cost component only)
WTP threshold	$50,000/QALY	$50,000/QALY
Discount rate	3% p.a.	3% p.a.

RESULTS

- Under the static pricing scenario, the ICER was estimated at USD 61,000/QALY - exceeding the USD 50,000 WTP threshold and classifying the intervention as not cost-effective from a US payer perspective (**Figure 3**)
- Implementation of the DDP framework resulted in biennial price reductions across the 10-year horizon, with cumulative drug costs falling by 14% relative to the static scenario (**Figure 4**)
- Under DDP, the ICER improved to USD 48,000/QALY - a 21% reduction that crossed the WTP threshold, reclassifying the intervention as cost-effective (**Figure 3**)
- PSA results demonstrated that the probability of cost-effectiveness at USD 50,000/QALY increased from 42% under static pricing to 63% under DDP - 21 percentage point improvement (**Figure 5**)
- Total discounted drug costs under DDP were USD 368,000 versus USD 428,000 under static pricing over the 10-year horizon, representing an absolute cost saving of approximately USD 60,000 per patient
- Incremental QALYs gained were consistent across both scenarios (2.8 QALYs), confirming that the ICER improvement under DDP was driven entirely by cost reduction rather than any change in clinical outcomes
- The magnitude of ICER improvement was most sensitive to timing of first price reduction; early reassessment at year 2 versus year 4 shifted the ICER by approximately USD 4,200/QALY

RESULTS

Figure 3: ICER comparison ($/QALY)



- The WTP threshold was crossed at a cumulative price reduction of approximately 12% — meaning even modest reductions well below the 20% maximum cap were sufficient to render the intervention cost-effective at USD 50,000/QALY
- Model inputs, disease parameters, and drug pricing trajectories are hypothetical; findings represent a proof-of-concept and should not be interpreted as clinical or policy evidence for any specific therapy, indication, or reimbursement context
- The DDP mechanism model relied on simplified, rule-based price adjustments triggered by cumulative QALY thresholds; real-world outcomes-based agreements involve substantially greater complexity, including legal contracting, administrative infrastructure, and manufacturer-payer negotiation dynamics not captured in this framework
- Generalizability beyond the US context is limited; results are specific to a USD 50,000/QALY WTP threshold and a third-party payer perspective, and may not be directly applicable to HTA frameworks, reimbursement systems, or pricing regulations in other jurisdictions

Figure 4: Cost-effectiveness acceptability curve

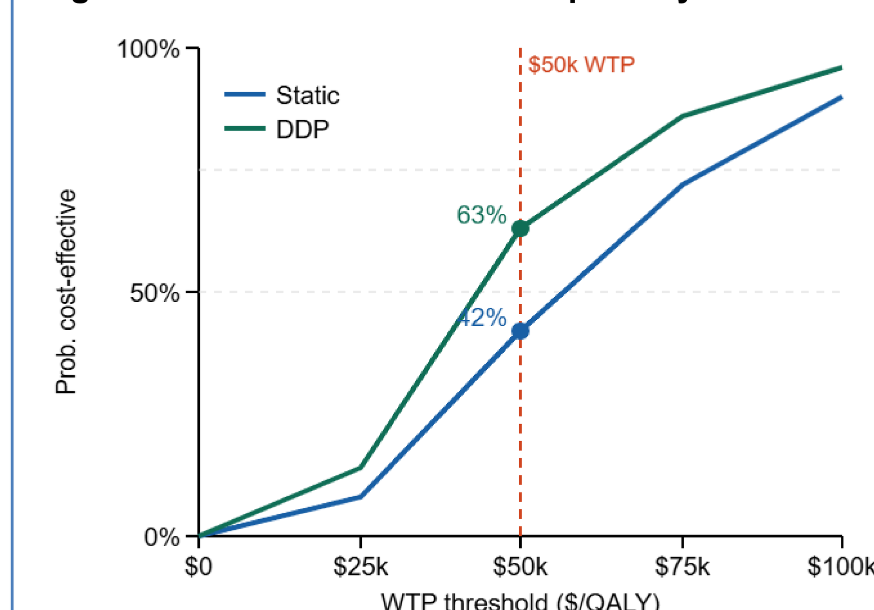


Figure 5: Drug price trajectory (% baseline)

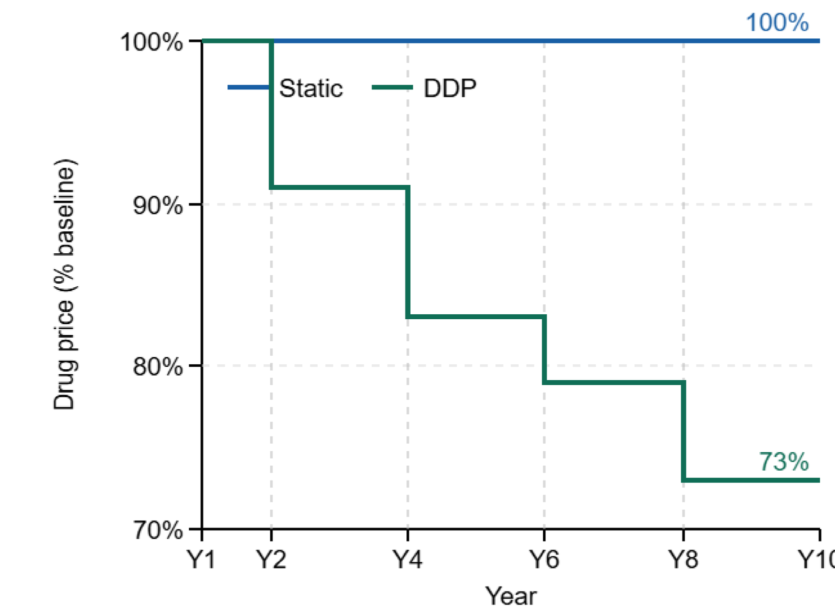
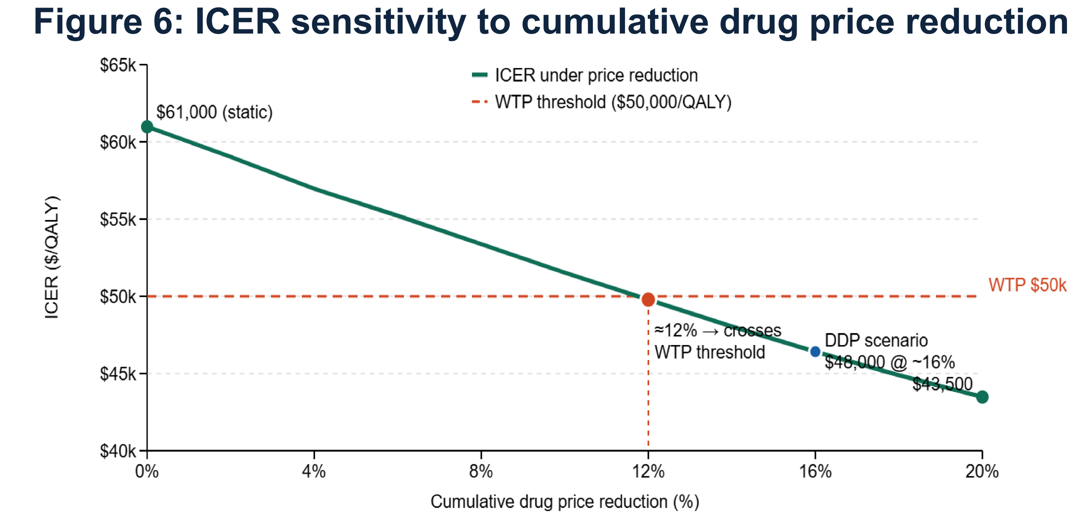


Figure 6: ICER sensitivity to cumulative drug price reduction



CONCLUSION

- This analysis demonstrates that incorporating DDP assumptions into a Markov cohort CEA model generates meaningfully different - and more policy-relevant - ICER estimates compared to conventional static pricing approaches, with the ICER improving from USD 61,000 to USD 48,000/QALY, representing a 21% reduction that shifted the cost-effectiveness classification from unfavorable to acceptable at a USD 50,000/QALY WTP threshold
- The probability of cost-effectiveness increased from 42% to 63% under DDP, and the WTP threshold was crossed at a cumulative price reduction of just 12% - well below the 20% maximum modelled - highlighting that even conservative outcomes-based pricing adjustments can materially alter reimbursement decisions
- From a health economic modelling perspective, these results expose a structural limitation in conventional CEA methodology: static drug cost assumptions may systematically overestimate ICERs in therapeutic areas where outcomes-based contracting or dynamic pricing mechanisms are actively shaping net real-world prices, with direct implications for HTA submissions and coverage decisions in the US market

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Abbreviations
CEA: Cost-Effectiveness Analysis; DDP: Dynamic Drug Pricing; ICER: Incremental Cost-Effectiveness Ratio; HTA: Health Technology Assessment; N/A: Not Applicable; OBAs: Outcomes-based Agreements; p.a.: Per Annum; PBM: Pharmacy Benefit Manager; QALY: Quality-adjusted life years; SoC: Standard of Care; USD: United States Dollar; WTP: Willingness-to-Pay

Disclosure:
KP, PB, AS, and SP the authors declare that they have no conflict of interest

ISPOR, May 17-20, 2026, Philadelphia, PA, United States