



Background/Objectives

T1D and CKD risk: Patients with type 1 diabetes (T1D) patients have >50% lifetime risk of developing chronic kidney disease (CKD).¹⁻²

Glycemic control: HbA1c reduction helps lower diabetes complications and slow CKD progression.

Sotagliflozin clinical trial results: Reduced HbA1c by 0.46% vs. insulin monotherapy in T1D patients.³

Evidence gap: Long-term economic value of sotagliflozin in T1D with CKD is unknown.

Objectives

- To evaluate the cost-effectiveness of sotagliflozin as an add-on to insulin in patients with T1D and CKD from a U.S. payer perspective.
- To understand key drivers of sotagliflozin’s value within the economic model.

Methodology

Model Overview: A Markov model was constructed to estimate the cost-effectiveness of sotagliflozin add-on to insulin therapy among patients with T1D and concurrent grade3 CKD versus insulin alone.

Markov Model

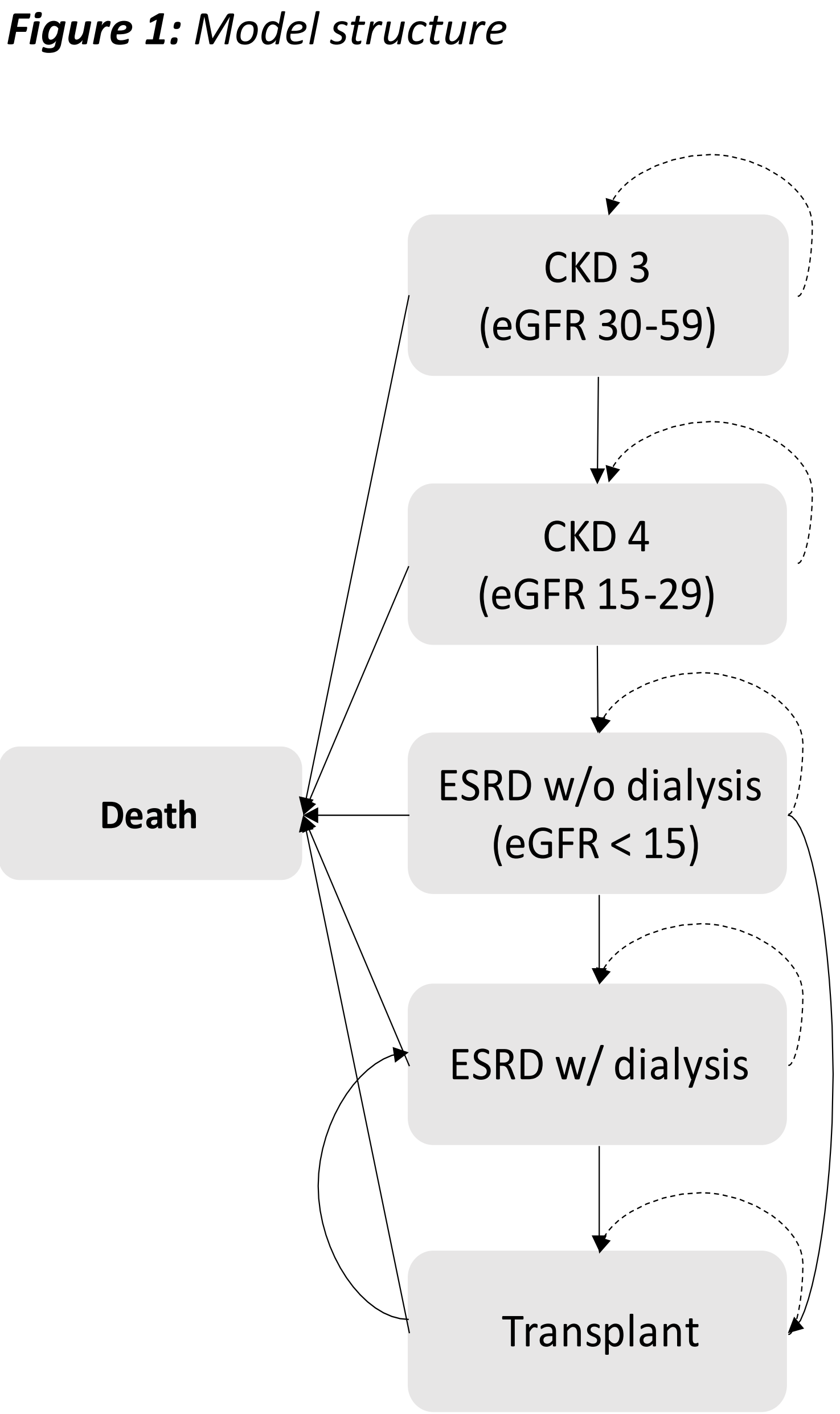
- 4 CKD Markov health states based in eGFR, transplant, and death (Figure 1)
- Markov transitions
 - Based on disease progression, treatment effects, and mortality risk
 - No reversion except for failed transplants, which transitions to ESRD with dialysis in the next cycle
- Initial patient population: Patients with CKD stage 3
- Timing: 1-month cycles and a 30-year (lifetime) horizon

Dynamic Pricing

- To capture sotagliflozin’s future price declines driven by generic entry (genericization)
- 60% price reduction for sotagliflozin starting in year 14^{4,5}

Table 1: PICOTS Criteria of Model

PICOTS Criteria	Description
Population	Patients with T1D and CKD Stage 3 (eGFR 30–59)³ - Age ≥18 years (mean age: 43) - HbA1c: 7.0%–11.0 - BMI ≥18.5 kg/m²
Intervention	Sotagliflozin (400 mg once daily) + Insulin
Comparator	Insulin monotherapy
Outcomes	Clinical: Life-years, CKD stage distribution, Number of patients prevented from dialysis, Number of patients prevented from transplant Economic: QALYs gained, Healthcare costs, Incremental cost-effectiveness ratio, Net monetary benefit
Timing	30 years (Lifetime), 1-month cycle
Setting	US payer



Key Model Inputs

Efficacy

- State transition: Derived using
 - Treatment effect of sotagliflozin on HbA1c vs. SoC (-0.79% vs. -0.33% for sotagliflozin vs. SoC after 24 weeks of treatment; difference = -0.46%p)³ and
 - HR of disease progression for a 1%p improvement in A1c of 1.107⁶
- Mortality
 - Pre-ESRD: Derived using treatment effect of sotagliflozin on HbA1c (-0.46%p)³ and
 - HR of death for a 1% improvement in A1c of 1.56⁷

Utility

CKD health state-specific HRQoL and disutility due to AEs.⁸⁻¹⁵

Cost

Pharmaceutical cost, CKD stage-specific management cost, transplant, and AE treatment costs

- Pharmaceutical cost: \$634.42 and \$246.06 per month for sotagliflozin vs. insulin¹⁶
- 3% cost offset of insulin in the sotagliflozin add-on group due to reduced insulin dose⁸
- 60% price reduction for sotagliflozin starting in year 14 due to genericization^{4,5}
- CKD stage-specific management cost: Cost offset from reduced hospitalization and ED visit due to sotagliflozin's benefits in HF management¹⁷⁻¹⁹

Table 2: Abbreviated Table of Inputs

Category	Parameter	Sotagliflozin add-on	Insulin monotherapy
Transition Probability ^{3, 6,21-23}	Stage 1 → Stage 2	0.43%	0.45%
	Stage 2 → Stage 3	0.58%	0.61%
	Stage 3 → Stage 4	1.58%	1.66%
	Stage 4 → ESRD w/o dialysis	0.55%	0.58%
	ESRD w/o dialysis → ESRD w/dialysis	2.38%	2.50%
	ESRD (w/ or w/o dialysis) → Transplant	0.45%	0.47%
	Transplant → ESRD w/dialysis	0.71%	0.71%
	Pharmacy	\$634.42	\$246.06
Cost ^{16-19,24}	Transplant (per event)	\$62,167	\$68,724
	Genericization	60% price reduction for sotagliflozin starting in year 14	
Modeling Assumption ^{4,5,20,26}	WTP per QALY	\$150,000	
	Discount rate	3%	

Sensitivity Analysis

- Non-pharmacy parameters were adjusted by +/-20%.
- Monthly sotagliflozin cost was adjusted by +/- \$100.

Scenario Analyses

- Different model structure: No dynamic pricing
- Different efficacy assumption: Application of mortality benefits from improved A1c to all patients in any health states
- Different health state distribution at model start^{19,25}

Results

Transplant utilization until year 10 by 5.4% due to delayed progression to ESRD. (Supplement Figure 1)

Survival and Quality-adjusted life years by 1.27 years (13.08 vs. 11.81) and **0.64** (7.70 vs. 7.63) **per patient**, respectively, primarily due to prolonged time in pre-ESR stages. (Figure 2)

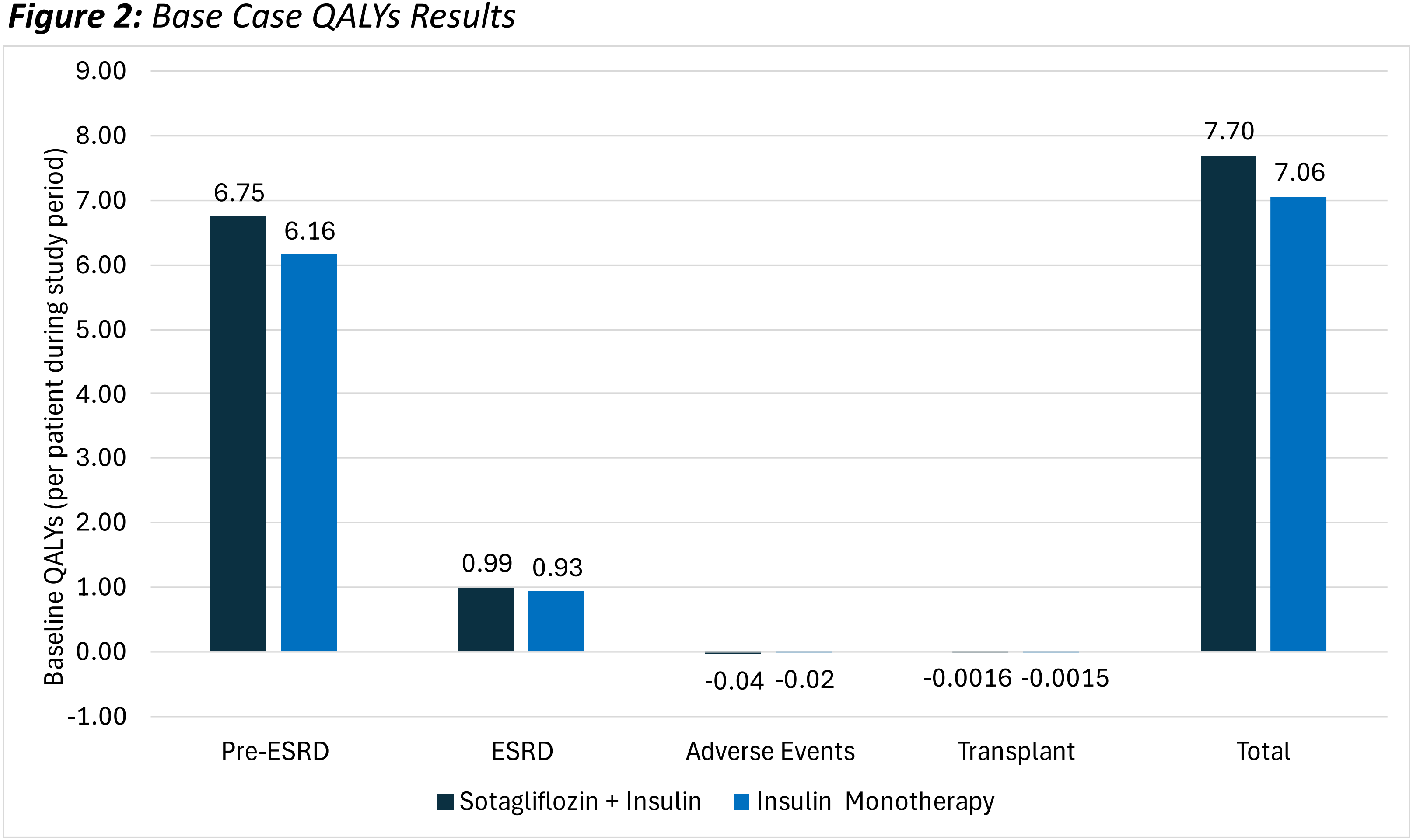
Transplant utilization after year 10 due to increased survival. (Supplement Figure 1)

Costs by \$72,914 (\$494,201 vs. \$411,760) **per patient**, largely due to increased pharmacy costs (Supplemental Figure 2)

Incremental Cost-effectiveness Ratio (ICER)

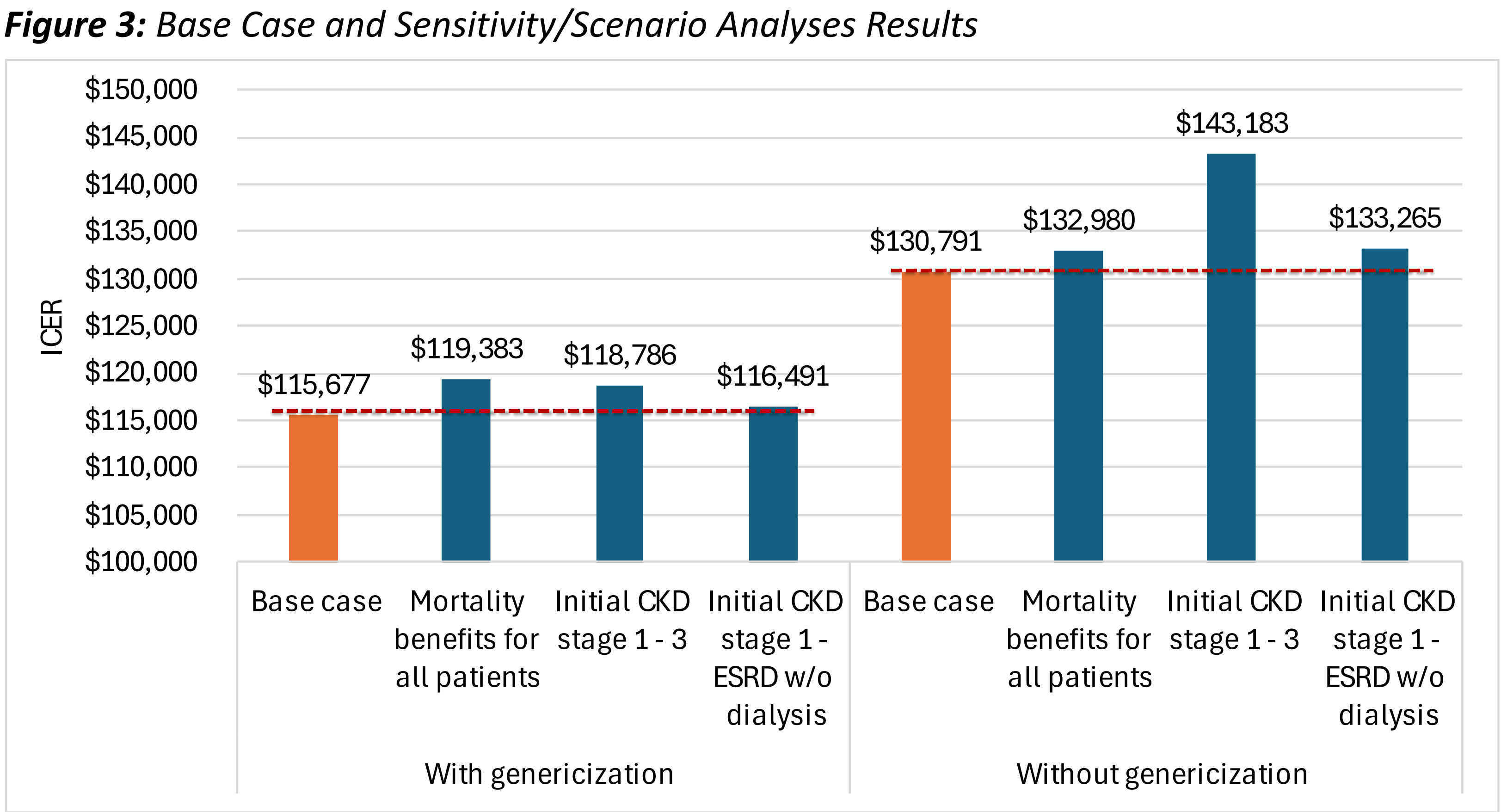
\$115,677 (\$130,791 w/o genericization)

(Figure 3)



Sensitivity/Scenario Analyses Results

- Sensitivity analysis:** Economic value of sotagliflozin add-on was most sensitive to pharmacy costs, followed by pre-ESRD utility. (Supplement Figure 3)
- Scenario analysis:** Sotagliflozin add-on remained cost-effective under all clinical scenarios evaluated. (Figure 3)



Discussion

- Sotagliflozin is a cost-effective adjunct to insulin therapy** for patients with **T1D and CKD**, providing both clinical benefits and a favorable ICER below the \$150,000/QALY threshold.
- Limitations:** In cases where T1D+CKD data were limited, some parameterization used T2D+CKD estimates. Sotagliflozin efficacy extrapolated from 6-month trial, adjusted with DCCT. Direct benefits due to reduced cardiac events (MI, stroke) above and beyond impact from reduced eGFR not estimated directly.