



# A Novel Biomarker for the Early Detection of Diabetic Kidney Disease: A Budget Impact Analysis

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## Background

- Diabetic kidney disease (DKD) is a common complication of type 2 diabetes (T2DM) and a major driver of progression to end-stage renal disease (ESRD).
- ESRD imposes a substantial financial burden on Taiwan's National Health Insurance, with annual dialysis expenditures exceeding NT\$ 47 billion.
- Current risk assessment using eGFR and UACR may not fully capture early renal decline, particularly in early-stage DKD.
- DNlite-IVD103, a urinary uPTM-Fetuin-A biomarker test, may support prognostic assessment of renal function decline and guide targeted management in patients with early DKD.

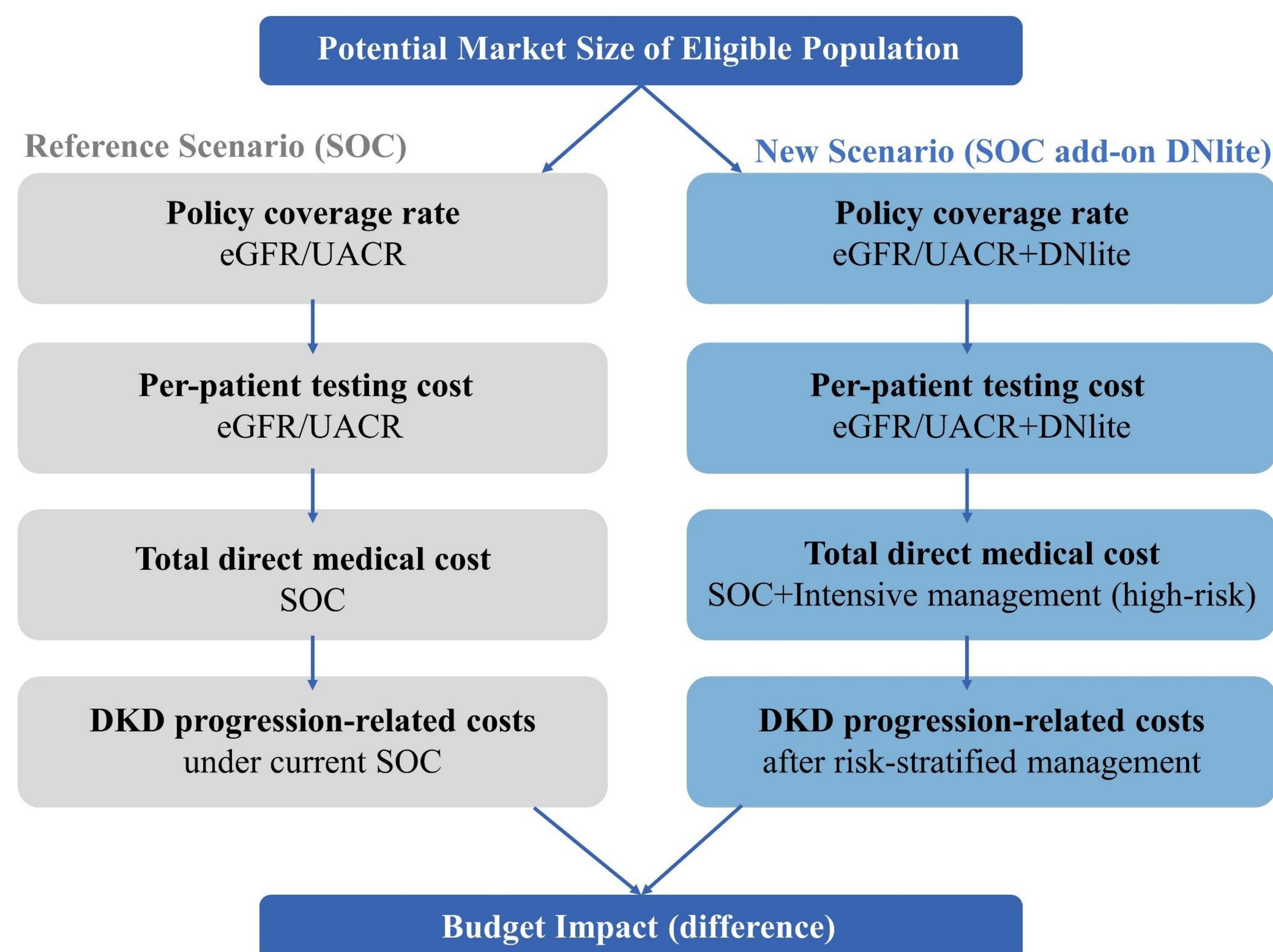
## Objectives

- This study estimates the 5-year budget impact of reimbursing DNlite-IVD103 as an add-on screening strategy for patients with T2DM and early DKD, compared with standard of care (SOC).

## Methods

- A 5-year budget impact model combined with a Markov model was developed to compare current SOC with SOC add-on DNlite-IVD103 from 2026 to 2030.

Figure 1. Model Structure



- Population estimates were derived from the MJ Health Database and age-adjusted to the national T2DM population. Clinical and cost inputs were obtained from published literature.
- A base eligible population of approximately 0.21 million patients (T2DM with KDIGO G1–G2) was identified. To optimize resource prioritization, the strategy further targeted individuals with hypertension (HTN) and hypertriglyceridemia (HTG).

Table 1. Stepwise Estimation of the Priority Screening Population

Steps	Screening criteria	N	Adjusted %
0	T2DM	9,862	100.00%
1	Early DKD (G1–G2)	969	9.09%
2	G1–G2 + HTN	481	5.40%
3	G1–G2 + HTN + HTG	292	3.05%

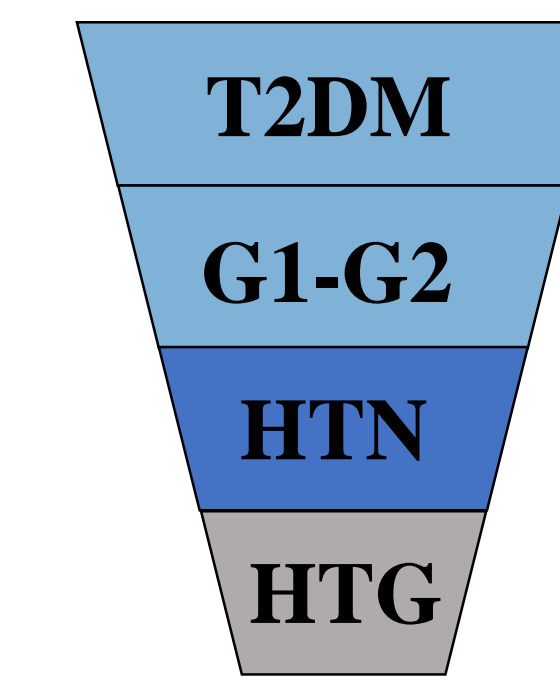


Table 2. Key Model Inputs

Parameters	Base-case value (NTD)
Policy coverage rate	10%, 15%, 20%, 25%, 30%
DNlite-IVD103 test cost	\$2,800
Testing frequency	Once over 5 years
High-risk classification rate	18%
Intensive management cost	\$10,182
Adherence to intensified management	80%
Reduction in DKD progression	20%

Intensive management: (1) more frequent follow-up, (2) earlier uptake of kidney-protective therapy (SGLT2i) and (3) earlier referral to nephrology care.

## Results

Figure 2. Annual Net Budget Impact by Strategy

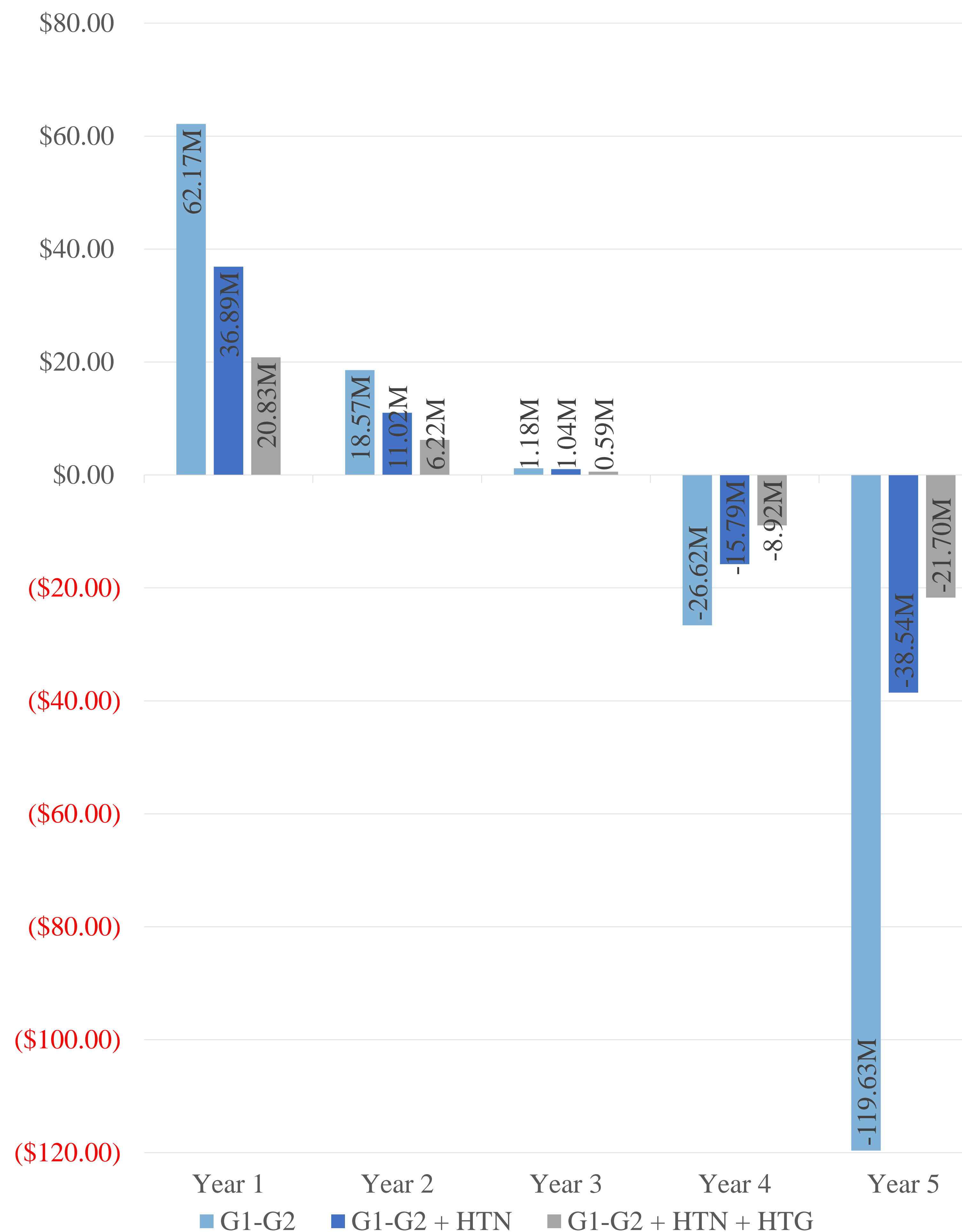


Figure 3. Cumulative Net Budget Impact by Strategy

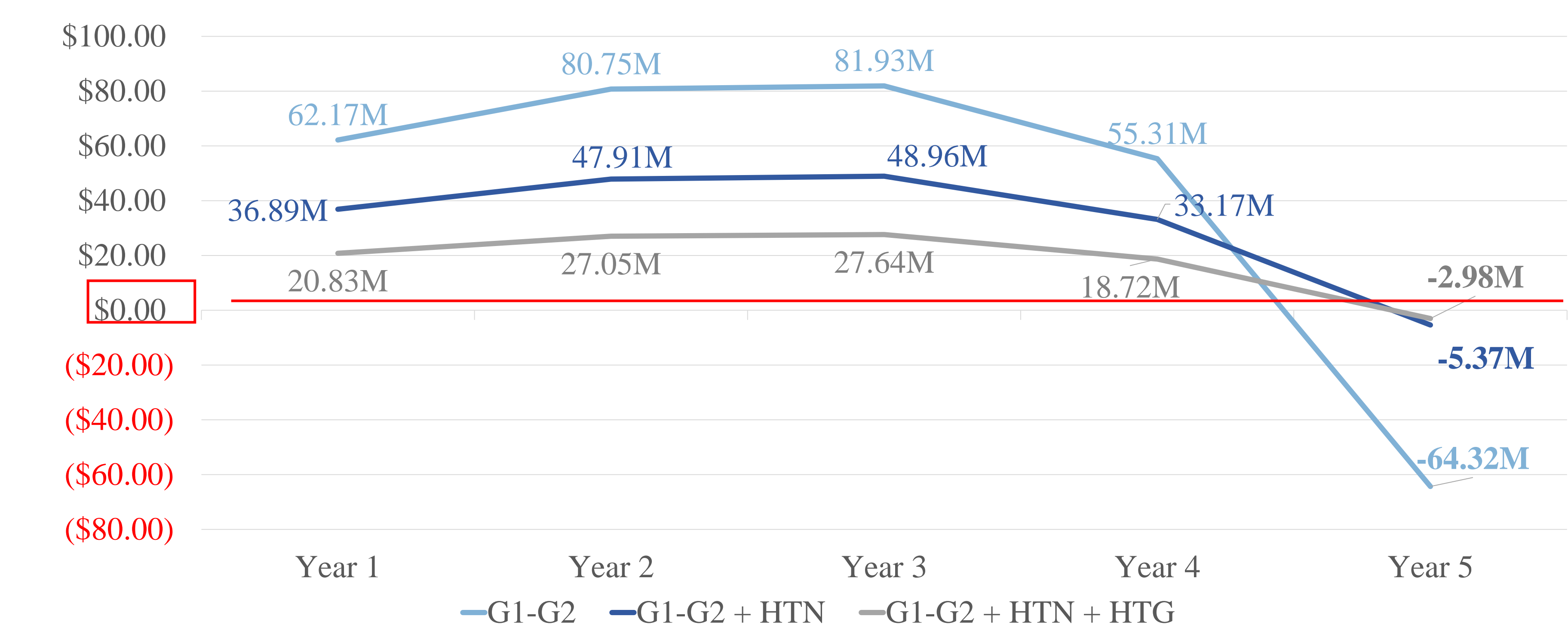
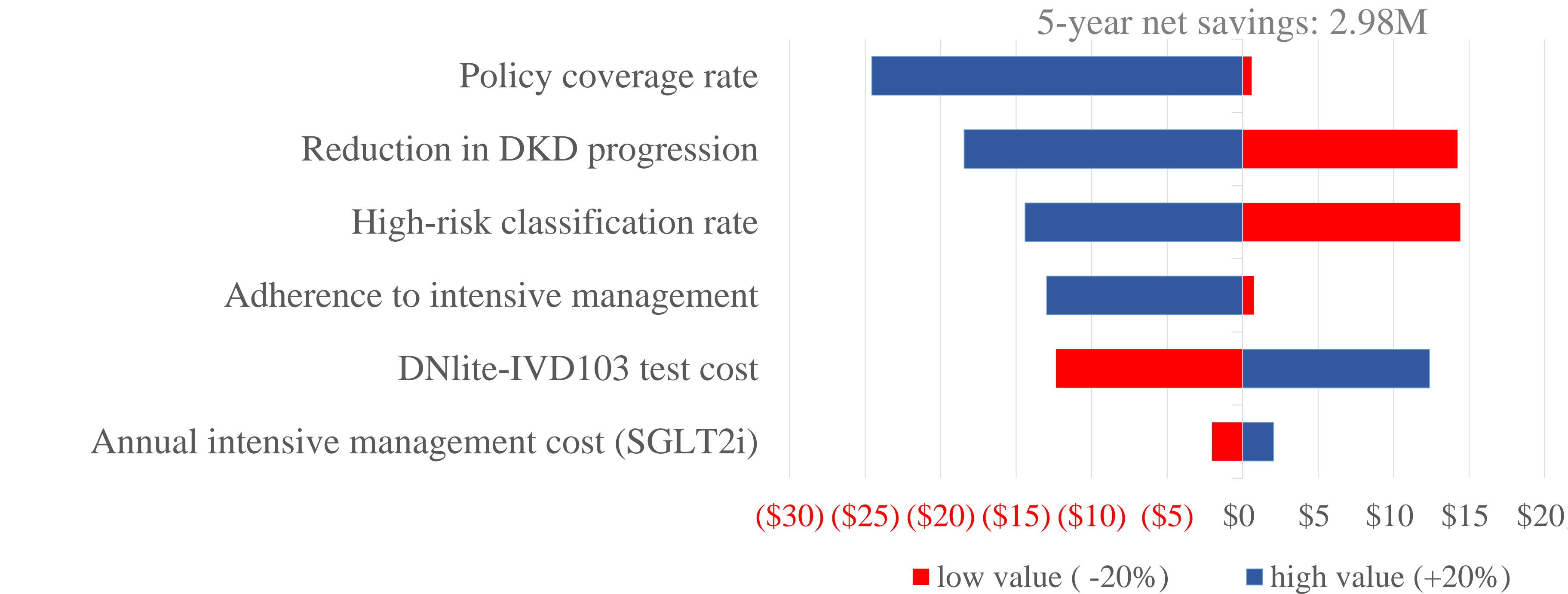


Figure 4. Deterministic Sensitivity Analysis



## Conclusion

- A targeted implementation strategy for DNlite-IVD103 may offer a budget-controllable approach to early DKD risk stratification, with cumulative net savings achieved by 2030.