# Determination of Payer Budget Impact from Using an Innovative In Vitro Diagnostic in the Management of Diabetic Kidney Disease

Burchenal W[1] , Datar M[1] , Peters KE[2] , Fernandez GC[2] , Morrison JC[2] , Lipscombe RJ[2]
[1]Boston Healthcare Associates, Boston, MA, USA, [2]Proteomics International, Perth, WA, Australia

## Background

- Up to 1 in every 3 adults with type 2 diabetes (T2D) also have chronic kidney disease, with over 95% of patients being asymptomatic.[1] Early detection and treatment of diabetic kidney disease (DKD) is essential to prevent further kidney injury.[2]
- Kidney disease costs the US Medicare system $114 billion annually.[3]
- PromarkerD is an innovative biomarker-based blood test that predicts risk of DKD and renal decline in T2D patients. Test scores are categorized as low-, moderate- or high-risk as determined by pre-specified cut-offs (set at 10% and 20%). PromarkerD helps predict the risk of DKD before kidney damage occurs.*

## Aim

- To evaluate the budget impact from implementing a proactive testing regime using the PromarkerD test for assessing chronic kidney disease in patients with T2D versus current standard-of care (SOC) without PromarkerD.

## Methods

- A hypothetical cohort of 1 million patients with T2D and no/mild DKD (eGFR >30mL/min/1.73m$^2$, KDIGO categories G1-3b)[4] were analyzed over 4 years (as shown by the blue box in Figure 1).
- The budget impact model evaluated potential net savings to US payers from covering the PromarkerD test versus standard-of-care (SOC) through: slower DKD stage progression; delayed or avoided dialysis and transplants; and reduction in dialysis crashes.
- The model also evaluated the potential relative costs associated with PromarkerD, including: PromarkerD test costs every 12, 8 or 6 months for low-, moderate-, and high-risk patients, respectively;[2]

Costs of preventative medications in high-risk PromarkerD patients (Table 1); Treatment costs for each DKD stage, including costs associated with dialysis and transplant (Table 1).

**Figure 1.** Prognosis of CKD by GFR and albuminuria category.

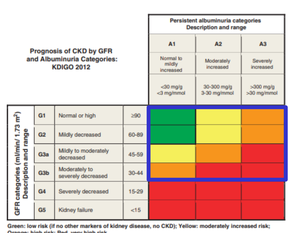



**Table 1.** Annual Costs per Patient at Each DKD Stage.[5, 6, 7, 8]

| Cost per Patient at Each DKD Stage | Treatment Cost (USD) | Preventative Medications (PromarkerD High-Risk Patients) (USD) |
|---|---|---|
| Stage G1 | $16,257 | $1,031 |
| Stage G2 | $18,288 | $1,421 |
| Stage G3a | $21,068 | $1,450 |
| Stage G3b | $30,800 | $2,082 |
| Stage G4 (Non-Target) | $40,537 | N/A |
| Stage G5 (Non-Target) | $70,219 | N/A |
| ESRD | | N/A |
| Treatment costs[8] | $109,783 | |
| Dialysis[8] | $70,959 | |
| Additional cost of dialysis crash[9] | $49,199 one time | |
| Transplant[10] | $262,000 one time | |
| Post-transplant care[10] | $40,000 | |

## Methods

Model assumptions and parameters were derived from prior literature and PromarkerD clinical studies.

- Rates of progression were taken from prior PromarkerD clinical studies.[11]
- Only high-risk patients were prescribed preventative medications, with 80% adherence assumed.[12]
- 20% decline in progression through DKD stages due to PromarkerD implementation compared to SOC.[13] In sensitivity analyses, a range of progression rates (5-35%) were assessed, for provisional test costs of $150 as well as $100 and $200.
- Preventative medication costs were derived from the difference in medication costs between SOC and recommended medications for high-risk PromarkerD patients.
- Proportion of patients insured by Medicare vs. Commercial insurance was 60% vs. 40%.
- All savings and costs were inflation-adjusted to 2021 USD. A discount rate of 3% was used.[14]

## Results

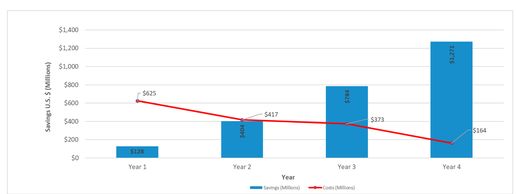
- Of the 1 million patients tested, 220,000 were predicted to be 'high-risk' and received additional preventative treatment.
- PromarkerD testing could produce savings for US payers of $2.4 billion over 4 years, against costs of $1.5 billion, resulting in **net savings of $862 million per million T2D patients over 4 years** (Table 2).

**Table 2.** Comparative savings and costs of using PromarkerD over SOC.

| Budget Impact Model (Over 4 years) | Costs (USD) |
|---|---|
| Savings | $2.4 billion |
| Costs | $1.5 billion |
| Net Savings | **$862 million** |

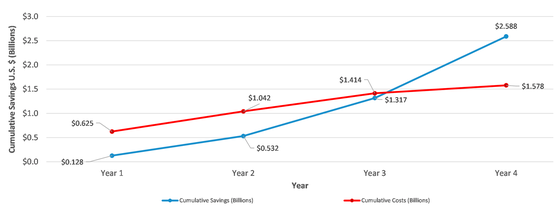
- The **total annual savings provided by PromarkerD equal the costs after 2 years**. Savings increase exponentially in subsequent years, far outweighing the associated costs compared to the current SOC without PromarkerD (Figure 2).

**Figure 2.** Annual (undiscounted) Savings for PromarkerD.




- The **breakeven point occurs at year 3**, after which the total savings are greater than the total costs (Figure 3).

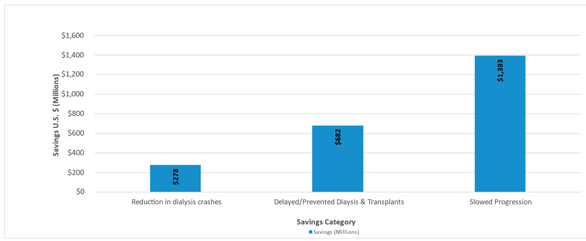
**Figure 3.** Cumulative (undiscounted) Savings versus Cost of PromarkerD implementation over 4 years.




## Results

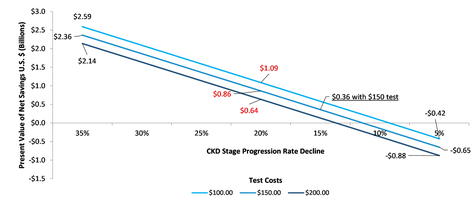
- Over 4 years, **most savings are associated with slowing the progression of DKD** ($1.4 billion, 59% of total savings), compared to the savings from delaying or preventing dialysis ($682 million, 29%), or reduction in dialysis crashes ($278 million, 12%) (Figure 4).

**Figure 4.** Gross Present Value of Savings over 4 years by Category.




- In sensitivity analysis, different progression rates and costs of the PromarkerD test were assessed. Using a 15% decline in progression would still result in a significant net savings over 4 years ($360 million with a $150 test). Net savings were also achieved using a PromarkerD test price of $100 (>$1 billion) and $200 ($640 million) (Figure 5).

**Figure 5.** Net Present Value of Savings (discounted) from PromarkerD Implementation over 4 years.




## Conclusions

- Changing SOC by implementing an alternative PromarkerD testing regime in T2D patients could enable early intervention for high-risk patients, thereby slowing progression and lessening the need for expensive dialysis and transplants, as well as reducing unnecessary adoption of new and costly therapeutic interventions in low-risk patients.
- This study demonstrates substantial near-term savings ($862 million per million T2D patients) to US payers in the treatment of DKD, through early, accurate and cost-effective prognosis with the PromarkerD test.

## References

* Defined as incident diabetic kidney disease (eGFR <60mL/min/1.73m²) in the next four years. If the eGFR level at the time of the test is already <60mL/min/1.73m², then the risk of a further decline in kidney function is defined as an eGFR decline ≥30% in the next four years.

[1] National Chronic Kidney Disease Fact Sheet, 2017.
[2] Tuttle KR, et al. Diabetic Kidney Disease: A Report from an ADA Consensus Conference. Diabetes Care, 2014.
[3] 2018 United States Renal Data System Annual Data Report | Volume 1, Chapter 7, 2018.
[4] KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease | Volume 3, 2012.
[5] Honeycutt AA et al. Medical costs of CKD in the Medicare population, 2013.
[6] Knight TG, et al. Clinical and economic outcomes in Medicare beneficiaries with stage 3 or stage 4 chronic kidney disease and anemia: the role of intravenous iron therapy, 2015.
[7] Wang V et al. The Economic Burden of Chronic Kidney Disease and End-Stage Renal Disease, 2016
[8] Golestaneh L et al. All-cause costs increase exponentially with increased chronic kidney disease stage, 2017
[9] Lui FX, et al. Economic Evaluation of Urgent-Start Peritoneal Dialysis Versus Urgent-Start Hemodialysis in the United States | Medicine, Volume 93, Issue 28, 2014.
[10] United Network for Organ Sharing, 2020.
[11] Peters KE, et al. Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II, 2017.
[12] Hugtenburg, J. G., et al. Definitions, variants, and causes of nonadherence with medication: a challenge for tailored interventions. Patient Preference and Adherence, 2013.
[13] Neuen BL, et al. SGLT2 inhibitors for the prevention of kidney failure in patients with type 2 diabetes: a systematic review and meta-analysis, 2019.
[14] Gold MR, Siegel JE, Russell LB, Weinstein MC. Cost-effectiveness in health and medicine. New York: Oxford University Press, 1996.

**Websites: www.promarkerd.com, www.proteomics.com.au**

**Boston Healthcare Associates was paid to conduct this study as an independent consultant to Proteomics International.**