Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease

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Background

- Diabetic kidney disease (DKD) develops in 1 in 3 people with type 2 diabetes (T2D) and is the leading cause of end-stage renal disease (ESRD).[1]
- Most people with CKD (~90%) are unaware they have the disease,[1] with early detection and treatment essential to prevent further kidney injury.[2]
- DKD costs the US Medicare system $50 billion annually.[3]
- PromarkerD is an innovative biomarker-based blood test that can predict future renal function decline in the next 4 years in people with T2D who have no or mild existing DKD (eGFR >30 mL/min/1.73m^2).
- PromarkerD predicts incident DKD (reduction in eGFR to <60 mL/min/1.73m^2) or eGFR decline ≥30% in people with baseline eGFR <60 mL/min/1.73m^2.
- PromarkerD test scores are categorized as low-, moderate- or high-risk to optimize DKD management.

Aim

- To develop a budget impact model to estimate the net savings to US payers over a 10-year time horizon from covering the PromarkerD test versus current standard-of-care (SOC) without PromarkerD.

Methods

- The total number of people with T2D and no/mild DKD (KDIGO categories G1-3b)[4] in the US (~31 million)[5] were included in the budget impact model (Figure 1).
- The budget impact model evaluated potential savings to US payers from covering the PromarkerD test versus 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.

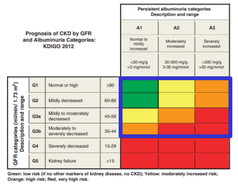


Table 1. Annual Costs per Patient at Each DKD Stage.[6-11]

Cost per Patient at Each DKD Stage	Annual 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	$109,783	
Dialysis	$70,959	
Additional cost of dialysis crash	$49,199 one time	
Transplant	$262,000 one time	
Post-transplant care	$40,000	

Methods

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

- The prevalence of DKD by KDIGO categories was based on US population data.[12]
- Rates of DKD stage progression were estimated from prior PromarkerD clinical studies.[13,14]
- Only high-risk patients were prescribed preventative medications, with 80% adherence assumed.[15]
- A 20% decline in DKD stage progression due to PromarkerD implementation compared to SOC was used.[16] A range of progression rates were also assessed (5-35%).
- A provisional test price for PromarkerD was set at $150 USD. Test prices of $100 and $200 were also used.
- 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%, respectively.
- All savings and costs were inflation-adjusted to 2021 USD. A discount rate of 3% was used.[17]

Results

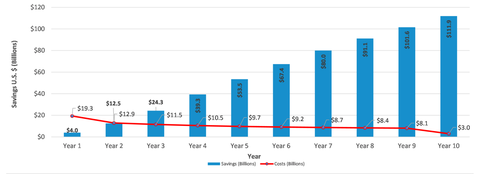
- Of the 31 million patients tested with T2D and no/mild DKD, 6.8 million were predicted by PromarkerD to be 'high-risk' and received additional preventative medications.
- PromarkerD testing could produce savings for US payers of $473 billion over 10 years, against costs of $89 billion, resulting in **net savings of $384 billion over 10 years** (Table 2).

Table 2. Comparative Savings and Costs of using PromarkerD over SOC.

Budget Impact Model (Over 10 years)	Costs (USD)
Savings	$473 billion
Costs	$89 billion
Net Savings	**$384 billion**

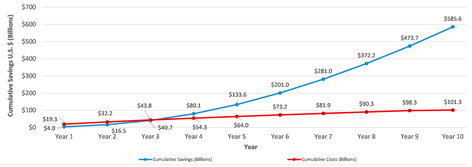
- The **total annual savings provided by PromarkerD equal the costs after 2 years.** Savings increase exponentially in subsequent years, far outweighing the associated costs compared to the current SOC without PromarkerD (Figure 2).

Figure 2. Annual (undiscounted) Savings for PromarkerD.



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

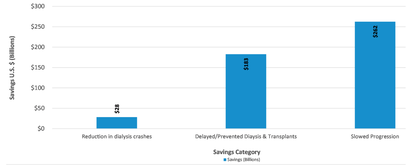
Figure 3. Cumulative (undiscounted) Savings versus Costs of PromarkerD Implementation.



Results

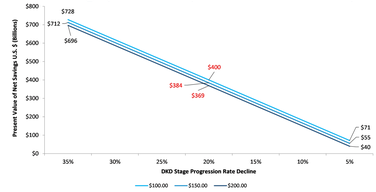
- Over 10 years, **most savings are associated with slowing the progression of DKD** ($262 billion, 55% of total savings), compared to the savings from delaying or preventing dialysis and transplants ($183 billion, 39%), or reduction in dialysis crashes ($28 billion, 6%) (Figure 4).

Figure 4. Gross Present Value of Savings over 10 years by Category.



- In sensitivity analysis, assuming a 5% decline in DKD progression rate still resulted in net savings over 10 years ($40-$71 billion with a $100-$200 PromarkerD test). Net savings were also achieved at the 20% progression rate using a PromarkerD test price of $100 ($400 billion) and $200 ($369 billion) (Figure 5).

Figure 5. Net Present Value of Savings (discounted) from PromarkerD Implementation over 10 years.



Conclusions

- This economic study demonstrates that improved management of people with T2D through the use of early, accurate and cost-effective prognosis with the PromarkerD test could result in savings of $384 billion over 10 years to US payers in the treatment of DKD.
- Employing this alternative PromarkerD testing regime over the current SOC would enable proactive early intervention for T2D patients at high-risk of DKD, thereby decreasing the need for expensive interventions such as dialysis and transplants, or unnecessary adoption of new therapeutic treatments in those at low-risk.

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