



Proteomics International

LABORATORIES LTD

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US Medicare confirms reimbursement price for PromarkerD

- **Centers for Medicare & Medicaid Services (CMS) have confirmed the payment rate for the PromarkerD predictive test for diabetic kidney disease of US\$390.75 in the United States**
- **CMS is the single largest payer for health care in the United States, with Medicare and Medicaid collectively responsible for 42 per cent of healthcare spending and providing health coverage to more than 100 million Americans**
- **Approximately 32 million adults live with diabetes in the United States whilst globally this number totals 537 million adults**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce that the US Centers for Medicare & Medicaid Services (CMS) has published its final determination of the national reimbursement price in the United States for the PromarkerD predictive test for diabetic kidney disease.

The CMS is the federal agency in the United States that is responsible for providing health coverage to more than 100 million Americans through Medicare and Medicaid. The reimbursement rate set by CMS applies to all patients accessing government-funded healthcare in the United States. Medicare covers health care costs for people over the age of 65, while Medicaid covers eligible low-income Americans. CMS is the single largest payer for health care in the United States, with Medicare and Medicaid collectively responsible for 42 per cent¹ of healthcare spending. CMS has assigned a payment rate of US\$390.75 for PromarkerD [ASX: 29 September], which is to be delivered through Sonic Healthcare USA [ASX: 10 May]. The rate, set by the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests, follows a period of public comment and will become effective from 1 January 2024.

Proteomics International Managing Director Dr Richard Lipscombe said, *“As we prepare for the US launch of PromarkerD, the CMS price is an essential component of the roll-out strategy, both because of the number of people it covers, and because many private payers follow CMS pricing.”*

The reimbursement price comes after the American Medical Association (AMA) approved a unique CPT® Proprietary Laboratory Analyses (PLA) code 0385U for PromarkerD earlier this year [ASX: 3 January].

Globally there are 537 million adults living with diabetes². In the United States an estimated 32 million people—or 11 per cent of the adult population—live with diabetes and in Europe 61 million (7%) live with diabetes. The total cost of diabetic kidney disease (DKD) is US\$130 billion per year in the US alone³, according to the US Renal Data System.

The PromarkerD predictive test can identify kidney function decline in type 2 diabetes patients up to four years before clinical symptoms appear⁴. Patients identified as at high-risk of DKD by PromarkerD could then

¹ www.kff.org/mental-health/issue-brief/10-things-to-know-about-medicaid/

² International Diabetes Federation Diabetes Atlas 10th edition, 2021

³ US Renal Data System 2020

⁴ doi.org/10.2337/dc17-0911; doi.org/10.1016/j.jdiacomp.2019.07.003; [doi:10.3390/jcm9103212](https://doi.org/10.3390/jcm9103212)

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be prescribed early therapeutic interventions such as SGLT2-inhibitors or potentially GLP-1 agonists to slow or stop the onset of disease; SGLT2-inhibitors are widely used diabetes drugs, now also indicated for the treatment of DKD, and recently the GLP-1 agonist, semaglutide (Ozempic®) was also found to be renal protective [ASX: PIQ September Quarterly, 26 October]. Published research shows early intervention with an SGLT2-inhibitor class drug leads to a significant reduction in the PromarkerD risk scores for developing DKD⁵ [ASX: 3 May].

PromarkerD has the potential to be used a complementary diagnostic test. Early diagnosis of DKD using PromarkerD could help inform doctors' treatment decisions to improve clinical outcomes for patients by increasing adoption of renal-protective interventions in patients at high risk for kidney decline, whilst lowering the likelihood of aggressive treatment in those at low risk⁶ [ASX: 2 August 2022]. Reducing or delaying the progression of the disease would reduce the incidence of dialysis and kidney transplant, improving quality of life for patients and saving healthcare systems millions of dollars.

Authorised by the Board of Proteomics International Laboratories Ltd (ASX: PIQ).

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About PromarkerD (www.PromarkerD.com)

Diabetic kidney disease (DKD) is a serious complication arising from diabetes which if unchecked can lead to dialysis or kidney transplant. PromarkerD is a prognostic test that can predict future kidney function decline in patients with type 2 diabetes and no existing DKD. The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of the disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)). A cloud-based algorithm integrates the results into a patient risk report. In clinical studies published in leading journals PromarkerD correctly predicted up to 86% of otherwise healthy diabetics who went on to develop diabetic kidney disease within four years.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD virtual booth please see: www.PromarkerD.com/product

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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⁵ doi.org/10.3390/jcm12093247

⁶ doi.org/10.1371/journal.pone.0271740