



Proteomics International

LABORATORIES LTD

ASX Release

26 November 2025

ASX code: PIQ

US Medicare sets reimbursement price for next-generation PromarkerD predictive test for diabetic kidney disease

- **The US Centers for Medicare & Medicaid Services (CMS) have set the payment rate for the next-gen PromarkerD predictive test for diabetic kidney disease at US\$390.75**
- **CMS determination underpins Proteomics International's US launch strategy, broadening patient access and strengthens the Company's discussions with private payers and strategic partners**
- **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**
- **Major health impact: Potential to improve outcomes for over 32 million adults in the US with diabetes and at risk of diabetic kidney disease (DKD) by enabling earlier intervention, improving care and reducing healthcare costs for DKD which exceed \$130 billion annually**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics, is pleased to announce that the US Centers for Medicare & Medicaid Services (CMS) has published its final determination of the national reimbursement price for the next-generation Promarker®D test system, the predictive test for diabetic kidney disease (DKD).

The new reimbursement price of US\$390.75 follows the American Medical Association (AMA) earlier approval of a unique CPT® Proprietary Laboratory Analyses (PLA) code 0579U for next-gen PromarkerD [ASX: 3 July]. The price under the Clinical Laboratory Fee Schedule will apply from 1 January 2026 to patients accessing government-funded healthcare through the Medicare program in the United States. It represents a major milestone in facilitating broad clinical access to the PromarkerD test as the Company ramps up its US roll-out in 2026.

The CMS reimbursement rate is particularly important as the agency is the single largest payer of healthcare in the United States, with Medicare and Medicaid collectively responsible for approximately 42% of total healthcare expenditure. A CMS pricing determination strengthens the Company's discussions with private payers and strategic partners. Private health insurers frequently reference CMS pricing when setting their own reimbursement rates, amplifying the commercial reach of the determination.

Proteomics International Managing Director Dr Richard Lipscombe said, *"The new CMS pricing determination and PLA code for PromarkerD are pivotal to our next phase of commercialisation in the United States. The CMS decision validates the clinical and economic value of PromarkerD and ensures a clear reimbursement pathway for healthcare providers. This will drive adoption, patient access, and commercial partnerships in the United States."*

PromarkerD is currently available in California [ASX: 20 June] through Proteomics International's Clinical Laboratory Improvement Amendment (CLIA) certified Reference Laboratory, ensuring

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compliance with US regulatory standards and scalability.

The PLA code and CMS pricing are a significant landmark in the commercialisation of PromarkerD. The assignment of a PLA code provides a dedicated billing pathway for PromarkerD, enabling healthcare providers and laboratories to be reimbursed for its use under the US healthcare system. With CMS pricing established, the Company will now seek to obtain private health insurer coverage alongside US Medicare coverage via the Molecular Diagnostic Services Program (MoIDX)¹ and a Local Coverage Determination (LCD). Further updates will be provided on these activities in due course.

PromarkerD is a world-leading predictive test that can identify patients with type 2 diabetes who are at risk of developing diabetic kidney disease (DKD) up to four years before clinical symptoms appear². Early identification allows physicians to prescribe renal-protective therapies, such as SGLT2-inhibitors or GLP-1 agonists, which have been shown to slow or prevent kidney function decline.

Published studies have demonstrated that early intervention guided by PromarkerD testing could lead to a significant reduction in a patient's risk score for DKD³. By delaying or preventing disease progression, PromarkerD has the potential to reduce the incidence of dialysis and kidney transplant, delivering substantial cost savings to healthcare systems and improving quality of life for millions of patients.

Globally, an estimated 537 million adults are living with diabetes, including 32 million in the United States⁴. The total cost burden of diabetic kidney disease in the US alone exceeds US\$130 billion annually⁵, highlighting the urgent need for predictive diagnostics such as PromarkerD to support early intervention and preventive care.

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

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About Promarker®D (www.PromarkerD.com)

Diabetes-related chronic 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 blood test to detect a unique 'fingerprint' of the early onset of the disease. The multivariate test measures a select panel of protein and clinical biomarkers, before 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. Country specific use of this product is subject to the relevant regulatory approvals.

Proteomics International recommends that patients concerned about DKD seek advice from their doctors.

Further information on DKD is available through the www.mytest.health web portal.

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 precision 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.

¹ www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35160

² doi.org/10.3390/jcm12093247

³ [doi:10.3390/jcm9103212](https://doi.org/10.3390/jcm9103212)

⁴ International Diabetes Federation 2021

⁵ US Renal Data System 2020

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