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Proteomics diabetes test gets important US health insurance nod

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Proteomics International is on the verge of releasing its groundbreaking PromarkerD diabetes-related blood test across the United States, a milestone step ahead the device's international commercialisation.

PromarkerD has just been assigned an American Medical Association PLA billing code, required for doctors to order the test and for facilities to bill for its use. From October 1, patients and healthcare providers will be able to submit claims for the test to be reimbursed by their health insurers – an essential step towards a broader market uptake.



Proteomics International's PromarkerD diabetes-related blood test has just been assigned an American Medical Association billing code, required for doctors in the United State to order the test and for facilities to bill for its use.

PromarkerD was designed to meet an area of unmet need by identifying diabetic patients at risk of developing kidney disease four years before any symptoms appear.

According to the company's latest clinical study, its patented next-generation PromarkerD test accurately predicted kidney function decline in up to 86 per cent of patients who otherwise showed no symptoms, replicating the results from earlier clinical trials.

‘Ensuring kidney health is a priority for our company and obtaining this dedicated PLA code is a crucial milestone in our strategy to improve access to meaningful diagnostic tests.’

Proteomics International managing director Dr Richard Lipscombe

Catching early signs of diabetic kidney disease means patients can receive preventive care well before they develop costly and life-threatening end-stage kidney disease, avoiding the need for dialysis or a kidney transplant.

The simple finger-prick blood test could potentially throw a lifeline to more than 32 million Americans living with type 2 diabetes, given more than half of all adults with diabetes in the US will develop kidney complications. These cases contribute to a colossal US\$130 billion in annual healthcare costs - more than a quarter of the nation's Medicare budget.

Proteomics International managing director Dr Richard Lipscombe said: *“Ensuring kidney health is a priority for our company and obtaining this dedicated PLA code is a crucial milestone in our strategy to improve access to meaningful diagnostic tests. Expanding access to PromarkerD will help to improve kidney health for patients everywhere.”*

The PLA code is widely used across America's complex health insurance system to report the use of medical procedures and services. It also allows insurers to monitor their use. The code was issued to Proteomics International USA for the company's certified reference laboratory in Irvine, which is supporting the device's commercial release across America.

Proteomics officially launched a next-gen PromarkerD test in the US last month at the annual meeting of the American Diabetes Association and began rolling it out in California. Currently, the test is paid for out of pocket.

The company last week presented its recommended US pricing to the Centres for Medicare and Medicaid Services for tests ordered from next year. The centres, which represent the US's massive public insurance schemes, will release their preliminary pricing in September after consulting an internal clinical advisory panel.

Proteomics says the progress in the lucrative and influential US market means PromarkerD is now well-positioned for global commercialisation and expanded regulatory approvals.

It may be the first cab off the rank in Proteomics' expanding arsenal of precision diagnostics targeting areas of unmet need, developed from its protein biomarker research and powered by its cutting-edge Promarker platform.

The company's standard protein blood test is also behind its PromarkerEso test for oesophageal cancer and PromarkerEndo diagnostic for early-stage endometriosis.

Bringing any new medical treatment or device to market always requires years of labour. With the lab work under its belt, Proteomics is now ticking off the regulatory checklist for PromarkerD at pace, putting the company well on its way to achieving a revolution in diabetic care.

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