RENALYTIXAI

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Renalytix AI plc
("RenalytixAI", the "Company" or the "Group")

US CPT® reimbursement code effective for *KidneyIntelX™*

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, announces that CPT reimbursement code 0105U for its *KidneyIntelX™* test has become effective nationally in the United States as of October 1, 2019. The CPT PLA code for *KidneyIntelX™* was issued on July 1, 2019 and became effective one quarter later to allow insurance payors time to load new test codes into their systems.

Effective immediately, CPT PLA code 0105U can be used to report *KidneyIntelX™* services to private and public payors throughout the United States for reimbursement. Further details are contained in the Company's announcement dated July 1, 2019. The Company intends to pursue coverage determinations from both Medicare and private insurance payors beginning in 2019 for patients with kidney disease and Type 2 diabetes.

KidneyIntelX™ is designed to predict progression of kidney disease and ultimately improve outcomes and health care system economics in patients with Type 2 diabetes and existing kidney disease. *KidneyIntelX™* uses machine-learning algorithms to assess a combination of predictive blood-based biomarkers and features from a patient's electronic health record to generate a prognostic risk score for rapid-progression of kidney disease.

One of the greatest drivers of health care cost today is patients with rapidly-progressing diabetic kidney disease who are not identified in time and who face progressive kidney failure and unplanned transition to dialysis. Approximately 12 million people have diabetic kidney disease in the United States[1]. Each year kidney disease results in the death of more people than breast and prostate cancer[2].

The CPT terminology is the most widely accepted medical nomenclature used across the US to report medical, surgical, radiology, laboratory, anaesthesiology, genomic sequencing, evaluation and management services under public and private health insurance programmes. The CPT PLA code awarded to *KidneyIntelX™* is a recent addition to the CPT Code set known as a CPT Proprietary Laboratory Analysis (PLA) Code. PLA codes are alphanumeric CPT codes with a corresponding descriptor for labs or manufacturers that want to identify their test more specifically.

CPT PLA codes describe proprietary clinical laboratory analyses and can be provided either by a single ("solesource") laboratory or licensed or marketed to multiple providing laboratories for tests that are cleared or approved by the US Food and Drug Administration. These codes include advanced diagnostic laboratory tests (ADLTs) and clinical diagnostic laboratory tests (CDLTs) as defined under the Protecting Access to Medicare Act (PAMA) of 2014.

Notes
[1] https://cjasn.asnjournals.org/content/12/12/2032
[2] https://www.ncbi.nlm.nih.gov/pubmed/30738630

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About Kidney Disease
Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control estimates there that 15% of United States adults or 37 million people currently have chronic kidney disease. It is reported that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day 13 patients die in the United States while waiting for a kidney transplant.
* https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

About RenalytixAI
RenalytixAI is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit renalytixai.com