U.S. CPT® Code Granted for KidneyIntelX™

July 1, 2019

CPT Code a key component for reimbursement from private medical insurance and Medicare

NEW YORK, July 1, 2019 /PRNewswire/ -- Renalytix AI plc (LON: RENX), a developer of artificial intelligence-enabled clinical diagnostics for kidney disease, announced today that the American Medical Association (AMA) has granted a CPT® Proprietary Laboratory Analyses (PLA) Code for its lead product, *KidneyIntelX* ™. The new code, 0105U, has been approved and published by the AMA CPT Editorial Panel, and is scheduled to become effective on October 1, 2019.

A payment rate for the new code will be established for Medicare patients through the 2019 Clinical Lab Fee Schedule (CLFS) Annual Public Meeting process. Renayltix AI will shortly provide comments and a recommendation on the appropriate basis for establishing a national Medicare price for this new CPT code expected to be effective January 1, 2020.

"This is an important step as we prepare for *KidneyIntelX's* scaled roll-out in the United States," said Michael J. Donovan, Ph.D., MD, Chief Medical Officer, RenalytixAI. "A CPT Code is instrumental in obtaining insurance coverage and reimbursement, and will increase access to *KidneyIntelX* testing results for patients with chronic kidney disease."

The CPT terminology is the most widely accepted medical nomenclature used across the United States to report medical, surgical, radiology, laboratory, anesthesiology, genomic sequencing, evaluation and management services under public and private health insurance programs. Recently added to the CPT Code set, PLA Codes are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to identify their test more specifically.

KidneyIntelX is designed to improve identification and clinical management of patients with Type 2 diabetes with fast-progressing kidney disease in an effort to curtail the estimated $114 billion annual cost[1] of chronic and end-stage kidney disease to the United States healthcare system. *KidneyIntelX* uses machine learning algorithms to assess a combination of predictive blood-based biomarkers, including sTNFR1, sTNFR2 and KIM1, and features from a patient's electronic health record.

In a recent study published April 1, 2019, and publicly announced by RenalytixAI on the same date, algorithms used at the core of *KidneyIntelX* significantly increased the ability to positively predict which patients went on to experience rapid kidney function decline (RKFD). For this group of patients experiencing RKFD and at significant risk of progressing to end-stage kidney disease and dialysis, there are several clinical management strategies and proven therapeutic options available. One of the greatest drivers of health care cost today is RKFD patients who are not diagnosed in time and face unplanned kidney failure through emergency room 'crash' dialysis.

About Kidney Disease
Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. In the United States alone, over 40 million people are classified as having chronic kidney disease, with nearly 50 percent of individuals with advanced (Stage IV) disease unaware of the severity of their reduced kidney function. As a result, many patients progress to kidney failure in an unplanned manner, ending up having dialysis in the emergency room without ever seeing a clinical specialist, such as a nephrologist. Every day 13 patients die in the United States while waiting for a kidney transplant.

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

[1]United States Renal Data System - https://www.usrds.org/adrhighlights.aspx.

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