



US Executive Order on Advancing American Kidney Health

July 12, 2019

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Renalytix AI welcomes US Administration's dedication to advancing American kidney health

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, welcomes the Executive Order signed by the President of the United States of America on 10 July 2019 to launch *Advancing American Kidney Health*, a new initiative to improve the lives of Americans suffering from kidney disease, expand options for American patients, and reduce healthcare costs.

The Executive Order sets out the policy of the United States to prevent kidney failure whenever possible through better diagnosis, treatment and incentives for preventative care. The Secretary of Health and Human Services (the "Secretary") is expected to launch an awareness initiative to educate patients and support programmes that promote kidney disease awareness. In addition, the Secretary will select a payment model to identify and treat at-risk populations earlier in disease development. The model should broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalisations, and increasing the rate of transplants.

RenalytixAI's lead product, *KidneyIntelX™*, is being developed to improve the identification and clinical management of patients with Type 2 diabetes with fast-progressing kidney disease. *KidneyIntelX™* uses a machine learning algorithm to assess a combination of predictive blood-based biomarkers and features from a patient's electronic health record. In May 2019, *KidneyIntelX™* was granted Breakthrough Device designation by the U.S. Food and Drug Administration (FDA) and on 1 July 2019 the American Medical Association (AMA) has granted a [CPT® Proprietary Laboratory Analyses \(PLA\)](#) Code for *KidneyIntelX™*. The new code, 0105U, is scheduled to become effective on 1 October 2019.

In setting out the purpose of the Executive Order, it says:

The state of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the current demand for transplants.

Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.

Read the [full text of the Executive Order](#).

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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 diagnostic 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.