



## CMS Pricing Determination becomes effective

January 3, 2020

Renalytix AI plc (AIM: RENX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, announces that the national price for KidneyIntelX™ set by the Centers for Medicare and Medicaid Services ("CMS") became effective as of 1 January 2020. This establishes a national price of \$950 for the test for Medicare patients and is effective until December 2022.

This announcement follows the publication of the final 2020 Clinical Laboratory Fee Schedule ("CLFS") by CMS, announced by the Company on 3 December 2019 (RNS: 4621V). For patients covered by Medicare the national price paid for outpatient laboratory testing is established through the CLFS process. Each year, new laboratory test codes are added to the CLFS and pricing is developed through a public comment process and review and finalisation by CMS. The pricing for tests like KidneyIntelX™ is set for a three-year period. At the end of that time, the price will be reset based on an average of reported private payor payments for the test or laboratory service. If the calculated average price would result in a reduction in the price paid for KidneyIntelX™ for Medicare patients, the decrease will be capped at no more than 15%.

Leveraging the validation associated with a national price established by Medicare, the Company is pursuing coverage determinations in 2020 and 2021 to ensure KidneyIntelX™ is available to patients with public and private health insurance coverage throughout the United States.

The person responsible for arranging the release of this announcement on behalf of the Company is James McCullough, CEO.

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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.