

# RENALYTIX AI

## CMS Issues Preliminary Medicare Pricing Determination for KidneyIntelX™

September 30, 2019

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Renalytix AI plc (AIM: RENX), a developer of artificial intelligence enabled clinical diagnostics for kidney disease, announces that Centers for Medicare & Medicaid Services ("CMS") has published its preliminary determination for national Medicare pricing for the Company's *KidneyIntelX™* test to be included in the national 2020 Clinical Laboratory Fee Schedule<sup>1</sup>. The preliminary determination sets a price of \$950 for each test. CMS considered recommendations received through an open meeting and brief comment period along with the consensus of an independent advisory panel.

A public comment period follows the publication of these preliminary determinations with comments accepted by CMS up until October 27. Final pricing determinations are expected to be published in November 2019 and will become effective on January 1, 2020. The price set for *KidneyIntelX* will be effective for a three-year period, ending on December 31, 2022. The Company intends to pursue coverage determinations from both Medicare and private insurance payors at this pricing level beginning in 2019 for patients with kidney disease and Type 2 diabetes.

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<sup>2</sup>. Each year kidney disease results in the death of more people than breast and prostate cancer<sup>3</sup>.

*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.

In a recent study published on-line, April 1, 2019<sup>4</sup>, the rate of rapid progression of kidney disease for patients identified as *high-risk* by *KidneyIntelX* was shown to be approximately 10 times greater than patients identified in the *low risk* group. For patients experiencing rapid progression of kidney disease, and therefore most likely to advance toward end-stage renal disease and dialysis, there are several clinical management strategies and proven therapeutic options to slow the rate of disease progression and/or halt its progress.

This announcement follows confirmation of the vote in favour of recommending 'crosswalk' pricing for *KidneyIntelX* by the independent Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests as referenced in the Company's results release dated September 3, 2019.

A further announcement is expected in November following confirmation of the final pricing determination for *KidneyIntelX* from Medicare.

### Notes

<sup>1</sup> [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory\\_Public\\_Meetings.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html)

Click on link: "CY 2020 – Clinical Laboratory Fee Schedule Test Codes Preliminary Determinations [ZIP, 48KB]"

<sup>2</sup> <https://cjasn.asnjournals.org/content/12/12/2032>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pubmed/30738630> <sup>4</sup> <https://www.biorxiv.org/content/10.1101/587774v1>

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