



## KidneyIntelX Medicare Update

October 25, 2022

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Renalytix PLC

25 October 2022

### Renalytix plc ("Renalytix" or the "Company")

#### KidneyIntelX Medicare Update

**NEW YORK and SALT LAKE CITY, October 25, 2022** -- Renalytix plc (NASDAQ: RNLX) (LSE: REXX) today announced that, building on recently established private payer and Medicaid insurance coverage contracts for KidneyIntelX, the Federal Medicare Administrative Contractor (MAC) National Government Services (NGS) has initiated payment of claims for KidneyIntelX testing for patients with Medicare coverage that have met appropriate medical necessity criteria.

Medicare payment for KidneyIntelX is based on the National Limitation Amount (NLA) of \$950 per reportable result established on the Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Fee Schedule (CLFS). KidneyIntelX has a CPT code (0105U) that was priced at \$950 and became effective as of January 1, 2020.

Medicare patient samples are being processed in the Company's New York laboratory. Under Medicare billing rules, all claims for KidneyIntelX testing are evaluated by the regional MAC for New York, NGS, for payment.

CMS has various pathways for Medicare payment for innovative diagnostic tests like KidneyIntelX, including National Coverage Determination (NCD) by the CMS central office, Local Coverage Determination (LCD) by the MAC, and review of individual claims (ICR) by the MAC. Effective July 1, 2022, claims for KidneyIntelX tests have been processed and paid by NGS using the ICR process. Under this payment methodology, NGS reviews each claim to determine its medical necessity based on the clinical evidence supporting its intended use. Payment timelines are within Medicare's 30-day targeted timeframe for payment.

Separately, Renalytix has submitted a formal request to NGS to establish an LCD for KidneyIntelX. NGS will continue to review claims individually for payment while the LCD review process is underway.

#### ***For further information, please contact:***

**Renalytix plc**  
James McCullough, CEO

[www.renalytix.com](http://www.renalytix.com)  
**Via Walbrook PR**

**Stifel (Nominated Adviser, Joint Broker)**  
Alex Price / Nicholas Moore

**Tel: 020 7710 7600**

**Investec Bank plc (Joint Broker)**  
Gary Clarence / Daniel Adams

**Tel: 020 7597 4000**

**Walbrook PR Limited**  
Paul McManus / Lianne Applegarth / Alice Woodings

**Tel: 020 7933 8780** or [renalytix@walbrookpr.com](mailto:renalytix@walbrookpr.com)  
Mob: 07980 541 893 / 07584 391 303 / 07407 804 654

**CapComm Partners**

**Tel: 415-389-6400** or [investors@renalytix.com](mailto:investors@renalytix.com)

### **About Kidney Disease**

Kidney disease is a public health epidemic affecting over 850 million people globally.<sup>2</sup> The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people<sup>3</sup>, have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3<sup>4</sup>. Despite its magnitude, early-stage (1-3) CKD is underdiagnosed and undertreated, largely because it's asymptomatic at this time in the disease. As many as 9 in 10 adults with CKD, and 2 in 5 adults with severe CKD do not know they have the condition.<sup>3</sup>

### **About Renalytix**

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an in-vitro diagnostics and laboratory services company that is the global founder and leader in the new field of bioprognosis<sup>TM</sup> for kidney health. The leadership team, with a combined 200+ years of healthcare and in-vitro diagnostic experience, has designed its KidneyIntelX laboratory-developed test to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D with early CKD stages 1-3. We believe that by understanding how disease will progress, patients and providers can take action early to improve outcomes and reduce overall health system costs. For more information, visit [www.renalytix.com](http://www.renalytix.com).

### **About KidneyIntelX<sup>TM</sup>**

KidneyIntelX<sup>TM</sup> is a laboratory-developed test demonstrated to be a reliable, bioprognostic<sup>TM</sup> methodology that yields a simple-to-understand, custom risk score, enabling prediction of which adult patients with T2D and early CKD (stages 1-3) are at low, intermediate or high risk for rapid progressive decline in kidney function. By combining information from KidneyIntelX with newer cardio- and reno-protective therapies, doctors will have more information in determining which patients are at higher versus lower risk for rapid disease progression and may be able to more appropriately target resources and guideline-recommended treatments to advance kidney health. KidneyIntelX is supported by a growing body of clinical, utility and health economic studies (including a validation study of two large cohorts) and has a demonstrated a 72% improvement in predicting those patients who are at high risk for rapid progressive decline in kidney function versus the current standard of care (eGFR and UACR). KidneyIntelX has also received Breakthrough Device Designation from the U.S. Food and Drug Administration and has submitted for De Novo marketing authorization. To learn more about KidneyIntelX and review the evidence, visit [www.kidneyintelx.com](http://www.kidneyintelx.com).

### **Forward Looking Statements**

Statements contained in this Report on Form 6-K (this "Report") regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the effects of our cost-saving initiatives; our commercial expansion opportunities; the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether and to what extent KidneyIntelX will be successfully adopted by physicians and distributed and marketed, our expectations regarding reimbursement decisions, reimbursement processes and approval of claims and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and

potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our annual report on Form 20-F filed with the SEC on October 21, 2021, and other filings we make with the SEC from time to time. All information in this Report is as of the date of this Report, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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