CMS publishes Draft Local Coverage Determination

February 9, 2024

RNS Number : 5654C
Renalytix PLC
09 February 2024

Renalytix plc

("Renalytix" or the "Company")

Centers for Medicare & Medicaid Services Publishes Draft Local Coverage Determination for KidneyIntelX and kidneyintelX.dkd

LONDON and SALT LAKE CITY, February 9, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces that on February 8, 2024 the Centers for Medicare and Medicaid Services ("CMS") published a draft Local Coverage Determination ("LCD") for the Company's KidneyIntelX and kidneyintelX.dkd testing. The draft LCD can be accessed at https://www.cms.gov/medicare-coverage-database/. The established Medicare price for KidneyIntelX and kidneyintelX.dkd is $950 per test. Distinct CPT Codes (Common Procedural Terminology Codes) have been established for KidneyIntelX and kidneyintelX.dkd and are published in CMS' 2024 Clinical Lab Fee Schedule.

The draft LCD specifies coverage for use of KidneyIntelX or kidneyintelX.dkd for patients with diagnosed Type 2 diabetes and Stage 1-3b Chronic Kidney Disease is reasonable and necessary. Any specified limitations for use conform to the U.S. Food and Drug Administration ("FDA") label for kidneyintelX.dkd.

The LCD was submitted by National Government Services ("NGS"). NGS is a subsidiary of Elevance Health, Inc. (previously Anthem, Inc.), a Medicare Administrative Contractor with CMS and responsible for claim review and payment for testing performed in the Company's New York City laboratory. A 45-day public comment period began on February 8, 2024, and ends on March 23, 2024.

The Company formally requested an LCD from NGS, and submitted substantial peer reviewed published evidence in support of coverage of KidneyIntelX and kidneyintelX.dkd. NGS held a Contractor Advisory Committee meeting on August 29, 2023, where a panel of external experts reviewed and discussed the clinical evidence. We believe that based on the evidence, and the FDA's De Novo Marketing Authorization for the kidneyintelX.dkd ™ test, that there was a strong basis for NGS determining that these tests are reasonable and necessary for Medicare beneficiaries. Following the Open Public Meeting NGS will review public comments and issue a final LCD which is expected in calendar year 2024.

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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™ 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 and 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.

Forward-Looking Statements

Statements contained in this press release 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: timing and outcome of LCD determination. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. The Company may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on the Company's 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; the Company has only recently commercially launched KidneyIntelX; and risks relating to the impact on the Company's business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in the Company's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of its annual report on Form 10-K filed with the SEC on September 28, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 14, 2023 and other filings the Company makes with the SEC from time to time. All information in this press release is as of the date of the release, and the Company undertakes 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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