



## Oncocyte Announces Final Local Coverage Determination from Noridian Healthcare Solutions for DetermaRx™, Securing National Medicare Payment for the Test Starting August 2020

Jul 20, 2020

*Noridian's decision aligns with Palmetto GBA's final LCD for the test announced in April*

*Compelling clinical evidence on DetermaRx™ drives the establishment of a new class of predictive tests for Medicare coverage*

*DetermaRx™ becomes the first and only test for this new class of tests for early stage non-small cell lung cancer*

IRVINE, Calif., July 20, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today announced that Noridian, the Centers for Medicare & Medicaid Services (CMS) Medicare Administrative Contractor for laboratories located in California, has issued a final local coverage determination (LCD) for DetermaRx™. The decision aligns with Palmetto's criteria for the test, which established coverage for Stage I and IIA patients with non-squamous, non-small cell lung cancer (NSCLC) following surgical resection, and establishes Medicare coverage for approximately 70% of eligible patients. Notably, the decision also establishes a new class of predictive tests for Medicare coverage, based primarily on the comprehensive clinical evidence presented in support of DetermaRx.

There are an estimated 40,000 surgically resected Stage I and IIA non squamous NSCLC patients in the United States each year. With an estimated 350,000 patients potentially eligible for the test on an annual basis globally, the company believes there may be a total addressable market opportunity of approximately \$500 million for the test, subject to pricing and adoption rates. Oncocyte recently announced that it has agreements in place for the distribution of the test in India, the Middle East, Africa and Israel.

DetermaRx is the first and only predictive test for the identification of patients with Stage I-IIA non-squamous non-small cell lung cancer who are at high-risk for recurrence following surgery and are likely responsive to adjuvant chemotherapy.

"Gaining the final LCD from Noridian, Medicare's local payment administrator, is the final step in our quest for reimbursement and is essential for increasing patient access to our critical test nationally. We are thrilled to announce this significant milestone," said Padma Sundar, SVP of Commercial at Oncocyte. "This news is further validation of the value of DetermaRx in improving patient outcomes by assisting physicians in a critical treatment decision for the timely management of early stage lung cancer post-resection. Importantly, the detailed Determination from Noridian, which included the creation of a new

class of predictive tests, firmly positions Oncocyte as a true pioneer in the lung cancer diagnostics community. We look forward to continued expansion and availability of our test throughout the country and globally.”

Please visit [CMS.gov](https://www.cms.gov) to view the full final LCD from Noridian.

## **About Oncocyte Corporation**

Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the cancer care continuum, with the goal of improving patient outcomes by accelerating and optimizing diagnosis and treatment. The Company recently launched DetermaRx™, a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence post-resection, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint immunotherapies.

DetermaRx and DetermaIO are trademarks of Oncocyte Corporation.

## **Oncocyte Forward Looking Statements**

Oncocyte cautions you that this press release contains forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates,” “may,” and similar expressions) are forward-looking statements. These statements include those pertaining to the commercial launch of DetermaRx, development of DetermaIO, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from acquisitions, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our financial and operational results, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to our supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients’ use of any diagnostic tests we commercialize, and risks inherent in acquisitions such as failure to realize anticipated benefits, unexpected expenditures or assumed liabilities, unanticipated difficulties in conforming business practices including accounting policies, procedures and internal controls, greater than estimated allocations of resources to develop and commercialize technologies, or failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the “Risk Factors” and other cautionary statements found in Oncocyte’s Securities and Exchange Commission filings, which are available from the SEC’s website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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Source: OncoCyte Corporation

