Oncocyte Expands Market Opportunity for VitaGraft™ Kidney

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- Medicare coverage expanded following study showing that monitoring with Oncocyte's assay significantly reduces time to rejection diagnosis in patients with newly developed donor-specific antibodies (DSA)
- MolDX confirms eligibility for billing under current Local Coverage Determination (LCD) and Z-Code
- Up to 20% of patients will have detectable DSA within the first five years post kidney transplant, representing greater than 10,000 patients per year in the US.[1] From time of onset of dnDSA, 24% of patients will lose their allograft within 3 years compared to the 96% five-year allograft survival for patients without DSA.[1]
- Early detection of transplant rejection is growing in significance as novel therapeutic treatments show promising early results in antibody mediated rejection.

IRVINE, Calif., Jan. 06, 2025 (GLOBE NEWSWIRE) -- Oncocyte Corp. (NASDAQ: OCX), a leader in diagnostic technology, today announced a significant milestone in the advancement of patient care for kidney transplant patients.

The Molecular Diagnostics program (MolDX) has confirmed the use of VitaGraft Kidney to monitor patients with newly developed donor-specific antibodies (dnDSA+) for antibody-mediated rejection (AMR). This achievement follows the publication of a groundbreaking study demonstrating VitaGraft Kidney's ability to detect AMR in dnDSA+ patients up to 11 months earlier than the current standard of care.

"Kidney transplant management is changing. There are currently no approved medications for managing AMR. In the past year, we have supported two publications that show anti-CD38 therapies have a chance at treating the disease," said Oncocyte CEO Josh Riggs. "Assuming the data continue to prove out for those drugs, catching AMR as early as possible becomes critical, highlighting the importance of this claims expansion. We have now shown that you can use our test to both catch AMR early and monitor anti-CD38 therapy. Eventually, we expect to attach all these claims to our clinical kitted product that is currently in development."

For context, Oncocyte aims to deliver scientifically proven molecular diagnostic tests that can be run more affordably and more quickly at local laboratories. Oncocyte is at a pivotal stage in commercializing its proprietary diagnostic technology for use in organ transplant patients. Its technology is designed to enable local laboratories to run a kitted test that quantifies an established biomarker, donor-derived cell-free DNA (dd-cfDNA). Oncocyte's scientists have played a pivotal role in establishing dd-cfDNA as a trusted biomarker, and the company now is commercializing a groundbreaking diagnostic test using this market-disruptive approach.

An affirmative initial Medicare coverage decision is a key milestone toward successfully commercializing an assay, and subsequent claims expansion grows the total addressable market for an assay. For VitaGraft Kidney, Palmetto GBA, the Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services (CMS), first issued a positive coverage decision in August 2023, confirming that the test had met the criteria for coverage under MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568). (Palmetto administers the MolDX program to oversee claims processing and determine whether molecular diagnostic tests meet coverage criteria for Medicare reimbursement.)

This latest claims expansion grows the total number of testing opportunities.

Highlights:

- Expanded Medicare coverage under LCD L38568 now includes VitaGraft Kidney for organ rejection surveillance in dnDSA+ patients.
- Enables earlier detection of antibody-mediated rejection (AMR) without the need for invasive biopsies.
- Supported by clinical evidence demonstrating VitaGraft Kidney's ability to identify AMR up to 11 months earlier than current protocols.
- Associated with two Z-codes for improved accessibility:
  - Z01TT: VitaGraft Kidney – Baseline + First Plasma Test
  - Z04D6: VitaGraft Kidney - Subsequent
- Expansion focuses on high-risk patients; the coverage does not extend to routine surveillance testing.

Citations:

1. *Company estimates based on* Everly M, Rebellato M, Haisch C, et al. (2013). Incidence and Impact of De Novo Donor-Specific Alloantibody in Primary Renal Allografts. Transplantation Journal 95(3):410-417. (Link)

About VitaGraft Kidney™
VitaGraft Kidney is a non-invasive, blood-based transplant monitoring test that quantifies donor-derived cell-free DNA (dd-cfDNA) in kidney transplant recipients. Utilizing highly precise digital polymerase chain reaction (digital-PCR) technology, VitaGraft Kidney provides fast results and reliable diagnostic insights to help clinicians assess graft health and manage patient care proactively.

About Oncocyte
Oncocyte is a leading diagnostics technology company. The company's tests are designed to help provide clarity and confidence to physicians and their patients. VitaGraft™ is a clinical blood-based solid organ transplantation monitoring test. GraftAssure™ is a research use only (RUO) blood-based solid organ transplantation monitoring test. DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies. DetermaCNI™ is a blood-based monitoring tool for monitoring therapeutic efficacy in cancer patients. For more information about Oncocyte, please visit https://oncocyte.com/. For more information about our products, please visit the following web pages:

VitaGraft Kidney™ - https://oncocyte.com/vitagraft-kidney/VitaGraft Liver™ - https://oncocyte.com/vitagraft-liver/

GraftAssure™ - https://oncocyte.com/graftassure/DetermaIO™ - https://oncocyte.com/determa-io/
DetermaCNI™ - https://oncocyte.com/determa-cni/

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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, among other things, Oncocyte’s commercialization efforts and progress with respect to its molecular diagnostic tests and its proprietary diagnostic technology for use in organ transplant patients, the expectation of successful commercialization and growth of the total addressable market for VitaGraft Kidney, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte’s third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients’ use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential 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 (SEC) 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