Favorable Medicare Coverage Decision Supports Commercial Adoption of iMDx GraftAssure Assay Portfolio

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- Industry-wide coverage policy expands reimbursement framework for donor-derived cell-free DNA testing
- Supports iMDx's commercial strategy in transplant monitoring
- Final policy establishes recurring testing baseline opportunity, providing reimbursement clarity on surveillance testing for hospitals, physicians, and laboratories
- Final policy cites iMDx-affiliated research, affirming iMDx's scientific leadership in the industry

NASHVILLE, Tenn., July 16, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today highlighted a favorable new Medicare policy supporting expanded coverage for donor-derived cell-free DNA (dd-cfDNA) testing in transplant care.

The company believes the updated policy, known as a local coverage determination, or LCD, supports the commercial adoption of its GraftAssure™ family of assays by reinforcing and expanding the Medicare reimbursement framework for dd-cfDNA testing. The policy was issued by MolDX, which is a program run by the Centers for Medicare & Medicaid Services, or CMS, specifically designed to review and decide under what conditions the U.S. government will pay for genetic and molecular tests.

"The Medicare policy released today is Christmas in July for molecular transplanted organ health monitoring," iMDx CEO Josh Riggs said. "We are encouraged to see that CMS was responsive to the voices of the clinical community and increased the allowed amount of testing like ours."

iMDx believes the favorable policy provides additional clarity for hospitals, clinicians, and laboratories, supports patient access to reimbursable dd-cfDNA testing, and further aligns with the company's strategy to enable in-house dd-cfDNA testing.

Specifically:

- The policy reaffirms the value of dd-cfDNA testing in transplanted organ health monitoring.
- The new policy establishes a baseline for long-term surveillance testing for transplanted organ patients, which gives clarity to hospitals, clinicians, and laboratories, representing iMDx's future expected kitted transplanted organ rejection monitoring assay customers.
- The policy supports a higher testing frequency through the allowance of *surveillance* coverage in addition to the already-covered *for-cause* testing. This higher testing frequency, outlined below, is favorable to the company's publicly stated $2 billion total addressable market for kitted transplanted

organ testing. The company also believes that the higher frequency of allowed testing strengthens the economic case for transplant centers to bring dd-cfDNA testing in-house.

- iMDx's immediate focus is kidney transplant testing, followed by heart transplant testing. The final policy establishes the following covered surveillance testing frequencies, which represent an increase across all organ types compared with the previous policy. In addition, relative to the draft policy published last year for public comment, the company notes the following changes
    - Year 1: Reimbursable kidney transplant surveillance testing in the first-year post-transplant has increased from four tests in the draft policy to six tests in the final policy. Heart testing frequency remains unchanged at twelve tests in the first year after transplant surgery.
    - Years 2 and 3: In the second and third years after a transplant surgery, dd-cfDNA testing frequency for both kidney and heart transplant patients doubled from two tests per year in the draft policy to four tests per year in the final policy.
    - Years 4 and beyond: For the remaining life of the patient, the draft policy had proposed two tests per year. The final policy removes that testing rate ceiling, provided the testing frequency has clinical utility, which iMDx believes is a favorable development for patients, clinicians, and providers.

Notably, the final policy – like the one it supersedes -- also cites iMDx-affiliated research utilizing GraftAssure technology.

As a reminder, iMDx's flagship technology has a reimbursement rate from Medicare of $2,753 per result. This rate is for GraftAssureCore, a lab-developed test to measure dd-cfDNA that is run in the company's Tennessee laboratory. Eventually, through a process known as "bridging," that reimbursement rate would extend to GraftAssureDx, which has been submitted for FDA review and is awaiting FDA marketing authorization. The company seeks to allow other labs to purchase the GraftAssureDx kits to perform the test themselves and bill Medicare at the same rate, which would happen after FDA marketing authorization is achieved.

About iMDx's GraftAssure technology

iMDx is at a pivotal stage in commercializing its GraftAssure technology, which iMDx expects to be an industry-transforming transplanted organ rejection monitoring test. The company aims to deliver proven, more affordable, faster tests that can be run in-house at local transplant center laboratories. iMDx has designed a molecular test that it can sell as a test kit to help enable transplant center laboratories to run tests locally and deliver critical test results far more quickly than the current send-out tests. The company is now seeking FDA marketing authorization to sell these kits to transplant centers in the U.S.

Over time, iMDx sees three potential paradigm shifts in transplanted organ health monitoring:

1. Bringing testing closer to the patient: The first is a shift in where donor-derived cell-free DNA (dd-cfDNA) testing is performed – migrating out of centralized reference laboratories and into hospital-based laboratories capable of delivering results locally. The company seeks to demonstrate that in-house testing is better for patients and physicians. (As a reminder, dd-cfDNA is an established biomarker for assessing the health of a transplanted organ through a simple blood draw).

2. Expanding the clinical role of dd-cfDNA: The second is the growing potential for dd-cfDNA testing, powered by digital PCR technology, to support earlier detection of allograft injury, longitudinal monitoring of transplant health, and assessment of response to emerging anti-rejection therapies.

3. Advancing from rule-out to comprehensive decision support: The third is a transition from the current rule-out-biopsy testing paradigm toward a more comprehensive rule-out and rule-in approach, enabled by GraftAssure's ability to measure both dd-cfDNA percentage and absolute, or true, concentrations as copies per milliliter of plasma.

iMDx Transplant Products and Product Candidates in Development

iMDx's flagship transplant testing technology quantifies a molecular biomarker known as donor-derived cell-free DNA (dd-cfDNA). The Company's scientists in Germany and the U.S. have played a critical role over the past decade in developing the science that helped establish dd-cfDNA as a trusted biomarker of transplant rejection. iMDx is commercializing this technology using a market-disruptive business strategy. Under the GraftAssure™ brand, iMDx's transplant diagnostics include the following:

- GraftAssureCore – The company's laboratory-developed test (LDT), currently reimbursed by CMS and performed at iMDx's CLIA-certified laboratory in Franklin, Tennessee.
- GraftAssureIQ – A research-use-only (RUO) kit intended and labeled for non-clinical applications.
- GraftAssureDx – The in vitro diagnostic (IVD) kit currently under FDA review for use in clinical decision-making.

About Insight Molecular Diagnostics, Inc.

Insight Molecular Diagnostics is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. Investors may visit https://investors.imdxinc.com/ for more information.

GraftAssureCore™, GraftAssureIQ™, GraftAssureDx™, GraftAssure™, DetermaIO™, and DetermaCNI™ are trademarks of Insight Molecular Diagnostics Inc.

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, expected FDA marketing authorization to sell GraftAssureDx, anticipated paradigm shifts in transplanted organ health monitoring, transplant and other product candidates in development, 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 Insight Molecular Diagnostics' 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 Insight Molecular Diagnostics 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 Insight Molecular Diagnostics, particularly those mentioned in the “Risk Factors” and other cautionary statements found in Insight Molecular Diagnostics’ 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. Insight Molecular Diagnostics 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.

FDA

CAUTION: This press release concerns certain products that are under clinical investigation, and which have not yet been cleared or authorized for marketing by the U.S. Food and Drug Administration. These products are currently limited by federal law to investigational use, and no representation is made as to the safety or effectiveness of these products for the purposes for which they are being investigated.

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