



NEWS RELEASE

# CareDx Announces Transplant Community Secures Win Reaffirming Longstanding Medicare Coverage for AlloSure and AlloMap Testing

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CMS Recognizes the Importance of Surveillance Testing for Early Detection of Allograft Rejection

CMS to Retire Proposed Draft Policy that Would Have Restricted Coverage

BRISBANE, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA) - The Transplant Company™ – today announced that the Centers for Medicare and Medicaid Services (CMS) has **announced its plan** to retire a draft LCD that would have restricted coverage for non-invasive blood-based surveillance testing for allograft rejection. Combined with the February 2024 removal of restrictive language in the accompanying Billing Article and based on discussions with CMS, CareDx believes that longstanding coverage for AlloSure®, AlloMap® and HeartCare® has effectively been restored.

“ We appreciate the Agency and its local contractors for listening to the voices of thousands of patients and clinicians who tirelessly advocated for access to non-invasive surveillance testing based on its clinical utility in detecting early signs of rejection. We believe their efforts were instrumental in restoring longstanding Medicare coverage,” said John W. Hanna, CareDx President and CEO.

The longstanding Medicare coverage for AlloSure and AlloMap testing includes surveillance monitoring of organ transplant rejection, without requiring ties to invasive biopsies. In March 2023, Medicare issued a Billing Article that, among other restrictions, required clinicians to indicate that the surveillance testing was being performed instead of a surveillance biopsy. This resulted in a decrease in testing as not all transplant centers perform surveillance biopsies, particularly for kidney transplant monitoring.

AlloSure donor-derived cell-free DNA (dd-cfDNA) and AlloMap gene-expression profiling (GEP) are non-invasive blood tests that assess allograft injury and immune quiescence respectively, both important indicators of transplanted organ health. The clinical utility of AlloSure Kidney, AlloSure Heart, AlloSure Lung, AlloMap Heart and HeartCare have been widely demonstrated in peer-reviewed clinical studies.

CareDx has been a longstanding proponent for improving access to the latest transplantation innovations and supported the **Honor the Gift** and **Health Equity in Transplantation** coalitions in their recent efforts to restore Medicare coverage for non-invasive surveillance testing. CareDx has historically supported important transplant legislative policies, including the 21<sup>st</sup> Century Cures Act to help bring new innovations to patients who need them faster, the Living Donor Protection Act to promote live organ donations and protect donors from discrimination, and through the Honor the Gift Coalition, the passage of the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019 (Immuno Bill).

## About CareDx – The Transplant Company

CareDx, Inc., headquartered in Brisbane, California, is a leading precision medicine solutions company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers. CareDx offers testing services, products, and digital healthcare solutions along the pre- and post-transplant patient journey; and is the leading provider of genomics-based information for transplant patients. For more information, please visit: [www.CareDx.com](http://www.CareDx.com).

## Forward-Looking Statements

This press release includes forward-looking statements related to CareDx, Inc. including statements regarding the potential benefits and results that may be achieved with AlloSure®, AlloMap® and HeartCare®. These forward-looking statements are based upon information that is currently available to CareDx and its current expectations, speak only as of the date hereof, and are subject to risks and uncertainties that could cause actual results to differ materially from those projected, including general economic and market factors; and other risks discussed in CareDx's filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed by CareDx with the SEC on February 28, 2024, the Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024 filed by CareDx with the SEC on May 9, 2024 and the Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2024 filed by CareDx with the SEC on July 31, 2024, and other reports that CareDx has filed with the SEC. Any of these may cause CareDx's actual results, performance, or achievements to differ materially and adversely from those anticipated or implied by CareDx's forward-looking statements. CareDx expressly disclaims any obligation, except as required by law, or undertaking to update or revise any such forward-looking statements.

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