



NEWS RELEASE

CareDx's HeartCare Multimodality Service Receives Medicare Coverage for Heart Transplant Surveillance

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HeartCare Combines Testing Using Both AlloMap Gene Expression Profiling and AlloSure Donor-Derived Cell-Free DNA

BRISBANE, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA), a leading precision medicine company focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers – today announced Medicare coverage for HeartCare, a multimodality testing service that includes both AlloMap® Heart and AlloSure® Heart, in a given patient encounter, for heart transplant surveillance. Coverage is effective April 1, 2023. AlloMap Heart and AlloSure Heart are also covered by Medicare individually.

"Today is a major milestone for heart transplant care and for the use of multimodality technologies to improve patient outcomes with HeartCare," said Reg Seeto, CEO and President of CareDx. "I could not be prouder of our organization's unwavering commitment to serving patients and leading transplant innovation. I want to thank MoIDX for recognizing the critical clinical value of multimodality in heart transplant surveillance."

"Medicare's coverage of HeartCare reflects the growing scientific evidence supporting its use for routine graft surveillance in lieu of a biopsy. We have witnessed a significant reduction in the need for endomyocardial biopsies in our clinical practice by incorporating paired testing with AlloMap and AlloSure, which provides complementary information about allograft health," said Jeffrey Teuteberg, MD, Professor of Medicine, Section Chief of Heart Failure, Cardiac Transplantation, and Mechanical Circulatory Support, Stanford University.

Studies showed that multimodal testing with HeartCare, including both AlloMap and AlloSure, dramatically reduced

dependency on endomyocardial biopsies (EMBs).^{1,2} These publications showed a reduction in biopsies with HeartCare when compared to prior use of an AlloMap-only protocol, without impacting outcomes.^{1,2} These studies also showed that when using HeartCare, a negative AlloMap result that accompanied a positive AlloSure result was associated with fewer biopsies than if every AlloSure result above threshold led to a biopsy.^{1,2} When both tests were negative, 99.5% of biopsies were deferred.^{1,2}

“Since the introductions of AlloMap gene expression profiling and AlloSure donor-derived cell-free DNA, followed by their subsequent incorporation in ISHLT guidelines, we’ve seen widespread adoption of these noninvasive testing services at leading heart transplant centers in the U.S.,” said Eugene DePasquale, MD, Medical Director, Heart Transplant Program, Keck Medicine, USC. “The additive value of both biomarkers will lead to a new standard of care, from routine endomyocardial biopsies to noninvasive surveillance, using HeartCare as a robust strategy for the surveillance of heart transplant recipients.”

The use of HeartCare has been supported by the new International Society for Heart and Lung Transplantation (ISHLT) guidelines recommending the use of AlloMap gene expression profiling (GEP) and donor-derived cell-free DNA (dd-cfDNA), as in AlloSure, in routine heart transplant surveillance: AlloMap has been in the ISHLT guidelines since 2010 and both in the 2022 update.³ In a guide published in the Journal of the American College of Cardiology: Heart Failure, the transition from routine invasive EMBs to a less invasive acute rejection monitoring protocol was described for clinicians.⁴

AlloMap became commercially available in 2005 and has the distinction of being the only gene expression profiling test that has been FDA cleared for use in heart transplant patients.⁵ In 2020, CareDx launched HeartCare, which includes both AlloMap GEP and AlloSure dd-cfDNA, to provide a comprehensive view of organ rejection by assessing immune quiescence and graft injury. HeartCare is currently used in over 1 in 2 newly transplanted patients and in over 90 percent of heart transplant centers in the U.S.⁵

AlloMap Heart, AlloSure Heart, and HeartCare are covered by Medicare under MoIDX LCD L38568 and will be listed on the **Palmetto GBA DEX Exchange**. HeartCare is covered for the first year, starting two months post-transplant.

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: **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 CareDx's HeartCare, AlloSure and AlloMap, and the Medicare coverage for 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 risks that CareDx does not realize the expected benefits of HeartCare, AlloSure, AlloMap or the Medicare coverage for HeartCare; risks that AlloSure Heart, AlloMap Heart or HeartCare may not be listed on the Palmetto GBA DEX Exchange; 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, 2022 filed by CareDx with the SEC on February 27, 2023, the quarterly report on Form 10-Q for the quarter ended March 31, 2023 filed by CareDx with the SEC on May 10, 2023, 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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