



NEWS RELEASE

CareDx Comments on Issuance of Proposed LCD for Molecular Testing for Solid Allograft Rejection

2023-08-11

CareDx Welcomes Open Process to Gain Transplant Community Feedback on Critical Medicare Coverage Decision

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 commented on the issuance of proposed changes to the Local Coverage Determination (LCD) MoIDX Molecular Testing for Solid Organ Allograft Rejection that covers AlloSure®, AlloMap® and HeartCare.

CareDx is pleased that MoIDX is providing the public with the opportunity to participate in an open and transparent process, as advocated by CareDx and many others across the transplant community. In the proposed LCD (DL38568) MoIDX continues to recognize the value of surveillance testing in certain scenarios, as well as other uses for these tests in transplant; however, the proposed LCD would change the existing LCD to inappropriately restrict coverage in a manner similar to the restrictions that CareDx believes were impermissibly introduced in the Medicare Billing Article revisions issued on March 2 and May 4, 2023.

MoIDX and Noridian have opened a public comment period that extends through September 23, 2023, to solicit feedback from clinicians, patients, and the transplant community for consideration in drafting a final LCD. CareDx will continue to review the proposed LCD and looks forward to providing comments on the draft policy. CareDx believes that broad coverage of these tests based upon the clinicians' assessment of need for their transplant patients is both appropriate and also consistent with MoIDX's longstanding coverage policies.

"While CareDx welcomes an open process for gaining public feedback on the proposed LCD as required by CMS

rules, we are disappointed in the way the coverage policy was changed with two Billing Articles issued in the six months prior to this proposed LCD. This has created unnecessary clinician confusion, chaos, and disruption to patient care,” said Reg Seeto, CEO and President of CareDx. “CareDx will continue to fight for access to transplant innovation for these highly vulnerable patients.”

CareDx is the only company covered under this LCD that is 100 percent focused on serving transplant patients. CareDx has invested hundreds of millions of dollars and over two decades to support the transplant community, leading with innovation. CareDx is the first and only company approved by MoIDX for gene expression profiling in heart with AlloMap Heart, the first and only approved for donor-derived cell-free DNA (dd-cfDNA) in lung with AlloSure Lung and the first dd-cfDNA approved in kidney with AlloSure Kidney. CareDx is also the first and only approved in multimodality with HeartCare.

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.

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 proposed LCD for Molecular Testing for Solid Allograft Rejection (the “LCD”). 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 or AlloMap; the potential impact of a final LCD on patient care; general economic and market factors; regulatory risks; 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, the quarterly report on Form 10-Q for the quarter ended June 30, 2023 filed by CareDx with the SEC on August 8, 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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Source: CareDx, Inc.