



NEWS RELEASE

CareDx Comments on MoIDX Publication of New Billing and Coding Article

2023-03-03

Article Addresses Coverage of Molecular Testing for Solid Organ Allograft Rejection Following Contractor Advisory Committee Meetings

BRISBANE, Calif.--(BUSINESS WIRE)-- CareDx, Inc. (Nasdaq: CDNA) – The Transplant Company™ focused on the discovery, development, and commercialization of clinically differentiated, high-value healthcare solutions for transplant patients and caregivers – today commented on the release of a Billing Article related to MoIDX Molecular Testing for Solid Organ Allograft Rejection that covers AlloSure® and AlloMap®. The Billing Article is effective March 31, 2023.

“After discussions with MoIDX regarding yesterday’s Billing Article release, it is now our understanding that MoIDX does not plan to modify the foundational LCD but instead issued this Billing Article revision for clarification purposes,” said Reg Seeto, CEO and President of CareDx.

This revised Billing Article applies across covered solid organ transplantation tests for kidney and heart (“Testing Services”).

The Billing Article addresses Testing Services coverage under the foundational LCD in three main areas:

1. The foundational LCD covers patients utilizing the Testing Services for cause and for surveillance:

- Testing Services are covered for cause in lieu of biopsy or to further inform on the need for or results of a

biopsy.

- Testing Services are covered for surveillance, where the physician would have otherwise ordered a surveillance biopsy.

For Testing Services reimbursement, the ordering physician needs to clarify that they would have otherwise considered a biopsy – either a protocol surveillance or for cause biopsy. Notably, reimbursement is not necessarily limited to centers that have surveillance biopsy protocols.

2. AlloSure Heart Standalone Reimbursement: In heart transplantation, both AlloSure Heart and AlloMap Heart can now be billed individually to Medicare, whereas in the past AlloSure Heart could only be billed with AlloMap Heart. This change will now enable AlloSure Heart to be reimbursed independently.

Notably,

- Most of CareDx's heart transplant patients are covered by commercial payers, while the Billing Article is limited to Medicare patients. Furthermore, approximately 50 percent of 2022 AlloSure Heart revenues were from non-Medicare reimbursement.
- CareDx has a new source of reimbursement as 19 percent of AlloSure Heart volume year-to-date was ordered alone, independent of AlloMap Heart. This represents a new opportunity for reimbursement in the Medicare population.

3. Pathway for Multimodality: In the Billing Article revision, two billed tests in a single patient encounter will not be covered. MoIDX has indicated that this coverage would be considered with additional data supporting this use. This provides a path for multimodality with sufficient data.

Notably,

- CareDx plans to update its HeartCare® submission to MoIDX. The Company does not expect that this will require a new LCD.
- CareDx's AlloMap Kidney Test was submitted as a standalone test to MoIDX, as well as the planned UroMap® submission. Future plans include submitting for multimodal use with additional data.

As next steps, CareDx plans to have follow-up discussions with MoIDX, submit additional data for HeartCare, and update its procedures in line with the revised Billing Article.

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 AlloMap, AlloSure, the matters addressed in the new billing and coding article related to MoIDX (the “Billing Article”), statements regarding CareDx’s interpretation of the Billing Article and discussions with MoIDX, CareDx’s expectations regarding the foundational LCD, statements regarding potential opportunities provided to CareDx under the Billing Article, and CareDx’s plans to update its billing procedures to address the new Billing Article, to update its HeartCare submission to MoIDX, to submit for multimodal use with additional data and to further communicate with MoIDX. 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 AlloMap or AlloSure; the impact of the Billing Article; any further MoIDX publications or communications regarding the matters set forth in the Billing Article; 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, 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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