



September 28, 2015

## CareDx Responds to Proposed CMS Clinical Laboratory Fee Schedule Changes

### *AlloMap® and 7 Other Established Clinical Diagnostic Tests Impacted*

BRISBANE, Calif., Sept. 28, 2015 (GLOBE NEWSWIRE) -- CareDx, Inc. (Nasdaq:CDNA), a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant recipients, is responding to the Centers for Medicare & Medicaid Services (CMS) *Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations for CY 2016* issued on September 25, 2015. In the draft CLFS, CMS is proposing drastic changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. The draft CLFS is subject to an open comment period until November 24, 2015. CareDx and other stakeholders believe that additional information provided by stakeholders during the open comment period should be reflected in the final guidance. Final changes to the CLFS will go into effect on January 1, 2016.

CareDx is working with industry peers, the medical community, patients, the Coalition for 21<sup>st</sup> Century Medicine, elected representatives in state and federal government, and other stakeholders to ensure that value-based reimbursement is maintained for AlloMap and other molecular diagnostics tests. The Company concurs with experts in the field that the approaches to establish national reimbursement for new technology - specifically technology that is inadequately described and valued by existing codes on the current CLFS - should not rely on the so-called crosswalk methodology, in which reimbursement is based on the price of other tests which may or not be comparable.

In the CMS CLFS proposal, pricing for AlloMap was assigned by crosswalk to an existing code that was established for gene sequence analysis of hereditary non-polyposis colorectal cancer. This pricing assignment method associates AlloMap, a gene expression analysis, with a test method, laboratory workflow, and clinical utility that are substantially different and unrelated to AlloMap. In addition, use of the crosswalk methodology is counter to comments made at the July 2015 Annual Clinical Laboratory Public Meeting and the recommendation from the CMS Advisory Panel on Clinical Diagnostic Laboratory Tests, which recommended use of the gapfill methodology. Under the currently proposed fee schedule AlloMap reimbursement would be reduced by 77% from the currently reimbursed rate of \$2,821.00 to \$644.62.

In addition to the technical limitations of the crosswalk methodology, CareDx believes the approach is also an inaccurate means of valuing AlloMap. The AlloMap test has been utilized by transplant centers since 2005 and is well established in the continuum of care for heart transplant recipients. AlloMap has been reimbursed by Medicare Administrative Carriers (MACs) since 2006, and received FDA 510(k) clearance in 2008.

There is a large body of clinical evidence reported in peer-reviewed journals supporting the clinical validity and utility of AlloMap. Results from randomized interventional trials published in both the *New England Journal of Medicine* and *Circulation* have demonstrated non-inferiority of clinical outcomes in patients who receive non-invasive surveillance with AlloMap as compared to patients managed with endomyocardial biopsy. In recognition of the level of evidence available, AlloMap is recommended for non-invasive monitoring of heart transplant recipients by the International Society of Heart and Lung Transplantation. AlloMap is currently utilized by 110 of 130 transplant centers in the United States, and for many patients has reduced the need for invasive biopsies thus lowering the cumulative risk of biopsy-related adverse events.

### **About CareDx**

CareDx, Inc., based in Brisbane, California, is a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value, non-invasive diagnostic surveillance solutions for transplant recipients. The Company has commercialized AlloMap®, a gene expression test that aids clinicians in identifying heart transplant recipients with stable graft function who have a low probability of moderate/severe acute cellular rejection. CareDx is also pursuing the development of additional products for post-transplant monitoring of other solid organs that use a variety of technologies, including next generation sequencing, to detect donor-derived cell-free DNA to monitor the health of organs after transplantation. For more information, please visit: [www.CareDx.com](http://www.CareDx.com).

### **Forward Looking Statements**

This press release contains forward-looking statements including, but not limited to statements regarding the Company's expectations regarding future potential, development, commercial activities and anticipated future financial results. All

statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward looking statements, including CareDx's limited operating history and experience with developing new markets; risk relating to new partnerships and commercialization of those relationships; CareDx's dependence on the sales of one test, AlloMap, for substantially all of its current revenue, its dependence on Medicare for a substantial portion of its revenue, its dependence on health insurers and other third-party payers to provide coverage for its current test and future tests, if any, as well as other risks stated in CareDx's filings with the SEC located at [www.sec.gov](http://www.sec.gov). CareDx disclaims any obligation to publicly update or revise any forward looking statements to reflect events that occur or circumstances that exist after the date on which they were made.

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