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Heart Transplant Patients And Cardiologists Concerned About Proposed Substantial Cut In Reimbursement Rate For Non-Invasive Testing To Manage Rejection Risk

CareDx Expresses Hope That CMS Will Reconsider After Receiving More Information

WASHINGTON, Oct. 8, 2015 /PRNewswire/ -- CareDx, Inc. (NASDAQ: CDNA), a molecular diagnostics company, today called for a reversal of a recent proposal by the Centers for Medicare & Medicaid Services (CMS) to drastically reduce reimbursement for its FDA-cleared diagnostic test AlloMap, which measures gene expression levels to help clinicians determine a heart transplant recipient's risk for organ rejection.

*See latest coverage of this story on **CNBC**.* [Link]

CareDx, based in Brisbane, California, developed AlloMap and has been distributing the test since 2005. AlloMap is used in the vast majority of heart transplant centers nationwide, with more than 75,000 commercial tests performed to date. AlloMap's unique surveillance system allows patients to avoid many invasive biopsies. Results are reported to health care providers less than 48 hours after the test is administered, which is a critical time when assessing the risk of organ rejection.

At a national telephonic press conference held this morning, Dr. Jon Kobashigawa, Chair of Heart Transplantation Medicine at Cedars-Sinai Heart Institute, heart transplant patients, and Peter Maag, President and CEO of CareDx, called on CMS to reconsider and reverse its proposed 77 percent decrease in reimbursement -- from $2,821.00 to $644.62, which, if left unchanged, would take effect as of January 1, 2016 and prevent patient access to AlloMap's less expensive, less invasive, and less stressful surveillance solution.

"We look forward to working with CMS to maintain the established AlloMap reimbursement rate and to demonstrate, after providing more facts and data, that an erroneous approach was used as the basis of the reduction, - comparing AlloMap to a non-related and different test," said Lanny J. Davis, an attorney recently retained by CareDx.

Davis continued: "If this proposed reduction remains unchanged after January 1, it would threaten the viability of CareDx as a business. The inevitable result: the only remaining alternative for heart transplant patients would be biopsy -- more invasive, more stressful, and *more expensive to Medicare and taxpayers,* since it is a procedure performed in a hospital."

CareDx has assembled an advisory team that also includes Washington, D.C. attorney Peter Kazon of Alston & Bird. Kazon is one of the nation's leading experts on clinical laboratory test reimbursement policies of CMS and state Medicaid programs. The company has also engaged Michael Beebe from ADVI, a leading reimbursement consultancy with a strong track record of supporting companies on Medicare issues.

The press conference represents initiatives by heart transplant patients and clinicians around the country to come together to call for the reversal of the CMS proposed reimbursement reduction.

AlloMap is a unique tool in heart transplant health care and is currently the only test produced and marketed by CareDx. Even at the current reimbursement rate, CareDx has not posted a significant profit since it first offered the test in 2005. The price reduction would result in a price well below the company's cost of performing the test.

Commenting further on the proposed reimbursement reduction, Peter Maag, noted, "The erroneous proposed reduction in reimbursement for the AlloMap test is based on the price that Medicare pays for a test used to identify a gene related to hereditary colorectal cancer: a completely different type of test with little relevance to AlloMap. The colorectal cancer test analyzes a single gene, uses a different test method, has different costs, and provides different results and clinical impact. It is for a hereditary condition that is tested only once, rather than a surveillance test used routinely to assess a heart transplant patient's risk of rejection. Another striking difference between the use of AlloMap and its proposed cross-walk code is the urgency of test reporting - we provide 90% of all AlloMap results to clinicians within 48 hours of a blood draw, while it takes weeks to get results of the other test. We will work with CMS to discuss a reconsideration of their approach."

Mr. Maag also noted that the methodology used by CMS to set the price - called "crosswalk" - was contrary to most of the industry recommendations made at the July 2015 Annual Clinical Laboratory Public Meeting, convened by CMS, and was directly contrary to the recommendation of CMS's own Advisory Panel on Clinical Diagnostic Laboratory Tests, an expert panel

required by law to advise CMS on pricing.

AlloMap is now well-established as an effective monitoring tool in the care of heart transplant patients. The test is currently utilized in 110 of 130 transplant centers in the U.S. and received FDA 510(k) de novo clearance in 2008. AlloMap is often referenced as one of the first examples of precision or personalized medicine already put into widespread clinical practice.

The proposed Clinical Lab Fee Schedule (CLFS) for 2016 affects several other companies with well-established diagnostic tests. The schedule is subject to an open comment period through October 26 and CMS has scheduled a hearing with its Advisory Panel on the proposed pricing for October 19.

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.

Forward Looking Statements
This press release contains forward-looking statements including, but not limited to statements regarding the Company's expectations regarding the effect of possible CMS decisions on the Company's financial results and commercial operations. Forward looking statements are subject to uncertainties that could cause actual performance or results to differ materially from those expressed in the forward looking statements, including the Company's ability to enter new businesses or other geographies if it is forced to discontinue AlloMap testing in the United States. 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/heart-transplant-patients-and-cardiologists-concerned-about-proposed-substantial-cut-in-reimbursement-rate-for-non-invasive-testing-to-manage-rejection-risk-300156754.html

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