



CardioDx Announces Medicare Coverage for Corus CAD Gene Expression Test for the Diagnosis of Obstructive Coronary Artery Disease

Coverage of Blood-Based Test Has Potential to Improve Quality of Care and Lower Costs of Diagnosis of Obstructive Coronary Artery Disease Beyond Traditional Methods

PALO ALTO, Calif. – August 08, 2012 – CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, today announced that Palmetto GBA, a national contractor that administers Medicare benefits, has established coverage for the company's Corus[®] CAD gene expression test for the evaluation of patients presenting with typical and atypical symptoms suggestive of coronary artery disease. With this decision, the Corus CAD gene expression test is now a covered benefit for more than 40 million Medicare enrollees in the U.S.

With a simple blood draw, Corus CAD can safely, accurately and conveniently help primary care clinicians and cardiologists assess whether or not a stable non-diabetic patient's symptoms are due to obstructive coronary artery disease (CAD), enabling many patients to avoid unnecessary invasive testing and exposure to imaging-related radiation risks or imaging agent intolerance. The test has been clinically validated in multiple independent patient cohorts, including two prospective, multicenter U.S. trials, PREDICT and COMPASS. Additionally, a retrospective, multicenter chart review study and the prospective IMPACT trial at Vanderbilt University demonstrated that Corus CAD use yielded significant and clinically relevant changes in patient management decisions in both primary care and cardiology settings.

"While the Corus CAD test was recognized by TIME Magazine as a top 10 medical breakthrough in 2010, the year the PREDICT validation study was published, fulfilling Medicare reimbursement criteria is now a major step forward," said Eric Topol, M.D., Principal Investigator of the PREDICT trial, Chief Academic Officer at Scripps Health and Professor of Genomics at The Scripps Research Institute. "Utilization of this gene expression test could lead to avoidance of a large number of unnecessary cardiac catheterization procedures and scans involving radiation." Dr. Topol has no financial relationship whatsoever with CardioDx.

Studies have shown that typical and atypical presentations of stable chest pain account for up to two percent of outpatient office visits each year in the U.S., but as many as 62 percent of stable patients who undergo elective invasive angiographic procedures are found to have no obstructive coronary artery blockage, despite broad usage of prior noninvasive imaging. The authors of a 2010 *New England Journal of Medicine* study of nearly 400,000 coronary angiography patients concluded that current modalities used to identify patients for elective invasive angiography to diagnose obstructive coronary artery disease have limitations, and that better methods are needed for patient risk stratification.

"Identifying those symptomatic patients without a coronary blockage who may be able to avoid imaging or invasive testing is a significant problem for physicians, involving up to 10,000 patients daily in the U.S.," said David Levison, President and CEO of CardioDx. "By providing Medicare beneficiaries access to Corus CAD, this coverage decision enables patients to avoid unnecessary procedures and risks associated with cardiac imaging and elective invasive angiography, while helping payers address an area of significant health care spend."

About Corus CAD

With a simple blood draw, Corus CAD can help primary care clinicians and cardiologists exclude obstructive coronary artery disease as the cause of a stable non-diabetic patient's symptoms. It is the first sex-specific test for obstructive coronary artery disease, accounting for critical biological differences between men and women. The test is safe and does not expose patients to radiation risks or imaging agent intolerance. Corus CAD is intended for use in stable patients presenting with typical and atypical symptoms suggestive of obstructive coronary artery disease. Corus CAD is not intended for use in patients who are diabetic, have been diagnosed with prior myocardial infarction (MI) or have had a previous revascularization procedure, or are currently taking steroids, immunosuppressive agents or chemotherapeutic agents.

The Corus CAD test measures the RNA levels of 23 genes. Because blood cell RNA levels are altered when obstructive coronary artery disease is present, the Corus CAD score aids clinicians in assessing whether an individual patient's symptoms may be due to obstructive coronary artery disease.

Corus CAD is commercially available through an innovative patient sample kit that includes everything needed for blood collection and express delivery to the company's CLIA-certified Palo Alto, Calif. laboratory. Test results are delivered promptly to the clinician's office. Corus CAD is currently available in the United States.

Corus CAD has been recognized by *The Wall Street Journal's* Technology Innovation Awards, honored as a Gold Edison Award recipient, and named one of *TIME's* Top Ten Medical Breakthroughs.

For more information please visit <http://www.cardiodx.com/media-kit/>.

About CardioDx

CardioDx, Inc., a pioneer in the field of cardiovascular genomic diagnostics, is committed to developing clinically validated tests that empower clinicians to better tailor care to each individual patient. Strategically focused on coronary artery disease, cardiac arrhythmia and heart failure, CardioDx is poised to expand patient access and improve healthcare quality and efficiency through the commercialization of genomic technologies. For more information, please visit www.cardiodx.com.

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Media Contact:

Nicole Osmer

650.454.0504

nicole@nicleosmer.com