Clinical Policy Title: CORUS® CAD gene expression test

Clinical Policy Number: CCP.1112

Effective Date:	**October 1, 2014**
Initial Review Date:	June 18, 2014
Most Recent Review Date:	July 17, 2019
Next Review Date:	July 2020

Policy contains:

- CORUS® CAD Gene Expression Test.
- Coronary artery disease.
- Risk assessment.

Related policies

None.

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers the use of CORUS® CAD Gene Expression Test to predict clinical events or alter the treatment of individuals to be investigational and, therefore, not medically necessary.

Limitations:

All other uses of CORUS® CAD Gene Expression Test are not medically necessary.

Alternative covered services:

- Exercise/stress electrocardiography exercise/stress or resting.
- Exercise/stress echocardiography with or without a contrast agent.
- Nuclear myocardial perfusion imaging.
- Stress myocardial perfusion and wall motion magnetic resonance imaging.
- Coronary computed tomography angiography.

- Invasive coronary angiography.

Background

Heart disease is the leading cause of death in the United States in both men and women. The most common type of heart disease is coronary artery disease. The most common cause of the disorder is atherosclerosis. Atherosclerosis is a hardening and narrowing of arteries that slowly and often silently progresses to ischemia, or may rupture causing thrombosis within an artery (U.S. Centers for Disease Control and Prevention, 2017).

In 2016, 247,432 Americans died from coronary artery disease (ICD-10 code I25), a decline of nearly 50 percent from 1999. About 94 percent of these 2016 deaths were persons age 54 or older, and the age-adjusted male mortality rate was 94 percent higher than the female rate. Asian non-Hispanics had the lowest rate of any major racial/ethnic group, compared to Hispanics (36 percent greater), white non-Hispanics (80 percent greater) and black non-Hispanics (107 percent greater) (U.S. Centers for Disease Control and Prevention, 2018).

Conservative estimates suggest that angina pectoris (angina) is the initial manifestation of coronary artery disease in at least 50 percent of patients (Fihn, 2012). Symptoms of angina are usually uncomfortable pressure, fullness, squeezing, or pain in the center of the chest and discomfort in the neck, jaw, shoulder, back, or arm (American Heart Association, 2015). Persons presenting with chest pain may represent the initial clinical recognition of chronic stable angina, reflecting either gradual progression of obstruction in their coronary arteries or an increase in supply/demand mismatch precipitated by a change in activity or concurrent illness (e.g., anemia or infection), or acute coronary syndrome, most likely caused by an unstable plaque causing acute thrombosis (Fihn, 2012). Other patients, in particular women and the elderly, can present with atypical symptoms such as nausea, vomiting, midepigastric discomfort, or sharp (atypical) chest pain (Mieres, 2005).

Risk assessment in patients who present with chest pain but are not known to have coronary artery disease is performed to assess the probability of obstructive coronary artery disease before additional testing. Patients who present with acute angina are categorized as stable or unstable, and patients with unstable angina should be further categorized as being at high, moderate or low risk (Fihn, 2012). Choice of testing (either noninvasive or invasive) in patients with symptoms suspicious for coronary artery disease takes into consideration the pretest probability of the disorder and the testing/action thresholds for patients based on American College of Cardiology/American Heart Association guidelines for stable angina and appropriate use criteria for the various modalities (Dolor 2012; Fihn, 2012; American Heart Association, 2018).

Invasive coronary angiography is the reference (gold) standard for clinical care of patients who have chest pain suggestive of coronary artery disease and are at high risk for the obstructive form of the disorder (Fihn, 2012). Coronary angiography enables visualization of the coronary arteries with greater anatomic precision and resolution, and combines diagnosis and treatment in a single procedure. As an

invasive procedure, the risks associated with coronary angiography include arterial bleeding at the access site, procedure-related embolus, arterial dissection, exposure to ionizing radiation and, on rare occurrences, internal bleeding (Dolor, 2012).

Noninvasive tests are important options for patients at intermediate risk of obstructive coronary artery disease or for whom invasive catheterization is contraindicated (Fihn, 2012). Noninvasive tests include, but are not limited to, the following (Dolor, 2012):

- Exercise/stress electrocardiography exercise or resting.
- Exercise/stress echocardiography with or without a contrast agent.
- Nuclear myocardial perfusion imaging.
- Stress myocardial perfusion and wall motion magnetic resonance imaging.
- Coronary computed tomography angiography.

Standard care in low to medium risk patients presenting with symptoms suggesting coronary artery disease involves a family history, risk factor assessment, and stress testing with or without non-invasive imaging. A positive stress test is often followed by invasive coronary angiography. This standard approach results in fewer than 40 percent of those referred for angiography being diagnosed with obstructive disease; a more sensitive test is needed (Vargas, 2013).

Gene expression profiling is a method of laboratory testing that measures messenger ribonucleic acid (mRNA) expressed from various genes in many different cell types. Gene expression is not a genetic test, which predicts the likelihood of developing a disease, but one that, in this case, provides information on the status of obstructive coronary artery disease. Using gene expression profiling to predict the likelihood of the disorder has the potential to increase the proportion of patients selected for coronary angiography who truly have the disease and reduce the number of patients who might otherwise be inappropriately exposed to radiation, contrast agent, and an invasive procedure.

According to the manufacturer, CORUS® CAD (CardioDx Inc., Redwood City, California) is blood-based, diagnostic gene expression test for identifying patients unlikely to have obstructive coronary artery disease in patients with typical and atypical presentations of stable chest pain (CardioDx, 2014). CORUS® CAD measures 23 distinct RNA sequences associated with atherosclerosis biology and involving inflammation, cell death, and adaptive and innate immunity. The test involves a routine blood draw administered in the clinician's office. The CORUS® CAD test score is provided on a scale of 1 – 40; a score < 15 indicates a low risk of underlying obstructive coronary artery disease. The results are available within 72 hours. CORUS® CAD is the only sex-specific test for the assessment of obstructive coronary artery disease that accounts for critical biological differences between men and women (CardioDx, 2014).

CORUS® CAD is intended for use in stable, nondiabetic patients presenting with symptoms suggestive of obstructive coronary artery disease, and who (CardioDx, 2014):

- Have not been diagnosed with prior myocardial infarction nor have had a previous

revascularization procedure.
- Are not currently taking steroids, immunosuppressive agents, or chemotherapeutic agents.

The CORUS® CAD test is not a manufactured test kit and has not been reviewed by the US. Food and Drug Administration. It is a commercially available laboratory-developed assay offered by the CardioDx Commercial Laboratory. Laboratories that perform gene expression tests are regulated under the Clinical Laboratory Improvement Amendments Act of 1988 (42 CFR §493).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- Cochrane reviews.

Searches were conducted on May 22, 2019, using the terms “gene expression profiling,” "coronary artery disease,”, and “Corus® CAD.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Guidelines recommending the use of CORUS® CAD are not yet in existence. The U.S. Preventive Services Task Force recommendation statement addressing coronary artery disease risk assessment did not address the technique (U.S. Preventive Services Task Force, 2009). It was mentioned, but not recommended, in an American Hospital Association scientific statement (Arnett, 2007). The American Heart Association has issued a statement deemed CORUS® CAD to be “useful and valid” in the workup of patients with suspected coronary artery disease (Musunuru, 2017).

Medicare considers the CORUS® CAD test necessary for patients with stable symptoms that have a history of chest pain, suspected anginal equivalent to chest pain, or a high risk of coronary artery disease, but no known prior myocardial infarction or revascularization procedures – but investigational

for all other indications (Centers for Medicare & Medicaid Services, Local Coverage Determination L36713, 2018).

AmeriHealth Caritas identified no systematic reviews or meta-analyses for this topic. An Agency for Healthcare Research and Quality report entitled "Update on Mapping the Landscape of Genetic Tests for Non-Cancer Diseases/Conditions" summarized a list of genetic tests in current clinical use with specific applicability to older adults; CORUS® CAD was listed with supportive evidence from four studies listed on the manufacturer's website, but no critical appraisal of the studies was conducted (Raman, 2012). These studies, and other large-scale analyses, are included below.

An early analysis leading to CORUS® CAD involved RNA samples from a 195 patient registry (CATHGEN) yielding 2,438 genes with significant coronary artery disease association ($P < .05$). The analysis identified age, sex, and diabetic status as the factors with the largest effects on gene expression. Diabetic status was the largest clinical factor affecting CAD associated gene expression changes (Elashoff, 2011).

Personalized Risk Evaluation and Diagnosis in the Coronary Tree (PREDICT). PREDICT is a validation study of a gene expression profiling algorithm in 526 nondiabetic patients (57 percent male) with a clinical indication for coronary angiography (Rosenberg, 2010). Obstructive coronary artery disease was defined as 50 percent or greater stenosis in one or more major coronary arteries by quantitative coronary angiography. Results of the gene expression profiling were compared to the Diamond-Forrester risk score and coronary angiography. Overall, 37 percent of subjects had obstructive coronary artery disease and 26 percent had no detectable disease.

A follow up of the PREDICT study (n = 1160) found a 30-day major cardiovascular event rate of 23 percent, and a further 2.2 percent at 12 months. Patients with a gene expression score over 15 had close to a significantly higher risk of an event. For those with low gene expression scores, the predictive value was 90 percent for a major cardiovascular event with revascularization, and 99 percent for a major event alone (Rosenberg, 2012). The follow up PREDICT trial of 1160 patients with suspected obstructive coronary artery disease found a prevalence of 46.7 percent in men and 22.0 percent in women. The gene expression score independently predicted coronary artery disease in men, women, and the overall populations, each statistically significant. (Lansky, 2012).

Coronary Obstruction Detection by Molecular Personalized Gene Expression (COMPASS). COMPASS is a validation study of a blood-based gene expression profiling in 537 symptomatic, nondiabetic patients referred for myocardial perfusion imaging (Thomas, 2013; Herman, 2014). The sensitivity, specificity, and negative predictive values of the test were 89 percent, 52 percent, and 96 percent, respectively, at a pre-specified threshold of ≤ 15; 46 percent of patients were below this score.

The overall accuracy of the gene expression profiling score in predicting cardiac events was superior to myocardial perfusion imaging in patients who were referred for myocardial perfusion testing. However, the reported sensitivity of myocardial perfusion imaging was considerably lower than generally reported in the literature. Also, it is unclear from the COMPASS study whether patients with a positive myocardial

perfusion imaging could safely forego further testing based on a low gene expression profiling score.

Using data from the PREDICT and COMPASS studies, one analysis examined the association between the gene expression profiling and coronary arterial plaque burden and stenosis by CT-angiography (Voros, 2014). The gene expression profiling was significantly associated with plaque burden by coronary artery calcium scoring ($r = 0.50$; $p < 0.001$) and CT-angiography (segment involvement score index: $r = 0.37$, $p < 0.001$); a low score (≤ 15) had sensitivity of 0.71 and a high score (≥ 28) had a specificity of 0.97 for the prediction of zero versus non-zero coronary artery calcium. Results suggest a moderate correlation between gene expression profiling score and coronary arterial plaque burden and stenosis by CT-angiography.

Analytic stability of stored samples found that after five years, mean score of 526 PREDICT subjects changed from 20.3 to 19.8, and mean score of 173 COMPASS subjects increased from 15.9 to 17.3 after one year, indicating a 2.5 percent increase in risk of obstructive coronary artery disease (Daniels, 2014).

Investigation of a Molecular Personalized Coronary Gene Expression Test on Primary Care Practice Pattern (IMPACT-PCP). The IMPACT-PCP study assessed the impact of a gene expression profiling test on patient management decisions in patients who presented with chest pain and related symptoms at four primary care practices (Herman, 2014). A change in the diagnostic testing pattern before and after gene expression profiling testing was noted in 145 of 251 patients (58 percent observed versus 10 percent predefined expected change; $P < .001$). The gene expression profiling was associated with a decrease in intensity of testing in 60 percent (76 of 127) of patients with a low gene expression profiling.

One study examined the cost-effectiveness of coronary artery disease diagnostic strategies including "no test," a gene expression profiling score, myocardial perfusion imaging, and sequential strategies combining gene expression profiling and myocardial perfusion imaging in patients presenting to clinicians with symptoms suggestive of obstructive coronary artery disease (Phelps, 2014). Diagnostic testing for obstructive CAD with a novel gene expression profiling strategy in a two-threshold model is cost-effective by conventional standards. This diagnostic approach is more efficient than usual care of myocardial perfusion imaging alone or a one-threshold gene expression profiling strategy in most scenarios.

Patterns of Care Associated with the Use of Corus CAD in Real World Clinical Care Settings (PRESET). PRESET is an ongoing study to assess the impact of a gene expression profiling score on subsequent cardiac referral decisions by primary care providers (Ladapo, 2015). Of the 342 stable, non-acute patients evaluated, each 10-point decrease in gene expression profiling score was associated with a 14-fold decreased odds of cardiac referral ($P < .0001$). Patients with a low gene expression profiling had a 94 percent reduced odds of referral relative to elevated gene expression profiling patients ($P < .0001$), with follow-up supporting a favorable safety profile.

A review of 288 females from the PRESET trial assessed the ability of Corus® CAD to identify persons with obstructive coronary artery disease presenting with symptoms suggestive of the disorder. One year after

producing age/sex/gene expression scores, clinicians referred 9 percent of those with low scores versus 44 percent of those with elevated scores for further cardiac evaluation ($P < .0001$). After one year, women with low scores experienced fewer major adverse cardiac events (1.3 percent versus 4.2 percent, $P = .16$) (Gul, 2019).

While these results are encouraging, one study identified many unanswered clinical, biological, and technical considerations that should be taken into account before more widespread clinical use. Specifically, the article noted that CORUS® CAD must be tested in a broader population, against existing non-invasive standards. Factors accounting for inter-individual, temporal, and between-disease state variations should be studied. Technical factors such as RNA quality, storage time of whole blood, and RNA processing amplification batch should be considered. Clinical feasibility and cost-effectiveness should also be better understood (Zeller, 2013).

An analysis of 2370 non-diabetics were showed that age- and sex-specific gene expression scores from a blood-based genomic test were significantly linked with obstructive coronary artery disease ($P < .001$). Compared to noninvasive testing, these expression scores improved prediction for the disorder. Predictions were significant for near-term revascularization procedures, but not non-revascularization events (Voora, 2017).

Policy updates:

A total of one guideline/other andtwo peer-reviewed articles were added to, and six peer-reviewed articles removed from this policy in May 2019.

The clinical policy number was changed from CP#02.01.12 to CCP.1112 in May 2019.

References

Professional society guidelines/other:

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Centers for Medicare & Medicaid National Coverage Determinations:

No National Coverage Determinations identified as of the writing of this policy.

Local coverage determinations:

L36713 CORUS® CAD Test.
L37612 MolDx: Corus® CAD Assay.
L37673 MolDx: Corus® CAD Assay.
L37675 MolDx: Corus® CAD Assay.
L37770 Mol Dx: CORUS® Assay.
L37787 MolDx: Corus® CAD Assay.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comment
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, reported as a risk score	

ICD-10 Code	Description	Comment
I20.1	Angina pectoris with documented spasm	
I20.8	Other forms of angina pectoris	
I20.9	Angina pectoris, unspecified	
R06.02	Shortness of breath	

R07.2	Precordial pain	
R07.82	Intercostal pain	
R07.89	Other chest pain	
R07.9	Chest pain, unspecified	

HCPCS Level II Code	Description	Comment
N/A		