

Local Coverage Determination (LCD): MolDX: Corus® CAD Assay (L37675)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

LCD ID

Original Effective Date

L37675

For services performed on or after 02/10/2019

LCD Title

MoIDX: Corus® CAD Assay

Revision Effective Date

N/A

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL37675

Retirement Date

N/A

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12/26/2018

Notice Period End Date

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are

considered to be reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This is a non-coverage policy for the Corus® CAD test (CardioDX, Redwood City, CA). The test was previously covered by this contractor as a "rule out" test for stable non-diabetic patients presenting to a primary care physician with the new onset of symptoms suggestive of coronary artery disease (CAD). It was presented and marketed as a "rule out" assay, such that rarely would a patient with a gene expression score (GES) of less than 15 require cardiology referral and/or diagnostic work-up. The assay was never evaluated as a "rule in" assay. Since initial coverage of the assay, the manufacturer has failed to demonstrate that testing resulted in improved patient outcomes or that testing changed physician management to result in improved patient outcomes.

Summary of Evidence

This contractor will detail the conflicting scientific evidence that was reviewed and is the basis for this non-coverage determination. Stable non-diabetic patients who present to a primary care physician with typical or non-typical symptoms suggestive of CAD are the intended use population for this test. Testing is not intended for patients with a known history of CAD or MI, patients with previous interventions or revascularization procedures, or patients taking steroids, immunosuppressive agents or chemotherapy at the time of testing.

Data regarding its clinical usefulness in elderly (Medicare-aged) patients, particularly males, is significantly lacking in all scientific articles. The average age of the study population in the PREDICT and COMPASS trials is younger than age 65. Many studies have included CardioDX personnel, and/or received funding from CardioDX for the study.

CorusCAD Assay Description¹:

The Corus CAD test is a quantitative gene expression test intended to rule out coronary artery disease (CAD) in stable nondiabetic patients. In this context, CAD is defined as coronary artery stenosis of $\geq 50\%$ as measured by quantitative coronary angiography. The test is expressed as a score from 1-40, with a score of < 15 ruling out CAD. The test score is a function of the expression levels of 23 genes consisting of six groups which reflect multiple biological processes or cell types.² Some of the gene groupings are sex-specific. The gene groupings are weighed and combined into an algorithm along with the patient's age and sex.² The algorithm age function for men is linear, while that of women is nonlinear.

Intended Use Population:

The intended use population includes stable patients with typical symptoms suggestive of CAD such as shortness of breath or chest discomfort, tightness, pain or pressure. Atypical symptoms suggestive of CAD include tightness or pressure in the throat, jaw, shoulder, abdomen, back or arm; squeezing, heaviness or burning sensation in the upper body; abdominal discomfort or fullness; indigestion or heartburn; nausea; or unexplained fatigue.

In the original dossier reviewed in 2012, CardioDX asserted the following:

"The Corus CAD test is the first blood-based diagnostic tool that can safely **exclude** (emphasis added) obstructive coronary artery disease (CAD) as the cause of stable chest pain symptoms in patients with no known history of CAD presenting in the office for a clinical work-up."

"The Corus CAD Gene Expression Test is optimized to determine which stable chest pain patients do not have obstructive CAD so that the additional cost and burden of the cardiovascular work-up can be avoided."

"Corus CAD is intended for non-diabetic patients with stable typical and atypical symptoms suggestive of CAD (i.e., stable chest pain) who have no history of prior myocardial infarction or coronary revascularization procedures and who are seeking care in an outpatient clinical practice."

"Based directly on COMPASS results proving a negative predictive value (NPV) of 96%, almost half of Corus CAD intended use patients would be ruled out of the chest pain work-up via scores of < 15 . This Corus CAD based strategy would allow patient without obstructive CAD to avoid referral to cardiology procedures and enable their clinicians to confidently pursue other causes for their symptoms."

This following assertion is still present on the sponsor's website, accessed in November 2017 (Corus CAD, 2017):

"Corus CAD demonstrated "high sensitivity (89%) and highly negative predictive value (96%) at a score threshold < 15 in the COMPASS study population in men and women."¹

Evidence Discussion:

The major publications initially submitted to support coverage of the test were the PREDICT³ and the COMPASS⁴ trials. The GES was developed and initially validated on peripheral blood to assess the likelihood of obstructive CAD in nondiabetic patients referred for invasive coronary angiography (ICA) and analyzed by quantitative coronary angiography (QCA) in the PREDICT trial.⁵ Patients were eligible for the PREDICT trial if they had a history of chest pain, suspected angina-equivalent symptoms, or a high risk for CAD and had no known previous MI, revascularization, or obstructive CAD (oCAD). Patients were ineligible if they had AMI, high-risk unstable angina, CHF, cardiomyopathy or valve disease, systemic infectious or inflammatory conditions, or were receiving immunosuppressive or chemotherapeutic agents at the time of catheterization. A total of 1569 subjects met study criteria. Of these, 226 were used in gene discovery; the remaining 1343 were divided into independent algorithm development and validation cohorts sequentially based on date of enrollment. The sensitivity and specificity for a score threshold of 14.75, corresponding to a disease likelihood of 20% from the validation set data, was 85% and 43% respectively. The corresponding negative and positive predictive values were 85% and 46% respectively, with 33% of patients having scores below 14.75. The trial showed that the higher the Corus CAD score, the more likely it was that the patient had 50% or greater stenosis in one of the major epicardial vessels as verified by QCA. However, whether the 50% stenosis represents a single lesion or diffuse coronary artery disease cannot be ascertained by the assay.

In the prospective, observational PREDICT trial, 1160 patients were evaluated for major adverse cardiovascular events and interventional procedures for 12 months after index catheterization.³ This cohort was 58% male with an average age of 60. The data showed that a low GES appeared to identify a population at low risk for both oCAD and subsequent invasive procedures or cardiac events. Lansky et al demonstrated that 36.2% of patients and only 22.0% of women referred for diagnostic angiography for suspected oCAD had oCAD, and demonstrated a characteristic age-dependent rise in the prevalence of oCAD after 60 years of age for women. The authors report that the GES had a significant association with all measures of CAD extent and severity, with a 2-fold increase in risk of oCAD for every 10-point increment in GES. They note that the GES was the second strongest independent predictor of CAD (following age) in the overall population and the strongest predictor of oCAD in women.

The prospective multi-center COMPASS⁴ validation trial of 431 patients, a follow-up trial to PREDICT, compared the performance of Corus CAD to nuclear stress testing or myocardial perfusion imaging (MPI). The patient population was limited to nondiabetic, largely white US population without known CAD, prior revascularization or MI, and known inflammatory or autoimmune disorders but with symptoms suggestive of CAD. The mean age of patients was 56 +/- 10 years with 48% women. The pre-specified primary end point was GES receiver-operating characteristics analysis to discriminate $\geq 50\%$ stenosis (15% prevalence by core laboratory analysis). Area under the receiver-operating characteristics curve for GES was 0.79 (95% confidence interval, 0.73–0.84; $P < 0.001$), with sensitivity, specificity, and negative predictive value of 89%, 52%, and 96%, respectively, at a pre-specified threshold of ≤ 15 . Forty-six percent (46%) of patients had scores below 15. The authors report that the GES outperformed clinical factors by receiver-operating characteristics and reclassification analysis and showed significant correlation with maximum percent stenosis.

Obstructive disease prevalence in the COMPASS population (15%) was significantly lower than that in the PREDICT study (37%) and in another large angiography registry⁶. This resulted in a higher GES NPV in this MPI-referred population (96%) compared with the angiographic population (83%) and a larger proportion of patients with scores ≤ 15 (46% versus 33%). The authors report the optimal GES threshold, maximizing the sum of sensitivity and specificity, was 19 (sensitivity, 84%; specificity, 67%; NPV, 96%; with 59% of patients below this threshold. They also note that the GES high sensitivity and NPV is most suitable as a "rule out" test, but note that in this study 54% of patient has scores > 15 . They suggest that a GES score > 15 likely represent patients with non-obstructive CAD who have significant plaque burden and stenosis because the GES was proportional to maximum percent stenosis. The authors conclude that the GES showed significant improvement over clinical estimation of oCAD and outperformed MPI in identifying anatomically defined oCAD in symptomatic patients. They conclude that the "high sensitivity (89%) and the NPV (96%) for obstructive CAD at the pre-specified GES threshold of 15 in this symptomatic population with relatively low (15%) CAD prevalence suggests that this test is a highly sensitive

measure of coronary atherosclerosis.”

Since the original coverage of the test by this Medicare contractor, a number of articles have been published describing subsequent analyses of the test. These studies include the IMPACT,⁷ the IMPACT-PCP,⁸ and the PROMISE trials.⁹

The IMPACT trial was a 2-arm, prospective and matched historical cohort study.⁷ Pretest probability of oCAD was based on a cardiologist’s clinical judgement based on clinical risk factors, quality of angina symptoms and results of prior electrocardiogram stress testing, if performed. The pretest probability of oCAD was graded as low (<20%), intermediate (20%-50%) or high (>50%) based on 2 methods: 1) a set of questions to derive a Diamond-Forrester pretest probability, and 2) the physician’s self-assessed pretest probability for the patient have obstructive CAD. Both the clinical impression and decision on the further evaluation and management of the subject was determined prior to Corus CAD testing. The primary objective of the study was to assess whether the use of the GES altered the cardiologist’s evaluation and management of the patient, as defined by the change of management pattern between the preliminary versus final decision (defined as either a downgrade or upgrade in the intensity of the diagnostic plan). A total of 88 patients were enrolled in this study. Eighty-three (83) patients were eligible for primary endpoint analysis. Of these, 58 (69%) were females, largely premenopausal females with atypical symptoms. The average age of study subjects was 53.3 +/- 11 years. The authors suggest that the GES provides clinical utility in a low-risk population referred to a cardiologist for evaluation for suspected CAD. They note a change in the diagnostic work-up of 58% of patients, “a highly clinically relevant and statistically significant rate of change”. They “observed a directional change in testing, which was congruent with the role of the GES to exclude patients without CAD and to further risk-stratify patients: patients with low GES were more likely to have decrease in the diagnostic testing intensity, whereas patients with elevated GES were more likely to have an increase in diagnostic testing intensity”.

McPherson et al report that “GES was incorporated into the cardiologist’s office setting and improved upon usual care around the assessment of clinical factors and the need for cardiac imaging”.⁷ They also report that the GES provides a personalized tool for evaluating the likelihood of CAD: the test, specific age and gender, quantitatively measures gene expression signals in a given patient. Second, the prospective/retrospective study design allowed the physician to act as his or her own control in the comparison with the 2 separate patient groups, adding further validity to the findings of change in the diagnostic plan as a result of GES testing. Third, use of this office-based tool was not associated with untoward outcomes in the care of GES tested patients at 6 month follow-up, as no major cardiac adverse events were observed.”

The preceding paragraph from McPherson et al discussion demonstrates poor study design, small patient population tested and misunderstanding of clinical utility. The decision to treat or not to treat is left to the clinician. The study fails to define the treatment pathways for patient management when the GES result is above and below the test break-point. Although the authors claim demonstration of clinical utility in their title, their study is merely a decision impact or a survey without defined treatment pathways, and has no clinical significance because the study variables are not controlled. In the prospective cohort, 52 patients had GES ≤ 15. Six of 52 received additional testing although the reason for the testing is unknown. The remaining 46 patients received no referral and no testing. Eighteen (18) of 31 patients with GES >15 received additional testing, while 13 of the 31 patients with GES > 15 received no testing. Finally, although the test is purported to assist the primary care physician with a result that guides referral or non-referral for further cardiac evaluation, cardiologists (not the intended user of the test) were the focus of this paper. A deeper analysis of the IMPACT-cardiology provider study data (provided by the vendor) reveals that no men over age 65 had a Corus CAD score < 16 (Personal communication, 2017). Furthermore, neither the number of Medicare age men nor the percentage of GES scores greater or less than 15 could be discerned from this additional study data.

The IMPACT-PCP was a prospective study involving nine (9) clinicians at 4 community-based primary care practitioners, although clinicians were allowed to incorporate GES testing at their own discretion as part of their

clinical decision-making processes.⁸ As in the previous study, a pre-GES report captured the clinician's preliminary clinical assessment and management decision. The primary objective of the study was to assess whether the use of the GES altered the clinicians' preliminary and final management decision. Two hundred fifty-one (251) patients were eligible for primary end point analysis. Females comprised 56% of the study patients (140/251). The average age was 56.2 +/- 13 years. The mean GES was 16 +/- 10; 127 patients (951%) had a GES ≤ 15. The average pretest probability of oCAD as determined by the primary care clinicians was 28 +/- 17% GES was associated with decreased intensity of testing in 82% (76/93) of patients with a low GES, and increased intensity of testing in 94% (49/52) of patients with high GES.

Herman et al. claim their "study demonstrated the clinical utility of the GES among patients presenting to the primary care clinician with typical and atypical symptoms suggestive of obstructive CAD".⁸ The authors indicated that the GES was associated with a decrease in intensity of testing in 60% of patients with a low GES. They state that utilization of the GES allowed physicians to reclassify patients for subsequent testing, improving on usual care while potentially reducing patient exposure to ionizing radiation.

As in the IMPACT – cardiology study, the IMPACT-PCP is fraught with poor study design, small patient sample, and misunderstanding of clinical utility. To meet Medicare's reasonable and necessary criteria for coverage, the results of a study must result in improved patient outcomes, or change in physician behavior resulting in improved patient outcomes. In neither the initial IMPACT nor the IMPACT-PCP study has clinical utility been demonstrated.

The interim analysis of the REGISTRY¹⁰ trial involved 342 patients in a prospective, multicenter observational registry evaluated by primary care physicians who independently used their own discretion to incorporate the GES results into clinical management decisions. The average age of the study population was 54.7 years with 53% female patients. The GES results ranged from 1 to 40, with a mean score of 16.2 +/- 10, and a median of 16. Approximately 49% of patients (167/342) had a low (≤ 15) GES. Cardiac referral rates by low and elevated GES groups were 6% (10/167) and 70% (122/175), respectively. Women and younger patients tended to have lower referral rates. Given the findings of the interim analysis, further enrollment was suspended based on predetermined stopping rules, as the primary end point demonstrating a statistically significant association between GES and referral rates was achieved. The interim analysis became the final analysis. However, it is not possible to draw conclusions on the value of GES in Medicare aged men with low (<15) or non-low (>15) GES scores.

Again, REGISTRY study is poorly designed and has failed to demonstrate any clinical utility. Referral rates provide no scientific information when treatment pathways are not clearly defined and adhered to.

The PROMISE (Prospective Multicenter Imaging Study for Evaluation of Chest Pain) trial was a randomized controlled study that compared diagnostic testing strategies in outpatients presenting with symptoms of oCAD. The primary objective of the PROMISE sub-study¹¹ was to use baseline blood samples from nondiabetic trial participants to test the hypothesis that the GES was associated with CAD-related events in nondiabetics and that patients with low GES had a low likelihood of subsequent events. Clinical utility and physician prescribing practices were not evaluated in this study.

The Voora study¹¹ enrolled more than 2,000 patients with a mean age approaching Medicare age (60.3 years). When the vendor was queried why 97% of men enrolled in this study had GES scores >15, the vendor stated that "this finding is indicative of the fact that obstructive CAD is more common in symptomatic males, especially older males, and represents the higher likelihood of these patients having oCAD at the present time." When further queried regarding the appropriateness of Corus CAD testing of elderly males when the majority of aged males are elevated, the vendor cited physician referral rates to cardiology or advanced cardiac testing as evidence of clinical utility, which the reader already knows does not meet the requirement for clinical utility. The vendor states that "the calculated referral rate for elderly males is 54% as compared to 40% for all males", although the number of elderly

males is not provided by the vendor.

The vendor also cites elderly referral rates of 12% (5/40) for low GES versus 49% (67/136) elderly patients with elevated GES, but the data has not been forthcoming. They state that “the data demonstrate that clinicians are using the test as a continuous variable in all populations, and are not referring all male patients with scores above 15. The clinical utility of the Corus CAD test is in its ability to aid clinicians in avoiding unnecessary cardiac procedures for patients at lower risk and likelihood of CAD given their age, gender, and other clinical variables.”

During a recent communication with the company, a representative stated that the threshold of 15 is described as a numerical score or “break point” on which statistical performance (sensitivity, specificity, negative and positive predictive values) is based. It is not a strict binary cut-off and is not intended to distinguish which patients have oCAD and which do not (personal communication). The Corus CAD score represents the likelihood (probability) that a given patient has oCAD, not the presence or absence of an obstructive lesion. During recent communication regarding this assay, the vendor stated that the “Corus CAD test was created to evaluate patients with symptoms suggestive of CAD. The Corus CAD test is designed to be used in combination with other tests. Corus CAD is not designed to rule in or rule out the presence of obstructive coronary disease, as only the physician can make that determination with certainty based on invasive coronary angiography. The non-invasive Corus CAD test score provides the current likelihood of obstructive CAD based on data from our validation trials. The test can help clinicians determine which patients are at lower risk and therefore may be good candidates for avoiding further cardiac testing. At the end of the evaluation comprising Corus CAD and other cardiac testing, the physician may rule out oCAD, may rule-in oCAD or may be unable to rule out or rule in oCAD as the cause of the patient’s symptoms.

Analysis of Evidence (Rationale for Determination)

Level of Evidence

Quality – Low

Strength – Poor

Weight – Low

This contractor is rescinding coverage for the Corus CAD test. The vendor has provided no evidence that use of the test results in improved patient outcomes (clinical utility). Thus this test does not meet Medicare’s reasonable and necessary criteria for coverage. A number of the published papers have stressed that physician behavior has changed on the basis of the test. However, clinical utility is not established by clinician referrals to cardiology or for further cardiac evaluation. These articles provide no defined treatment protocol(s) to manage patients with a GES of any value. Furthermore, clinicians are left to interpret the test results as they see fit. The test is neither a “rule out” or “rule in” test, and is marketed to primary care and cardiologists without providing value to the patient or physician management of the patient. Finally, the Corus CAD test is not included in any professional society management or treatment guidelines.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
81493	CORONARY ARTERY DISEASE, MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 23 GENES, UTILIZING WHOLE PERIPHERAL BLOOD, ALGORITHM REPORTED AS A RISK SCORE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

No ICD-10 codes are acceptable

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

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Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56229 - Response to Comments: MoIDX: Corus® CAD Assay

LCD(s)

DL37675 - MoIDX: Corus® CAD Assay

Related National Coverage Documents

N/A

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