Medica Coverage Policy

<table>
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<tr>
<th>Policy Name:</th>
<th>Gene Expression Profiling Assay for Prediction of Coronary Artery Disease</th>
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<td>Effective Date:</td>
<td>1/21/2019</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Gene expression profiling assay (e.g., Corus® CAD) is investigative and unproven and therefore NOT COVERED for all clinical indications, including but not limited to predicting the likelihood of obstructive coronary artery disease (CAD). There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policy, Genetic Testing and Pharmacogenetic Testing.

Description
The expression levels of various genes in circulating white blood cell or whole blood samples have been reported to discriminate between cases of obstructive CAD and healthy controls. Multiplex gene expression testing can be combined with other risk factors to predict the likelihood of obstructive CAD in patients who present with chest pain or other suggestive symptoms, or in asymptomatic patients who are at high risk of CAD.

The Corus® CAD assay measures the activity of 23 specific genes involved in the development or response to atherosclerosis and obstructive CAD. Corus® CAD incorporates age, sex, and the expression levels of these genes using an algorithm with weighted gene expression levels to generate a quantitative score. The score ranges from 1-40 and indicates the likelihood of a narrowing or blockage in the heart arteries due to atherosclerosis or plaque of at least 50%. The expression of these genes is analyzed using quantitative reverse transcription polymerase chain reaction (RT-PCR) technique.

Corus® CAD genomic test is designed for use in an outpatient setting with clinically stable patients presenting with typical and atypical symptoms suggestive of obstructive CAD or who have a high risk of CAD. Corus® CAD is not intended for use in patients with diabetes, who have been diagnosed with prior MI or have had a previous revascularization procedure, or are currently taking steroids, immunosuppressive agents or chemotherapeutic agents.
FDA Approval
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the test is not marketed for general distribution. The Corus® CAD (CardioDx®, Inc., Palo Alto, CA) is a laboratory-developed test (LDT) available under the auspices of CLIA.

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
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

Original Effective Date: 1/21/2019
Re-Review Date(s): 2/10/2020 – administrative update; format