

## **Medical Policy Manual**

**Topic:** Computerized 2-lead Resting Electrocardiogram Analysis for the Diagnosis of Coronary Artery Disease

**Date of Origin:** December 2011

**Section:** Medicine

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**Policy No:** 145

**Effective Date:** December 1, 2013

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Computerized 2-lead resting electrocardiogram (ECG or EKG) analysis is a computerized analysis of a 2-lead resting ECG that has been proposed as an alternative to standard non-invasive diagnostic testing (e.g. stress testing) for coronary artery disease (CAD). Currently, CAD is presumptively diagnosed using clinical history (such as the presence of angina) with results from one or more non-invasive tests (e.g. stress testing, either at rest or with exercise, combined with single-photon emission computed tomography [SPECT], or echocardiogram). Where diagnostic testing and clinical history indicate, the diagnosis of CAD can be confirmed with coronary angiography, the gold standard for diagnosing CAD.

Testing with currently available computerized 2-lead resting ECG analysis devices consists of four steps:

1. The study device records a 2-lead ECG tracing for 82 seconds, using leads II and V5. Using proprietary hardware and software, the analog ECG tracing is then amplified, digitized, and down-sampled to a rate of 100 Hz.
2. The digitized information is encrypted and transmitted to a central server for a series of mathematical transformations and signal averaging.

3. Following these transformations, the patterns found in the tracing are compared to a large reference database collected by the manufacturer, generating a severity score which indicates the likelihood that CAD is present.
4. A report with the severity score and an interpretation guide is sent back to the requesting provider. The score ranges from 0-20, with a value of 4.0 or greater suggested as the indicator of the presence of clinically significant CAD.

## Regulatory Status

The 3DMP™ device (Premier Heart™, LLC), also known as the MultiFunction CardioGram™ (MCG) system, has received 510(k) approval from the U.S. Food and Drug Administration (FDA). The FDA determined that this device was substantially equivalent to existing devices for use in ECG analysis.

## MEDICAL POLICY CRITERIA

Computerized 2-lead resting electrocardiogram analysis is considered **investigational** for all indications, including but not limited to diagnosing coronary artery disease.

## SCIENTIFIC EVIDENCE

Except for the most advanced cases, treatment of coronary artery disease (CAD) is confined to lifestyle changes and one or more medications for blood pressure, cholesterol, or blood sugar. Within this clinical context, the validation of a new diagnostic test for diagnosis of CAD must:

- Demonstrate diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) of the new test compared with that of the test or tests it purports to replace, in this case, stress testing; and
- Lead to differential treatment and improved health outcomes beyond that conferred by the standard of care (in other words, demonstrate clinical utility).

This is best achieved by randomly allocating new versus current diagnostic testing to an appropriate patient spectrum, determining treatment based on test results, and allowing for long-term follow-up of health outcomes.

## Literature Appraisal

The published literature on computerized 2-lead resting ECG analysis is limited to a systematic review and meta-analysis, consisting of one or more non-randomized studies.

### Systematic Reviews and Meta-Analyses

- A 2012 comparative effectiveness review commissioned by the Agency for Healthcare Research and Quality (AHRQ) studied the effectiveness of resting ECG analysis as compared with other strategies in the noninvasive diagnosis of CAD in women.<sup>[1]</sup> A search of the literature current to September 2011 yielded only one primary study of sufficient quality for inclusion; this study investigated the

MultiFunction CardioGram (MCG) system.<sup>[2]</sup> Nevertheless, interpretation of results from this review is limited by the pooling of results from this study with that of other types of ECG tests (including stress tests). Separate analyses are needed to provide evidence on the safety and effectiveness of the MCG system versus standard stress testing.

- A meta-analysis of the MCG system was published by Strobeck and colleagues in 2009 which pooled the results of several case series discussed below.<sup>[3-6]</sup> Although the researchers included all available studies of the MCG system, interpretation of results from this analysis is limited by the inclusion of only patients already scheduled for angiogram (indicating potential for spectrum bias in that the test was used in patients which had already been identified as being at high risk of disease). Additional meta-analysis of results from studies which include a clear target population are needed to estimate the relative accuracy and clinical utility of this device as proposed for use in the clinical setting.

### Randomized Controlled Trials (RCTs)

There are no RCTs evaluating the clinical utility of computerized 2-lead resting ECG analysis compared with stress testing.

### Non-randomized Studies

Clinical utility outcomes are not reported in any of the non-randomized studies of computerized 2-lead resting ECG analysis, which instead address the diagnostic accuracy of this procedure:

- In 2011, Strobeck and colleagues published a study examining the performance of the MCG system compared with stress single-photon emission computed tomography (SPECT) imaging and coronary angiogram for the diagnosis of clinically relevant CAD (defined as obstruction  $\geq 70\%$  of one or more coronary arteries).<sup>[7]</sup> Patients were consecutively enrolled into the study based upon risk factors for CAD and there was no loss to follow-up. Results of the MCG system were double-blinded and clinicians interpreting the stress SPECT or coronary angiogram were blinded to the results of all other testing. Results included MCG sensitivity of 91% (95% Confidence Interval [CI]: 79%-97%) and specificity of 87% (95% CI: 76%-94%) compared with SPECT sensitivity of 85% (95% CI: 72%-93%) and specificity of 14% (95% CI: 7%-25%). Superiority (or non-inferiority) was not tested. In contrast with the results found in this study, a more recent meta-analysis of SPECT testing reported a pooled sensitivity of 0.83 (0.81-0.91) and specificity of 0.77 (0.64-0.86).<sup>[8]</sup> The reduced specificity reported in the Strobeck study may have been related to the performance of angiography in patients with valvular disease, since these patients may have higher rates of false-positive SPECT exams compared to patients with suspected ischemia.
- Several studies from 2002 to 2009 report on the diagnostic accuracy of the MCG system compared with coronary angiogram.<sup>[4-6]</sup> Study subjects were patients already scheduled for coronary angiograms in the outpatient setting. Indeed, 32%-57% of patients were identified as having clinically relevant CAD (defined as obstruction of 60% or 70% of one or more coronary arteries). Results included a MCG sensitivity range of 89 % to 95% and a specificity range of 81% to 89% in the detection of clinically relevant CAD.

In general, these studies contribute to the body of knowledge concerning the diagnostic accuracy of the computerized 2-lead resting ECG analysis and may be used to provide direction for future research. However, the conclusions presented here are limited by:

- Lack of comparison between the MCG system and other non-invasive CAD tests, in particular, stress testing.<sup>[4-6]</sup> The comparison to angiography, while useful from a research perspective, has a limited role in determining clinical utility given that the MCG system would not be used as a replacement for angiography.
- Inconsistent definitions of clinically relevant CAD (60%<sup>[6]</sup> or 70%<sup>[2,4,5,7]</sup> obstruction of a coronary artery) which limit comparisons between studies.
- High rates of exclusion (between 15% to 32%) of study samples, leading to potential bias in study outcomes.<sup>[4-6]</sup>
- Potential bias in the spectrum of patients selected: only patients already scheduled for angiography were tested with the MCG system.<sup>[4-6]</sup> The diagnostic accuracy of this test may differ when used within a broader spectrum of patients.
- Lack of blinding in the interpretation of the coronary angiogram and the computerized 2-lead resting ECG, thus potentially leading to additional bias.<sup>[6]</sup>

## Clinical Practice Guidelines

There are no evidence-based practice guidelines from professional societies that recommend the computerized 2-lead resting ECG analysis device for the diagnosis of coronary artery disease.

## Summary

While it is suggested that computerized 2-lead resting electrocardiogram (ECG or EKG) analysis may be more accurate than current non-invasive tests for diagnosing coronary artery disease (CAD), neither the diagnostic accuracy, nor the clinical utility, of this technology have been established. Therefore the use of this type of testing is considered investigational for all indications, including but not limited to the diagnosis of coronary artery disease. Randomized, controlled, prospective trials with sufficient follow-up are needed to determine whether its use for the detection of CAD has a positive impact on net health outcomes.

## REFERENCES

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9. BlueCross BlueShield Association Medical Policy Reference Manual "Computerized 2-lead Resting Electrocardiogram Analysis for the Diagnosis of Coronary Artery Disease." Policy No. 2.02.25

## CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	0206T	Computerized database analysis of multiple cycles of digitized cardiac electrical data from two or more ECG leads, including transmission to a remote center, application of multiple nonlinear mathematical transformations, with coronary artery obstruction severity assessment
HCPCS	None	