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MASSACHUSETTS

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Medical Policy

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

Table of Contents

Policy Number: 312
BCBSA Reference Number: 2.02.25

Related Policies
- Signal-Averaged Electrocardiography (ECG), #134

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) for diagnosing coronary artery disease is **INVESTIGATIONAL**.

Medicare HMO Blue^{SM} and Medicare PPO Blue^{SM} Members
BCBSMA does not cover computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) for diagnosing coronary artery disease for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD.

National Coverage Determination (NCD) for Cardiointegram (CIG) as an Alternative to Stress Test or Thallium Stress Test (20.27)
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=259&ncdver=1&bc=AgAAgAAAAAAA&

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)

This is **NOT** a covered service.

Commercial Members: PPO, and Indemnity

This is **NOT** a covered service.

Medicare Members: HMO Blue^{SM}

This is **NOT** a covered service.

Medicare Members: PPO Blue^{SM}

This is **NOT** a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
0206T	Algorithmic analysis, remote, of electrocardiographic-derived data with computer probability assessment, including report.

ICD-9 Diagnosis Codes
Investigational for all diagnoses.

Description
The standard 12-lead resting electrocardiogram (ECG) has limited diagnostic accuracy in the detection of coronary artery disease (CAD).Computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) is a computerized analysis of a 2-lead resting electrocardiogram that has been proposed for use as a diagnostic test for coronary artery disease (CAD). It is intended to improve on the performance of the standard ECG for diagnosing CAD. The study device records a 2-lead ECG tracing for 82 seconds, using leads II and V_5 together with proprietary hardware and software. The analog ECG tracing is then amplified, digitized, down-sampled to a rate of 100 Hz, and encrypted for digital transmission. The digitized information is transmitted to a central server for further analysis. The patterns found in the tracing are compared to a large reference database collected by the manufacturer. A severity score is generated, indicating the likelihood that CAD is present. The severity score ranges from 0-20, with a score of 4.0 suggested as the cutoff for the presence of clinically significant CAD.

Examples of a multifunction cardiogram include the 3DMP device from Premier Heart™, LLC. All computerized 2-lead resting electrocardiogram devices for diagnosing coronary artery disease are considered investigational regardless of the commercial name, manufacturer or FDA approval status.

Summary
A total of 4 studies from 3 clinical series report on the accuracy of multifunction cardiogram for diagnosing CAD. These studies report sensitivities and specificities that are in the high range, with sensitivity ranging from 89.1–94.8% and specificity in the range of 81.1–88.9%. However, these studies have several limitations that limit their internal and external validity. In all of the studies, the population is a convenience sample of patients who were already scheduled for angiography. These patient populations are thus subject to a referral or "work-up" bias in that the population of patients that might be considered for the multifunction cardiogram in clinical practice is not the same population that is being referred for angiography. Also, the number of patients enrolled but not included in the analysis was relatively high, ranging from 14.9–32% of the total number of patients enrolled. This high rate of exclusion from analysis leaves the potential for a biased estimate of the sensitivity and specificity of the test. Finally, in one of the 3 series, the angiogram and multifunction cardiogram were not interpreted in an independent, blinded manner, thus potentially leading to additional bias.

There are no studies that attempt to determine the clinical utility of the multifunction cardiogram. Even if this test does have good accuracy for diagnosing CAD, its role in clinical practice would still need to be determined. Use of the multifunction cardiogram to screen for CAD would be a departure from usual practice, as screening for CAD has not been shown to improve outcomes. In the non-acute setting, the traditional resting ECG has a limited role in diagnosing CAD. The most common method for diagnosing CAD for this purpose is stress testing. There is no evidence comparing the accuracy of multifunction cardiogram to stress testing. The comparison to angiography, while useful from a research perspective, has a limited role in determining clinical utility given that multifunction cardiogram would not be used as a replacement for angiography.

Because of these limitations, the evidence is not sufficient to determine the impact of the computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) on health outcomes, and therefore the use of this device is considered investigational.

Policy History

Date	Action
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates No changes to policy statements.
4/2011	Reviewed Medical Policy Group - Cardiology and Pulmonology No changes to policy statements.
2/2/2011	New policy, effective 2/2/2011 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Grube E, Bootsveld A, Yuecel S et al. Computerized two-lead resting ECG analysis for the detection of coronary artery stenosis. Int J Med Sci 2007; 4(5):249-63.
2. Grube E, Bootsveld A, Buellesfeld L et al. Computerized two-lead resting ECG analysis for the detection of coronary artery stenosis after coronary revascularization. Int J Med Sci 2008; 5(2):50-61.
3. Weiss MB, Narasimhadevara SM, Feng GQ et al. Computer-enhanced frequency-domain and 12-lead electrocardiography accurately detect abnormalities consistent with obstructive and nonobstructive coronary artery disease. Heart Dis 2002; 4(1):2-12.
4. Hosokawa J, Shen JT, Imhoff M. Computerized 2-lead resting ECG analysis for the detection of relevant coronary artery stenosis in comparison with angiographic findings. Congest Heart Fail 2008; 14(5):251-60.
5. Strobeck JE, Shen JT, Singh B et al. Comparison of two-lead, computerized, resting ECG signal analysis device, the MultiFunction-CardioGram, or MCG (a.k.a. 3DMP), to quantitative coronary angiography for the detection of relevant coronary artery stenosis (>70%) – a meta-analysis of all published trials performed and analyzed in the US. Int J Med Sci 2009; 6(4):143-55.