

Corporate Medical Policy

Computerized 2-Lead Resting Electrocardiogram (Multifunction Cardiogram)

File Name:	computerized_2_lead_resting_electrocardiogram_multifunction_cardiogram
Origination:	2/2011
Last CAP Review:	4/2012
Next CAP Review:	4/2013
Last Review:	4/2012

Description of Procedure or Service

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). This policy will review the evidence on accuracy and clinical utility of the multifunction cardiogram.

Background

The standard 12-lead resting electrocardiogram (ECG) has limited diagnostic accuracy in the detection of coronary artery disease. Because of its limited accuracy, the resting ECG has only a limited role in the diagnosis of chronic CAD. Stress testing, either at rest or with exercise, combined with single-photon emission computed tomography (SPECT) or echocardiographic imaging, is the most common initial test in the diagnostic work-up of chronic CAD. Sensitivities and specificities for stress testing vary, but generally fall in the 75%-90% range. Cardiac angiography is the gold standard for diagnosing CAD, and is used in situations where CAD needs to be confirmed following stress testing.

The multifunction cardiogram is intended to improve on the performance of the standard ECG for diagnosing CAD. The study device records a 2-lead EKG tracing for 82 seconds using leads II and V5 together with proprietary hardware and software. The analog EKG tracing is then amplified, digitized, down-sampled to a rate of 100Hz, and encrypted for digital transmission. The digitized information is transmitted to a central server for further analysis. At the central server, the tracings undergo a series of mathematical transformations and signal averaging. There are 6 mathematical transformations included: power spectrum, coherence, phase angle shift, impulse response, cross-correlation, and transfer function. Following these transformations, 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.

Regulatory Status

There is at least one commercially available multifunction cardiogram, the 3DMP device, manufactured by Premier Heart™, LLC (Port Washington, NY). In April 2003, the 3DMP device was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in EKG analysis.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

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Policy

Computerized 2-lead resting electrocardiogram (multifunction cardiogram) is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Computerized 2-Lead Electrocardiogram is covered

Not Applicable

When Computerized 2-Lead Electrocardiogram is not covered

Computerized 2-lead resting electrocardiogram (multifunction cardiogram) is considered investigational for the diagnosis of coronary artery disease.

Policy Guidelines

A literature review was performed through PubMed for the period of January 2011 through March 2012. There are no new 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. 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0206T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

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.

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.

Food and Drug Administration (FDA). 501 (k) Summary Number K992703 for Cardiotron EKG Multi-phase Information Analysis System. Retrieved on November 1, 2010 from http://www.accessdata.fda.gov/cdrh_docs/pdf/k992703.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.25, 11/11/2010

Specialty Matched Consultant Advisory Panel review 4/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.25, 11/10/11

Medical Director review 3/2012

Specialty Matched Consultant Advisory Panel review 4/2012

Policy Implementation/Update Information

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| 2/1/11 | New policy implemented. Computerized 2-lead resting electrocardiogram (multifunction cardiogram) is considered investigational for the diagnosis of coronary artery disease.(mco) |
| 5/10/11 | Specialty Matched Consultant Advisory Panel review 4/2011. References updated. (mco) |
| 1/10/12 | References updated. No changes to Policy Statement. (mco) |
| 5/15/12 | Specialty Matched Consultant Advisory Panel review 4/2012. Policy Guidelines updated. Medical Director review 4/2012. (mco) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.