Computerized 2-Lead Resting Electrocardiogram (Multifunction Cardiogram)

File Name: computerized_2_lead_resting_electrocardiogram_multifunction_cardiogram
Origination: 2/2011
Next CAP Review: 4/2017
Last Review: 5/2016

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 ECG tracing for 82 seconds using leads II and V5 together with proprietary hardware and software. The analog ECG 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. In April 2003, the Premier Heart MCG™ system (Premier Heart, Port Washington, NY) 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 ECG 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 analysis (multifunction cardiogram) is considered investigational for the diagnosis of coronary artery disease.

Policy Guidelines

Evidence for the screening of coronary artery disease (CAD) with computerized 2-lead electrocardiography, includes several diagnostic accuracy studies. Relevant outcomes include test accuracy, test validity, and morbid events. Most published studies have reported high specificities in the range of 90% or greater, although 1 study reported a lower specificity (67%). Reported sensitivities are somewhat lower, ranging from 48% to 88.9%. However, these studies have several methodologic limitations that reduce their internal validity. In all but one, the population is a convenience sample of patients who underwent 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 are not the same population being referred for angiography. Also, the number of patients enrolled but not included in the analysis was relatively high, ranging from 14.9% to 32% of the total number of enrollees. These high rates of exclusion raise the potential for biased estimates of test sensitivity and specificity. Finally, in one of the cohorts, angiogram and multifunction cardiogram results were not interpreted in an independent and blinded manner. These methodologic limitations create a substantial degree of uncertainty regarding the reported results for diagnostic accuracy. The clinical utility of the multifunction cardiogram is uncertain. Even if this test has good accuracy for diagnosing CAD, its application in clinical practice would still need to be determined. Use of the multifunction cardiogram to screen for CAD would depart from usual practice, because screening for CAD has not been shown to improve outcomes. In the nonacute setting, the most common method for diagnosing CAD is stress testing. There is no evidence comparing the accuracy of multifunction cardiogram with stress testing. The evidence is insufficient to determine the effects 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.
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\textit{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.

\textbf{Scientific Background and Reference Sources}


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.


Medical Director review 3/2012

Specialty Matched Consultant Advisory Panel review 4/2012


Specialty Matched Consultant Advisory Panel review 4/2013

Medical Director review 4/2013


Medical Director review 4/2014


Specialty Matched Consultant Advisory Panel review 4/2015

Medical Director review 4/2015


Medical Director review 4/2016
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Medical Director review 5/2016

Policy Implementation/Update Information

2/1/11       New policy implemented. Computerized 2-lead resting electrocardiogram (multifunction cardiogram) is considered investigational for the diagnosis of coronary artery disease. (mco)


1/10/12      References updated. No changes to Policy Statement. (mco)


1/15/13      References updated. No changes to Policy Statement. (mco)


12/31/13     References updated. No changes to Policy Statements. (mco)


1/27/15      References updated. Policy Statement unchanged. (td)


7/01/16      Regulatory status and policy guidelines updated. References updated. Medical Director review 5/2016. (jd)

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.