Medical Policy

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

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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 BlueSM and Medicare PPO BlueSM 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)

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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</table>
Medicare HMO Blue™
This is not a covered service.

Medicare PPO Blue™
This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes
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.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
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<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0206T</td>
<td>Algorithmic analysis, remote, of electrocardiographic-derived data with computer probability assessment, including report.</td>
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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 V₅ 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**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>7/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>12/2015</td>
<td>Adding coding language.</td>
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<tr>
<td>11/2011-4/2012</td>
<td>Medical policy ICD 10 remediation: Formatting, editing and coding updates</td>
</tr>
<tr>
<td></td>
<td>No changes to policy statements.</td>
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<tr>
<td></td>
<td>No changes to policy statements.</td>
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**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. Strobeck JE, Shen JT, Singh B, et al. Comparison of a 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):143-155. PMID 19381351