Electrocardiographic Body Surface Mapping

Description of Procedure or Service

Electrocardiographic body surface mapping (BSM) is an electrocardiographic (ECG) technique that uses multiple (generally 80 or more) electrocardiography leads to detect cardiac electrical activity. The use of multiple leads may result in improved diagnostic accuracy of acute myocardial infarction (AMI) or acute coronary syndrome (ACS), compared to the standard 12-lead ECG. No BSM ECG devices with 80 or more leads are currently commercially available in the United States.

Background

Electrocardiographic body surface mapping (BSM) consists of an 80-lead disposable electrode array in the form of a vest that includes a conducting gel that is applied to the patient’s chest and back. The vest can be applied in less than 5 minutes. This system displays clinical data in three forms; a colorimetric 3-D torso image, an 80-lead single beat view, and the 12-lead ECG. The colorimetric torso images are said to allow the practitioner to rapidly scan the heart for significant abnormalities.

Currently, in patients presenting to the emergency department with symptoms suggestive of myocardial ischemia, a standard 12-lead ECG is obtained. In the presence of ST segment elevation on the ECG, personnel are activated to respond in a timely manner to open a presumed coronary artery occlusion, either by mechanical means though balloon angioplasty, or medically through intravenous thrombolytic drugs. The 12-lead ECG has a specificity of 94%, leading to relatively few erroneous interventions. However, the sensitivity is about 50%. These patients may be further stratified by scoring systems and time-sensitive cardiac enzymes, which may require up to 24 hours of monitored observation.

BSM is being considered as a method to assist in the rapid identification of patients who would benefit from earlier coronary artery intervention than is achieved utilizing current standard of care. The negative predictive value of the test, which has the potential to identify patients who do not require further evaluation with serial cardiac enzymes and clinical observation, is not currently receiving attention as a research topic.

Regulatory Status

In March 2002, the device PRIME ECG® (Verathon, Bothell, WA) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that the device was substantially equivalent to existing devices for use in recording of ECG signals on the body surface. As of July 2014, neither the PRIME ECG device nor its successor, the Heartscape™ 3D ECG System are being marketed in the United States.
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***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.

Policy

BCBSNC does not cover electrocardiographic body surface mapping. It is considered investigational. 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 Electrocardiographic Body Surface Mapping is covered

Not Applicable

When Electrocardiographic Body Surface Mapping is not covered

Electrocardiographic body surface mapping is considered investigational for the diagnosis or management of cardiac disorders, including but not limited to acute coronary syndrome.

Policy Guidelines

Electrocardiographic body surface mapping (BSM) is an electrocardiographic (ECG) technique that uses multiple (generally 80 or more) electrocardiography leads to detect cardiac electrical activity. The use of multiple leads may result in improved diagnostic accuracy, compared to that of the standard 12-lead ECG. No body surface mapping devices with 80 or more leads are currently commercially available in the United States.

The evidence for use of electrocardiographic (ECG) body surface mapping (BSM) in patients with suspected or confirmed cardiac disorders includes a number of studies on the association between ECG BSM and acute myocardial infarction. Relevant outcomes are overall survival, disease-specific survival, test performance, and morbid events. No prospective trials using BSM to guide treatment have been conducted. Results of published studies have been variable and an Agency for Healthcare Research and Quality review did not find statistically significant differences in the diagnostic accuracy of BSM and 12-lead ECG. Under ideal conditions, it is possible that BSM has a higher sensitivity than 12-lead ECG alone for acute coronary events. However, the data also suggest that the specificity may be lower, highlighting concerns regarding false-positive results. In clinical practice, patients with symptoms suspicious for ischemia are not diagnosed with 12-lead ECG alone but in combination with clinical presentation and serial cardiac enzymes. There is no evidence demonstrating that electrocardiographic BSM leads to changes in management that improve health outcomes. The evidence is insufficient to determine the effect of the technology on health outcomes.

The American College of Cardiology Foundation guidelines for electrocardiography standardization and interpretation recognize that while the studies of body surface maps from large electrode arrays have provided useful information about localization of ECG information on
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the thorax, at this time their complexity precludes their use as a substitute for the standard 12-lead ECG for routine recording purposes.

The 2012 AHRQ technology assessment did not find a statistically significant difference in the diagnostic accuracy of BSM compared to a standard 12-lead ECG. Among the individual studies, the difference in sensitivity is variable, and there is uncertainty around whether there is higher sensitivity that is clinically significant. The specificity of BSM may be lower than 12-lead ECG, as some studies report lower specificity but others do not. Because of the uncertainty in the sensitivity and specificity in the available studies, it is not possible to estimate the tradeoff between additional cases of ACS detected and false-positive results leading to further unnecessary testing. Further prospective studies are needed that include relevant clinical populations and that compare the incremental value of BMS when used as part of the overall diagnostic workup for ACS.

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: 0178T, 0179T, 0180T

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.

Scientific Background and Reference Sources


Specialty Matched Consultant Advisory Panel review 10/2010

Electrocardiographic Body Surface Mapping


Specialty Matched Consultant Advisory Panel review 10/2011

Specialty Matched Consultant Advisory Panel review 10/2012

Specialty Matched Consultant Advisory Panel review 10/2013


Senior Medical Director review 11/2014

Specialty Matched Consultant Advisory Panel review 10/2015

Medical Director review 10/2015


Medical Director review 10/2016

Policy Implementation/Update Information

8/31/09 New policy issued. Electrocardiographic body surface mapping is considered investigational for the diagnosis or management of cardiac disorders including acute coronary syndrome. (adn)

12/7/09 Specialty Matched Consultant Advisory Panel review meeting 10/30/09. No change to policy statement. (adn)

6/22/10 Policy Number(s) removed (amw)

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10/1/13 References updated. Policy Guidelines updated. No changes to Policy Statements. (mco)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/2013. No changes to Policy Statements. (mco)


10/1/15 Description section revised. Policy Guidelines section extensively revised. Policy Statement remains unchanged. References updated. (td)

12/30/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. Medical Director review 10/2015. (td)


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.