Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Electrocardiographic Body Surface Mapping

Policy #: 309
Latest Review Date: February 2023
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **electrocardiographic body surface mapping** as a **non-covered benefit** and as **investigational** for all indications including, but not limited to, acute coronary syndrome.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

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. It is suggested that the use of multiple leads may result in improved diagnostic accuracy of acute myocardial infarction (AMI) or acute coronary syndrome (ACS), compared with that of the standard 12-lead ECG. No BSM ECG devices with 80 or more leads are currently commercially available in the United States.

Electrocardiographic body surface mapping (BSM) consists of an 80-lead disposable electrode array in the form of a vest and includes a conducting gel that is applied to the patient's chest and back. The vest can be affixed to the patient in less than five 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 electrocardiograph (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 acute coronary syndrome (ACS), 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 through 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 approximately 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.

KEY POINTS:

The most recent literature search was performed through February 9, 2023.

Assessment of a diagnostic technology focuses on the following three parameters: 1) technical performance; 2) diagnostic accuracy (sensitivity, specificity, positive and negative predictive value) in relevant clinical populations; and 3) clinical utility, i.e., demonstration that the diagnostic information can be used to improve patient outcomes.

Summary of Evidence

For individuals who have suspected or confirmed acute cardiac syndrome who receive ECG BSM, the evidence includes a number of studies on the association between ECG BSM and AMI. Relevant outcomes are overall survival, disease-specific survival, test accuracy, test validity, and morbid events. No prospective trials using BSM to guide treatment were identified. 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 a 12-lead ECG for acute coronary events. However, studies have reported lower specificity with ECG BSM compared with 12-lead ECG, which may lead to false-positive results. 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.

Practice Guidelines and Position Statements

American College of Cardiology Foundation

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 the thorax, at this time their complexity precludes their use as a substitute for the standard 12-lead ECG for routine recording purposes.

U.S. Preventive Services Task Force Recommendations

The use of 80-lead body surface mapping ECG is not a preventive service.

KEY WORDS:

Electrocardiography, Heartscape, PRIME ECG, 80-lead electrocardiogram, multi-lead electrocardiogram, electrocardiographic body surface mapping, electrocardiographic body surface potential mapping

APPROVED BY GOVERNING BODIES:

In March 2002, the device “PRIME ECG®” (Verathon, Bothell, WA) was cleared for marketing by FDA through the 510(k) process. FDA determined that the device was substantially equivalent to existing devices for use in recording of ECG signals on the body surface. As of

April 2016, neither the PRIME ECG device nor its successor, the Heartscape™ 3D ECG System are being marketed in the United States. Product code: DPS.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

As of 01/01/2018, there is no specific code for this procedure. Use unlisted code 93799 to report.

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POLICY HISTORY:

Adopted for Blue Advantage, July 2007
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Medical Policy Group, June 2009
Medical Policy Group, February 2011
Medical Policy Group, August 2011
Medical Policy Group, August 2012
Medical Policy Group, December 2013
Medical Policy Group, August 2014
Medical Policy Group, August 2015
Medical Policy Group, July 2017
Medical Policy Group, December 2017
Medical Policy Group, September 2019
Medical Policy Group, February 2021
Medical Policy Group, February 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, February 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
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