Public Statement:

Electrocardiographic body surface mapping (BSM) is a technique that uses multiple (generally 80 or more) electrocardiography (ECG) leads to detect cardiac electrical activity. It is suggested that the use of multiple leads may result in improved diagnostic accuracy compared to the standard 12-lead ECG. There is no current scientific evidence that use of this technique improves health outcomes, and this service is not covered.

Medical Policy Statement:

Electrocardiographic body surface mapping is considered investigational and is not covered.

Background:

The PRIME ECG® System (Heartscape Technologies) was cleared for marketing by the U.S. Food and Drug Administration (FDA) in March 2002 through the 510(k) process as being substantially equivalent to existing devices. The PRIME ECG system with Diagnostic Algorithm was cleared through the same process in June 2003. The indication is recording of ECG signals on the body surface. This system 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. According to the FDA material, 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 ST segment abnormalities.

The data on use of electrocardiographic body surface mapping (BSM) are limited. The published studies to date involve relatively small numbers of patients, given the prevalence of the condition. While most studies have shown higher sensitivity for BSM, some have shown lower specificity. Owens reported that BSM had sensitivity of 80% and specificity of 92% compared to the standard 12-lead electrocardiograph (ECG) with values of 57% and 94%, respectively (Owens, 2004). These results were based on 294 patients with acute chest pain (182 had an acute infarct) done in a pre-hospital setting with the infarct diagnosis based on cardiac enzymes measured at 12 hours. Menown reported that use of BSM improved the early diagnosis of right ventricular or posterior infarcts in those with acute inferior wall infarction (Menown, 2000). Among 62 patients with inferior myocardial infarction, posterior ST changes of at least 1 mV were seen on ECG in 1 patient compared to posterior wall BSM changes in 17 patients. However, none of the published studies identified have demonstrated if use of the electrocardiographic body surface mapping leads to improved clinical outcomes.

A more recent publication also describes the use of the 80-lead technique in the emergency department evaluation of patients with chest pain (Self, 2006). The authors comment that use of this approach has been hampered by slow acquisition time and the complexity of interpretation but that technological advances are overcoming these limitations. However, they also add that the future of BSM in emergency medicine is unclear and that more research is needed to define its benefits and limitations.

A multicenter (10-site) trial—the optimal cardiovascular diagnostic evaluation enabling faster treatment of myocardial infarction (OCCULT-MI) trial—that involves about 1,400 patients in an emergency department setting has begun recruiting patients to evaluate this device.

The American College of Cardiology 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 (Kliegfield, 2007). Further assessment of this technology in the evaluation of acute chest pain is being conducted in a clinical trial (NCT00560248). Therefore, the impact of electrocardiographic body surface mapping on clinical outcomes is unknown.
References:


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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