BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Signal-Averaged Electrocardiography

Policy #:318
Category: Medical

Latest Review Date: December 2020
Policy Grade: **Effective January 2, 2013, this remains an active policy but no longer scheduled for regular literature reviews and updates.**

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:

Effective for dates of service on or after May 19, 2011:

Blue Advantage will treat **signal-averaged electrocardiography** as a **non-covered** benefit and as **investigational**, including, but not limited to:

- its use as a technique of risk stratification for arrhythmias after prior myocardial infarction; or
- in patients with cardiomyopathy; or
- in patients with syncope; or
- as an assessment of success after surgery for arrhythmia; or
- in the detection of acute rejection of heart transplants; or
- as an assessment of efficacy of antiarrhythmic drug therapy; or
- in the assessment of success of pharmacological, mechanical, or surgical interventions to restore coronary artery blood flow.

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:

Signal-averaged electrocardiography (SAECG) is a technique involving computerized analysis of small segments of a standard ECG to detect abnormalities, termed ventricular late potentials (VLPs), that would be otherwise obscured by "background" skeletal muscle activity. VLPs reflect aberrant, asynchronous electrical impulses arising from viable isolated cardiac muscle bordering an infarcted area and are thought to be responsible for ventricular tachyarrhythmias. Therefore, VLPs, as measured by SAECG, have been investigated as a risk factor for arrhythmic events in patients with a variety of cardiac conditions, including cardiomyopathy and prior history of myocardial infarction (MI). Patients considered at high risk of ventricular arrhythmias and thus sudden death may be treated with drugs to suppress the emergence of arrhythmias or implantable cardiac defibrillators (ICD) to promptly detect and terminate tachyarrhythmias when they occur. Because sudden cardiac death, whether from arrhythmias or pump failure, is one of the most common causes of death after a previous myocardial infarction, there is intense interest in risk stratification to target therapy. Patient groups are divided into those who have not experienced a life-threatening arrhythmia (i.e., primary prevention) and those who have (i.e., secondary prevention). SAECG is just one of many risk factors that have been investigated. Others include left ventricular ejection fraction (LVEF), arrhythmias detected on Holter monitor or electrophysiologic studies, heart rate variability, and baroreceptor sensitivity. T-wave alternans is another technique for risk stratification; it measures beat-to-beat variability, while SAECG measures beat-averaged conduction.

KEY POINTS:
The most recent update of this policy includes a literature review through December 3, 2020.

Summary
For individuals receiving signal averaged electrocardiography, the evidence includes prospective studies, small comparative studies, and retrospective reviews. Relevant outcomes are overall survival, morbid events, and treatment related morbidity. Signal-averaged ECG has some ability to risk-stratify patients at risk for ventricular arrhythmias. However, this predictive ability is modest, and this technique has not been used to stratify patients into clinically relevant categories of risk. Some RCTs have used signal-averaged ECG for selection of patients at high risk of ventricular arrhythmias, but these studies have not demonstrated outcome benefits for the treatments under study. Signal-averaged ECG has also been tested as a diagnostic test for a variety of cardiac-related disorders, but the evidence is insufficient to demonstrate clinical utility for any of the conditions tested. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American Heart Association
The American Heart Association, American College of Cardiology Foundation, and Heart Rhythm Society published a scientific statement in 2008 that included signal averaged ECG. They conclude that "routine use of SAECG to identify patients at high risk for SCD is not adequately supported…"

The 2006 ACC, American Heart Association (AHA), and European Society of Cardiology (ESC) guidelines for management of patients with ventricular arrhythmias and prevention of sudden death list SAECG with a Class IIb recommendation (Class IIb noted as usefulness/efficacy is less well established by evidence/opinion). The report notes that SAECG may be useful to improve the diagnosis and risk stratification of patients with ventricular arrhythmias or of those at risk for life-threatening ventricular arrhythmias.
A recent consensus document from the AHA, ACC Foundation, and Heart Rhythm Society indicates the SAECG may identify patients with prior MI at risk for sudden cardiac death and that further studies are required to assess the utility of this test.

KEY WORDS:
Electrocardiography, Signal-Averaged, SAECG, Signal-Averaged Electrocardiography

APPROVED BY GOVERNING BODIES:
Not applicable

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

CODING:

CPT Codes:

93278	Signal-Averaged Electrocardiography (SAECG), With or without ECG

REFERENCES:

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Prevention of Sudden Cardiac Death): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Circulation 2006; 114(10):1088-132.

POLICY HISTORY:

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Medical Policy Group, February 2012
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Medical Policy Group, November 2019
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