MEDICAL POLICY

Excellus

MEDICAL POLICY DETAILS	
Medical Policy Title	**SIGNAL AVERAGED ELECTROCARDIOGRAPHY (SAECG)**
Policy Number	**2.01.02**
Category	**Technology Assessment**
Effective Date	**09/21/00**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, signal-averaged electrocardiography, has not been proven to be medically effective and is considered **investigational** for all indications, including but not limited to, the following:

A. use for risk stratification regarding ventricular arrhythmia in patients following acute myocardial infarction;
B. in patients with cardiomyopathy;
C. in patients with syncope;
D. as an assessment of success after surgery for arrhythmia;
E. in the detection of acute rejection of heart transplants;
F. as an assessment of efficacy of antiarrhythmic drug therapy; or
G. in the assessment of success of pharmacological, mechanical, or surgical interventions to restore coronary artery blood flow.

II. Based on our criteria and assessment of the peer-reviewed literature, the Premier Heart 3DMP Computerized EKG System has not demonstrated a benefit to patient outcomes and is considered **investigational** as a technique of evaluating patients suspected of having coronary artery disease.

Refer to Corporate Medical Policy #2.01.45 regarding Microvolt T-Wave Alternans testing.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Signal-averaged electrocardiography (SAECG) is a non-invasive diagnostic test used to identify those patients that are at high risk of ventricular tachycardia, ventricular fibrillation, or sudden cardiac arrest. The signal-averaged ECG is a modification of a conventional ECG recording in which the signals are first amplified, then filtered, and finally averaged with the assistance of computer software to detect abnormalities, termed “ventricular late potentials” (VLP), that would otherwise be obscured by “background” skeletal muscle activity. VLP’s 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, VLP's 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.

Since 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 guide therapy.

The Premier Heart Digital Database-Driven MultiPhase (3DMP) electrocardiograph (EKG) System, by Cardiotron, provides a computer analysis of digitalized 12-lead EKG waveform in the frequency domain (power spectral estimate) to aid in the early detection of significant coronary artery disease.

RATIONALE

Signal-averaged ECG equipment requires FDA premarket approval to market the device as an instrument for recording low amplitude/high frequency components of the surface electrocardiogram for P wave analysis.

Signal-averaged electrocardiography has been thoroughly studied as a risk stratification tool for potentially fatal arrhythmias in patients with previous myocardial infarction. For the purpose of post-MI risk stratification, SAECG has been reported to have a sensitivity of 56-68%, a specificity of 74-81%, and positive predictive accuracy of about 20% for the occurrence of an event in the next 2 years.

Evidence demonstrates that SAECG has little clinical value in selecting patients who are at high risk for an arrhythmic event. Evidence is also lacking to demonstrate that the information could be used to alter treatment strategy and improve health outcomes. No prospective clinical studies have demonstrated the utility of this testing in improving clinical outcomes.

The 2010 AHRQ Technology Assessment, ECG-Based Signal Analysis Technologies, concluded there is currently little available evidence that pertains to the utility of ECG-based signal analysis technologies as a diagnostic test among patients at low to intermediate risk of CAD who present at the outpatient setting with the chief complaint of chest pain. The limited evidence that is available demonstrates proof of concept, particularly for the PRIME ECG and 3DMP devices. Further research is needed to better categorize the performance characteristics of these devices to determine in what circumstances, if any, these devices might precede, replace, or add to the standard ECG for the diagnosis of CAD among patients who present with chest pain in the outpatient setting.

The Premier Heart 3DMP EKG System, by Cardiotron, provides a computer analysis of digitalized 12-lead EKG waveform in the frequency domain (power spectral estimate) to aid in the early detection of significant coronary artery disease. The 3DMP system was cleared by the FDA in 2000 based on a 510(k) application that it was substantially equivalent as a programmable, diagnostic computer. The system is marketed as a noninvasive method of identifying patients with coronary artery disease. There are no evidence-based guidelines from national professional organizations that address clinical utility of 3DMP in evaluating patients suspected of having coronary artery disease.

In the 2016 Dinov et al study aimed to evaluate the utility of signal-averaged electrocardiogram (SAECG) for predicting outcomes after VT ablation. The main drawbacks (study limitations) were its small sample size (n=50) and the relatively short follow-up (median of 12 months). The authors stated that this study should be considered for the purpose of generating hypothesis. Although study results suggest that SAECG may be useful to assess the success after VT ablation, further well-designed studies are needed to determine its clinical utility for this patient population.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
93278 **(E/I)**	Signal-averaged electrocardiography (SAECG) with or without ECG

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HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

Code	Description
Investigational for all codes	

REFERENCES

BlueCross BlueShield Association. Signal averaged electrocardiography - archived. Medical Policy Reference Manual Policy #2.02.04. Archived 2012 Dec 13.

Buzea CA, et al. Role of signal-averaged electrocardiography and ventricular late potentials in patients with chronic obstructive pulmonary disease. Rom J Intern Med 2015 Apr-Jun;53(2):133-9.

Dinov B, et al. Signalaveraged electrocardiography as a noninvasive tool for evaluating the outcomes after radiofrequency catheter ablation of ventricular tachycardia in patients with ischemic heart disease: Reassessment of an old tool. Circ Arrhythm Electrophysiol. 2016;9(9).

*Engel G, et al. Electrocardiographic arrhythmia risk testing. Curr Probl Cardiol 2004 Jul;29(7):365-432.

*Grimm W. et al. Noninvasive arrhythmia risk stratification in idiopathic dilated cardiomyopathy: results of the Marburg Cardiomyopathy Study. Circ 2003 Dec 9;108(23):2883-91.

*Haghjoo M, et al. Does the abnormal signal-averaged electrocardiogram predict future appropriate therapy in patients with implantable cardioverter-defibrillators? J Electrocardiol 2006 Apr;39(2):150-5.

*Horenstein MS, et al. Efficacy of signal-averaged electrocardiography in the young orthotopic heart transplant patient to detect allograft rejection. Pediatr Cardiol 2006 Sep-Oct;27(5):589-93.

*Huikuri HV, et al. Prediction of sudden cardiac death after myocardial infarction in the beta-blocking era. J Am Coll Cardiol 2003 Aug 20;42(4):652-8.

Liao YC, et al. The application of signal average ECG in the prediction of recurrences after catheter ablation of ventricular arrhythmias in arrhythmogenic right ventricular dysplasia/cardiomyopathy. Int J Cardiol. 2017 Jan 18.

Narayan SM, Cain ME. Use of the signalaveraged electrocardiogram in nonischemic heart disease and cardiac transplantation. UpToDate [online serial[. Waltham, MA: UpToDate; reviewed May 2015.

*Nasir K, et al. Filtered QRS duration on signal-averaged electrocardiography predicts inducibility of ventricular tachycardia in arrhythmogenic right ventricle dysplasia. Pacing Clin Electrophysiol 2003 Oct;26(10):1955-60.

*Perloff JK, et al. Usefulness of post-ventriculotomy signal averaged electrocardiograms in congenital heart disease. Am J Cardiol 2006 Dec 15;98(12):1646-51.

Priori SG, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J. 2015 Nov 1;36(41):2793-867.

*Zipes DP, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006 Sep 5;48(5):e247-346.

*Key Article

KEY WORDS

SAECG, Signal averaged ECG, 3DMP, Ventricular late potentials.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, SAECG is not addressed in National or Regional Medicare coverage determinations or policies.