Clinical Review Criteria
Signal-Averaged Electrocardiography (SAECG)

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Criteria
For Medicare Members
No review for Medicare members

For Non-Medicare Members
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Sudden cardiac death (SCD) is a major health problem worldwide. It has been estimated that between 184,000 and 462,000 Americans die suddenly each year from sustained ventricular tachycardia or ventricular fibrillation. The majority have coronary artery disease and left ventricular dysfunction. Multiple large clinical trials have shown that prophylactic implantable cardioverter defibrillator (ICD) can prevent or abort these arrhythmic events and reduce mortality. It is thus critically important to identify those patients at risk to prevent potentially lethal arrhythmias (Cain 1996, Iravanian 2005, Goldberger 2008, Pandey 2010, Stein 2008).

Several invasive and noninvasive approaches or tests have been studied to stratify the patient with risk of ventricular arrhythmia and sudden death. Noninvasive methods include measurement of QRS duration on the 12-lead ECG, measurement of heart rate variability (HRV) and baroreflex sensitivity, detection of non-sustained ventricular tachycardia; signal averaged electrocardiography (SAECG), and several others (Stein 2008).

SAECG was introduced in the 1970s primarily for the detection of patients at high risk of sudden cardiac death after myocardial infarction. It is based on the idea that most life-threatening ventricular arrhythmias are reentrant in nature among patients with structural heart disease. The arrhythmias require an area of slow conduction to allow their perpetuation. These areas of delayed conduction within the ventricular myocardium (ventricular late potentials) can often be demonstrated by invasive electrophysiological studies performed in sinus rhythm. SAECG seeks to detect the occurrence of late activation within the myocardium noninvasively via surface ECG electrodes. It involves computerized analysis of segments of a standard surface ECG to compare and average consecutive QRS complexes (usually around 300) and produce a filtered QRS complex that provides information on the presence of ventricular late potentials (Chandrasekaran 1999, Stein 2008, Liew 2010).

Medical Technology Assessment Committee (MTAC)
Signal-Averaged Electrocardiography (SAECG)
12/19/2011: MTAC REVIEW
Evidence Conclusion: The literature search did not identify any randomized controlled trials that examined the effect of stratifying patients at risk of sudden death based on SAECG, or its effect on improving health outcomes. The results of the published studies showed that the sensitivity of SAECG to
establishing the risk of ventricular arrhythmias and sudden death. There is also insufficient evidence to
method for arrhythmia risk stratification. However, there is insufficient published evidence to its efficacy in
improve outcome. Signal-averaged electrocardiography (SAECG) has been proposed as a noninvasive
demonstrate that the test or marker can be used to select patients for a therapy or intervention that will
dictated that SAECG in isolation is no longer useful for the identification of post-MI patients at risk of
arrhythmogenic substrate, leading to a noticeable reduction in the predictive power of this tool. The report
were documented with implantable ECG loop recorder. Patients were followed up for 2 years during which
25 (8%) experienced a fatal or non-fatal tacharrhythmias. The strongest predictor for these events was
heart rate variability (p<0.001) as measured by Holter monitor. This was followed by induction of sustained
monomorphic ventricular tachycardia during programmed electrical stimulation (P=0.003). QRS duration
measured from SAECG had a lower predictive value especially after adjustments were made for clinical
variables. An assessment made for AHRQ in 1998 also found that SAECG had variable sensitivity and
specificity, poor positive predictive value, but relatively high negative predictive value (NPV) for post MI
fatal arrhythmic events. The high NPV was attributed to the low incidence of fatal arrhythmic events post
MI, due to the increase use of antithrombotic therapy. The 2006 American College of Cardiology, American
Heart Association and European Society of Cardiology guidelines (Zippes 2006) 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 the presence of an abnormal SAECG was shown to increase the risk of arrhythmic events
by 6- to 8-fold in a post-MI setting. However, the restoration of patency to the infarct-related coronary artery
with fibrinolysis or angioplasty and the widespread use of surgical revascularization have modified the
arrhythmogenic substrate, leading to a noticeable reduction in the predictive power of this tool. The report
indicated that SAECG in isolation is no longer useful for the identification of post-MI patients at risk of
ventricular arrhythmias. A number of health plans consider signal-averaged electrocardiography
investigational and not medically necessary for all indications including risk stratification for arrhythmias
after a myocardial infarction. Conclusion: In evaluating any method for risk stratification it is important to
demonstrate that the test or marker can be used to select patients for a therapy or intervention that will
improve outcome. Signal-averaged electrocardiography (SAECG) has been proposed as a noninvasive
method for arrhythmia risk stratification. However, there is insufficient published evidence to its efficacy in
establishing the risk of ventricular arrhythmias and sudden death. There is also insufficient evidence to
determine clinical utility of SAECG testing in selecting patients for receiving pharmacological therapy, ICD
implantation or other treatments.

**Articles:** The literature search did not identify any large prospective or randomized trials that examined the
benefit of using SAECG for selecting patients for electro physiologic studies, or its clinical utility for
selecting patients for prophylactic therapies and/or interventions, and improving health outcomes. There
was a large number of earlier studies conducted in the 1990s that examined the accuracy of SAECG and
various other variables in predicting the risk of major arrhythmic events after a myocardial infarction, and a
meta-analysis (Bailey 2001) that pooled the results of these studies published before 2001. The search also
identified a more recent study (CARISMA study) that evaluated the ability of several invasive and
noninvasive risk markers to predict arrhythmias that can potentially be treated with an ICD, and another
study that compared the ability of SAECG and ejection fraction for predicting future cardiovascular events
including life threatening arrhythmias in different cardiac diseases. The meta-analysis and CARISMA study
were selected for critical appraisal: Bailey JJ, Berson AS, Handelsman H. Utility of current risk stratification
test for predicting major arrhythmic events after myocardial infarction. J Am Coll Cardiol 2001; 38:1902-
1911. See Evidence Table Huikuri HV, Raatikainen MJ, Moerch-Joergensen R, et al. Prediction of fatal or
near-fatal cardiac arrhythmia events in patients with depressed left ventricular function after an acute
myocardial infarction. Eur Heart J. 2009;30:689-698. See Evidence Table

The use of SAECG does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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Codes
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