**Kaiser Foundation Health Plan
of Washington**

Clinical Review Criteria
Signal-Averaged Electrocardiography (SAECG)

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Criteria
For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"*Signal-Averaged Electrocardiography (SAECG)*"** for medical necessity determinations. Use the Non-Medicare criteria below.

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.

If requesting review for this service, please send the following documentation:
- Last 6 months of clinical notes from requesting provider &/or specialist

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Signal-averaged electrocardiography (SAECG) is a technique involving computerized analysis of small segments of a standard ECG to detect abnormalities that would be otherwise obscured by "background" skeletal muscle activity.

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 predict arrhythmic events ranged from 15% to 75%. It had very low positive predictive value which indicates that it is not a useful when used alone to identify high risk patients. However, SAECG had a high negative predictive value, which may indicate that it could potentially be useful in identifying low-risk patients. Bailey and colleagues (2001) conducted a meta-analysis to examine the utility of various tests for risk stratification. The analysis included 44 studies that evaluated the accuracy of signal-averaged electrocardiography, heart rate variability, severe ventricular arrhythmia on ambulatory electrocardiography, left ventricular ejection fraction, and electrophysiological studies in predicting risk major arrhythmic events (MAE) after a myocardial infarction (MI). There were variations between the studies in patient characteristics, cutoff points for the tests, and reporting of cause of cardiac death. In addition, the authors of the meta-analysis did not evaluate the quality of the studies, test for homogeneity or publication bias. Overall the analysis shows that the sensitivity of all tests ranged from 42.8% to 62.4% and the specificity ranged from 77.4% to 85.8%. The pooled sensitivity of SAECG was 62.4% (95% CI; 56.4-67.9%) (ranging from 35%-94% in 22 studies involving 9,883 patients), and the pooled specificity was 77.4% (95% CI; 73.6-80.8%, range 62-95.5%). The technology had a low positive predictive value ranging from 8-29%, but a high negative predictive value (81-99%) suggesting that it may have the potential of avoiding unnecessary implantation of a cardioverter-defibrillator (ICD). 3-stage stratification yielded a low-risk group (80.0% with a two-year MAE risk of 2.9%), a high-risk group (11.8% with a 41.4% risk) and an unstratified group (8.2% with an 8.9% risk equivalent to a 2-year incidence of 7.9%). The authors concluded that sensitivities and specificities for the 5 tests were relatively similar and no one test was satisfactory alone for predicting risk. Combinations of tests in stages allowed the authors to stratify 92% of patients as either high-risk or low-risk. They noted that these data suggest that a large prospective study to develop a robust prediction model is feasible and desirable. The CARISMA study (Huikuri 2009) also evaluated the ability of several invasive and noninvasive risk markers to predict arrhythmias after an acute myocardial infarction, with the potential to be treated with an ICD. 5,869 consecutive patients from 10 European centers were screened 2-7 days after experiencing an acute myocardial infarction (AMI), but only 312 met the inclusion criteria and were included in the study. Risk stratification was performed 6 weeks after the AMI using echocardiography, Holter monitoring, microvolt T-wave alterans, SAECG, standard 12-lead ECG, and electrophysiological studies. The primary endpoint was ECG-documented fatal or near-fatal cardiac arrhythmia (ventricular fibrillation or symptomatic sustained ventricular tachycardia). The arrhythmic events were documented with implantable ECG loop recorder. Patients were followed up for 2 years during which 25 (8%) experienced a fatal or non-fatal tachyarrhythmias. 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 off 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.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
93278	Signal-averaged electrocardiography (SAECG), with or without ECG

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/03/2012	01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC], 09/05/2023[MPC], 03/12/2024[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

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Revision History	Description
09/01/2020	Added KPWA Medical Policy statement under Medicare section