



The Use of ECG-Based Signal Analysis Technologies to Detect Myocardial Ischemia or Coronary Artery Disease

Medical Evidence Development and Coverage Advisory Committee
(MEDCAC)

November 9, 2011

MEDCAC Background

- The questions below refer to the use of electrocardiogram (ECG) based signal analysis (SAECG) technologies used for the purpose of detecting coronary artery disease (CAD) in:
 - patients who are asymptomatic, but have increased risk factors for CAD or
 - in patients who present with signs/symptoms suggestive of acute coronary syndrome (ACS) with or without chest pain, and who are not triaged for emergent reperfusion therapy.

MEDCAC Background

- Furthermore, for the purposes of this meeting, SAECG technologies are defined as those that:
 - (1) assess electrical activity of the heart, and
 - (2) transform and/or interpret the signal through spatial imaging or advanced mathematical modeling to produce new indices and
 - (3) are commercially available in the United States. This does not include the standard 12 lead ECG or other technologies used only to diagnose arrhythmias.

MEDCAC Background

- Health outcomes of greatest interest include mortality, myocardial infarction, cardiac function and quality of life.



MEDCAC Voting Scale

For the voting questions, the following scale will be used to identify the level of confidence with 1 being the lowest or no confidence and 5 representing a high level of confidence. Also, for purposes of this MEDCAC, the terms ECG-based signal analysis technologies and SAECG technologies will be used interchangeably.

| | | | | |
|------------------------|---|---------------------------------|---|-------------------------|
| 1 Low Confidence | 2 | 3 Intermediate Confidence | 4 | 5 High Confidence |
|------------------------|---|---------------------------------|---|-------------------------|

MEDCAC Question #1

- 1. How confident are you that there is adequate evidence to determine whether or not SAECG technologies are able to reliably and accurately detect:
 - a. coronary artery disease in asymptomatic patients at risk for the disease
 - b. patients with signs and symptoms suggestive of ACS with or without chest pain

MEDCAC Question #2

- 2. If the result of Question 1 is at least intermediate (mean vote ≥ 2.5) in any of the conditions noted, how confident are you that ECG based signal analysis technologies are able to reliably and accurately detect:
 - a. coronary artery disease in asymptomatic patients at risk for the disease
 - b. patients with signs/symptoms suggestive of ACS with or without chest pain
- (If the result of Question 2 is at least intermediate (mean vote ≥ 2.5) in either of the conditions noted, continue onto the following questions for the specified disease process.)

MEDCAC Question #3

- **3. How confident are you that there is adequate evidence to determine whether or not the incremental information obtained from SAEKG technologies beyond that provided by the standard 12 lead ECG, improves physician decision making in the management of :**
 - **a. coronary artery disease in asymptomatic patients at risk for the disease**
 - **b. patients with signs/symptoms suggestive of ACS with or without chest pain**

MEDCAC Question #4

- **4. If the result of Question 3 is at least intermediate (mean vote ≥ 2.5), how confident are you that the incremental information obtained from SAECG technologies beyond that provided by the standard 12 lead ECG, improves physician decision making in the management of:**
 - **a. coronary artery disease in asymptomatic patients at risk for the disease**
 - **b. patients with signs/symptoms suggestive of ACS with or without chest pain**

MEDCAC Question #5

- **5. How confident are you that there is adequate evidence to determine whether or not the incremental information obtained from SAECG technologies beyond that provided by the standard 12 lead ECG, can eliminate the need (at the level of an individual patient) for**
 - **a. diagnostic laboratory testing (e.g. troponin)**
 - **b. noninvasive tests of cardiac anatomy/functioning (e.g. stress testing, echocardiography, etc)**
 - **c. invasive test of cardiac anatomy/functioning (i.e. coronary angiography)**

MEDCAC Question #6

- **6. If the result of Question 5 is at least intermediate (mean vote ≥ 2.5), how confident are you that the incremental information obtained from SAECCG technologies beyond that provided by the standard 12 lead ECG, can eliminate the need (at the level of an individual patient) for**
 - **a. diagnostic laboratory testing**
 - **b. noninvasive tests of cardiac anatomy/functioning (e.g. stress testing, echocardiography, etc)**
 - **c. invasive test of cardiac anatomy/functioning (i.e. coronary angiography)**

MEDCAC Question #7

- **7. How confident are you that there is adequate evidence to determine whether or not the use of SAECG technologies significantly improves patient health outcomes?**

MEDCAC Question #8

- 8. If the result of Question 7 is at least intermediate (mean vote ≥ 2.5), how confident are you that the use of SAECG technologies significantly improves patient health outcomes?



MEDCAC Questions 9 & 10

- 9. What evidence gaps exist in the field of signal analysis ECG devices?

- 10. How confident are you that these conclusions are generalizable to:
 - The Medicare patient population?
 - Community based settings?

Contact Information

Division of Items and Devices
Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Baltimore, Maryland 21244

Lisa.Eggleston@cms.hhs.gov

Susan.Miller2@cms.hhs.gov