CONTINUOUS AMBULATORY ECG MONITORING WITH SIMULTANEOUS ANALYSIS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Continuous ambulatory ECG monitoring with simultaneous analysis is mobile outpatient cardiac telemetry, or MCOT, and may also be referred to as outpatient cardiac telemetry. It has been investigated as an automatic electrocardiogram, arrhythmia detection and alarm system to provide cardiac monitoring and transmit real-time analysis from a low-risk individual’s home to a central monitoring facility.

Criteria:

- Continuous ambulatory ECG monitoring with simultaneous analysis is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
CONTINUOUS AMBULATORY ECG MONITORING WITH SIMULTANEOUS ANALYSIS (cont.)

Resources:


CONTINUOUS AMBULATORY ECG MONITORING WITH SIMULTANEOUS ANALYSIS (cont.)

Resources: (cont.)

FDA 510K Summary for HeartLink II:

- FDA-approved indication: Indications for use:

  1) Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.
  2) Specific criteria for indications for use are as follows:
  3) Patients with dizziness or lightheadedness.
  4) Patients with palpitations.
  5) Patients with syncope of unknown etiology.
  6) Patients who require monitoring for non life-threatening arrhythmias, such as atrial fibrillation, other supra-ventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block. This includes post operative monitoring for these rhythms.
  7) Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias.
  8) Patients requiring monitoring for arrhythmia-inducing co-morbid conditions such as hyperthyroidism or chronic lung disease.
  9) Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias.
  10) Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation.
CONTINUOUS AMBULATORY ECG MONITORING WITH SIMULTANEOUS ANALYSIS (cont.)

Resources: (cont.)

FDA 510K Summary for CardioNet ECG Monitor with Arrhythmia Detection (Model 1002):

- FDA-approved indication: The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

  1) Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g., atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

  2) Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

  3) Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

  4) Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).

  5) Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

  6) Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.

  7) Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.

  8) Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.
CONTINUOUS AMBULATORY ECG MONITORING WITH SIMULTANEOUS ANALYSIS  (cont.)

Resources: (cont.)

FDA 510K Summary for CardioNet ECG Monitor with Arrhythmia Detection (Model 1003):

- FDA-approved indication: The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

1) Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supra-ventricular tachycardias (e.g., atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

2) Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

3) Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

4) Patients who require outpatient monitoring of antiarrhythmic therapy: a) monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs; b) monitoring of effects of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).

5) Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

6) Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.

7) Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.

8) Patients requiring measurement, analysis and reporting of the QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.
CONTINUOUS AMBULATORY ECG MONITORING WITH SIMULTANEOUS ANALYSIS (cont.)

Resources: (cont.)

FDA 510K Summary for CardioNet ECG Monitor with Arrhythmia Detection (Model CN1004):

- FDA-approved indication: The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

  1) Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g., atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
  2) Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
  3) Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
  4) Patients who require monitoring of effects of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
  5) Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
  6) Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.
  7) Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
  8) Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

FDA 510K Summary for Card Guard CG-6108 Act-3L Continuous ECG Monitor and Arrhythmia Detector:

- FDA-approved indication: The Card Guard CG-6108 Act-3L Continuous ECG Monitor and Arrhythmia Detector intended use is for:

  Individuals who experience transient symptoms that may suggest cardiac arrhythmia.