MEDICAL POLICY

Excellus

SUBJECT: AMBULATORY EVENT MONITORS	EFFECTIVE DATE: 10/08/99 REVISED DATE: 07/19/01, 07/18/02, 06/19/03, 06/17/04, 04/21/05, 02/16/06, 12/21/06, 10/18/07, 11/20/08, 10/29/09, 10/28/10, 10/20/11 ARCHIVED DATE: 10/18/12 EDITED DATE: 10/17/13, 09/18/14, 09/17/15, 10/20/16, 10/21/17, 08/16/18
POLICY NUMBER: 2.01.03 CATEGORY: Technology Assessment	PAGE: 1 OF: 7

- ***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 peer-reviewed literature, use of patient activated or auto-activated external *memory* recording ambulatory event monitors (AEMs) that record and store information for periods longer than 48 hours and up to 14 days have been proven to be medically effective and therefore **medically appropriate** as an alternative to Holter monitoring in patients who experience infrequent symptoms when used to:
   A. Assess signs or symptoms possibly related to rhythm disturbances (e.g., palpitations, serious or significant syncope, near syncope); or
   B. Assess anti-arrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well characterized as reproducible and of sufficient frequency to permit analysis; or
   C. Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered.

II. Based upon our criteria and assessment of peer-reviewed literature, use of implanted ambulatory event monitors, either patient activated or auto-activated, have been proven to be medically effective and therefore **medically appropriate** only for evaluation of recurrent unexplained episodes of pre-syncope, syncope, "seizures", palpitations, or dizziness in patients who meet both of the following criteria:

   a. A cardiac arrhythmia is suspected as the cause of the symptoms; And
   b. Either of the following criteria are met:
      i. Members with heart failure, prior myocardial infarction or significant ECG abnormalities (see below): noninvasive ambulatory monitoring, consisting of 30-day pre-symptom external loop recordings or MCT, fails to establish a definitive diagnosis;
      ii. Members without heart failure, prior myocardial infarction or significant ECG abnormalities and symptoms occur so infrequently and unpredictably (less frequently than once per month) that noninvasive ambulatory monitoring (MCT or external loop recorders) are unlikely to capture a diagnostic ECG.

III. Based upon our criteria and assessment of peer-reviewed literature, standard memory recording AEMs have not been medically proven to improve patient outcomes and are considered **investigational** for all other indications, including but not limited to, the following:
   A. To measure heart rate variability in the assessment of a patients at risk for future cardiac events without symptoms of arrhythmia; or
   B. To monitor patients for myocardial ischemia by detecting ST segment changes.

IV. Based upon our criteria and assessment of peer-reviewed literature, home-based, real-time cardiac surveillance systems (mobile cardiac outpatient telemetry, MCOT) have not been medically proven to improve patient outcomes over standard memory recording devices and are considered **not medically necessary**.

This policy does not address Holter monitoring.

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:

Ambulatory Holter electrocardiography (EKG), which is a noninvasive test used to continuously record an EKG over a specified period of time, usually 24 to 48 hours, is used to evaluate symptoms suggestive of cardiac arrhythmias. It is particularly useful if symptoms occur on a daily or near daily basis. However, Holter monitoring may be ineffective if the patient experiences infrequent symptoms. Ambulatory event monitors (AEMs) were developed to provide longer periods of monitoring and may be useful when the initial evaluation by Holter monitoring is non-diagnostic or when symptoms are infrequent. Ambulatory event monitors (AEMs) are intermittent recorders that can be used for longer periods (weeks to months) of monitoring to provide briefer, intermittent recordings to investigate events that occur infrequently. In this technique, the recording device is either worn continuously and activated when the patient experiences symptoms or applied by the patient only when symptoms occur. Some recorders are implanted under the skin for long-term recordings. AEMs are useful if symptoms are quite brief or if symptoms include only very brief or no patient incapacitation so that the patient, or a companion, can activate the recorder. Cardiac event monitors have been developed with automatic trigger capabilities, which are designed to automatically record when certain preset conditions occur and avoid the need for the patient to activate the device. These devices are often capable of downloading data transtelephonically.

There are several types of AEMs available:

I. *Noncontinuous devices with memory*. These devices are carried by the patient and applied to the precordial area when symptoms occur or alternatively, a recording device may be worn on the wrist and activated when symptoms are present. The limitations are that an arrhythmia may be of short duration and not captured by the device or the patient may be incapacitated and unable to apply the device while symptomatic.

II. *Continuous memory loop devices*. These devices are worn continuously and can continuously store EKG data so that when symptoms occur the patient activates the device and the EKG is recorded from the memory loop for the preceding 30-90 seconds and approximately one minute after. The ZioPatch is capable of continuous recording a single-lead ECG for up to 14 days. The device adheres to the pectoral region and uses a single vector to obtain continuous single-lead ECG data. The patch is equipped with an event button that patients may trigger when experiencing symptoms, highlighting the ECG recording 45 s before and after activation. After monitoring is complete, the patients mails the device to a processing center where the data are analyzed using the manufacturer's algorithm and undergoes technical review, physician over-read and report generation. The ZIO® Event Card (iRhythm Technologies Inc, San Francisco, CA) is a prescription-only, single-use, disposable looping ECG monitor that can be worn for up to 30 days and is capable of holding up to two ECG recordings before the patient transmits data via the phone. When the patient feels a symptom the patient presses the RECORD button and the recording is stored in the device. The patient calls into iRhythm Clinical Centers (iCC) to transmit the data and the recording is reviewed while the patient is still on the phone. A report is generated and posted to a secure site and in certain instances, when the report meets account-specific notification criteria, the physician is contacted.

III. *Implantable continuous memory loop devices.* These devices are inserted under the skin in the chest area during an outpatient surgical procedure. When symptoms occur, the patient activates the hand-held activator over the recorder to activate the storage of cardiac rhythms. The device may be used for more than one year's duration and has a projected battery life of 14 months at which time the device must be surgically removed.

IV. *Auto-triggered devices.* Second generation continuous memory loop devices have an autoactivation component that allows the device to record rhythms automatically if the heart rate exceeds or goes below a preset limit.

V. *Home-based, real-time cardiac surveillance systems*. Also referred to as mobile cardiac outpatient telemetry (MCOT), these systems are automatically activated devices that require no patient intervention to capture or transmit an EKG when the cardiac rhythm violates certain preset alarm limits. Five such systems are currently commercially marketed: The CardioNet system (CardioNet, Inc.), the HEARTLink II system (Cardiac Telecom Corp), the VST™ (Vital Signs Transmitter, Biowatch Medical), and the Lifestar ambulatory cardiac telemetry (ACT) system (Card Guard Scientific Survival Ltd.), and SEEQ™ Mobile Cardiac Telemetry (MCT) Device (Medtronic). These systems allow automatic wireless transmission of abnormal ECG waveforms at the time of event occurrence from the patient's home to an attended monitoring center. In addition, the CardioNet system has a built-in cellular telephone that automatically transmits arrhythmic signals to the monitoring center when the patient is away from home. The SEEQ™ Mobile Cardiac Telemetry (MCT) Device is a wireless device intended for patients experiencing frequent symptoms that require short-term monitoring up to 30 days.

RATIONALE:

AEMs are a well-established technology that is typically used to evaluate episodes of cardiac symptoms (palpitations, dizziness, syncope), that would escape detection on a standard 24 or 48-hour Holter monitor. The use of AEMs assist in the clinical decision making process for treatment of patients experiencing symptoms of cardiac arrhythmia in whom the arrhythmia may not have otherwise been detected and may decrease the risk of morbidity. The diagnostic evaluation of syncope is determined by many factors, and unfortunately, the yield of AEMs in situations with this clinical condition is relatively low according to published peer-reviewed literature.

Other proposed uses of AEMs include evaluating ST segment changes as an indication of myocardial ischemia and assessing asymptomatic patients at risk for future cardiac events. The routine monitoring of asymptomatic patients after myocardial infarction is controversial, while Holter monitoring has been used to detect ST segment changes, it is unclear whether ST segment changes can be reliably detected by an AEM. The interpretation of ST segment change is limited by instability of the isoelectric line, which is in turn dependent on meticulous attention to skin preparation, electrode attachment, and measures to reduce cable movement.

In 1999, the American College of Cardiology in conjunction with the American Heart Association published guidelines for the use of ambulatory electrocardiography. These guidelines did not make an explicit distinction between Holter and ambulatory event monitor monitoring. Regarding the effectiveness of antiarrhythmic therapy, the ACC guidelines list one Class I* indication: "To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well characterized as reproducible and of sufficient frequency to permit analysis." The guidelines do not specify whether Holter monitoring or ambulatory event monitors are most likely to be used. However, the accompanying text notes that intermittent (AEM) monitoring may be used to confirm the presence of an arrhythmia during symptoms. There were no Class I indications for detection of myocardial ischemia. In addition, there were no Class I indications for ambulatory monitoring to assess risk for future cardiac events in patients without symptoms of arrhythmia. This latter category would suggest that routine monitoring of patients after myocardial infarction to detect nonsustained ventricular tachycardia as a risk factor for sudden cardiac death is not routinely recommended. (*Class I is defined as conditions for which there is evidence and/general agreement that a given procedure or treatment is useful and effective).

The AHA/ACCF Scientific Statement on the evaluation of syncope (2006) notes that the major limitation for the use of an event recorder is the complexity of its use, which results in patient errors with acquisition and transmission of data. The introduction of continuously recording monitors that have both patient-activated and automatic triggers appears to improve the diagnostic yield of event monitors. Implantable loop recorders are capable of recording bipolar ECG signals for approximately 14 months. The patient may use an activator to record the rhythm at the time of symptoms, and the device automatically records bradycardia and tachycardia. In patients with unexplained syncope, use of an implantable loop recorder for 1 year yielded diagnostic information in more than 90% of patients. This approach is more likely to

identify the mechanism of syncope than is a conventional approach that uses Holter or event monitors and electrophysiological testing and is cost-effective.

Single-center studies have reported on the diagnostic yield and timing of detection of arrhythmias in patients monitored with the Zio Patch for a variety of arrhythmias. These studies generally have reported greater numbers of arrhythmias detected during extended follow-up compared to 24- or 48-hour Holter monitoring.

Published studies regarding mobile cardiac outpatient telemetry (MCOT) such as CardioNet's Mobile Outpatient Cardiac Telemetry Service, have not demonstrated the incremental value of this system over existing ambulatory event monitoring devices. The role of this device in the diagnosis and treatment strategy of patients with possible cardiac arrhythmias is unknown. Additionally, there are no evidence-based guidelines from professional organizations regarding MCOT. Rothman, et al. (2007) reported a study of 305 patients who were randomized to a LOOP recorder or MCOT for up to 30 days. Results from 266 who completed at least 25 days of monitoring, 132 in the LOOP group and 134 in the MCOT group were analyzed. Of the 39 patients who did not complete the protocol, 20 (13 MCOT and 7 LOOP) did not complete the study due to non-compliance (non-wearing) with the device. A diagnostic endpoint (confirmation/ exclusion of arrhythmic cause of symptoms) was found in 88% of MCOT patients and 75% of LOOP patients ($p = 0.008$). The difference in rates was due primarily to detection of asymptomatic arrhythmias in the MCOT group consisting of rapid atrial fibrillation and/or flutter and ventricular tachycardia. These were thought to be clinically significant rhythm disturbances and the likely causes of the patients' symptoms. The paper does not comment on the clinical impact (changes in management) of these findings in patients for whom the rhythm disturbance did not occur simultaneously with symptoms. In this study, the median time to diagnosis in the total study population was 7 days in the MCOT group and 9 days in the LOOP group. A subset of only 50 patients received autotrigger loop recorders. In this subset, a diagnostic endpoint was found in 46% of the autotrigger LOOP group. The lower yield of the autotrigger loop recorder noted in this study is surprising; others have reported increased yield with this feature (Reiffel JA, et al). Since the autotrigger loop recorders have become a part of the standard diagnostic approach to patients who have infrequent symptoms that are thought likely to be due to arrhythmias, this is the test to which newer technologies must be compared. Further study of MCOT is needed to compare MCOT with the autotrigger loop recorder. MCOT is also being studied in the evaluation of patients who have had ablation procedures (Vasamreddy, et al.), and as a method to measure rhythm and rate control in patients with atrial fibrillation (Prystowsky, et al). Neither of these papers compares MCOT with standard approaches. Based on this analysis and the increased cost of this device, mobile cardiac telemetry is considered not medically necessary.

CODES: Number Description

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.

Code Key: Experimental/Investigational = (E/I), Not medically necessary appropriate = (NMN).

CPT:	33282	Implantation of patient-activated cardiac event recorder
	33284	Removal of implantable, patient-activated cardiac event recorder
	93228 (**NMN)**	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; physician review and interpretation with report

93229 **(NMN)**	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to30-days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional
93270	recording (includes connection, recording, and disconnection)
93271	transmission and analysis
93272	review and interpretation by a physician or other qualified health care professional
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed value with physician analysis, review and report; implantable loop recorder system
93290	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors
93291	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional
93298	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional
93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
0295T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial

		recording)
	0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report
	0298T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation
	0497T	External patient-activated, physician-or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection
	0498T	External patient-activated, physician-or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event
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HCPCS:	C1764	Event recorder, cardiac (implantable)
	E0616	Implantable cardiac event recorder with memory, activator and programmer
ICD10:	I45.6	Pre-excitation syndrome
	I45.89	Other specified conduction disorders
	I45.9	Conduction disorder, unspecified
	I47.0-I47.9	Paroxysmal tachycardia (code range)
	I48.0-I48.92	Atrial fibrillation and flutter (code range)
	I49.01-I49.02	Ventricular fibrillation and flutter (code range)
	I49.2	Junctional premature depolarization
	I49.40	Unspecified premature depolarization
	I49.8-I49.9	Other specified and unspecified cardiac arrhythmias (code range)
	R00.01	Bradycardia, unspecified
	R06.00	Dyspnea, unspecified
	R06.09	Other forms of dyspnea
	R06.3	Periodic breathing
	R06.83	Snoring
	R06.89	Other abnormalities of breathing
	R55	Syncope and collapse
	T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter

REFERENCES:

Agency for Healthcare Research and Quality (AHRQ). Remote cardiac monitoring. Technology Assessment. Contract No. 290-02-0019. Rockville, MD: AHRQ; December 12, 2007 [http://www.cms.gov/determinationprocess/downloads/id51ta.pdf] accessed 09/26/17.

BlueCross BlueShield Association. Ambulatory event monitors. Medical Policy Reference Manual Policy #2.02.08. 2017 May 08.

*Brignole M, et al. Early application of an implantable loop recorder allows effective specific therapy in patients with recurrent suspected neurally mediated syncope. Eur Heart J 2006 May;27(9):1085-92.

*Crawford MH, et al. ACC/AHA guidelines for ambulatory electrocardiography: executive summary and recommendations. A report of the American College of Cardiology/American Heart Association task force on practice guidelines (committee to revise the guidelines for ambulatory electrocardiography). Circ 1999 Aug 24;100(8):886-93.

Eisenberg EE, et al. Chronic ambulatory monitoring: results of a large single-center experience. J Innovations Cardiac Rhythm Manage. Nov 2014;5:1818-1823.

Giada F, et al. Recurrent unexplained palpitations (RUP) study comparison of implantable loop recorder versus conventional diagnostic strategy. J Am Coll Cardiol 2007 May 15;49(19):1951-6

Kadish AH, et al. Frequency of serious arrhythmias detected with ambulatory cardiac telemetry. Am J Cardiol 2010;105:1313-6.

*Krahn AD, et al. Randomized assessment of syncope trial – conventional diagnostic testing versus a prolonged monitoring system. Circ 2001:104(1):46-51.

Leshem-Rubinow E, et al. New real-time loop recorder diagnosis of symptomatic arrhythmia via telemedicine. Clin Cardiol 2011 Jul;34(7):420-425.

Rothman SA, et al. The diagnosis of cardiac arrhythmias: a prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. J Cardiovasc Electrophysiol 2007 Mar;18(3):241-7.

Strickberger SA, et al. AHA/ACCF Scientific Statement on the evaluation of syncope: from the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation: in collaboration with the Heart Rhythm Society: endorsed by the American Autonomic Society. Circulation 2006 Jan 17;113(2):316-27.

* key article

KEY WORDS:

Ambulatory Electrocardiographic (AECG) devices, Cardiac Event Detection (CED), CardioNet, Loop devices, Mobile Cardiac Outpatient Telemetry (MCOT), Ziopatch.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Electrocardiographic (EKG) Services. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=179&ncdver=2&bc=AgAAgAAAAAAA&.