Clinical Policy Bulletin:
Cardiac Event Monitors

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Policy

I. Aetna considers external intermittent cardiac event monitors (i.e., external loop recorders) and external intermittent cardiac event monitors with real-time data transmission and analysis (e.g., eCardio eVolution) medically necessary for any of the following conditions:
   A. To document an arrhythmia in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring (see CPB 0019 - Holter Monitors); or
   B. To document ST segment depression for suspected ischemia; or
   C. To document the benefit after initiating drug therapy for an arrhythmia; or
   D. To document the recurrence of an arrhythmia after discontinuation of drug therapy; or
   E. To document the results after an ablation procedure for arrhythmia; or
   F. To evaluate syncope and lightheadedness in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring.

Aetna considers external loop recorders experimental and investigational—all other indications because their effectiveness for indications other than the ones listed above has not been established.

II. Aetna considers mobile cardiovascular telemetry (MCT) (e.g., CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) Service; Cardiac Telecom and Health Monitoring Services of America’s Telemetry @ Home Service; Heartbreak ECAT (External Cardiac Ambulatory Telemetry) (Med net Healthcare Technologies), HEARTLink™ II ECG Arrhythmia Detector and Alarm System by Cardiac Telecom Corporation, LifeStar ACT by LifeWatch®, Inc., a subsidiary of Card Guard Scientific, SAVI® (Mediacom), Telemetry™ (Scott Care Cardiovascular Solutions) and Trove® (Biomedical Systems)) medically necessary for evaluation of recurrent unexplained episodes of pre-syncope, syncope, palpitations, or dizziness when both of the following criteria are met:
   A. A cardiac arrhythmia is suspected as the cause of the symptoms; and
B. Members have a non-diagnostic Holter monitor, or symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring.

Aetna considers MCT experimental and investigational for other indications because its effectiveness for indications other than the ones listed above has not been established.

III. Aetna considers an implantable loop recorder (e.g., Reveal Insertable Loop Recorder by Medtronic, Inc.) medically necessary for evaluation of recurrent unexplained episodes of presyncope, syncope, "seizures", palpitations, or dizziness when both of the following criteria are met:

A. A cardiac arrhythmia is suspected as the cause of the symptoms; and

B. Either of the following criteria is met:

1. For persons with heart failure, prior myocardial infarction or significant ECG abnormalities (see appendix), noninvasive ambulatory monitoring, consisting of 30-day presymptom external loop recordings or MCT, fails to establish a definitive diagnosis; or

2. For persons without heart failure, prior myocardial infarction or significant ECG abnormalities (see appendix), 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.

Aetna considers implantable loop recorders experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

Note: Depending on clinical presentation, the individual may have had a negative or non-diagnostic electrophysiological study (EPS); however, EPS is no longer considered a prerequisite to insertion of an implantable loop recorder.

IV. Aetna considers the use of long-term (greater than 48 hours) external ECG monitoring by continuous rhythm recording and storage (e.g., Zio Patch) medically necessary for the following indications:

A. To evaluate syncope and lightheadedness in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring (see CPB 0019 - Holter Monitors); or

B. To document an arrhythmia in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring.

V. Aetna considers the AliveCor Heart Monitor (iPhoneECG) experimental and investigational because its clinical value has not been established.

Requests for cardiac event monitoring that do not meet the above criteria and requests for repeat studies within 1 year of a previous study are subject to medical necessity review.
Background

Cardiac event monitors are small portable devices worn by a patient during normal activity for up to 30 days. The device has a recording system capable of storing several minutes of the individual's electrocardiogram (EKG) record. The patient can initiate EKG recording during a symptomatic period of arrhythmia. Cardiac event monitors have primarily been used to diagnose and evaluate cardiac arrhythmias. These monitors are particularly useful in obtaining a record of arrhythmia that would not be discovered on a routine EKG or an arrhythmia that is so infrequent that it is not detected during a 24-hour period by a Holter monitor.

Two different types of cardiac event monitors are available. Pre-symptom (looping memory) event monitors are equipped with electrodes attached to the chest, and are able to capture EKG rhythms before the cardiac event monitor is triggered (pre-symptom recording) (Healthwise, 2003). This feature is especially useful for people who lose consciousness when arrhythmias occur.

Post-symptom event monitors do not have chest electrodes (Healthwise, 2003). One type of post-symptom event monitor is worn on the wrist. When symptoms occur, the patient presses a button to trigger an EKG recording. Another type of post-symptom event monitor is a device that the patient carries within easy reach. When symptoms occur, the patient presses the electrodes on the device against their chest and presses a button to trigger the EKG recording.

Cardiac event monitors have been developed with automatic trigger capabilities, which are designed to automatically trigger an EKG recording when certain arrhythmias occur. Automated trigger cardiac event monitors are thought to be more sensitive, but less specific, than manually-triggered cardiac event monitors for significant cardiac arrhythmias. The simplest automatic trigger cardiac event monitors detect a single type of arrhythmia (e.g., atrial fibrillation), whereas more sophisticated monitors are capable of detecting several types of arrhythmias (e.g., PDSHEART, 2001; Instromedix, 2002; LifeWatch, 2004; Medicomp, 2005; eCardio Diagnostics, 2004). Automatic trigger cardiac event monitors may be especially useful for persons with asymptomatic arrhythmias, persons with syncope, and other persons (children, mentally retarded persons) who can not reliably trigger the monitor when symptoms occur.

Cardiac event monitors may come with 24-hour remote monitoring. Usually, EKG results are transmitted over standard phone lines at the end of each day to an attended monitoring center, where a technician screens EKG results and notifies the patient's physician of any significant abnormal results, based on predetermined notification criteria. Newer cardiac event monitors allow EKG results to be transmitted via e-mail over the internet (CardioPhonics, 2006). Some cardiac event monitors allow the patient to transmit EKG over standard telephone lines to the attended monitoring center immediately after symptoms occur (e.g., Versweyveld, 2001; Transmedex, 2001); other cardiac event monitors have been adapted to also allow immediate transmission of EKG results by cellular telephone (Philips, 2003; Schiller, 2004; CRY, 2004; HealthFrontier, 2004). If test results suggest a life-threatening emergency, monitoring center personnel may instruct the patient to go to the hospital or call an ambulance (Daja et al, 2001). The development of mobile technology may extend the use of cardiac event monitors from primarily diagnostic purposes to use primarily as an alarm system, to allow rapid intervention for the elderly and others at increased risk of cardiac events (Cox, 2003; Lloyds, 1999).

Standard cardiac event monitors come with 5 to 10 mins of memory. Cardiac event monitors with expanded memory capabilities have been developed, extending memory from approximately 20 to 30 mins (Instromedix, 2002; LifeWatch, 2002; Philips Medical Systems, 2003; PDSHeart, 2006) to
as much as several hours (CardioPhonics, 2001; CardioPhonics, 2006). Extended memory is especially useful for automatic trigger cardiac event monitors, because the automatic trigger may not reliably discriminate between clinically significant arrhythmias (true positives) and EKG artifacts (false positives), such that a more limited memory would be filled with false positives.

Mobile cardiovascular telemetry (MCT) refers to non-invasive ambulatory cardiac event monitors with extended memory capable of continuous measurement of heart rate and rhythm over several days, with transmission of results to a remote monitoring center. Mobile cardiovascular telemetry is similar to standard cardiac telemetry used in the hospital setting.

CardioNet (Philadelphia, PA) has developed an MCT device with extended memory, automatic ECG arrhythmia detector and alarm that is incorporated into a service that CardioNet has termed “Mobile Cardiac Outpatient Telemetry (MCOT).” The CardioNet device couples an automatic arrhythmia detector and cellular telephone transmission so that abnormal EKG waveforms can automatically be transmitted immediately to the remote monitoring center. The CardioNet device also has an extended memory characteristic of digital Holter monitors; the CardioNet device is capable of storing up to 96 hours of EKG waveforms. These ECG results are transmitted over standard telephone lines to the remote monitoring center at the end of each day. The physician receives both urgent and daily reports.

The manufacturer states that an important advantage of MCOT is that it is capable of detecting asymptomatic events and transmitting them immediately, even when the patient is away from home, allowing timely intervention should a life-threatening arrhythmia may occur. The CardioNet device’s extended memory allows the physician to examine any portion of the ECG waveform over an entire day. This extended memory ensures that it does not fill with EKG artifact (false positives) where the CardioNet’s automated ECG trigger is unable to reliably discriminate between artifact and significant arrhythmias (true positives). Potential uses of MCOT include diagnosis of previously unrecognized arrhythmias, ascertainment of cause of symptoms, and initiation of anti-arrhythmic drug therapy.

The CardioNet ambulatory ECG arrhythmia detector and alarm is cleared for marketing by the Food and Drug Administration (FDA) based on a 510(k) premarket notification due to the FDA’s determination that the CardioNet device was substantially equivalent to devices that were currently on the market. The CardioNet device is not intended for monitoring patients with life-threatening arrhythmias (FDA, 2002).

There is reliable evidence that MCT is superior to patient-activated external loop recorders for diagnosing cardiac arrhythmias. Rothman et al (2007) reported on a randomized controlled clinical study comparing the diagnostic yield of MCT (CardioNet MCOT) to patient-activated external looping event monitors for symptoms thought to be due to an arrhythmia. Subjects with symptoms of syncope, pre-syncope, or severe palpitations who had a non-diagnostic 24-hour Holter monitor were randomized to MCT or an external loop recorder for up to 30 days. The primary endpoint was the confirmation or exclusion of a probable arrhythmic cause of their symptoms. A total of 266 patients who completed the monitoring period were analyzed. A diagnosis was made in 88% of MCT subjects compared to 75% of subjects with standard loop recorders (p = 0.008). The authors noted that cardiac arrhythmias without associated symptoms, but nonetheless capable of causing the index symptoms, were the major determining factor accounting for the difference in diagnostic yield of MCT and patient-activated external loop recorders.

There is also evidence to suggest that MCT is superior to auto-triggered external loop recorders for diagnosing symptoms thought to be due to a cardiac arrhythmia. Loop recorders with auto-trigger algorithms have been used to improve the diagnostic yield of event monitors (Strickberger et al, 2006). Rothman et al (2007) explained that their study of MCT was not designed to evaluate auto-
triggered loop recorders, as this type of recorder was not available at all study sites. However, 2 of the 17 study sites used looping event recorders with an auto-trigger algorithm in all of their randomized patients (Rothman et al, 2007). A total of 49 subjects, or 16% of the randomized population were from these 2 sites. In a post-hoc analysis of this subgroup of patients, a diagnosis was made in 88% of MCT subjects compared to 46% of patients with auto-triggered external loop recorders. One possible factor accounting for the poor diagnostic yield of the auto-trigger loop recorders employed in this study is that they may have had limited memory which quickly filled with artifact. In addition, the CardioNet MCOT device used in this study uses dual EKG leads, whereas the auto-trigger loop recorders may have used single leads.

One limitation of the study by Rothman et al (2007) was the lack of blinding of the investigators or subjects. The investigators sought to overcome this bias by having all monitoring strips and diagnoses evaluated by another electrophysiologist that was blinded to assignment. Another limitation of this study is that it did not explore the potential for work-up bias; the study did not describe whether any of the study subjects had ever had previous work-ups for cardiac arrhythmias that included evaluation with an external loop recorder.

A number of retrospective uncontrolled studies have been published that have described the experience with MCT. Olson et al (2007) retrospectively examined the records of 122 consecutive patients evaluated using MCT for palpitations (n = 76), pre-syncpe/syncope (n = 17), or to monitor the effectiveness of anti-arrhythmic therapy (n = 29). The investigators reported on the proportion of patients with syncpe/pre-syncpe and palpitations whose diagnosis was established by MCT, and the proportion of patients monitored for medication titration who had dosage adjustments. This study is of similar design to an earlier study by Joshi et al (2005), which reported on the first 100 consecutive patients monitored by MCT.

Vasamreddy et al (2006) reported on a small (n = 19) prospective exploratory study examining the feasibility and results of using MCT for monitoring patients with atrial fibrillation before and after catheter ablation for atrial fibrillation. The authors concluded that MCT has potential utility for this use. The authors noted, however, that poor patient compliance with the study's MCT monitoring protocol represented an important limitation; only 10 of 19 subjects that were enrolled in the study completed the protocol, which required subjects to wear the MCT monitor 5 days per month for 6 months following the ablation.

Cardiac Telecom Corporation (Greensburg, PA) and Health Monitoring Services of America (Boca Raton, FL) have developed an MCT service called "Telemetry @ Home" that shares many similarities to the CardioNet Service. The Telemetry @ Home Service utilizes Cardiac Telecom’s Heartlink II Monitor, which has automatic arrhythmia detection and extended memory. The Heartlink II Monitor is able to wirelessly transmit abnormal EKG waveforms from a base station in the home to a remote monitoring center. Unlike the CardioNet Service, the Heartlink II Monitor does not have a built-in cellular telephone, so that the monitor does not automatically transmit abnormal waveforms when the patient is away from home out of range of the base station. The Heartlink II Monitor was cleared by the FDA based upon a 510(k) premarket notification.

Biowatch Medical (Columbia, SC) offers an MCT service called "Vital Signs Transmitter (VST)" that shares many similarities to other MCT services. According to the manufacturer, VST provides continuous, real-time, wireless ambulatory patient monitoring of 2 ECG channels plus respiration and temperature (Biowatch Medical. 2008; Gottipaty et al, 2008). The VST is a wireless belt-like device with non-adhesive electrodes that is worn around the patient's chest. The VST has an integrated microprocessor and wireless modem to automatically detect and transmit abnormal ECG waveforms. The monitor transmits ECG data via an integrated cellular telephone, when activated by the patient or by the monitor's real-time analysis software, to a central monitoring station, where
the tracing is analyzed by technicians. The technicians can then notify the patient’s physician of any serious arrhythmias, transmit ECG tracings, and provide patient intervention if required. The monitoring center also provides daily reports that can be accessed by the patient’s physician over the Internet. According to the manufacturer, a new VST device is being developed that will also provide data on the patient’s oxygen saturation, blood pressure, and weight (Biowatch Medical, 2008). The VST was cleared by the FDA based on a 510(k) premarket notification.

Lifewatch Inc. (Rosemount, IL) has developed an MCT service called LifeStar Ambulatory Cardiac Telemetry (ACT). The LifeStar ACT is similar to the CardioNet MCOT in that it has built-in cellular transmission so that results can be transmitted away from home. The LifeStar ACT cardiac monitoring system utilizes an auto-trigger algorithm to detect atrial fibrillation, tachycardia, bradycardia, and pauses, and requires no patient intervention to capture or transmit an arrhythmia when it occurs. The device can also be manually triggered by the patient during symptoms. Upon arrhythmia detection or manual activation, the LifeStar ACT transmits data via the integrated cellular telephone to LifeWatch, where the ECG is analyzed. The LifeStar ACT has a longer continuous memory loop that can be retrieved as needed by the monitoring center. The LifeWatch ACT was cleared by the FDA based on a 510(k) premarket notification.

A systematic evidence review of remote cardiac monitoring prepared for the Agency for Healthcare Research and Quality by the ECRI Evidence-based Practice Center (AHRQ, 2007) reached the following conclusions about the evidence for MCT: “This study [by Rothman et al, 2007] was a high-quality multicenter study with few limitations. Therefore, the evidence is sufficient to conclude that real-time continuous attended monitoring leads to change in disease management in significantly more patients than do certain ELRs [external loop recorders]. However, because this is a single multicenter study, the strength of evidence supporting this conclusion is weak. Also, the conclusion may not be applicable to ELRs with automatic event activation, as this model was underrepresented in the RCT [by Rothman et al, 2007] (only 16% of patients used this model).”

The Zio Patch (iRhythm Technologies, Inc., San Francisco, CA) is a recording device that provides continuous single-lead ECG data for up to 14 days (Mittal et al, 2011). The Zio Patch uses a patch that is placed on the left pectoral region. The patch does not require patient activation. However, a button on the patch can be pressed by the patient to mark a symptomatic episode. At the end of the recording period, the patient mails back the recorder in a prepaid envelope to a central monitoring station (Mittal et al, 2011). A report is provided to the ordering physician within a few days. The manufacturer states that it is indicated for use in patients who may be asymptomatic or who may suffer from transient symptoms (e.g., anxiety, dizziness, fatigue, light-headedness, palpitations, presyncope, shortness of breath, and syncope). The Zio ECG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received ECG data captured by long-duration, single-lead, continuous recording diagnostic devices (e.g., the Zio Patch and Zio Event Card). However, the clinical outcomes and cost-effectiveness of extended cardiac monitoring by means of the Zio Patch, the ZEUS system and similar devices have not been shown to be superior to other available approaches. Mittal et al (2011) noted that “clinical experience [with the Zio Patch] is currently lacking”. The author stated that it is not known how well patients can tolerate the patch for 1 to 2 weeks, and whether the patch can yield a high-quality artifact-free ECG recording through the entire recording period. The authors stated, furthermore, that “the clinical implications of not having access to ECG information within the recording period need to be determined”.

Rosenberg et al (2013) compared the Zio Patch, a single-use, non-invasive waterproof long-term continuous monitoring patch, with a 24-hour Holter monitor in 74 consecutive patients with paroxysmal atrial fibrillation (AF) referred for Holter monitoring for detection of arrhythmias. The Zio Patch was well-tolerated, with a mean monitoring period of 10.8 +/- 2.8 days (range of 4 to 14 days).
Over a 24-hour period, there was excellent agreement between the Zio Patch and Holter for identifying AF events and estimating AF burden. Although there was no difference in AF burden estimated by the Zio Patch and the Holter monitor, AF events were identified in 18 additional individuals, and the documented pattern of AF (persistent or paroxysmal) changed in 21 patients after Zio Patch monitoring. Other clinically relevant cardiac events recorded on the Zio Patch after the first 24 hours of monitoring, including symptomatic ventricular pauses, prompted referrals for pacemaker placement or changes in medications. As a result of the findings from the Zio Patch, 28.4 % of patients had a change in their clinical management. The authors concluded that the Zio Patch was well-tolerated, and allowed significantly longer continuous monitoring than a Holter, resulting in an improvement in clinical accuracy, the detection of potentially malignant arrhythmias, and a meaningful change in clinical management. Moreover, they stated that further studies are necessary to examine the long-term impact of the use of the Zio Patch in AF management.

Turakhia and colleagues (2013) noted that although extending the duration of ambulatory electrocardiographic monitoring beyond 24 to 48 hours can improve the detection of arrhythmias, lead-based (Holter) monitors might be limited by patient compliance and other factors. These researchers, therefore, evaluated compliance, analyzable signal time, interval to arrhythmia detection, and diagnostic yield of the Zio Patch, a novel leadless, electrocardiographic monitoring device in 26,751 consecutive patients. The mean wear time was 7.6 ± 3.6 days, and the median analyzable time was 99 % of the total wear time. Among the patients with detected arrhythmias (60.3 % of all patients), 29.9 % had their first arrhythmia and 51.1 % had their first symptom-triggered arrhythmia occur after the initial 48-hour period. Compared with the first 48 hours of monitoring, the overall diagnostic yield was greater when data from the entire Zio Patch wear duration were included for any arrhythmia (62.2 % versus 43.9 %, p < 0.0001) and for any symptomatic arrhythmia (9.7 % versus 4.4 %, p < 0.0001). For paroxysmal atrial fibrillation (AF), the mean interval to the first detection of AF was inversely proportional to the total AF burden, with an increasing proportion occurring after 48 hours (11.2 %, 10.5 %, 20.8 %, and 38.0 % for an AF burden of 51 % to 75 %, 26 % to 50 %, 1 % to 25 %, and less than 1 %, respectively). The authors concluded that extended monitoring with the Zio Patch for less than or equal to 14 days is feasible, with high patient compliance, a high analyzable signal time, and an incremental diagnostic yield beyond 48 hours for all arrhythmia types. These findings could have significant implications for device selection, monitoring duration, and care pathways for arrhythmia evaluation and AF surveillance.

Higgins (2013) stated that a number of substantial improvements to the 60-year old concept of the Holter monitor have recently been developed. One promising advance is the Zio Patch (iRhythm Technologies, Inc., CA), a small 2 × 5-inch patch, which can continuously record up to 14 days of a single ECG channel of cardiac rhythm without the need for removal during exercise, sleeping or bathing. Its ease-of-use, which enables optimal long-term monitoring, has been established in the ambulatory setting, although some insurance carriers have been reluctant to reimburse appropriately for this advance, an issue characteristic of other heart monitors, treated as ‘loss-leaders’. In this article, in addition to discussing possible reasons for this reluctance, a novel model for direct-to-consumer marketing of heart monitoring, outside of the traditional health insurance reimbursement model, is also presented. Additional current and future advances in heart rhythm recording are also discussed. Such potentially revolutionary opportunities have only recently become possible as a result of technologic advances.

The Center for Medicare and Medicaid Services (CMS) (2004) has determined that an ambulatory cardiac monitoring device or service is eligible for Medicare coverage only if it can be placed into the following categories:
Cardiac Event Monitors

I. Patient/Event Activated Intermittent Recorders:

A. Pre-symptom memory loop (insertable or non-insertable)
   - Attended;
   - Non-attended.

B. Post-symptom (no memory loop)
   Non-attended

II. Non-activated Continuous Recorders:

Dynamic electrocardiography (e.g., Holter monitor)
Non-attended.

The CMS has determined that an ambulatory cardiac monitoring device or service is not covered if it does not fit into these categories. The CMS noted that it may create new ambulatory electrocardiographic monitoring device categories "if published, peer-reviewed clinical studies demonstrate evidence of improved clinical utility, or equal utility with additional advantage to the patient, as indicated by improved patient management and/or improved health outcomes in the Medicare population (such as superior ability to detect serious or life-threatening arrhythmias) as compared to devices or services in the currently described categories".

Hanke et al (2009) noted that 24-hr Holter monitoring (24HM) is commonly used to assess cardiac rhythm after surgical therapy of atrial fibrillation (AF). However, this "snapshot" documentation leaves a considerable diagnostic window and only stores short-time cardiac rhythm episodes. To improve accuracy of rhythm surveillance after surgical ablation therapy and to compare continuous heart rhythm surveillance versus 24HM follow-up intra-individually, these investigators evaluated a novel implantable continuous cardiac rhythm monitoring (IMD) device (Reveal XT 9525, Medtronic Inc., Minneapolis, MN). A total of 45 cardiac surgical patients (male 37, mean age of 69.7 +/- 9.2 years) with a mean pre-operative AF duration of 38 +/- 45 m were treated with either left atrial epicardial high-intensity focus ultrasound ablation (n = 33) or endocardial cryothermy (n = 12) in case of concomitant mitral valve surgery. Rhythm control readings were derived simultaneously from 24HM and IMD at 3-month intervals with a total recording of 2,021 hours for 24HM and 220,766 hours for IMD. Mean follow-up was 8.30 +/- 3.97 m (range of 0 to 12 m). Mean post-operative AF burden (time period spent in AF) as indicated by IMD was 37 +/- 43 %. Sinus rhythm was documented in 53 readings of 24HM, but in only 34 of these instances by the IMD in the time period before 24HM readings (64 %, p < 0.0001), reflecting a 24HM sensitivity of 0.60 and a negative-predictive value (NPV) of 0.64 for detecting AF recurrence. The authors concluded that for "real-life" cardiac rhythm documentation, continuous heart rhythm surveillance instead of any conventional 24HM follow-up strategy is necessary. This is particularly important for further judgment of ablation techniques, devices as well as anti-coagulation and anti-arrhythmic therapy.

Hindricks et al (2010) quantified the performance of the first implantable leadless cardiac monitor (ICM) with dedicated AF detection capabilities. Patients (n = 247) with an implanted ICM who were likely to present with paroxysmal AF were selected. A special Holter device stored 46 hours of subcutaneously recorded ECG, ICM markers, and 2 surface ECG leads. The ICM automatic arrhythmia classification was compared with the core laboratory classification of the surface ECG. Of the 206 analyzable Holter recordings collected, 76 (37 %) contained at least 1 episode of core laboratory classified AF. The sensitivity, specificity, positive-predictive value, and NPV for

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identifying patients with any AF were 96.1%, 85.4%, 79.3%, and 97.4%, respectively. The AF burden measured with the ICM was very well-correlated with the reference value derived from the Holter (Pearson coefficient = 0.97). The overall accuracy of the ICM for detecting AF was 98.5%. The authors concluded that in this ICM validation study, the dedicated AF detection algorithm reliably detected the presence or absence of AF and the AF burden was accurately quantified.

Ip et al (2012) examined the outcomes of surgical ablation and post-ablation AF surveillance with a leadless ICM. A total of 45 patients with drug-refractory paroxysmal or persistent AF underwent video-assisted epicardial ablation using a bipolar radiofrequency clamp. An ICM was implanted subcutaneously post-ablation to assess AF recurrence. AF recurrence was defined as greater than or equal to 1 AF episode with a duration of greater than or equal to 30 s. The device-stored data were down-loaded weekly over the internet, and all transmitted events were reviewed. A total of 1,220 AF automatic and patient-activated AF episodes were analyzed over a follow-up of 12 +/- 3 months. Of these episodes, 46% were asymptomatic. Furthermore, only 66% of the patient-activated episodes were AF. Recurrence of AF was highest in first 4 weeks and substantially decreased 6 months post-ablation. The overall freedom from AF recurrence at the end of follow-up was 60%. When 48-hr Holter recordings were compared with the device-stored episodes, the sensitivity of the device to detect AF was 98%, and the specificity was 71%. The authors concluded that ICM provides an objective measure of AF ablation success and may be useful in making clinical decisions.

The AliveCor Heart Monitor (AliveCor, Inc., San Francisco, CA) is an iPhone-enabled heart monitor that has been known as the “iPhoneECG”. It is in a thin case with 2 electrodes that snaps onto the back of an iPhone 4 or 5. To obtain an electrocardiogram (ECG) recording, the patient just holds the device while pressing fingers from each hand onto the electrodes. The device can also obtain an ECG from the patient's chest. The AliveCor ECG iPhone application can record rhythm strips of any duration to be stored on the phone and uploaded securely for later analysis, sharing, or printing through AliveCor's website. The AliveCor Heart Monitor will operate for about 100 hours on a 3.0 V coin cell battery.

However, there is currently a lack of evidence to support the clinical value of the AliveCor Heart Monitor. Prospective, randomized controlled studies are needed to ascertain how the use of the AliveCor Heart Monitor would improve clinical outcomes in patients with cardiovascular diseases/disorders.

According to the company, research studies are currently in progress to explore effectiveness of the AliveCor Heart Monitor in the following areas: [http://www.medgadget.com/2012/12/alivecor-iphone-ecg-receives-fda-clearance.html](http://www.medgadget.com/2012/12/alivecor-iphone-ecg-receives-fda-clearance.html)

- Expanding physician assistant/registered nurse data collection abilities
- Long-term atrial fibrillation remote monitoring
- Medication-induced QT-duration response monitoring
- Multi-specialty care integration
- Post-ablation follow-up
- Preventive pediatric care
- Stress induced rhythm morphology changes

The implantable loop recorder (ILR) is a subcutaneous, single-lead, ECG monitoring device used for diagnosis in patients with recurrent unexplained episodes of palpitations or syncope. The 2009 ESC syncope guidelines include the following recommendations for use of ILRs:
ILR is indicated for early phase evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria (see appendix), and a high likelihood of recurrence within the battery life of the device.

An ILR is recommended in patients who have high-risk features (see appendix) in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment.

An ILR should be considered to assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain reflex syncope with frequent or traumatic syncopal episodes.

Ziegler et al (2012) stated that the detection of undiagnosed atrial tachycardia/atrial fibrillation (AT/AF) among patients with stroke risk factors could be useful for primary stroke prevention. These researchers analyzed newly detected AT/AF (NDAF) using continuous monitoring in patients with stroke risk factors but without previous stroke or evidence of AT/AF. Newly detected AT/AF (AT/AF greater than 5 mins on any day) was determined in patients with implantable cardiac rhythm devices and greater than or equal to 1 stroke risk factors (congestive heart failure, hypertension, age greater than or equal to 75 years, or diabetes). All devices were capable of continuously monitoring the daily cumulative time in AT/AF. Of 1,368 eligible patients, NDAF was identified in 416 (30%) during a follow-up of 1.1 ± 0.7 years and was unrelated to the CHADS2 score (congestive heart failure, hypertension [blood pressure consistently greater than 140/90 mm Hg or hypertension treated with medication], age greater than or equal to 75 years, diabetes mellitus, previous stroke or transient ischemic attack). The presence of AT/AF greater than 6 hours on greater than or equal to 1 day increased significantly with increased CHADS2 scores and was present in 158 (54 %) of 294 patients with NDAF and a CHADS2 score of greater than or equal to 2. Newly detected AT/AF was sporadic, and 78 % of patients with a CHADS2 score of greater than or equal to 2 with NDAF experienced AT/AF on less than 10 % of the follow-up days. The median interval to NDAF detection in these higher risk patients was 72 days (interquartile range: 13 to 177). The authors concluded that continuous monitoring identified NDAF in 30 % of patients with stroke risk factors. In patients with NDAF, AT/AF occurred sporadically, high-lighting the difficulty in detecting paroxysmal AT/AF using traditional monitoring methods. However, AT/AF also persisted for greater than 6 hours on greater than or equal to 1 day in most patients with NDAF and multiple stroke risk factors. Whether patients with CHADS2 risk factors but without a history of AF might benefit from implantable monitors for the selection and administration of anti-coagulation for primary stroke prevention merits additional investigation.

Cotter et al (2013) examined the usefulness of ILR with improved AF detection capability (Reveal XT) and the factors associated with AF in the setting of unexplained stroke. A cohort study was reported of 51 patients in whom ILRs were implanted for the investigation of ischemic stroke for which no cause had been found (cryptogenic) following appropriate vascular and cardiac imaging and at least 24 hours of cardiac rhythm monitoring. Age of patients ranged from 17 to 73 (median of 52) years. Of the 30 patients with a shunt investigation, 22 had a patent foramen ovale (73.3 %; 95 % CI: 56.5 % to 90.1 %). Atrial fibrillation was identified in 13 (25.5 %; 95 % CI: 13.1 % to 37.9 %) cases. Atrial fibrillation was associated with increasing age ($p = 0.018$), inter-atrial conduction block ($p = 0.02$), left atrial volume ($p = 0.025$), and the occurrence of atrial premature contractions on preceding external monitoring ($p = 0.004$). The median (range) of monitoring prior to AF detection was 48 (0 to 154) days. The authors concluded that in patients with unexplained stroke, AF was detected by ILR in 25.5 %. Predictors of AF were identified, which may help to target investigations. They stated that ILRs may have a central role in the future in the investigation of patients with unexplained stroke.
Mittal et al (2013) stated that in patients with atrial flutter who undergo cavo-tricuspid isthmus ablation, long-term ECG monitoring may identify new onset of AF. These investigators ascertained, through the use of an ILR with a dedicated AF detection algorithm, the incidence, duration, and burden of new AF in these patients and developed an optimal post-ablation ECG monitoring strategy. These researchers enrolled 20 patients with flutter, a CHADS2 score of 2 to 3, and no prior episode of AF. After cavo-tricuspid isthmus ablation, these investigators implanted an ILR, which was interrogated routinely; all stored ECGs were adjudicated. During a mean follow-up of 382 ± 218 days, 3 patterns were observed: (i) in 11 (55 %) patients, stored ECGs confirmed AF at 62 ± 38 days after ablation; (ii) in 4 (20 %) patients, although the ILR suggested AF, episodes actually represented sinus rhythm with frequent premature atrial contractions and/or over-sensing; (iii) in 5 (25 %) patients, no AF was observed. Episodes less than 4 hours were associated with low AF burden (less than 1 %) or false detections. The 1-year freedom from any episode of AF greater than 4 and greater than 12 hours was 52 % and 83 %, respectively. The authors concluded that these findings showed that many (but not all) patients develop new AF within the first 4 months of flutter ablation. Since external ECG monitoring for this duration is impractical, the ILR has an important role for long-term AF surveillance. They stated that future research should be directed toward identifying the relationship between duration/burden of AF and stroke and improving existing ILR technology.

An UpToDate review on “Cryptogenic stroke” (Prabhakaran and Elkind, 2013) states that “Paroxysmal atrial fibrillation (AF), if transient, infrequent, and largely asymptomatic, may be undetected on standard cardiac monitoring such as continuous telemetry and 24 or 48-hour Holter monitors. In a study that assessed longer-term monitoring using an outpatient telemetry system for a median duration of 21 days among 56 patients with cryptogenic stroke, paroxysmal AF was detected in 13 patients (23 %). The median time to detection of AF was 7 days. The majority of patients with paroxysmal AF were asymptomatic during the fleeting episodes. Other reports have noted that the detection rate of paroxysmal AF can be increased with longer duration of cardiac monitoring, and that precursors of AF such as frequent premature atrial contractions may predict those harboring paroxysmal AF. The optimal monitoring method -- continuous telemetry, ambulatory electrocardiography, serial electrocardiography, transtelephonic ECG monitoring, or implantable loop recorders -- is uncertain, though longer durations of monitoring are likely to obtain the highest diagnostic yield”.

Appendix

Table: Short-Term High Risk Criteria Which Require Prompt Hospitalization or Intensive Evaluation

<p>| Severe structural or coronary artery disease (heart failure, low LVEF, or previous myocardial infarction) |</p>
<table>
<thead>
<tr>
<th>Clinical or ECG features suggesting arrhythmic syncope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syncope during exertion or supine</td>
</tr>
<tr>
<td>Palpitations at the time of syncope</td>
</tr>
<tr>
<td>Family history of SCD</td>
</tr>
<tr>
<td>Non-sustained VT</td>
</tr>
<tr>
<td>Bifascicular-block (LBBB or RBBB combined with left anterior or left posterior fascicular block) or other intraventricular conduction abnormalities with QRS duration ≥120 ms</td>
</tr>
<tr>
<td>Inadequate sinus bradycardia (&lt;50 bpm) or sinoatrial block in absence of negative chronotropic medications or physical training</td>
</tr>
<tr>
<td>Pre-excited QRS complex</td>
</tr>
</tbody>
</table>
Prolonged or short QT interval
RBBB pattern with ST-elevation in leads V1-V3 (Brugada pattern)
Negative T waves in right precordial leads, epsilon waves, and ventricular late potentials suggestive of ARVC

**Important co-morbidities**

Severe anemia
Electrolyte disturbance

*Key:* ARVC: arrhythmogenic right ventricular cardiomyopathy; bpm: beats per minute; LBBB: left bundle branch block; LVEF: left ventricular ejection fraction; RBBB: right bundle branch block; SCD: sudden cardiac death; VT: ventricular tachycardia.


**CPT Codes / HCPCS Codes / ICD-9 Codes**

*External intermittent cardiac event monitors (i.e., external loop recorders) and external intermittent cardiac event monitors with real-time data transmission and analysis:*

**CPT codes covered if selection criteria are met:**

93268 External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 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 preview and interpretation by a physician or other qualified health care professional

**Other CPT codes related to the CPB:**

93224 - 93227 Electrocardiographic monitoring [Holter monitors and other event recording]

**ICD-9 codes covered if selection criteria are met:**

426.0 - 426.9 Conduction disorders [in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia or syncope is unlikely to be diagnosed by Holter monitoring]

427.0 - 427.9 Cardiac dysrhythmias [in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such
that the arrhythmia or syncope is unlikely to be diagnosed by Holter monitoring]

780.2 Syncope and collapse [in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia or syncope is unlikely to be diagnosed by Holter monitoring]

780.4 Dizziness and giddiness [light-headedness] [in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia or syncope is unlikely to be diagnosed by Holter monitoring]

785.1 Palpitations

ICD-9 Codes not covered for indications listed in the CPB (not all-inclusive):

430 - 438.9 Cerebrovascular disease [management of stroke]

Other ICD-9 codes related to the CPB:

410.00 - 414.9 Ischemic heart disease [to document ST segment depression for suspected ischemia]

V15.1 Personal history of surgery to heart and great vessels [ablation procedure for arrhythmia]

V58.69 Long-term (current) use of other medications [to document the benefit after initiating drug therapy for arrhythmia]

Mobile cardiovascular telemetry (MCT):

CPT codes covered if selection criteria are met:

93228 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; review and interpretation with report by a physician or other qualified health care professional

93229 Technical support for connection and patient instructions for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional

ICD-9 codes covered if selection criteria are met:

[continued...a cardiac arrhythmia is suspected as the cause in members that have a non-diagnostic Holter monitor, or symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring]

426.0 - 426.9 Conduction disorders
427.0 - 427.9  Cardiac dysrhythmias

780.2  Syncope and collapse [pre-syncope]

780.4  Dizziness and giddiness [light-headedness]

785.1  Palpitations

**Implantable loop recorder:**

**CPT codes covered if selection criteria are met:**

33282  Implantation of patient-activated cardiac event recorder

33284  Removal of an implantable, patient-activated cardiac event recorder

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 values with analysis, review and report by a physician or other qualified health care professional; implantable loop recorder system

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

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  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

**HCPCS codes covered if selection criteria are met:**

C1764  Event recorder, cardiac (implantable)

E0616  Implantable cardiac event recorder with memory, activator, and programmer

**ICD-9 codes covered if selection criteria are met:**

412  Old myocardial infarction [noninvasive ambulatory monitoring consisting of 30-day presymptom external loop recordings or MCT fails to establish a definitive diagnosis]

428.0 - 428.9  Heart failure [noninvasive ambulatory monitoring consisting of 30-day presymptom external loop recordings or MCT fails to establish a definitive diagnosis]

780.2  Syncope and collapse [pre-syncope] [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

780.39  Other convulsions [seizures NOS] [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]

780.4  Dizziness and giddiness [light-headedness] [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]

785.1  Palpitations [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]

794.31  Abnormal electrocardiogram [ECG] [EKG] [significant ECG abnormalities & noninvasive ambulatory monitoring consisting of 30-day presymptom external loop recordings or MCT fails to establish a definitive diagnosis]

Long-term (greater than 48 hours) external ECG monitoring by continuous rhythm recording and storage:

CPT codes covered if selection criteria are met:

0295T - 0298T  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 [Zio Patch]

ICD-9 codes covered if selection criteria are met [in persons with a non-diagnostic Holter monitor, or in persons whose symptoms occur infrequently (less frequently than daily) such that the arrhythmia is unlikely to be diagnosed by Holter monitoring]:

426.0 - 426.9  Conduction disorders
427.0 - 427.9  Cardiac dysrhythmias
780.2  Syncope and collapse [pre-syncope]
780.4  Dizziness and giddiness [light-headedness]
785.1  Palpitations

AliveCor Heart Monitor (iPhoneECG):

CPT codes not covered for indications listed in the CPB:

93040  Rhythm ecg, one to three leads; with interpretation and report

HCPCS codes not covered for indications listed in the CPB:

No specific code
Appendix - Short-Term High Risk Criteria Which Require Prompt Hospitalization or Intensive Evaluation:

Other ICD-9 codes related to the CPB:

412 Old myocardial infarction

428.0 - 428.9 Heart failure

794.31 Abnormal electrocardiogram [ECG] [EKG]

The above policy is based on the following references:


34. LifeWatch, Inc. and Instromedix. LifeWatch and Instromedix announce launch of cardiac event monitors with automatic afib detection [press release]. San Diego, CA: Instromedix;


94. Davis S, Westby M, Pitcher D, Petkar S. Implantable loop recorders are cost-effective when used to investigate transient loss of consciousness which is either suspected to be arrhythmic or remains unexplained. Europace. 2012;14(3):402-409.


