Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

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Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for ambulatory event monitors when the criteria below are met. BCBSKC will not provide coverage for mobile cardiac outpatient telemetry.

When Policy Topic is covered
The use of patient-activated or auto-activated external ambulatory event monitors may be considered medically necessary as a diagnostic alternative to Holter monitoring in the following situations:
- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope).
- Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered.
- Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor.

The use of implantable ambulatory event monitors, either patient-activated or auto-activated, may be considered medically necessary only in the small subset of patients who experience recurrent symptoms so infrequently that a prior trial of other external ambulatory event monitors has been unsuccessful.

When Policy Topic is not covered
Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) as a diagnostic alternative to ambulatory event monitors in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope) are expected to result in outcomes that are equivalent to alternatives such as autotrigger devices, but may be more costly than alternatives. In this situation, the more costly alternative may be considered not medically necessary. (See Considerations).

Other uses of ambulatory event monitors, including outpatient cardiac telemetry, are considered investigational, including but not limited to monitoring effectiveness of antiarrhythmic medication therapy, for patients with cryptogenic stroke and detection of myocardial ischemia by detecting ST segment changes.

Continuous ambulatory monitors that record and store information for periods longer than 48 hours are considered investigational.

Omnicardiograms are considered investigational as a technique to identify patients at risk of cardiac ischemia.

Description of Procedure or Service
There are a wide variety of devices available for outpatient cardiac rhythm monitoring. The primary purpose of these devices is the evaluation of suspected arrhythmias that have not been detected by office or hospital-based monitoring. These devices differ in the types of monitoring leads used, the duration and continuity of monitoring, the ability to detect arrhythmias without patient intervention, and the mechanism of delivery of the information from patient to clinician.

**Background**

A brief description of the major categories of devices is given below. There has been a trend in recent years toward using novel technology to increase the efficiency, comfort and convenience of these devices. These technological advances include the development of devices that are smaller and more convenient to use, as well as novel ways to rapidly transmit information such as by use of mobile devices. These advances in technology may present challenges in categorizing new devices.

Some of the newer devices are describe below for informational purposes in assigning them to the most relevant category. However, since there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review.

**Continuous monitoring devices (Holter Monitors and similar devices)**

Ambulatory Holter electrocardiography (EKG) is a widely used noninvasive test in which EKG is continuously recorded over an extended period of time, typically 24 to 48 hours, to evaluate symptoms suggestive of cardiac arrhythmias, i.e., palpitations, dizziness, or syncope. However, Holter monitoring will be ineffective if a patient experiences infrequent symptoms. Therefore, the sensitivity of Holter monitoring is low for detection of arrhythmias that are intermittent.

**Continuous monitoring devices with longer recording periods**

Some newer devices are similar to traditional Holter monitoring in concept, but offer other advantages such as the ability to monitor for longer periods of time.

- The Zio® Patch system (iRhythm Technologies, Inc., San Francisco, CA) is a long-term continuous monitoring system that is most analogous to a Holter monitor and is primarily used for asymptomatic monitoring. However, it has substantial advantages compared to a traditional Holter monitor device. This system consists of a patch worn over the left pectoral region of the body that records continuously for up to 14-days, and the patient keeps a symptom log. At the end of the recording period the patient mails back the recorder in a pre-paid envelope to a central station and a full report is provided to the physician within a few days.

- The BodyGuardian Remote Monitoring System™ (Preventice®, Inc., Minneapolis, MN) continuously detects and records a variety of physiologic data including ECG tracing, respiratory rate, and activity level for up to 30 days. The data can be transmitted to the physician’s office via a cellular telephone, and information can be viewed by the patient and physician through the internet.

**Non-continuous monitoring devices (Ambulatory Event Monitors and similar devices)**

Ambulatory event monitors (AEMs) were developed to provide longer periods of monitoring by using non-continuous monitoring. In this technique, the recording device is either worn continuously and activated only when the patient experiences symptoms, or is carried by the patient and applied and activated when symptoms are present. The recorded EKGs are then stored for future analysis or transmitted by telephone to a receiving station, e.g., a doctor’s office; hospital; or cardiac-monitoring service, where the EKGs can then be analyzed. AEMs can be used for extended periods of time, typically up to 1 month or until the patient experiences symptoms. Since the EKGs are recorded only during symptoms, there is good correlation with any underlying arrhythmia. Conversely, if no EKG abnormality is noted, a noncardiac etiology of the patient’s symptoms can be sought. Several different types of AEMs are available:

**Noncontinuous devices with memory**

These devices are carried by the patient and applied to the precordial area via nongel electrodes when the symptoms are occurring or, alternatively, a recording device may be worn on the wrist and then activated when symptoms are present. The limitation of these devices is that an arrhythmia of very
short duration would be difficult to record. In addition, noncontinuous devices require reasonable dexterity on the part of the patient to apply the device correctly during a symptomatic period. This is a particular limitation if the patient is incapacitated during symptomatic periods.

- The Zio® Event Card (iRhythm Technologies, Inc., San Francisco, CA) is a noncontinuous real-time recording device that can be worn up to 30 days. This device can be worn comfortably under clothing (including during sleep) as it weighs less than 2 oz. and is similar in size to a standard credit card. Upon activation by the patient, the card is able to record the previous 45 seconds of ECG activity into memory plus the first 15 seconds after the button is pushed. This is made possible because this device continuously scans for ECG activity but only records upon symptom activation. After the device is activated, the patient is responsible for calling the iRhythm National Clinical Center (NCCC) who then instructs the patient on how to send the event over the phone line.

- The REKA E100™ system is a noncontinuous single-lead cardiac event monitor. This device is the size of a hockey puck and weighs no more than a few ounces. There are two options depending on the patient's circulation: 1) a zero-lead device that is separate from the body and may be carried in a purse or coat pocket; or if a patient's circulation is determined to be inadequate, 2) a single electrode lead that the patient connects to the device at the time of an event. The zero-lead device records an event by patient activation and can record and store up to 2000 readings. The patient has the option of sending stored event information to the physician across a free-of-charge phone app or the internet in their computer. Internet transmission requires one of the following systems: Android, BlackBerry, iPhone 3, 3S, 4, and 4S, iPad, iPod Touch® Microsoft, or Windows.

**Continuous "memory loop" devices**

These devices are able to continuously store a single channel of EKG data in a refreshed memory. If the patient activates the device, the EKG is then recorded from the memory loop for the preceding 30 to 90 seconds and for the next minute or so. Therefore, these types of devices permit recording of the onset of arrhythmias and/or transient or incapacitating events. They obviously must be worn continuously.

**Implantable continuous “memory loop” devices**

An implantable loop recorder device is inserted just under the patient's skin in the chest area during an outpatient surgical procedure. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for more than 1 year.

**Autotrigger devices**

All of the previously described devices require activation by the patient. More recently, autotriggering technology has become available, which can be adapted to memory loop devices. For example, event monitors can be programmed to detect heart rates greater than 165 beats per minute, less than 40 beats per minute, or an asystole of greater than 3 seconds.

**Implantable continuous “memory loop” devices with autotrigger**

These devices combine the long-term monitoring available with implantable devices with the autotriggers seen on newer event monitors. These devices contain algorithms that are programmed to detect heart rates exceeding an upper or lower limit, asystole of greater than 3 seconds. They typically contain other autotriggers, such as a variable RR interval seen with atrial fibrillation. For example, the Reveal® XT ICM (Medtronic, Inc., Minneapolis, MN) is an implantable memory loop device cleared for marketing by the U.S. Food and Drug Administration (FDA) in 2008 that allows patient-activated rhythm recording, rhythm recording at prespecified time intervals, or auto-triggered rhythm recording. Sizes of implantable devices are decreasing: in February 2014, FDA cleared for marketing the Reveal LINQ™, a miniaturized implantable memory loop device that is approximately 1 mL that includes autotriggered or patient-activated rhythm recording.

**Mobile Cardiac Outpatient Telemetry**

Ambulatory event monitors store the recorded data, which are ultimately transmitted either to a physician’s office or to a central recording station. In contrast, outpatient cardiac telemetry provides real-time monitoring and analysis. For example, CardioNet Inc. (Conshohocken, PA) offers mobile
cardiac outpatient telemetry. In this system, the patient wears a 3-lead sensor, which constantly communicates with the CardioNet monitor, a lightweight unit that can be carried in a pocket or a purse. When an arrhythmia is detected according to preset parameters, the EKG is automatically transmitted to a central CardioNet service center, where the EKG is immediately interpreted, with results sent to the referring physician. The referring physician can request the level and timing of response, ranging from daily reports to stat results. Other systems for outpatient cardiac telemetry include the HEARTLink II system (Cardiac Telecom Corp.), the Vital Signs Transmitter (VST, Biowatch Medical, Columbia, SC), and the Lifespan Ambulatory Cardiac Telemetry (ACT) system (Card Guard Scientific Survival Ltd., Israel). The CardioNet system has a built-in cellular telephone that automatically transmits signals when the patient is away from home.

The VectraplexECG System is a real-time continuous Mobile Cardiac Outpatient Telemetry device to measure ischemic ECG changes that can be indicative of an MI. This device utilizes the internet to communicate real-time ECG changes to the physician. The patient is hooked up to a mini tablet by either 5 electrodes which communicate 15-lead ECG data or 10 electrodes that communicate 12-lead ECG data. While this system is primarily intended to monitor for ischemia, the continuous ECG monitoring would presumably detect rhythm disturbances as well as ischemic changes.

Omnicardiogram
Omnicardiogram is a device that consists of a microcomputer, which receives output from a standard electrocardiogram (ECG) and transforms it to produce a graphic representation of heart electrophysiological signals. It is thought this will detect subtle degrees of abnormality not apparent in the original ECG. This procedure is used primarily as a substitute for exercise tolerance testing with thallium imaging in patients for whom a resting ECG may be inadequate to identify changes compatible with coronary artery disease.

Rationale
This policy was created in 1998 and updated periodically with literature review. The most recent update covers the period through June 5, 2014. The following is a summary of the key literature to date.

Evaluation of Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry in the Detection of Arrhythmias

Ambulatory Event Monitors
Ambulatory event monitors (AEMs) are a well-established technology that are most typically used to evaluate episodes of cardiac symptoms (palpitations, dizziness, syncope), which, due to their infrequency, would escape detection on a standard 24- to 48-hour Holter monitor. Other proposed uses include monitoring the efficacy of antiarrhythmic therapy and evaluating ST segment changes as an indication of myocardial ischemia (MI). However, evidence is inadequate to validate these uses of AEMs. Although serial electrocardiography (EKG) monitoring has often been used to guide antiarrhythmic therapy in patients with symptomatic sustained ventricular arrhythmias or survivors of near sudden cardiac death, (1) it is not known what level of reduction of arrhythmic events constitutes successful drug therapy. Furthermore, the patient’s cardiac activity must be evaluated before and during treatment, such that the patient can serve as his or her own control. The routine monitoring of asymptomatic patients after MI is also controversial, especially after the Cardiac Arrhythmia Suppression Trial (CAST) showed that patients treated with encainide or flecainide actually had a higher mortality. 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.

Hoefman et al (2) published a systematic review on diagnostic tools for detecting cardiac arrhythmias. This analysis included studies of patients presenting with palpitations and compared the yield of remote monitoring for several classes of devices: Holter monitors; patient-activated event recorders; auto-
triggered event recorders; and implantable loop recorders. The yield varied among devices, with the autotrigger devices offering the highest range of detection (72% to 80%), followed by the patient-activated devices (17% to 75%), and Holter monitors (33% to 35%). No combined analysis was performed due to heterogeneity in patient population and study design. Limitations in the evidence base precluded any specific recommendations on selection of devices. The authors concluded that the choice of device should be driven largely by the presence, type, and frequency of symptoms experienced by each individual patient.

**Continuous Monitors With Longer Recording Periods**

Newer devices are available that record cardiac rhythms continuously, but for longer periods of time than traditional Holter monitors. For example, the Zio® Patch continuously records and stores information for up to 2 weeks. In addition to recording information for longer periods of time, this device uses “near-field” recording electrodes that differ from most other devices.

Several studies have evaluated the diagnostic yield of continuous monitoring for greater than 48 hours, either directly through comparison to Holter monitoring or indirectly through determination of the proportion of arrhythmias detected in the first 48 hours of monitoring.

Tuakhia et al published a study in 2013 evaluating the diagnostic yield of the Zio Patch. (3) Data from the manufacturer was used to identify 26,751 first-time users of the device. The most common clinical indications were palpitations (40.3%), atrial fibrillation (AF) (24.3%), and syncope (15.1%). The mean duration of use was 7.6 ± 3.6 days, and 95.9% of patients wore the device for more than 48 hours. At least 1 episode of arrhythmia was detected in 16,142 patients (60.3%). The authors compared the detection rate in the first 48 hours with the detection rate over the entire time period that the device was worn with 70.1% of patients having their arrhythmia detected within the first 48 hours and 29.9% having their first arrhythmia detected after the first 48 hours. The overall yield was significantly higher when comparing the total monitored period with the first 48 hours (62.2% vs 43.9%, p<0.0001). These data confirm previous studies that have shown that a substantial proportion of arrhythmias in symptomatic patients can be detected with a 48-hour period of monitoring and that longer monitoring periods increase the detection rate.

Barrett et al published a comparison of arrhythmia detection rates in 146 patients who underwent simultaneous monitoring with a 24-hour Holter monitor and a 14-day Zio Patch monitor.(4) Included were patients referred for evaluation of a suspected cardiac arrhythmia at single institution. For the detection of atrioventricular block, pause, polymorphic ventricular tachycardia, supraventricular tachycardia, or AF. Holter monitoring detected 61 arrhythmias, while the Zio Patch detected 96 (p<0.001). Over the course of the monitoring period, 60 arrhythmias were detected by both devices, with 36 detected by the Zio Patch that were not detected by Holter monitoring and 1 detected by the Holter that was not detected by the Zio Patch. The investigators conducted within-subject comparisons of arrhythmia detection for the 24-hour period during which both devices were worn. Holter monitoring detected 61 arrhythmia events, compared with 52 detected by the Zio Patch (p=0.013). This study further suggests that extended monitoring may increase the diagnostic yield of cardiac monitoring. However, a relatively large number of missed events occurred with the Zio Patch during the period of simultaneous monitoring, which may have clinical significance if its performance is similar in nonresearch settings.

**Section Summary**
The available evidence on continuously-worn cardiac monitors that can store data for longer periods of time than standard Holter monitoring indicates that such devices typically detect greater numbers of arrhythmias during extended follow-up than 24- or 48-hour Holter monitoring. However, a more appropriate comparison group for such monitors is ambulatory event monitors, and evidence on this comparison is lacking.

**Autotriggered Event Monitors and Loop Recorders**
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. Therefore, this is the test with which newer technologies should be compared.

Several studies, including an analysis of a database of 100,000 patients, compared the diagnostic yield of automatic and patient-activated arrhythmia recordings and reported an improved yield with autotriggering devices. (5-7) One comparative study of 50 patients noted that autoactivation may result in a large number of inappropriately stored events. (8)

Implantable autotrigger loop recorders have also been developed that are specifically geared toward detection of AF through the use of AF detection algorithms. Hindricks et al (9) evaluated the accuracy of an implantable autotriggered loop recorder in 247 patients at high risk for paroxysmal AF. All patients underwent simultaneous 46-hour continuous Holter monitoring, and the authors calculated the performance characteristics of the loop recorder using physician-interpreted Holter monitoring as the criterion standard. The sensitivity of the loop recorder for detecting AF episodes of 2 minutes or more in duration was 88.2%, rising to 92.1% for episodes of 6 minutes or more. AF was falsely identified by the loop recorder in 19 of 130 patients who did not have AF on Holter monitoring, for a false positive rate of 15%. The AF burden was accurately measured by the loop recorder, with the mean absolute difference between the loop recorder and Holter monitor of 1.4 ± 6.4%.

Hanke et al (10) compared an implantable autotrigger device with 24-hour Holter monitoring done at 3-month intervals in 45 patients who had undergone surgical ablation for AF. (10) After a mean follow-up of 8.3 months, the implantable loop recorder identified AF in 19 patients (42%) in whom Holter monitoring recorded sinus rhythm.

One small randomized controlled trial (RCT) was identified that compared the use of an implantable loop recorder with conventional follow-up in 78 patients with a first episode of syncope. (11) A significant number of patients had cardiomyopathy (23%), AF (15.4%), and/or bundle branch block on electrocardiography (ECG, 58%). Mean follow-up time was 27 months. A total of 21 patients (27%) had at least 1 arrhythmia detected, with a significant difference in detection rate for the implantable loop recorder group (36.6%) compared with the conventional follow-up group (10.8%, p=0.02).

The most appropriate indications for an implantable loop recorder (compared with an external loop recorder) are not well-established. Locati et al evaluated the diagnostic yield of an external loop recorder with extended memory capacity in the evaluation of patients with syncope, presyncope, or sustained palpitations in an effort to determine their role in the diagnostic workup of these conditions. (12) The authors evaluated 307 consecutive patients with external loop recorders (the SpiderFlash-A®, a patient-triggered device, and SpiderFlash-T® device, which has autotrigger capacity) who were enrolled in a registry at a single institution. The mean duration of recording was 24.1 days, with 85% of subjects having recording for 3 to 5 weeks. Ninety-two patients had syncope as their initial presentation; of those, a typical syncopal event occurred during the study monitoring period in 17 patients and an EKG recording during syncope was available in 16 patients. In 7 of these patients (44%), significant arrhythmias were recorded during syncope: bradycardia and pauses requiring pacemaker implant in 3 patients and fast supraventricular tachyarrhythmia (paroxysmal AF or paroxysmal supraventricular tachycardia) in 4 patients. Two hundred fifteen patients had palpitations or presyncope as their initial presentation; of those, a typical episode occurred during the study monitoring period in 184 patients, and many had multiple episodes (median 3 episodes per patient). In SpiderFlash-A recordings, sinus rhythm or sinus tachycardia was recorded in about one third of the cases, and about one third had sustained supraventricular tachycardia or AF at the time of the symptoms. In the SpiderFlash-T recordings, supraventricular tachycardia or AF was recorded in about 46% of the cases, while bradycardia or pauses was recorded in about 13% of the cases.

The most recent generation of event recorders has incorporated transmission using cellular phone technology. (13, 14) These devices incorporate a cell phone into the event monitor, allowing patients or autotrigger to transmit data directly from the device. This modification is intended to simplify the
transmission of data, thus minimizing the proportion of transmissions that are not successful. Leshem-Rubinow et al performed an observational study of 604 patients with palpitations, presyncope, and/or chest pain. This study demonstrated that the Cardio R® device (SHL-Medical, Tel Aviv, Israel) was able to efficiently diagnose and transmit heart rhythm information. Out of 604 patients, a rhythm disturbance that could account for symptoms was found in 49% of cases. The information was transmitted within 7 minutes in 93% of cases.

Section Summary
Automatic and patient-activated loop recorders play a role in the evaluation of symptoms possibly related to arrhythmias. The evidence does not clearly identify criteria for determining when implantable loop recorders should be considered. However, given the small but higher risk associated with an implantable device, it would be reasonable to consider the use of an implantable loop recorder after a trial of an external loop recorder does not yield a definitive diagnosis.

Mobile Cardiac Outpatient Telemetry
The published literature regarding outpatient cardiac telemetry was reviewed, with a specific focus on whether outpatient cardiac telemetry was associated with incremental benefit compared with the use of AEMs. Of specific interest was the benefit of real-time monitoring in an ambulatory population, presumably considered to be at a lower level of risk from significant arrhythmia such that an electrophysiologic study or inpatient telemetry was not required.

A number of uncontrolled case series report on outcomes of mobile cardiac outpatient telemetry (MCOT). (15-18) One such published study described the outcomes of a consecutive case series of 100 patients. (15) Patients with a variety of symptoms were included, most commonly, palpitations (47%), dizziness (24%), or syncope (19%), as well as efficacy of drug treatment (25%). Clinically significant arrhythmias were detected in 51% of patients, but half of these patients were asymptomatic. The authors comment that the automatic detection results in an increased diagnostic yield, but there was no discussion of its unique feature, ie, the real-time analysis, transmission, and notification of arrhythmia. In another uncontrolled case series, Tayal et al reported on a retrospective analysis of patients with cryptogenic stroke, who had not been diagnosed with AF by standard monitoring. (18) In this study, 13 of 56 patients (23%) with cryptogenic stroke were found to have AF with MCOT. Twenty-seven asymptomatic AF episodes were detected in the 13 patients, 23 of these were shorter than 30 seconds in duration.

One RCT was identified that compared MCOT to standard event monitors. (19) This study involved 305 patients who were randomly assigned to the LOOP recorder or MCOT and who were monitored for up to 30 days. The unblinded study enrolled patients at 17 centers; those enrolled were patients for whom the investigators had a strong suspicion of an arrhythmic cause of symptoms including those with symptoms of syncope, presyncope, or severe palpitations occurring less frequently than once per 24 hours and a nondiagnostic 24-hour Holter or telemetry monitor within the prior 45 days. Test results were read in a blinded fashion by an electrophysiologist. Most patients in the control group had a patient-triggered event monitor. Only a subset of patients (n=50) had autotrigger devices, thus precluding a comparison between MCOT and autotrigger devices.

A diagnostic end point (confirmation/exclusion of arrhythmic cause of symptoms) was found in 88% of MCOT patients and in 75% of LOOP patients (p=0.008). The difference in rates was primarily due to detection of asymptomatic (not associated with simultaneous symptoms) arrhythmias in the MCOT group, symptoms consisting of rapid AF and/or flutter (15 vs 1 patient) and ventricular tachycardia defined as more than 3 beats and rate greater than 100 (14 vs 2 patients). These were thought to be clinically significant rhythm disturbances and the likely causes of the patients’ symptoms. The article 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. Kadish et al (20) evaluated the frequency with which events transmitted by MCOT represented
emergent arrhythmias, thereby indirectly assessing the clinical utility of real-time outpatient monitoring. A total of 26,438 patients who had undergone MCOT during a 9-month period were retrospectively examined. Of these patients, 21% (5459) had an arrhythmic event requiring physician notification, and 1% (260) had an event that could be considered potentially emergent. These potentially emergent events included 120 patients with wide-complex tachycardia, 100 patients with sinus pauses 6 seconds or longer, and 42 with sustained bradycardia at less than 30 beats per minute.

Section Summary
The available evidence suggests that MCOT is likely at least as good at detecting arrhythmias as ambulatory event monitoring. However, compared with ambulatory event monitoring, MCOT is associated with the theoretical advantage of real-time monitoring, allowing for emergent intervention for potentially life-threatening arrhythmias. One study reported that 1% of arrhythmic events detected on MCOT over a 9-month period could be considered potentially emergent. However, no studies were identified that address whether the use of MCOT is associated with differences in the management of or outcomes after these potentially emergent events.

AEMs in the Detection of AF

While AEMs are used for the detection of a range of different arrhythmias, their ability to detect intermittent arrhythmias that may occur without significant symptoms has led to their use in the detection of paroxysmal AF.

Patients with AF treated with catheter ablation

Many patients with AF treated with catheter ablation are on long-term anticoagulation, and all patients treated with ablation are given anticoagulation for up to 3 months postprocedure. In patients with an apparently successful ablation who do not show signs or symptoms of recurrent AF at time periods longer than 3 months postablation, the decision on whether to continue treatment with anticoagulants needs to be made. Studies have demonstrated that late recurrences are not uncommon following ablation and that these recurrent episodes are often asymptomatic. (21, 22) In addition, the presence of recurrent episodes of AF is a predictor of future thromboembolic events. In one of the larger observational study of 565 patients following postablation, the 2 major predictors of thromboembolism were the CHADS(2) score and the presence of recurrent episodes of AF. (23)

In a prospective, randomized study, Kapa et al compared implantable loop monitors with conventional trans-telephonic recorders in the assessment of arrhythmia burden after catheter ablation of AF.(24) Forty-four patients were enrolled and randomized; all patients received the implantable loop recorder postablation. Six patients were excluded due to requests for device removal or loss to follow up. During the first 6 months after ablation, all subjects underwent conventional monitoring that consisted of twice daily 1-minute pulse rate assessments by the patient and three 30-day trans-telephonic monitoring periods. At 6 month postablation, patients were allocated to the randomization arm (decided in a 1:1 manner at initial enrollment) of either the implantable loop recorder (transmission of data every 31 days) or conventional monitoring (twice daily 1-minute pulse-rate assessment, and 1 trans-telephonic recording for 30 days at month 11). Over the first 6 months after ablation, conventional monitoring revealed AF in 7/38 patients (18%) and the implantable loop recorder confirmed AF in all of these patients. In an additional 11 patients (29%), AF was detected on implantable loop recorder. During the subsequent 6- month period, 5/18 patients in the conventional monitoring arm refused ongoing monitoring due to discomfort and lifestyle restrictions; of the remaining 13, 5 had a recurrence of AF(38%). In the implantable loop recorder group, 5/20 patients had recurrence of AF. In the implantable loop recorder arm, 71% patients had their antiarrhythmic drugs discontinued compared with 44% in the conventional monitoring group over the randomization period (p=0.04).

Several other observational studies have followed patients who stopped anticoagulation after an evaluation that included ambulatory monitoring was negative for recurrent episodes. These patients appear to have a low subsequent rate of thromboembolic events. In one such study of 3355 patients...
from 5 clinical centers, (25) 2692 discontinued anticoagulation at 3 to 6 months following ablation. During a mean follow-up of 28 months, 2 patients (0.07%) who were off anticoagulation experienced an ischemic stroke. This rate was not significantly different from the rate of stroke in patients who continued anticoagulation (0.45%). The rate of major hemorrhage was lower for patients who were off anticoagulation compared with those who continued (2 vs 0.04%, respectively; p<0.001).

**Section Summary**
This evidence makes a strong indirect argument that monitoring for asymptomatic episodes of AF by use of AEMs will lead to changes in management of long-term anticoagulation. These changes in management based on ambulatory monitoring are likely to lead to improved outcomes.

**Patients with cryptogenic stroke**

Patients with cryptogenic stroke are often monitored for the presence of AF, because AF is estimated to be the cause of cryptogenic stroke in more than 10% of patients and AF increases the risk of stroke. (26, 27) Oral anticoagulation in patients with AF reduces the risk of subsequent stroke and is recommended by American Heart Association/American College of Cardiology guidelines for patients with a history of stroke or transient ischemic attack (TIA). (28)

Approximately 5% of patients with cryptogenic stroke will have AF diagnosed on ECG and/or telemetry monitoring in the hospital. The use of continuous telemetry monitoring has been compared with Holter monitoring for patients hospitalized for stroke or TIA; these results are inconclusive as to which is the preferred method. (29, 30) Longer-term ambulatory event monitoring will identify additional patients with asymptomatic episodes, with rates of detection reported in the literature for an estimated 6% to 26% of patients. (26, 31, 32)

**Systematic Reviews.** Kishore et al conducted a systematic review and meta-analysis of prospective observational studies and RCTs that reported rates of detection of newly-diagnosed AF in patients with ischemic stroke or TIA who underwent any cardiac monitoring for at least 12 hours. (33) Thirty-two studies were included: 18 studies that included patients with ischemic stroke only, 1 study that included TIA only, and 13 studies included both ischemic stroke and TIA. The authors reported significant study heterogeneity. Among unselected patients (ie, selected on the basis of stroke pathogenesis, age, or prescreening for AF), the detection rate of any new AF was 6.2% (95% CI, 4.4% to 8.3%) and among selected patients was 13.4% (95% CI, 9.0% to 18.4%). In cryptogenic strokes, new AF was detected in 15.9% (95% CI, 10.9% to 21.6%). Among selected patients, the detection rate of AF during 24-hour Holter monitoring was 10.7% (95% CI, 3.4% to 21.5%), while the detection rate during monitoring beyond 24 hours (including more prolonged Holter monitoring, implantable and nonimplantable loop recorder, and MCOT) was 14.7% (95% CI, 10.7% to 19.3%).

The Kishore and other studies suggest that longer periods of cardiac monitoring increase the likelihood of AF detection. However, many of these asymptomatic episodes of AF are brief and the relationship to the preceding stroke uncertain, as there are other potential causes of asymptomatic stroke. The ideal study to evaluate the role of cardiac monitoring in the management of patients with cryptogenic stroke would be trials that randomize patients to a strategy involving event monitoring or routine care with evaluation of rates of detection of AF and stroke-related outcomes.

**RCTs.** There were four RCTs identified that evaluated ambulatory monitoring in patients with cryptogenic stroke. Two of these were small pilot trials. One small RCT published in 2013 randomized 40 patients with cryptogenic ischemic stroke or high-risk TIA to usual care or 21 days of mobile cardiac outpatient telemetry (MCOT). (34) There were no cases of atrial fibrillation detected in either group. Two patients in the MCOT group had nonsustained ventricular tachycardia detected, which was of uncertain clinical significance in relation to their stroke.

A second small pilot trial published in 2013 by Higgins et al randomized patients with ischemic stroke and no history of AF to standard practice investigations to detect AF or standard practice plus 7 days of
noninvasive cardiac event monitoring.(35) One hundred patients presenting within 7 days of a cryptogenic ischemic stroke were enrolled and randomized to standard practice investigations, which may have included 12-lead EKG, 24-hour Holter monitoring, and/or echocardiography, at the discretion of the treating practitioner, or standard practice plus cardiac event monitoring with Novacor R-test Evolution 3 device. At 90 days of follow-up, any-duration paroxysmal AF was more commonly detected in the event monitoring group: 48% vs 10% (risk difference, 38%, 95% CI, 21.8 to 54.1%, p<0.001).

Two larger RCTs were published in 2014. Sanna et al reported results from the CRYSTAL-AF study, an RCT to evaluate whether long-term monitoring of patients with cryptogenic stroke with implantable cardiac monitors (ICM) leads to changes in anticoagulant management and/or improved outcomes.(36, 37) The study randomized 441 patients to continuous monitoring with the Reveal XT ICM or routine care. Eligibility criteria included no known history of AF, cryptogenic stroke or TIA with infarct seen on computed tomography (CT) scan or magnetic resonance imaging, and no mechanism determined after a workup that included 12-lead EKG, 24-hour Holter monitoring, transesophageal echocardiography, CT or magnetic resonance angiography of the head and neck, and hypercoagulability screening (for patients younger than age 55). Analysis was intention-to-treat. Of the 441 randomly assigned patients, 416 (94.3%) completed 6 months of follow-up, 2 were lost to follow-up, 5 died, and 18 exited the study before 6 months. Crossover occurred in 12 patients in the ICM group and 6 in the control group. AF was detected in 8.9% of the ICM group compared with 1.4% of the control group (hazard ratio [HR]=6.43, 95% CI, 1.90 to 21.74). The median time from randomization to detection of AF was 41 days (interquartile range [IQR], 14 to 84) in the ICM group and 32 days (IQR, 2 to 73) in the control group. Most AF episodes in the ICM group were asymptomatic (74%), compared with 33% of those in the control group. The rate of AF detection was similarly greater in the ICM group at the 12-month follow-up point (12.4% vs 2.0%, HR=7.3, 95% CI, 2.6 to 20.8, p<0.001). The rate of use of oral anticoagulants was 10.1% in the ICM group versus 4.6% in the control group at 6 months (p=0.04) and 14.7% versus 6.0% at 12 months (p=0.007). Five of the 208 ICMs (2.4%) that were inserted were removed due to infection or erosion of the device pocket.

Also in 2014, Gladstone et al reported results from the EMBRACE study, an RCT that compared 30-day autotrigged cardiac event monitors with conventional 24-hour monitors for the detection of AF in patients with cryptogenic stroke. (38) Included patients were aged 55 or older, with no known history of AF, and an ischemic stroke or TIA of undetermined cause within the prior 6 months. All patients underwent standard screening for AF with 1 or more EKGs and 1 or more 24-hour Holter monitors. Five hundred seventy-two patients were randomized to receive an external event recorder (ER910AF Cardiac Event Monitor, Braemar) or 24-hour Holter monitoring. Among the intervention group subjects, 82% completed at least 3 weeks of monitoring. AF was detected in 10.1% in the ICM group versus 4.6% in the control group at 6 months (p=0.04) and 14.7% versus 6.0% at 12 months (p=0.007). Five of the 208 ICMs (2.4%) that were inserted were removed due to infection or erosion of the device pocket.

Other studies. Several nonrandomized studies have evaluated the role of implantable loop recorders in the diagnosis of paroxysmal AF in cryptogenic stroke. Ritter et al compared 7-day Holter monitoring with an implantable loop recorder. (39) A total of 60 patients with an acute cryptogenic stroke that was consistent with an embolic event were included. All patients received 7-day Holter monitoring, as well as an ICM. Patients were monitored with the ICM for a minimum of 1 year, or until an episode of AF was detected. A total of 10 patients (17%, 95% CI, 7% to 26%) had AF detected by ICM compared with 1 patient (1.7%, 95% CI, 0% to 5%) who had AF detected by Holter monitor (p=0.001 for between-group comparison of detection rate). The average time to detection with ICM was 64 days (range 1-556 days). All patients who had AF detected were treated with anticoagulation, and there were no recurrent strokes in either group.

Christensen et al reported results of long-term cardiac monitoring with implantable loop recorders in a population of 85 patients with cryptogenic stroke.(27) The device was explanted early in 5 patients, 3
due to a skin reaction and 2 due to discomfort; after more than 1 year of monitoring, an additional 3 patients chose early removal of the device. In 18 patients (20.7%), paroxysmal AF was detected during the study period, 4 by EKG (2 obtained in preparation for implantation procedure, 1 on EKG for pacemaker placement for a non-AF arrhythmia, and 1 on EKG due to symptomatic tachycardia), and 14 on the basis of the implantable loop recorder monitoring. The mean time from stroke onset to the first episode of AF on the loop recorder was 109 days. Although patients with detected AF received anticoagulation, rates of stroke or TIA were higher in the AF group than the non-AF group (33.3% vs 10.1%, p=0.024).

In a study by Etgen et al, patients with cryptogenic, MRI-proven stroke who were eligible for oral anticoagulation were offered evaluation with an implantable cardiac loop recorder (Reveal XT, Medtronic, Inc) and followed for the development/diagnosis of AF.(40) Evaluation for causes of stroke included MRI, 12-lead EKG, 24 to 72 hour continuous cardiac monitoring in a stroke unit, at least one 24-hour Holter monitor, extra- and transcranial neurosonography, echocardiography, CT/MRI angiography, and laboratory screening for prothrombotic states in patients aged younger than 55 years. Of 65 patients diagnosed with cryptogenic stroke at a single institution, 22 (33.8%) patients were implanted with a loop recorder, while the remaining patients were considered “not feasible” for the event recorder due to a contraindication to anticoagulation (n=20), cognitive problem (n=7), lack of sufficient cardiac follow-up (n=7), noncompliance (n=5), or refusal of insertion (n=4). Over 1 year of follow-up, paroxysmal AF was detected in 6 patients (27.3%).

Section Summary
Several randomized and nonrandomized studies demonstrate that implantable and external loop recorders are associated with higher rates of detection of AF among patients with cryptogenic stroke, including 2 larger RCTs published in 2014. These studies establish that use of longer-term monitors will uncover additional patients with AF. Because most patients who have AF detected will be treated with anticoagulation, and because anticoagulation is an effective treatment for stroke prevention, it can be concluded that longer-term monitoring of patients with cryptogenic stroke will improve outcomes. In the available trials, the detection rate was not higher with implantable compared with nonimplantable monitors.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from 1 physician specialty society (1 review) and 4 academic medical centers (5 reviews) while this policy was under review in 2009. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. There were differences among reviewers regarding outpatient cardiac telemetry, with some reviewers concluding it had a role in certain subsets of patients; for example, in those with sporadic AF. Other reviewers commented that the value of this technology should be considered in both providing a diagnosis and in making treatment decisions. At times, excluding arrhythmia as a cause of a patient’s symptoms is an important finding.

Summary
A variety of technologies are available for outpatient cardiac rhythm monitoring. These devices may be used for the evaluation of symptoms suggestive of arrhythmias, such as syncope or palpitations, but also may be used in the detection of atrial fibrillation (AF) in patients who have undergone cardiac ablation of AF or who have a history of cryptogenic stroke.

A number of studies have indicated that autotrigger event monitors detect additional episodes of arrhythmias compared with Holter monitoring or patient-triggered devices. This evidence has led to the acceptance of autotrigger event monitors as the criterion standard for detecting arrhythmias that occur infrequently. There is also evidence that autotrigger devices can pick up asymptomatic episodes of AF.
in patients treated with catheter ablation and that identifying asymptomatic episodes may lead to modifications in treatment. For patients with cryptogenic stroke, longer monitoring periods will detect additional episodes of AF, but the evidence is not sufficient to conclude that outcomes are improved. Implantable loop recording devices likely have greater sensitivity in detecting arrhythmias in patients presenting with symptoms suggestive of arrhythmia. The available evidence does not clearly define the indications for an implantable loop recorder; however, given the small but higher risk associated with an implantable device, it would be reasonable to consider the use of an implantable loop recorder after a trial of an external loop recorder does not yield a definitive diagnosis. Recent evidence from randomized controlled trials (RCTs) suggests that monitoring with external or implantable loop recorders increases the detection of AF in patients with a history of cryptogenic stroke; and outcomes are likely to be improved for patients who have AF detected.

Newer continuous monitoring devices are available that use novel technology and record information for longer periods than a Holter monitor, eg, up to 2 weeks. The available evidence for these devices suggests that they typically detect greater numbers of arrhythmias during extended follow-up than 24- or 48-hour Holter monitoring. However, a more appropriate comparison group for such monitors is ambulatory event monitors, and evidence on this comparison is lacking. Therefore, these continuous monitoring devices that record for longer time periods are considered investigational.

Mobile cardiac outpatient telemetry (MCOT) is another option for long-term cardiac monitoring. Evidence from 1 RCT and uncontrolled case series suggests that outcomes from the use of MCOT in the evaluation of arrhythmias are likely to be equivalent to outcomes from autotriggered event monitors. Although MCOT has the theoretical advantage of allowing a rapid response to a potentially emergent arrhythmia, none of the available studies have clearly shown an improvement in clinical utility as a result of using MCOT. Further studies are needed to compare MCOT with the autotrigger loop recorder to determine whether the faster response possible with real-time monitoring leads to improved outcomes. Thus, at the present time, outcomes from use of a MCOT are expected to be equivalent to outcomes from use of autotrigger or other types of devices. As a result, in situations where MCOT is more expensive than alternate devices such as the autotrigger device, MCOT is considered not medically necessary.

Practice Guidelines and Position Statements

In 2014, the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society issued guidelines on the management of patients with AF. These guidelines recommend the use of Holter or event monitoring if the diagnosis of the type of arrhythmia is in question or as a means of evaluating rate control.

Also in 2014, the American Academy of Neurology released updated guidelines on the prevention of stroke in patients with nonvalvular atrial fibrillation (NVAF). These guidelines make the following recommendations regarding the identification of patients with occult NVAF:

- Clinicians might obtain outpatient cardiac rhythm studies in patients with cryptogenic stroke without known NVAF, to identify patients with occult NVAF (Level of evidence: C).
- Clinicians might obtain cardiac rhythm studies for prolonged periods (e.g., for 1 or more weeks) instead of shorter periods (e.g., 24 hours) in patients with cryptogenic stroke without known NVAF, to increase the yield of identification of patients with occult NVAF (Level of evidence: C).

In 1999, ACC in conjunction with AHA published guidelines for the use of ambulatory electrocardiography. These guidelines did not make an explicit distinction between continuous (ie, Holter monitor) and intermittent (ie, 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 AEMs are most likely to be used. However, the accompanying text notes that
Intermittent monitoring may be used to confirm the presence of an arrhythmia during symptoms. This indication is addressed in the first policy statement above, i.e., evaluation of symptomatic patients. 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 MI to detect nonsustained ventricular tachycardia as a risk factor for sudden cardiac death is not routinely recommended. As noted in a review article by Zimetbaum and Josephson, (44) there is a paucity of data to document the impact on the final health outcomes, and, furthermore, it is not clear at what point after a myocardial infarction such monitoring would be optimal.

A consensus document on catheter and surgical ablation for AF was published in 2012. (45) This document did not contain formal clinical practice guidelines, but provided general recommendations based on literature review and expert consensus. The use of AEMs postablation was addressed in 2 sections of the document. First, in the section discussing the use of anticoagulation following ablation, the following statement was made:

- Patients in whom discontinuation of systemic anticoagulation is being considered should consider undergoing continuous ECG monitoring to screen for asymptomatic AF/AFL/AT.

In the section of the document dealing with postoperative rhythm monitoring of patients who are postablation the following statements were made:

- ECGs should be obtained at all follow-up visits.
- More intense monitoring should be mainly driven by the clinical impact of AF [atrial fibrillation] detection with strict monitoring being necessary (e.g., in patients with thromboembolic risk factors for determining the adequate anticoagulation approach).
- Frequent ECG recording using a manually activated event recorder and counseling patients to take their pulse to monitor for irregularity may serve as initial screening tools for asymptomatic AF episodes.
- A 1- to 7-day Holter monitor is an effective way to identify frequent asymptomatic recurrences of AF.
- A 4-week autotrigger event monitor, mobile cardiac outpatient telemetry system, or implantable subcutaneous monitor may identify less frequent AF.

Ambulatory event monitors and mobile cardiac outpatient telemetry are not preventive services and are therefore not included in the U.S. Preventive Task Force Recommendations for preventive services.

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Patients With Atrial Fibrillation: Executive Summary: A Report of the American College of


**Billing Coding/Physician Documentation Information**

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<tr>
<th>Code</th>
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<td>33282</td>
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<tr>
<td>33284</td>
<td>Removal of an implantable, patient-activated cardiac event recorder</td>
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<tr>
<td>93228</td>
<td>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</td>
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<td>93229</td>
<td>External mobile cardiovascular telemetry with electrocardiographic recording,</td>
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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 to 30 days, 24-hour attended monitoring; includes transmission, physician review and interpretation

93270  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; recording (includes connection, recording, and disconnection)

93271  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; transmission download and analysis

93272  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; physician review and interpretation

93799  Unlisted cardiovascular service or procedure
S9025  Omnicardiogram/cardiointegram
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

Additional Policy Key Words
N/A

Policy Implementation/Update Information
11/1/02  New policy. Added to DME section.
11/1/03  Deleted HCPCS codes removed from the policy.
11/1/04  No policy statement changes.
11/1/05  Changed other uses from not medically necessary to investigational. Moved from DME section to Medical section.
8/1/06  Policy updated with review of auto-activated ambulatory event monitors, outpatient cardiac telemetry, and omnicardiogram. Policy statement revised to indicate that outpatient cardiac telemetry and omnicardiogram are investigational.
11/1/06  No policy statement changes.
11/1/07  No policy statement changes.
11/1/08  No policy statement changes.
11/15/09  Policy statement on MCOT changed from investigational to not medically necessary.
11/1/10  No policy statement changes.
1/1/11  CPT code descriptors updated with 1/1/11 revised language
11/1/11  No policy statement changes.
11/1/12  Medically necessary indication for use of event monitors in patients with atrial fibrillation treated with catheter ablation revised for clarity and for wording to be consistent with
recent guidelines. Not medically necessary indication for MCOT changed to reflect revised language for not medically necessary technologies. Additional investigational indication added for monitoring patients with cryptogenic stroke.

**11/1/13** Medically necessary criteria for implantable loop monitors revised from “…a prior trial of Holter monitor and other external ambulatory event monitors has been unsuccessful” to “…a prior trial of other external ambulatory event monitors has been unsuccessful.”

**8/1/14** New medically necessary statement added for monitoring of patients with cryptogenic stroke. Clarified not medically necessary statement to include autotrigger device wording. Added investigational statement regarding continuous ambulatory monitors used for periods longer than 48 hours. Added CPT 0295T, 0296T, 0297T, 0298T.

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