I. **Policy**

**Ambulatory Event Monitors**

**External**

The use of patient-activated or auto-activated external ambulatory event monitors may be considered **medically necessary** in the following situations:

- Patients with infrequent (less frequent than every 48 hours), or who have undergone a nondiagnostic Holter monitor for symptoms suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).
- Patients who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered or to document the results of an ablative procedure for arrhythmia.
- Patients in whom antiarrhythmic drug therapy has been initiated or withdrawn to document the results of the intervention.
- Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation and in whom the results of a 24 hour Holter monitor are likely to be nondiagnostic.
- Patients suspected of having cardiac ischemia to record electrocardiographic changes.

The use of external ambulatory event monitors for all other indications is considered to be **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

**Mobile Cardiac Outpatient Telemetry (Real-Time, Outpatient Cardiac Monitoring, AEOG, or MCOT)**

Mobile Cardiac Outpatient Telemetry (Real-Time, Outpatient Cardiac Monitoring, AEOG, or MCOT) may be considered **medically necessary** for any of the following indications:
Adult Clinical Criteria

- For the diagnosis of recurrent symptoms related to an arrhythmia (i.e., presyncope, syncope, dizziness, or palpitations) that occur infrequently (less frequent than once every 48 hours), AND for which a diagnosis has not been determined after standard diagnostic workup (e.g., complete clinical history and physical examination, standard 12-lead electrocardiography [ECG], cardiac imaging) and not likely to be diagnosed with a Holter monitor
  - The ordering provider must document the prior testing performed and the results
- For diagnosis in patients who experienced a cryptogenic stroke and have a negative work-up for AF when the etiology of the symptoms/conditions of arrhythmia has not been determined after standard diagnostic workup (e.g., a complete clinical history and physical examination, standard 12-lead ECG, cardiac imaging), and not likely to be diagnosed with a Holter monitor.
- To evaluate function of pacemakers or implantable cardioverter defibrillators (ICD) in order to assess any of the following:
  - Symptoms of palpitation, syncope, or near syncope to assess device function to exclude myopotential inhibition and pacemaker mediated tachycardia
  - Symptoms of palpitation, syncope, or near syncope to assist in programming parameters such as rate-responsivity and automatic mode switching
  - Suspected component failure or malfunction when device interrogation is not definitive in establishing a diagnosis
  - Response to adjunctive pharmacologic therapy in individuals receiving frequent ICD therapy

Pediatric Clinical Criteria

In accord with the American College of Cardiology/American Heart Association, pediatric AECG monitoring, including MCOT monitoring, may be considered medically necessary for the evaluation of the following indications:

- Antiarrhythmic drug efficacy
- Asymptomatic congenital atrioventricular (AV) block, nonpaced
- Syncope, near syncope, or dizziness with recognized heart disease, previously documented arrhythmia, or pacemaker dependency
- Syncope or near syncope associated with exertion when the cause is not established by other methods
- Hypertrophic or dilated cardiac myopathies
- Possible or documented long QT syndromes
- Palpitations in individuals with prior surgery for congenital heart disease and significant residual hemodynamic abnormalities
The use of MCOT or AEOG is considered to be investigational for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

**Implantable Ambulatory Event Monitors**

The use of implantable ambulatory event monitors, either patient-activated or auto-activated, may be considered medically necessary in the following situations:

- In the small subset of patients who experience recurrent symptoms thought to be due to a cardiac arrhythmia so infrequently that prior evaluation with an external ambulatory event monitor or MCOT has been unsuccessful.
- In patients with cryptogenic stroke who have had a negative standard work-up for atrial fibrillation, including evaluation with an external ambulatory event monitor or MCOT (see Policy Guidelines section)

The use of implantable ambulatory event monitors is considered to be investigational for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

**Policy Guidelines for Real-time outpatient cardiac monitoring**

Real-time outpatient cardiac monitoring is contraindicated for use in patients at high risk of developing sustained ventricular tachycardia or ventricular fibrillation and/or would be more appropriately cared for in a hospital setting.

This service is not indicated for all patients with arrhythmias. It should be used only in circumstances where traditional Holter monitoring or cardiac event recording is not expected to provide adequate information or has been unrevealing.

This system is also not indicated for use as a screening tool.

This monitoring is expected to not be reported more than once in a 30 day period and is expected to not be reported more than twice in a twelve month period.

**Cross-references:**

- **MP-2.007** Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure
- **MP-4.003** Medical Necessity
II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*  BlueJourney PPO*  FEP PPO**

*Refer to Novitas Solutions Local Coverage Determination (LCD) L34997 Real Time Outpatient Telemetry and L34953 Cardiac Event Detection Monitoring. Also refer to the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 20.15, “Electrocardiographic Services” for additional medically necessary indications.

** Refer to FEP Medical Policy Manual, MP-2.02.08 Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry. The FEP Medical Policy Manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

A brief description of the major categories of devices is given next. There has been a trend in recent years toward using novel technology to increase the efficiency, comfort, and convenience of these devices. These technologic 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 described next for informational purposes in assigning them to the most relevant category. However, because 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 (ECG) is a widely used noninvasive test in which ECG 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, syncope. However, Holter monitoring will be ineffective in detecting arrhythmias 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 continuous monitors that 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 that records and stores information for longer time periods. It is primarily used for asymptomatic monitoring. This system consists of a patch worn over the left pectoral region of the body that records continuously for up to 14 days, while the patient keeps a symptom log. At the end of the recording period, the patient mails back the recorder in a prepaid 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.

Noncontinuous Monitoring Devices (AEMs and Similar Devices)

AEMs were developed to provide longer periods of monitoring by using noncontinuous 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 ECGs are then stored for future analysis or transmitted by telephone to a receiving station e.g., a doctor’s office; hospital; cardiac-monitoring service, where the ECGs can then be analyzed. AEMs can be used for extended periods of time, typically up to 1 month or until the patient experiences symptoms. Because the ECGs are recorded only during symptoms, there is good correlation with any underlying arrhythmia. Conversely, if no ECG 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 non-gel 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 ounces 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 electrocardiography (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), which then instructs the patient on sending 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 2 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. Patients have 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 ECG data in a refreshed memory. If the patient activates the device, the ECG 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 AF. 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 autotriggered 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.

MCOT

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 MCOT. 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 ECG is automatically transmitted to a central CardioNet service center, where the ECG 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 LifeStar™ 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 Vectraplex ECG™ System is a real-time continuous MCOT device to measure ischemic ECG changes that can be indicative of a myocardial infarction (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.

REGULATORY STATUS

Some of the newer devices are described in the “Background” section for informational purposes. However, because there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review.

IV. RATIONALE

The most recent review covers the period through June 3, 2015. The following is a summary of the key literature to date.
The assessment of efficacy for a diagnostic study involves a determination of whether patients managed with a particular study have improved health outcomes compared with those who are managed with alternative to available alternatives. The optimal study design for this purpose is a randomized controlled trial (RCT) that compares the therapeutic intervention with existing alternative treatments and includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, such as arrhythmia detection rates, may also be adequate if there is an established link between the intermediate outcome and true health outcomes.

For some of the ambulatory event monitors (AEMs) discussed in this policy, including monitors that include real-time monitoring and analysis, the technologies represent an enhancement to existing technology and are intended to improve outcomes compared with event monitors. As such, to demonstrate an improvement in health outcomes, there must be a clinically significant incremental benefit when the additional technology, such as real-time monitoring, is added.

Another methodologic issue is the appropriate comparison group. AEMs may be used in a variety of clinical situations, including in patients who have suspected arrhythmias (e.g., due to the presence of cardiac symptoms), in patients who have had treatment for atrial fibrillation (AF) and in whom discontinuation of systemic anticoagulation is being considered, and in patients who are suspected to have AF due to a prior cryptogenic stroke. The evidence for the use of AEMs for each of these clinical situations is discussed separately. The appropriate comparison group (i.e., standard of care) differs depending on the clinical situation.

**Evaluation of AEMs and Mobile Cardiac Outpatient Telemetry in the Detection of Arrhythmias**

**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 electrocardiographic (ECG) monitoring has often been used to guide antiarrhythmic therapy in patients with symptomatic sustained ventricular arrhythmias or survivors of near sudden cardiac death, 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 flecaainide 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 al² 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; autotriggered event recorders; and implantable loop recorders. The yield varied among devices, with the autotrigger devices offering the highest range of detection (72%-80%), followed by the patient-activated devices (17%-75%), and Holter monitors (33%-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.

Turakhia 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%), 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<0.001). 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.

In 2015, Bolourchi et al evaluated the diagnostic yield of 14 days of monitoring with the Zio Patch in a cross-sectional study of 3209 children who were included in a manufacturer registry. Patient age ranged from 1 month to 17 years. Indications for monitoring included palpitations (n=1138 [95.5%]), syncope (n=450 [14.0%]), unspecified tachycardia (n=291 [9.1%]), paroxysmal supraventricular tachycardia (SVT) (n=264 [8.2%]), and chest pain (n=261 [8.1%]). The overall prevalence of any arrhythmia was 12.1%, with 44.1% of arrhythmias occurring after the first 48 hours of monitoring. Arrhythmias were detected in 10.0% of patients who were referred for palpitations, 6.7% of patients referred for syncope, 14.8% of patients referred for tachycardia, 22.7% of patients referred for paroxysmal SVT, and 6.5% of patients referred for chest pain.

**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 AEMs, 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. One comparative study of 50 patients noted that autoactivation may result in a large number of inappropriately stored events.

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. The authors evaluated 307 consecutive patients with external loop recorders (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 ECG 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.

**Implantable Loop Recorders**

The most appropriate indications for an implantable loop recorder (compared with an external loop recorder) are not well-established. In some cases, implantable loop recorders have been used for the evaluation of arrhythmias that happen so infrequently that they were not detected during conventional monitoring.

One small RCT 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 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).

In 2014, Podoleanu et al reported results of an open-label RCT comparing 2 strategies for evaluating syncope, an experimental strategy involving the early use of an implantable loop recorder and a conventional strategy.12 The study included patients who had a single syncope (if severe and recent, or at least 2 syncopes in the past 12 months. The syncope had to be unexplained at the end of clinical examination and a workup including 12-lead ECG, echocardiography, and head-up tilt-test. The 78 included patients were randomized either to receive an implantable loop recorder (the Reveal or Reveal Plus device; Medtronic, Minneapolis, MN; n=39) immediately or to be investigated according to the conventional evaluation strategy (n=39), excluding the use of an implantable loop recorder. After 14 months of follow up, a certain cause of syncope was established in 18 (46.2%) of patients in the implantable loop recorder group and in 2 (5%) of conventionally managed patients (p<0.001). Arrhythmic causes of syncope in the implantable loop recorder group included 2 cases of atrioventricular (AV) block (5%), 4 cases of sinus node disease (10%), 1 case of AF (2.5%), 1 cases of ventricular fibrillation (2.5%), and 3 other tachycardias (8%). In the conventionally managed group, 8 patients had a diagnosis of presumed reflex syncope. Although this study suggests that the diagnosis of arrhythmic disorders in patients with syncope is higher in patients evaluated with implantable loop recorders, it is difficult to assess whether the management in the standard therapy group is representative of typical practice because the management was not standardized.

In a report from an observational registry of patients who received or were about to receive an implantable loop recorder (the Reveal Plus, DX, or XT device) because of unexplained syncope, Edvardsson et al described the yield of monitoring in 570 patients who were implanted and followed for at least a year or until diagnosis.13 Most patients (97.5%) had a standard ECG before initiation of
the implantable loop recorder, 11.8% had prior external loop recorder, and 54.6% had in-hospital ECG monitoring. During the monitoring period, 218 patients (38%) had recurrent syncope. The proportion of specific diagnoses based on the implantable loop monitor is not reported, but of the subjects who had a recurrence, 42.2% had a pacemaker implanted, 4.6% had an implantable cardioverter defibrillator implanted, 4.1% received antiarrhythmic drug therapy, and 3.7% underwent catheter ablation.

Implantable autotrigger loop recorders have also been developed that are specifically geared toward detection of AF through the use of AF detection algorithms. Several nonrandomized studies have evaluated the accuracy of implantable autotriggered loop recorders for the diagnosis of AF. Hindricks et al\textsuperscript{14} 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\textsuperscript{15} 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. 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.

**Loop Recorders With Cellular Phone Transmission**

The most recent generation of event recorders has incorporated transmission using cellular phone technology.\textsuperscript{16,17} 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\textsuperscript{16} performed an observational study of 604 patients with palpitations, presyncope, and/or chest pain. This study demonstrated that the Cardio R\textsuperscript{®} device (SHL-Medical, Tel Aviv, Israel) was able to efficiently diagnose and transmit heart rhythm information. 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. The addition of real-time monitoring to outpatient ambulatory monitoring is considered an enhancement to existing technology.

One RCT was identified that compared mobile cardiac outpatient telemetry (MCOT) with standard event monitors. 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 patients vs 1 patient) and ventricular tachycardia defined as more than 3 beats and rate greater than 100 (14 patients 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 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.

A number of uncontrolled case series report on outcomes of MCOT. One such published study described the outcomes of a consecutive case series of 100 patients. 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 (i.e., 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. 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.

Section Summary
The available evidence suggests that MCOT is likely at least as good at detecting arrhythmias as ambulatory event monitoring. 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. The addition of real-time monitoring to outpatient ambulatory monitoring is considered an enhancement to existing technology.

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. 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 CHADS² score and the presence of recurrent episodes of AF.

In a prospective, randomized study, Kapa et al compared implantable loop monitors with conventional transtelephonic recorders in the assessment of arrhythmia burden after catheter ablation of AF. 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 transtelephonic monitoring periods. At 6 months 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 transtelephonic recording for 30 days at month 11). Over the first 6 months after ablation, conventional monitoring revealed AF in 7 of 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 of 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 of 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 1 such study of 3355 patients from 5 clinical centers,28 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.29,30 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).31

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.32,33 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.29,34,35

Systematic Reviews
In 2015, Sposato et al reported results of a systematic review and meta-analysis of studies reporting rates of new AF diagnosis after cryptogenic stroke or TIA based on cardiac monitoring, stratified into 4 sequential phases of screening: phase 1 (emergency department) consisted of admission ECG;
phase 2 (in hospital) comprised serial ECG, continuous inpatient ECG monitoring, continuous inpatient cardiac telemetry, and in-hospital Holter monitoring; phase 3 (first ambulatory period) consisted of ambulatory Holter; and phase 4 (second ambulatory period) consisted of MCOT, external loop recording, and implantable loop recording.\textsuperscript{36} In total, 50 studies with 11,658 patients met the inclusion criteria. Studies were mixed in their patient composition: 22 (28%) included only cryptogenic stroke cases, 4 (5%) stratified events into cryptogenic and noncryptogenic, and 53 (67%) included unselected patient populations. The summary proportion of patients diagnosed with poststroke AF was 7.7\% (95\% CI, 5.0 to 10.8) in phase 1, 5.1\% (95\% CI, 3.8\% to 6.5\%) in phase 2, 10.7\% (95\% CI, 5.6\% to 17.2\%) in phase 3, and 16.9\% (95\% CI, 13.0\% to 21.2\%) in phase 4. The overall AF detection yield after all phases of sequential cardiac monitoring was 23.7\% (95\% CI, 17.2\% to 31.0\%). In phase 4, there were no differences between the proportion of patients diagnosed with poststroke AF by MCOT (15.3\%; 95\% CI, 5.3\% to 29.3\%), external loop recording (16.2\%; 95\% CI, 0.3\% to 24.6\%), and implantable loop recording (16.9\%; 95\% CI, 10.3\% to 24.9\%; \textit{p}=0.97).

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.\textsuperscript{37} 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 (i.e., selected on the basis of stroke pathogenesis, age, or prescreening for AF), the detection rate of any new AF was 6.2\% (95\% confidence interval [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, because 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.

\textbf{Randomized Controlled Trials}

There were 4 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 MCOT.\textsuperscript{38} There were no cases of AF 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.\(^{39}\) 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 ECG, 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-day follow-up, any-duration paroxysmal AF was more commonly detected in the event monitoring group: 48% versus 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.\(^{40,41}\) 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 (MRI), and no mechanism determined after a work-up that included 12-lead ECG, 24-hour Holter monitoring, transesophageal echocardiography, CT or magnetic resonance angiography of the head and neck, and hypercoagulability screening (for patients <55 years old). 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], 14-84) in the ICM group and 32 days (IQR, 2-73) 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 autotriggered cardiac event monitors with conventional 24-hour monitors for the detection of AF in patients with cryptogenic stroke.\(^{42}\) 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 ECGs 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 45 of 280 patients (16.1%) in the intervention group, compared with 9 of 277 (3.2%) in the control group (risk difference, 12.9 percentage points; 95% CI, 8.0 to 17.6; \(p<0.001\)). At 90-day follow-up, patients in...
the intervention group were more likely to be treated with anticoagulants than the control group (18.6% vs 11.1%; absolute treatment difference, 7.5 percentage points; 95% CI, 1.6 to 13.3; p=0.01).

Other Studies

Implantable Loop Recorders
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. 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 (between-group comparison of detection rate, p<0.001). The average time to detection with ICM was 64 (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. 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 ECG (2 obtained in preparation for implantation procedure, 1 on ECG for pacemaker placement for a non-AF arrhythmia, 1 on ECG 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. Evaluation for causes of stroke included MRI, 12-lead ECG, 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%).

External Loop Recorders
Plas et al reported the results of a prospective study of 94 patients with cryptogenic stroke who underwent 24 hours of monitoring with an external loop recorder with an automated AF detection
The 24-hour automated loop recorder revealed paroxysmal AF in 4 patients (4%) and paroxysmal atrial flutter in 1 patient (1%).

Continuous Monitors With Longer Recording Periods
In a cohort study using data available from the device’s manufacturer, Tung et al reported the yield of a continuously recording device with longer recording period (the Zio® Patch) for the detection of AF among patients with stroke or TIA. The study evaluated monitoring reports for all patients who underwent monitoring with the ZIO Service in the United States from January 2012 to June 2013 and had an indication for monitoring listed as stroke or TIA, for a total of 1171 monitoring reports. The previous diagnostic workup patients had following stroke or TIA was not described. The median wear time was 13.0 days. The frequency of AF at 14 days was 5% (4.4% paroxysmal AF, 0.6% chronic AF), with a mean duration before the first AF episode of 1.5 days (median, 0.4 days). Supraventricular tachycardia (SVT) of 4 beats or more was present in 70.2% of recordings. This study reported generally early detection of AF, but without information about whether patients had previously undergone inpatient or outpatient Holter monitoring, the significance of this is less clear. In addition, the explanation and significance of the high rate of SVT detection is unknown.

Mobile Cardiac Outpatient Telemetry
In 2015, Favilla et al reported results of a retrospective cohort study of 227 patients with cryptogenic stroke or TIA who underwent 28 days of monitoring with mobile cardiac outpatient telemetry. AF was detected in 14% of patients (31/227), of whom 3 reported symptoms at the time of AF. Oral anticoagulation was initiated in 26 patients (84%) diagnosed with AF. Of the remaining 5 (16%) who were not anticoagulated, 1 had a prior history of gastrointestinal bleeding, 3 were not willing to accept the risk of bleeding, and 1 failed to follow up.

In an earlier retrospective cohort study, Miller et al retrospectively analyzed paroxysmal AF detection rates among 156 patients who were evaluated with MCOT within 6 months of a cryptogenic stroke or TIA. Over a median period of MCOT monitoring of 21 (range, 1-30) days, AF was detected in 17.3% of patients. The mean time to first occurrence of AF was 8.8 (range, 1-21) days.

Section Summary
Several randomized studies demonstrate that implantable and external loop recorders are associated with higher rates of detection of AF compared with Holter monitoring among patients with cryptogenic stroke, including 2 larger RCTs published in 2014. Because most patients with a history of stroke 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. There are no controlled trials for the use of MCOT for the detection of AF after cryptogenic stroke.

AF Detection in Unselected Patients
In 2015, Turakhia et al reported results of a single-center noncomparative study evaluating the feasibility and diagnostic yield of a continuously recording device with longer recording period.
(Zio® Patch) for AF screening in patients with risk factors for AF. The study included 75 patients older than age 55 with at least 2 of risk factors for AF (coronary disease, heart failure, hypertension, diabetes, or sleep apnea), without a history of prior AF, stroke, TIA, implantable pacemaker or defibrillator, or palpitations or syncope in the prior year. Of the 75 subjects, 32% had a history of significant valvular disease, and 9.3% had prior valve replacement. Most subjects were considered to be at moderate to high risk of stroke (CHA₂DS₂-VASc ≥2 in 97% of subjects). AF was detected in 4 subjects (5.3%), all of whom had CHA₂DS₂-VASc scores of 2 or greater. All patients with AF detected had an initial episode within the first 48 hours of monitoring. Five patients had episodes of atrial tachyarrhythmias lasting at least 60 seconds detected.

**Section Summary**

For the use of ambulatory monitoring for the diagnosis of AF in asymptomatic but higher risk patients, a small noncomparative study demonstrated that 14-day monitoring with the Zio Patch is feasible. The use of population-based screening for asymptomatic patients is not well-established, and several studies are underway to evaluate population-based screening are currently underway and may influence the standard of care for AF detection in patients without symptoms or a history of stroke or TIA. To determine whether outcomes are improved for ambulatory monitoring for AF in patients without a history of stroke/TIA or treated AF, studies comparing the outcomes for various outpatient diagnostic screening strategies for AF would be needed.

**Summary of Evidence**

For the use of autoactivated event monitors for arrhythmia detection in patients with suspected arrhythmias, 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.

For the use of autoactivated event monitors for detection of atrial fibrillation (AF) in patients who have been treated with catheter ablation, there is 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 the use of autoactivated event monitors for the detection of AF in patients with cryptogenic stroke, the most direct evidence consists of 1 well-designed and well-controlled randomized controlled trial (RCT) which demonstrated improved AF detection rates for patients managed with 30 days of autotriggered event monitoring compared with those managed with 24-hour Holter monitoring. Observational studies support this finding. There are recognized management changes which lead to improved outcomes for patients with stroke and AF (i.e., initiation of oral anticoagulation). Therefore, the published evidence is sufficient to determine that autotrigger event monitors improve the net health outcome for patients with suspected arrhythmia, for patients who have undergone catheter ablation for AF and in whom discontinuation of systemic anticoagulation is being considered, and for patients with cryptogenic stroke.
Similarly, for the use of implantable event monitors for the detection of AF in patients with cryptogenic stroke, the most direct evidence consists of an RCT comparing the use of an autotriggered implantable monitor with routine care in patients with cryptogenic stroke. This study demonstrated improvements in AF detection rate with event monitoring, compared with routine care. The published evidence is sufficient to determine that implantable event monitors for AF detection improve the net health outcome for patients with cryptogenic stroke.

For the evaluation of patients with infrequent symptoms who have not had arrhythmias detected with standard Holter monitoring or external event monitors, there is little direct evidence regarding outcomes associated with implantable loop recorders. 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, for patients presenting with signs or symptoms suggestive of an arrhythmia, 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.

Newer continuous monitoring devices are available that use novel technology and record information for longer periods than a Holter monitor (e.g., up to 2 weeks). The available evidence for these devices consists of cross-sectional studies that show they typically detect greater numbers of arrhythmias during extended follow-up than 24- or 48-hour Holter monitoring. However, the appropriate comparison group would be patient- or autotriggered event monitors, and no studies were identified that compared longer recording devices with patient- or autotriggered event monitors. Direct evidence for improved outcomes with the use of these types of monitors is lacking. The evidence for a significant incremental improvement in outcomes when continuous monitoring devices are used is lacking. Therefore, the available published evidence is considered insufficient to determine that continuous monitoring devices with longer recording periods improve the net health outcome for patients with suspected arrhythmias.

Mobile cardiac outpatient telemetry (MCOT) is another option for long-term cardiac monitoring. For the use of MCOT for the evaluation of patients with suspected arrhythmias, evidence from 1 RCT and uncontrolled case series suggests that MCOT is likely to be as effective at detecting arrhythmias as 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. Direct evidence for improved health outcomes with the use of MCOT for the evaluation of suspected arrhythmias is lacking, and evidence for a significant incremental improvement in outcomes with MCOT, compared with standard management, is lacking. Therefore, the available published evidence is considered insufficient to determine that MCOT improves the net health outcome for patients with suspected arrhythmias.

Similarly, for the use of MCOT for the detection of AF either in patients following catheter ablation of AF or following cryptogenic stroke, there is no direct evidence comparing MCOT with other
detection methods. Single-arm studies report relatively high rates of AF detection with MCOT in patients with cryptogenic stroke. Direct evidence for improved health outcomes with the use of MCOT for the evaluation of AF and evidence for a significant incremental improvement in outcomes with MCOT, compared with standard management, is lacking. Therefore, the available published evidence is considered insufficient to determine that MCOT improves the net health outcome for patients who require evaluation for AF.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
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 societies or academic medical centers, unless otherwise noted.

2009 Input
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. There were differences among reviewers regarding outpatient cardiac telemetry, with some reviewers concluding it had a role in certain subsets of patients; e.g., 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.

2014 Input
In response to requests, input was received from 3 physician specialty societies and 4 academic medical centers (3 reviews) while this policy was under review in 2014. Clinical input was obtained to provide information related to MCOT and new devices. There was not consensus about whether MCOT is medically necessary. While reviewers agreed that MCOT is comparable with event monitors for arrhythmia detection, they did not agree on whether the real-time monitoring provides incremental benefit over external event monitors or is associated with improved health outcomes compared with external event monitors. There was consensus in support of the medical necessity of externally worn event monitors with longer continuous recording periods as an alternative to Holter monitors or event monitors. For implantable memory loop devices with smaller size than older-generation devices, there was consensus that these devices improve the likelihood of obtaining clinically useful information due to improved ease of use, but there was not consensus that such devices improve clinical outcomes and are 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 and AHA published guidelines for the use of ambulatory electrocardiography. These guidelines did not make an explicit distinction between continuous (i.e., Holter monitor) and intermittent (i.e., ambulatory event monitor [AEM]) monitoring. Regarding the effectiveness of antiarrhythmic therapy, the ACC guidelines list 1 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 previous first policy statement (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 myocardial infarction (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, 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 MI such monitoring would be optimal.

A consensus document on catheter and surgical ablation for AF was published in 2012. 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 [electrocardiographic] monitoring to screen for asymptomatic AF/AFL/AT [atrial fibrillation/atrial flutter/atrial tachycardia].

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 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.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD).

**V. Definitions**

**Holter Monitor** is a portable device small enough to be worn by a patient during normal activity. It consists of an electrocardiograph and a recording system capable of storing up to twenty-four hours of the patient's EKG record.

**Myocardial Infarction** is the loss of heart muscle as a result of coronary artery occlusion.

**Syncope** is a sudden but transient total loss of consciousness with spontaneous resolution.

**VI. Benefit Variations**
The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

**VII. Disclaimer**
Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a
member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Mobile Cardiac Outpatient Telemetry is Covered when Medically Necessary:

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<tr>
<td>Z79.899</td>
<td>Other long term (current) drug therapy</td>
</tr>
<tr>
<td>Z87.74</td>
<td>Personal history of (corrected) congenital malformations of heart and circulatory system</td>
</tr>
</tbody>
</table>
Z95.0  Presence of cardiac pacemaker

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

Ambulatory Event Monitors are Covered when medically necessary:

<table>
<thead>
<tr>
<th>CPT Codes®</th>
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<tbody>
<tr>
<td>33282</td>
<td>33284</td>
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<tr>
<td>93268</td>
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<td>93271</td>
<td>93272</td>
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<tr>
<td>93285</td>
<td>93291</td>
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<tr>
<td>93297</td>
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<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0616</td>
<td>Implantable cardiac event recorder with memory, activator, and programmer</td>
</tr>
<tr>
<td>C1764</td>
<td>Event recorder, cardiac (implantable)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Codes*</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I20.1</td>
<td>Angina pectoris with documented spasm</td>
</tr>
<tr>
<td>I42.1</td>
<td>Obstructive hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>I42.2</td>
<td>Other hypertrophic cardiomyopathy</td>
</tr>
<tr>
<td>I45.9</td>
<td>Conduction disorder, unspecified</td>
</tr>
<tr>
<td>I48.0</td>
<td>Paroxysmal atrial fibrillation</td>
</tr>
<tr>
<td>I48.2</td>
<td>Chronic atrial fibrillation</td>
</tr>
<tr>
<td>I48.91</td>
<td>Unspecified atrial fibrillation</td>
</tr>
<tr>
<td>I49.40</td>
<td>Unspecified premature depolarization</td>
</tr>
<tr>
<td>I49.8</td>
<td>Other specified cardiac arrhythmias</td>
</tr>
<tr>
<td>I49.9</td>
<td>Cardiac arrhythmia, unspecified</td>
</tr>
<tr>
<td>I63.8</td>
<td>Other cerebral infarction</td>
</tr>
<tr>
<td>I63.9</td>
<td>Cerebral infarction, unspecified</td>
</tr>
<tr>
<td>R55</td>
<td>Syncope and collapse</td>
</tr>
<tr>
<td>R42</td>
<td>Dizziness and giddiness</td>
</tr>
<tr>
<td>R00.0</td>
<td>Tachycardia, unspecified</td>
</tr>
<tr>
<td>R00.2</td>
<td>Palpitations</td>
</tr>
<tr>
<td>Z86.73</td>
<td>Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits</td>
</tr>
<tr>
<td>Z79.01</td>
<td>Long term (current) use of anticoagulants</td>
</tr>
</tbody>
</table>

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.
IX. REFERENCES


<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number</td>
<td>MP-2.036</td>
</tr>
</tbody>
</table>


46. Tung CE, Su D, Turakhia MP, et al. Diagnostic Yield of Extended Cardiac Patch Monitoring in Patients with Stroke or TIA. Front Neurol. 2014;5:266. PMID 25628595


Other Sources:


Novitas Solutions. Local Coverage Determination (LCD) L34997: Real-Time, Outpatient Cardiac Monitoring. Effective 10/1/15. [Website]: http://www.novitas-solutions.com/webcenter/portal/NovitasSolutions?_afrLoop=8084184539456000#!%40%40%3F_afrLoop%3D8084184539456000%26_adf.ctrl-state%3Dyype973bue_31

### MEDICAL POLICY

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>AMBULATORY EVENT MONITORS AND MOBILE CARDIAC OUTPATIENT TELEMETRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY NUMBER</td>
<td>MP-2.036</td>
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#### X. POLICY HISTORY

<table>
<thead>
<tr>
<th>MP 2.036</th>
<th>CAC 2/25/03</th>
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<tbody>
<tr>
<td></td>
<td>CAC 7/29/03</td>
</tr>
<tr>
<td></td>
<td>CAC 11/30/04</td>
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<td></td>
<td>CAC 10/25/05</td>
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<td>CAC 2/27/07</td>
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<td></td>
<td>CAC 4/24/07</td>
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<tr>
<td></td>
<td>CAC 5/27/08</td>
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<tr>
<td>J12 MAC 12/12/08</td>
<td>CAC 3/31/09 Consensus</td>
</tr>
<tr>
<td></td>
<td>CAC 3/30/10 Consensus</td>
</tr>
<tr>
<td></td>
<td>CAC 7/26/11 Adopted BCBSA: Ambulatory event monitoring (AEM) criteria for monitoring of antiarrhythmic therapy revised from Medically Necessary to Investigational. Medicare variation added for AEM.</td>
</tr>
<tr>
<td></td>
<td>1/31/2012 – Admin Change as per instructions regarding Holter Monitor.</td>
</tr>
<tr>
<td>CAC 3/26/13</td>
<td>Minor review</td>
</tr>
<tr>
<td></td>
<td>This is a partial adopt BCBSA policy. Section on Mobile Cardiac Outpatient Telemetry (Outpatient Cardiac Telemetry) does not match BCBSA.</td>
</tr>
<tr>
<td></td>
<td>Regarding use of patient-activated or auto-activated external ambulatory event monitors. The following was added as medically necessary. “Patients with atrial fibrillation who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered”</td>
</tr>
<tr>
<td></td>
<td>References updated.</td>
</tr>
<tr>
<td></td>
<td>FEP variation added to reference the FEP manual.</td>
</tr>
<tr>
<td></td>
<td>Background/Description updated to be current with advancing technology.</td>
</tr>
<tr>
<td></td>
<td>Added reference to Novitas Solutions Local Coverage Determination (LCD) L27520 Real Time Outpatient Telemetry in Medicare variation.</td>
</tr>
<tr>
<td>02/18/2013</td>
<td>Unspecified codes removed from policy</td>
</tr>
<tr>
<td>05/13/13</td>
<td>Administrative code review completed.</td>
</tr>
<tr>
<td>1/27/15</td>
<td>Minor review. Adopting BCBSA with the following changes. Added the following medically necessary indication for patient-activated or auto-activated external ambulatory event monitors</td>
</tr>
<tr>
<td></td>
<td>Patients with cryptogenic stroke who have a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor</td>
</tr>
</tbody>
</table>
**MEDICAL POLICY**

<table>
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<td>MP-2.036</td>
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</table>

Changed policy statements for MCOT. Deleted list of MN criteria. Added information regarding least costly alternative. Added reference to MP 4.003 Medically Necessary. Added policy guidelines.

Changed policy statement for implantable monitors. Deleted requirement to have holter monitor testing prior to implantation and added criteria to have other external ambulatory event monitoring for an extended period of at least 21 days prior to implantation.

Added statement regarding use of continuous ambulatory monitors that record and store information for periods longer than 48 hours (was coded as investigational). Now may be considered medically necessary as a diagnostic alternative to Holter monitoring or patient-activated or auto-activated external ambulatory event monitors in the following situations:

- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., 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

Coding reviewed. Added reference to LCD L32679 in the Medicare variation.

**11/2/15** Administrative change. LCD number changed from L32679 and L27520 to L34953 and L34997 due to Novitas update to ICD-10.

**CAC 1/26/16** Minor revision. Added a statement that use of an implantable ambulatory event monitor is medically necessary for patients with cryptogenic stroke who have had a negative standard work-up for atrial fibrillation including a 24-hour Holter monitor. Policy statement related to the use of mobile cardiac outpatient telemetry changed from “not medically necessary” to “investigational”. Policy guidelines revised. Rationale and reference update. Coding updated.

**06/22/2016-** Admin Coding update.

**Administrative Update 1/1/17** New Diagnosis Codes added effective 10/1/16. Variations reformatted.
Administrative Update 2/1/17  Policy revised to indicate that Mobile Cardiac Outpatient Telemetry (Real-Time, Outpatient Cardiac Monitoring, AEOG, or MCOT) is now considered medically necessary for select adult and pediatric patients who meet specific policy indications and all other indications are considered investigational.

Also for the use of external ambulatory external even monitors three new indications were added to include:

- Patients in whom antiarrhythmic drug therapy has been initiated to document the results of therapy
- Patients in whom antiarrhythmic drug therapy has been withdrawn to record recurrence of an arrhythmia
- Patients suspected of having cardiac ischemia to record electrocardiographic changes

Two of the existing indications for external ambulatory event monitors were revised to include additional criteria/indications:

- Patients with infrequent (less frequent than every 48 hours), or those with a nondiagnostic Holter monitor who experience symptoms suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).
- Patients who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered or to document the results of an ablative procedure for arrhythmia

A statement was added that all other indications for external ambulatory event monitors are considered investigational.

Continuous ambulatory monitors that record and store information for periods longer than 48 hours criteria were removed from the policy.

Coding Reviewed