

# *Retired Effective March 20, 2017*

## *Refer to Contract Benefits*



BlueCross BlueShield  
of Alabama

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### **Name of Blue Advantage Policy:**

### **Mobile Cardiac Outpatient Telemetry and Hybrid Devices**

Policy #: 460  
Category: Medical

Latest Review Date: July 2015  
Policy Grade: **Effective January 2, 2013, this remains an active policy but no longer scheduled for regular literature reviews and updates.**

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### **Background:**

*Blue Advantage* medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. Safe and effective;
2. Not experimental or investigational\*;
3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

## **Description of Procedure or Service:**

Ambulatory event monitors store recorded cardiac rhythm data, which are ultimately transmitted either to a physician's office or to a central recording station. In contrast to Holter monitors or event records, outpatient cardiac telemetry is real-time outpatient cardiac monitoring system that is automatically activated and requires no patient intervention to either capture or transmit an arrhythmia when it occurs. Upon arrhythmia detection, the device utilizes a standard telephone line or wireless communications and transmits the electrocardiogram (EKG) waveform to the receiving center. The patient's physician is made aware of arrhythmias based on pre-determined notification criteria, tailored to the patient by the physician. Real-time cardiac monitoring provides continuous (beat-to-beat) outpatient EKG monitoring for periods ranging up to several weeks.

For example, CardioNet Inc. now owned by BioTelemetry (Malvern, PA) offers mobile cardiac outpatient telemetry (MCOT). In this system, the patient wears a three-lead sensor, which constantly communicates with the CardioNet monitor, a lightweight unit that can be carried in a pocket or a purse. Patients wear CardioNet MCOT for up to 21 days of monitoring. CardioNet monitors patients 24 hours a day via the small sensor and monitor the patient wears as they continue with their normal daily routine. As events occur, patient activity is automatically transmitted to the CardioNet Monitoring Center for analysis and response. 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), the Lifestar Ambulatory Cardiac Telemetry (ACT) system (Card Guard Scientific Survival Ltd., Israel), and the SEEQ™ Mobile Cardiac Telemetry System (Medtronic, Minneapolis, MN). The eCardio Verité™ system (eCardio, Houston, TX) is a multifunctional model that can be changed between a patient-activated event monitor and a continuous telemetry monitor.

The VectraplexECG™ System is a real-time continuous MCOT device to measure ischemic ECG changes that can be indicative of a myocardial infarction (MI). This device uses the Internet to communicate real-time ECG changes to the physician. The patient is hooked up to a mini-tablet by either five 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.

There are also hybrids or "extended daily monitoring" devices on the market. These 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.

**Policy:**

**On or after August 1, 2011 refer to LCD L30038 Long-Term Wearable Electrocardiographic Monitoring (WEM) to review MCOT.**

**Effective for dates of service on or after April 5, 2011 –July 31, 2011:**

**Blue Advantage will treat outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) as a non-covered benefit as a diagnostic alternative in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope) and as investigational.**

**Effective for dates of service on or after May 19, 2011:**

**Blue Advantage will treat Hybrid ambulatory cardiac monitoring devices as a non-covered benefit and as investigational.**

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**

**Use in the Detection of Arrhythmias**

**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 to the use of ambulatory event monitors. 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.

One randomized, controlled trial was identified that compared MCOT to 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 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. The majority of 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 auto-trigger devices.

A diagnostic endpoint (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 consisting of rapid atrial fibrillation and/or flutter (15 patients vs. one patient) and ventricular tachycardia defined as more than three beats and rate greater than 100 (14 patients vs. two patients). These were thought to be clinically significant rhythm disturbances and the likely causes of the patients' symptoms. The paper does not comment on the clinical impact (changes in management) of these findings in patients for whom the rhythm disturbance did not occur simultaneously with symptoms. In this study, the median time to diagnosis in the total study population was seven days in the MCOT group and nine 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 nine-month period were retrospectively examined. Of these patients, 21% (5,459) 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 six seconds or longer and 42 with sustained bradycardia at less than thirty 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, including, 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 atrial fibrillation by standard monitoring. In this study, 13 of 56 patients (23%) with cryptogenic stroke were found to have atrial fibrillation with MCOT. Twenty-seven asymptomatic atrial fibrillation episodes were detected in the 13 patients, 23 of these were shorter than 30 seconds in duration.

### Section Summary

MCOT is another option for long-term cardiac monitoring. The current evidence on MCOT establishes that it does record cardiac electric signals, without patient activation, for subsequent analysis. Currently, the literature does not provide any adequate comparative data for MCOT

compared to the autotrigger device. One retrospective, uncontrolled study reported that only a small minority of events (1%) detected by MCOT were potentially emergent. None of the available studies have clearly shown an improvement in clinical utility as a result of using MCOT. Further study of MCOT is needed to compare MCOT with the autotrigger loop recorder in order to determine whether the faster response possible with real-time monitoring leads to improved outcomes.

#### 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 two 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. 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  $7.6 \pm 3.6$  days, and 95.9% of patients wore the device for more than 48 hours. At least one 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. 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 one 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 non-research 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 3,209 children who were included in a manufacturer registry. Patients' age ranged from one 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.

### **Use in the Detection of Atrial Fibrillation**

#### 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 three reported symptoms at the time of AF. Oral anticoagulation was initiated in 26 patients (84%) diagnosed with AF. Of the remaining five (16%) who were not anticoagulated, one had a prior history of gastrointestinal bleeding, three were not willing to accept the risk of bleeding, and one 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 six months of a cryptogenic stroke or TIA. Over a median period of MCOT monitoring of 21 days (range: one to 30 days), AF was detected in 17.3% of patients. The mean time to first occurrence of AF was 8.8 days (range: one to 21 days).

#### 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 U.S. 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 and 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 four 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.

## **AF Detection in Unselected Patients**

### Continuous Monitors with Longer Recording Periods

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 (the Zio® Patch) for AF screening in patients with risk factors for AF. The study included 75 patients over age 55 with at least two 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 (CHA<sub>2</sub>DS<sub>2</sub>-VASc  $\geq 2$  in 97% of subjects). Atrial fibrillation was detected in four subjects (5.3%), all of whom had CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of greater than or equal to two. 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**

Newer continuous monitoring devices are available that use novel technology and record information for longer periods than a Holter monitor, e.g., up to two weeks. The available evidence for these devices consists of cross-sectional studies that show that 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 are 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 one 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 auto-trigger 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.

### **Key Words:**

Mobile outpatient cardiac telemetry, MCOT, outpatient cardiac telemetry, OCT, Verite´, Zio® Patch, Zio™ ECG Utilization Service, ZEUS, VectraplexECG™, BodyGuardian Remote Monitoring System™, HeartLinkII™, VST™, LifeStar™ ACT, CardioNet®, SEEQ™

### **Approved by Governing Bodies:**

A number of MCOT devices have received approval by the U.S. Food and Drug Administration including, Mobile Cardiac Outpatient Telemetry™ (MCOT™) (CardioNet Inc.), the HEARTLink II™ system (Cardiac Telecom Corp.), the VST™ (Vital Signs Transmitter, Biowatch Medical), NUVANT™ Mobile Cardiac Telemetry (MCT) System (Corventis, Inc.), and the LifeStar™ Ambulatory Cardiac Telemetry (ACT) system (Card Guard Scientific Survival Ltd).

The Zio® Patch (iRhythm Technologies Inc., Sand Francisco, CA) received FDA 510(k) approval in May 2009.

There is no specific FDA approval for the Verite´ device. According to eCardio, these devices utilize the FDA 510(k) approval for the Braemer ER900 device.

### **Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.



## **Current Coding**

Any existing or future devices for this service should be billed in accordance with the CPT-4 manual, the CPT Changes: An Insider's View book, and the CPT Assistant intent and instructions. If the service is not consistent with these sources, the service should be billed with the not otherwise classified (NOC) code.

### CPT Codes:

- 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 (**Effective 01/01/2012**)
- 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) (**Effective 01/01/2012**)
- 0297T** External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report (**Effective 01/01/2012**)
- 0298T** External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation (**Effective 01/01/2012**)
- 93228** External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
- 93229** ; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional

### **For hybrid devices:**

- 93799** Unlisted cardiovascular service or procedure

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### **Policy History:**

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Medical Policy Group, March 2017

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*