

# Protocol

## Ambulatory Event Monitors and Mobile Outpatient Cardiac Telemetry

(20208)

(Formerly Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/14	<b>Next Review Date:</b> 01/15
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 05/07, 07/08, 09/09, 09/10, 01/11, 01/12, 01/13, 01/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required for mobile cardiac outpatient telemetry if, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

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

### Background

A brief description of the major categories of devices is given below. There has been a trend in recent years toward using novel technology to increase the efficiency, comfort, and convenience of these devices. These 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 describe below for informational purposes in assigning them to the most relevant category. However, since there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review.

### Continuous monitoring devices (Holter monitors and similar devices)

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

### Continuous monitoring devices with longer recording periods

Some newer devices are 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 pre-paid envelope to a central station and a full report is provided to the physician within a few days.

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

#### Non-continuous monitoring devices (ambulatory event monitors and similar devices)

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

#### Noncontinuous devices with memory

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

- The Zio® Event Card (iRhythm Technologies, Inc., San Francisco, CA) is a noncontinuous real-time recording device that can be worn up to 30 days. This device can be worn comfortably under clothing (including during sleep), as it weighs less than two 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 two options, depending on the patient's circulation: 1) a zero-lead device that is separate from the body and may be carried in a purse or coat pocket; or if a patient's circulation is determined to be inadequate, 2) a single electrode lead that the patient connects to the device at the time of an event. The zero-lead device records an event by patient activation and can record and store up to 2,000 readings. The patient has the option of sending stored event information to the physician across a free-of-charge phone app or the Internet in their computer. Internet transmission requires one of the following systems: Android, Blackberry, iPhone 3, 3S, 4, and 4S, iPad, iPod Touch® Microsoft, or Windows.

#### Continuous "memory loop" devices

These devices are able to continuously store a single channel of EKG data in a refreshed memory. If the patient

activates the device, the EKG is then recorded from the memory loop for the *preceding* 30 to 90 seconds and for the next minute or so. Therefore, these types of devices permit recording of the onset of arrhythmias and/or transient or incapacitating events. They obviously must be worn continuously.

#### Implantable continuous “memory loop” devices

An implantable loop recorder device is inserted just under the patient’s skin in the chest area during an outpatient surgical procedure. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for more than one year. The Reveal® Insertable Loop Recorder (Medtronic) is an implantable memory loop device recently approved by the U.S. Food and Drug Administration (FDA).

#### 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 three 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 three seconds. They typically contain other autotriggers, such as a variable RR interval seen with atrial fibrillation.

#### *Mobile Cardiac Outpatient Telemetry*

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

#### **Policy (Formerly Corporate Medical Guideline)**

The use of patient activated or auto-activated external ambulatory event monitors may be considered **medically necessary** as a diagnostic alternative to Holter monitoring in the following situations:

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

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

Outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry or MCOT) is considered **not medically necessary** 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) because:

- The clinical (health) outcomes with this technology are expected to be equivalent to those obtained using other devices, yet outpatient cardiac telemetry is generally more costly than those alternative approaches;
- MCOT is generally determined to be more costly than other devices and therefore **not medically necessary**.

Continuous ambulatory monitors that record and store information for periods longer than 72 hours are considered **investigational**.

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

### Medicare Advantage

For Medicare Advantage cardiac event detection involving the use of a long term monitor by a patient, which includes both ambulatory event monitors and MCOT, is **medically necessary** for:

1. Detection, characterization, and documentation of symptomatic transient arrhythmias when the frequency of the symptoms is limited and use of a 24-hour ambulatory EKG is unlikely to capture and document the arrhythmia;
2. Regulation of antiarrhythmic drug dosages, when needed to assess efficacy of treatment;
3. To monitor patients who have had surgical or ablative procedures for arrhythmias.

Although the service is a 30-day service, it is recognized that the event recorder may be discontinued once the symptom-producing arrhythmia has been documented and diagnosed or following multiple transmissions during symptoms, without arrhythmia. It is unlikely that the arrhythmias would always be diagnosed on the first day of recording, or that the service would always last only one day. The average duration of monitoring is anticipated to last 10-14 days, or more.

The receiving station must be staffed on a 24-hour basis with personnel trained to read EKGs (e.g., critical nurses or paramedics) who should be able to direct the patient for the management of all emergencies. An answering service/answering machine would not fulfill this requirement. Also, systems utilizing computers to dial the physician's office so the physician receives transmission by way of a relay are not appropriate since there is no 24-hour personnel attendance.

Testing for more than 30 consecutive days is only **rarely medically necessary** and the need for continued testing must be justified by the treating physician. Failure to document an arrhythmia during a 30-day test period is not sufficient justification for a second or subsequent test. It is **unlikely to be medically necessary** to repeat a second test within a year in the absence of new or recurrent undiagnosed symptoms.

Because event recorders must be patient activated, they are **not medically appropriate** for any patient who is unresponsive, comatose, severely confused or otherwise unable to recognize symptoms and activate the recorder. Also they are **not medically appropriate** for recently discharged post-infarct patients or for routine monitoring in the absence of treatable symptoms.

External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage may be considered medically necessary for the same indications as dynamic electrocardiography (e.g., Holter™ monitoring).

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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