Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

(20208)

Medical Benefit

Effective Date: 04/01/12  
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Preauthorization*

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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**

*Ambulatory Event Monitors*

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. Ambulatory event monitors (AEMs) were developed to provide longer periods of 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.

*Continuous “memory loop” devices*

These sophisticated 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 **preceeding** 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.

**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 patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).

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 Holter monitor and other external ambulatory event monitors has been unsuccessful.

The use of auto-activated external ambulatory event monitors may be considered medically necessary in patients treated for atrial fibrillation to monitor asymptomatic episodes in order to evaluate treatment response.

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); this is considered **not medically necessary** because the clinical (health) outcomes with this technology have not been shown to be superior to other available approaches, yet outpatient cardiac telemetry is generally more costly than those alternative approaches.

Other uses of ambulatory event monitors, including outpatient telemetry, are considered **investigational**, including but not limited to monitoring effectiveness of antiarrhythmic therapy 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 and 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 is not appropriate since there is no 24-hour personnel attendance.

Testing for more than 30 consecutive days is only **rarely medically necessary**. 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.

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.


