Introduction

Mobile cardiac outpatient telemetry is a small device that is connected to wires that are attached to the chest. It sends information to a distant doctor’s office when an uneven heart rhythm is detected. It is considered an alternative to other heart monitors. There is not enough information from studies to be certain that this type of device works as well as other heart monitors in reducing heart problems and death. The use of this device is not yet proven.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient cardiac telemetry (aka, mobile cardiac outpatient telemetry)</td>
<td>Using outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry) as a diagnostic alternative to ambulatory event monitors is considered investigational.</td>
</tr>
</tbody>
</table>
### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>93228</td>
<td>External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real-time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional.</td>
</tr>
<tr>
<td>93229</td>
<td>External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; 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.</td>
</tr>
</tbody>
</table>

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### Related Information

N/A

### Evidence Review

### Description

Various devices are available for outpatient cardiac rhythm 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 delivering the information from patient to clinician. These devices may be used to evaluate symptoms suggestive of arrhythmias (eg, syncope, palpitations), and may be used to detect atrial
fibrillation (AF) in patients who have undergone cardiac ablation of AF or who have a history of cryptogenic stroke.

### Background

**Cardiac Arrhythmias**

Cardiac monitoring is routinely used in the inpatient setting to detect acute changes in heart rate or rhythm that may need urgent response. For some conditions, a more prolonged period of monitoring in the ambulatory setting is needed to detect heart rate or rhythm abnormalities that may occur infrequently. These cases may include the diagnosis of arrhythmias in patients with signs and symptoms suggestive of arrhythmias as well as the evaluation of paroxysmal atrial fibrillation (AF).

Cardiac arrhythmias may be suspected because of symptoms suggestive of arrhythmias, including palpitations, dizziness, or syncope or presyncope, or because of abnormal heart rate or rhythm noted on exam. A full discussion of the differential diagnosis and evaluation of each of these symptoms is beyond the scope of this review, but some general principles on the use of ambulatory monitoring are discussed.

Arrhythmias are an important potential cause of syncope or near syncope, which in some cases may be described as dizziness. An electrocardiogram (ECG) is generally indicated whenever there is suspicion of a cardiac cause of syncope. Some arrhythmic causes will be apparent on ECG. However, for patients in whom an ECG is not diagnostic, longer monitoring may be indicated. The 2009 joint guidelines from the European Society of Cardiology and 3 other medical specialty societies suggested that, in individuals with clinical or ECG features suggesting an arrhythmic syncope, ECG monitoring is indicated; the guidelines also stated that the “duration (and technology) of monitoring should be selected according to the risk and the predicted recurrence rate of syncope.”¹ Similarly, guidelines from the National Institute for Health and Care Excellence (2014) on the evaluation of transient loss of consciousness, have recommended the use of an ambulatory ECG in individuals with a suspected arrhythmic cause of syncope. The type and duration of monitoring recommended is based on the individual’s history, particularly the frequency of transient loss of consciousness.² The Holter monitor is recommended if transient loss of consciousness occurs several times a week. If the frequency of transient loss of consciousness is every 1 to 2 weeks, an external event recorder is recommended; and if the frequency is less than once every 2 weeks, an implantable event recorder is recommended.
Similar to syncope, the evaluation and management of palpitations is patient-specific. In cases where the initial history, examination, and ECG findings are suggestive of an arrhythmia, some form of ambulatory ECG monitoring is indicated. A position paper from the European Heart Rhythm Association (2011) indicated that, for individuals with palpitations of unknown origin who have clinical features suggestive of arrhythmia, referral for specialized evaluation with consideration for ambulatory ECG monitoring is indicated.3

**AF Detection**

AF is the most common arrhythmia in adults. It may be asymptomatic or be associated with a broad range of symptoms, including lightheadedness, palpitations, dyspnea, and a variety of more nonspecific symptoms (eg, fatigue, malaise). It is classified as paroxysmal, persistent, or permanent based on symptom duration. Diagnosed AF may be treated with antiarrhythmic medications with the goal of rate or rhythm control. Other treatments include direct cardioversion, catheter-based radiofrequency- or cryo-energy-based ablation, or one of several surgical techniques, depending on the patient’s comorbidities and associated symptoms.

AF is associated with the development of thrombi in the atria, often the left atrial appendage. Patients with AF are at risk for ischemic stroke due to the risk of embolism of the thrombus. Multiple clinical trials have demonstrated that anticoagulation reduces the ischemic stroke risk in patients at moderate or high risk of thromboembolic events. Oral anticoagulation in patients with AF reduces the risk of subsequent stroke and was recommended by American Heart Association, American College of Cardiology, and Heart Rhythm Society in 2014 joint guidelines on patients with a history of stroke or transient ischemic attack.4

Ambulatory ECG monitoring may play a role in several situations in the detection of AF. In patients who have undergone ablative treatment for AF, if ongoing AF can be excluded with reasonable certainty, including paroxysmal AF which may not be apparent on ECG during an office visit, anticoagulation therapy could potentially be stopped. In some cases where identifying paroxysmal AF is associated with potential changes in management, longer term monitoring may be considered. There are well-defined management changes that occur in patients with AF. However, until relatively recently the specific role of long-term (ie, >48 hours) monitoring in AF was not well-described.

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.5,6 Paroxysmal AF confers an elevated risk of stroke, just as persistent and permanent AF do. In individuals with a high risk of stroke, particularly those with a history of
ischemic stroke that is unexplained by other causes, prolonged monitoring to identify paroxysmal AF has been investigated.

**Cardiac Rhythm Ambulatory Monitoring Devices**

Ambulatory cardiac monitoring with a variety of devices permits the evaluation of cardiac electrical activity over time, in contrast to a static ECG, which only permits the detection of abnormalities in cardiac electrical activity at a single point in time.

A Holter monitor is worn continuously and records cardiac electrical output continuously throughout the recording period. Holter monitors are capable of recording activity for 24 to 72 hours. Traditionally, most Holter monitors had 3 channels based on 3 ECG leads. However, some currently available Holter monitors have up to 12 channels. Holter monitors are an accepted intervention in a variety of settings where a short period (24-48 hours) of comprehensive cardiac rhythm assessment is needed (eg, suspected arrhythmias when symptoms [syncope, palpitations] are occurring daily). These devices are not the focus of this review.

Various classes of devices are available for situations where longer monitoring than can be obtained with a traditional Holter monitor is needed. Because there may be many devices within each category, a comprehensive description of each is beyond our scope. Specific devices may vary in how data are transmitted to the location where the ECG output is interpreted. Data may be transmitted via cellular phone or landline, or by direct download from the device after its return to the monitoring center. The device classes are described in Table 1.

**Table 1. Ambulatory Cardiac Rhythm Monitoring Devices**

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Description</th>
<th>Device Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncontinuous devices with memory (event recorder)</td>
<td>Devices not worn continuously but rather activated by patient and applied to skin in the precordial area when symptoms develop</td>
<td>Zio® Event Card (iRhythm Technologies)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>REKA E100™ (REKA Health)</td>
</tr>
<tr>
<td>Continuous recording devices with longer recording periods</td>
<td>Devices continuously worn and continuously record via ≥1 cardiac leads and store data longer than traditional Holter (14 d)</td>
<td>Zio® Patch system (iRhythm Technologies)</td>
</tr>
<tr>
<td>External memory loop devices (patient- or autotriggered)</td>
<td>Devices continuously worn and store a single channel of ECG data in a refreshed memory. When the device is activated, the ECG is then recorded from the memory loop for the</td>
<td>Patient-triggered: Explorer™ Looping Monitor (LifeWatch Services)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autotriggered: LifeStar AF Express™</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Auto-Detect Looping Monitor</td>
</tr>
<tr>
<td>Device Class</td>
<td>Description</td>
<td>Device Examples</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
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</tr>
<tr>
<td>Implantable memory loop devices (patient- or autotriggered)</td>
<td>Devices similar in design to external memory loop devices but implanted under the skin in the precordial region</td>
<td>Autotriggered or patient-triggered: Reveal® XT ICM (Medtronic) Autotriggered: BioMonitor, Biotronik</td>
</tr>
<tr>
<td>Mobile cardiac outpatient telemetry</td>
<td>Continuously recording or autotriggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis</td>
<td>CardioNet MCOT (BioTelemetry) LifeStar Mobile Cardiac Telemetry (LifeWatch Services) SEEQ Mobile Cardiac Telemetry (Medtronic)</td>
</tr>
</tbody>
</table>

ECG: electrocardiogram.

There are also devices that combine features of multiple classes. For example, the LifeStar ACT Ex Holter (LifeWatch Services) is a 3-channel Holter monitor, but is converted to a mobile cardiac telemetry system if a diagnosis is inconclusive after 24 to 48 hours of monitoring. The BodyGuardian® Heart Remote Monitoring System (Preventice Services) is an external autotriggered memory loop device that can be converted to a real-time monitoring system. The eCardio Verité™ system (eCardio) can switch between a patient-activated event monitor and a continuous telemetry monitor. The Spiderflash-T (LivaNova) is an example of an external autotriggered or patient-triggered loop recorder, but, like the Zio® Patch, can record 2 channels for 14 to 40 days.

**Summary of Evidence for Mobile Cardiac Outpatient Telemetry**

This policy addresses whether the addition of real-time monitoring (mobile cardiac outpatient telemetry, or MCOT) to ambulatory cardiac monitoring is associated with improved outcomes. Two factors must be addressed in evaluating MCOT: (1) the inherent detection capability of the monitoring devices and (2) whether the real-time transmission and interpretation of data confers an incremental health benefit. The proposed addition of real-time monitoring suggests that there may be a subset of individuals who require immediate intervention when an arrhythmia is detected. Because it is not clear which patients comprise that subset, or whether identification of those patients in the outpatient setting leads to improved outcomes such as
reduced risk of sudden cardiac death, the evaluation of the second factor requires additional studies that directly assess outcomes, not just arrhythmia detection rates.

One RCT by Rothman et al (2007) compared MCOT with standard event monitors. This trial involved 305 patients randomized to the LOOP recorder or to MCOT (CardioNet) and monitored for up to 30 days. The unblinded study at 17 centers enrolled patients 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 by an electrophysiologist blinded to the monitoring device assignment. Most patients in the control group had a patient-triggered event monitor. Only a subset of patients (n=50) had autotrigger devices, thus precluding comparison of MCOT and autotrigger devices. Of the 305 patients, 266 completed at least 25 days of monitoring. A diagnostic end point (confirmation or 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 differences were thought to be clinically significant rhythm disturbances and the likely causes of the patients' symptoms. The trialists did 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 trial, median time to diagnosis in the total study population was 7 days in the MCOT group and 9 days in the LOOP group.

Derkac et al (2017) retrospectively reviewed the BioTelemetry database of patients receiving ambulatory ECG monitoring, selecting patients prescribed MCOT (n=69,977) and patients prescribed AT-LER, an autotrigger looping event recorder (n=8513). Patients were diagnosed with palpitations, syncope and collapse, AF, tachycardia, and/or TIA. Patients given the MCOT were monitored for an average of 20 days and patients given the AT-LER were monitored an average of 27 days. The diagnostic yield using MCOT was significantly higher than that using AT-LER for several events: 128% higher for AF, 54% higher for bradycardia, 17% higher for ventricular pause, 80% higher for SVT, and 222% higher for ventricular tachycardia. Mean time to diagnosis for each asymptomatic arrhythmia was shorter for patients monitored by MCOT than by AT-LER. There was no discussion of management changes or health outcomes based on monitoring results.

Kadish et al (2010) evaluated the frequency with which events transmitted by MCOT represented emergent arrhythmias, thereby indirectly assessing the clinical utility of real-time outpatient monitoring. Medical records from 26,438 patients who had undergone MCOT during a 9-month period from a single service provider were retrospectively examined. During a mean
monitoring period of 21 days, 21% (5,459) had an arrhythmic event requiring physician notification. Of these, 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 have reported on arrhythmia detection rates of MCOT.\textsuperscript{11-14} One study (Joshi et al [2005]) described the outcomes of a consecutive case series of 100 patients.\textsuperscript{11} Included patients had the following symptoms: palpitations (47%), dizziness (24%), or syncope (19%). Patients being evaluated for efficacy of drug treatment (25%) were also included. Clinically significant arrhythmias were detected in 51% of patients, but half of these patients were asymptomatic. The authors commented that the automatic detection resulted in an increased diagnostic yield, but there was no discussion of its unique features (i.e., the real-time analysis, transmission, and notification of arrhythmia).

In the largest study evaluating the diagnostic yield of MCOT for AF, Favilla et al (2015) evaluated a retrospective cohort of 227 patients with cryptogenic stroke or TIA who underwent 28 days of monitoring with MCOT.\textsuperscript{15} AF was detected in 14% (31/227) of patients, of whom 3 reported symptoms at the time of AF. Oral anticoagulation was initiated in 26 (84%) patients diagnosed with AF. Of the remaining 5 (16%) not on anticoagulation therapy, 1 had a prior history of gastrointestinal bleeding, 3 were unwilling to accept the risk of bleeding, and 1 failed to follow up.

Miller et al (2013) retrospectively analyzed paroxysmal AF detection rates among 156 patients evaluated with MCOT within 6 months of a cryptogenic stroke or TIA.\textsuperscript{7} Over a median 21-day period of MCOT monitoring (range, 1-30 days), AF was detected in 17.3% of patients. Mean time to first occurrence of AF was 9 days (range, 1-21 days).

In an uncontrolled case series, Tayal et al (2008) retrospectively analyzed patients with cryptogenic stroke who had not been diagnosed with AF by standard monitoring.\textsuperscript{14} In this study, 13 (23%) of 56 patients with cryptogenic stroke had AF with MCOT. Twenty-seven asymptomatic AF episodes were detected in the 13 patients, and 23 of these were less than 30 seconds in duration. In contrast, Kalani et al (2015) reported a diagnostic yield for AF of 4.7% (95% CI, 1.5% to 11.9%) in a series of 85 patients with cryptogenic stroke.\textsuperscript{16} In this series, 82.4% of patients had completed transesophageal echocardiography, cardiac magnetic resonance imaging (cMRI), or both, with negative results. Three devices were used and described as MCOT devices: 34% received LifeStar ACT ambulatory cardiac telemetry, 41% received the LifeStar AF Express autodetect looping monitor, and 25% received the Cardiomedix cardiac event monitor. While the authors reported that there was a system in place to transmit the data for review, it is unclear whether data were sent in “real-time.”
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 addressed 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. There is insufficient evidence to demonstrate a clinically significant incremental benefit of MCOT.

For individuals who have signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes 1 RCT and nonrandomized studies evaluating rates of arrhythmia detection. Relevant outcomes are overall survival and morbid events. The available evidence has suggested that outpatient cardiac telemetry is at least as good at detecting arrhythmias as ambulatory event monitoring. However, studies have not evaluated whether the real-time monitoring feature of outpatient cardiac telemetry leads to reduced cardiac events and mortality. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore the use of this device is considered investigational.

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 specialty societies or academic medical centers, unless otherwise noted.

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. Input was obtained to provide information on mobile cardiac outpatient telemetry and new devices. There was no consensus whether mobile cardiac outpatient telemetry is medically necessary. While reviewers agreed that mobile cardiac outpatient telemetry is comparable to 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.

**Medicare National Coverage**

The Centers for Medicare & Medicaid Services implemented a national coverage determination in 2004 for electrocardiographic services. This national coverage determination includes descriptions of the Holter monitor and event recorders (both external loop recorders and implantable loop recorders). Ambulatory cardiac monitors are covered when there is documentation of medical necessity. Indications for use include detection of symptomatic transient arrhythmias and determination of arrhythmic drug therapy (to either initiate, revise, or discontinue the therapy).

**Regulatory Status**

Some of the newer devices are described in the Background section for informational purposes. Because there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this review. U.S. Food and Drug Administration product codes include: DSH, DXH, DQK, DSI, MXD, MHX.

**References**


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/09/16</td>
<td>New policy, add to Cardiology section. Use of MCOT is considered investigational. Policy will be effective 01/01/17.</td>
</tr>
<tr>
<td>10/25/16</td>
<td>Effective date revision. Policy will be effective 03/01/17.</td>
</tr>
<tr>
<td>02/24/17</td>
<td>Effective date revision. Policy will be effective 03/15/17.</td>
</tr>
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<td>Date</td>
<td>Comments</td>
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<td>03/15/17</td>
<td>Effective date revision. Policy will be effective 03/17/17.</td>
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<td>03/17/17</td>
<td>Effective date revision. Policy will be effective 03/31/17.</td>
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<tr>
<td>03/23/17</td>
<td>Effective date revision. Policy will be effective 03/24/17. Coding update; removed CPT codes 0295T-0298T. Minor formatting update.</td>
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<td>08/01/17</td>
<td>Annual Review, approved July 11, 2017. No changes to policy statement.</td>
</tr>
<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 9, 16 and 17 added. Policy statement unchanged.</td>
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Deutsche (German):

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- 200 Independence Avenue SW, Room S09F, HHH Building

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Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalang nga adda ket naglaon iti napateg nga impormasion maipeangg et iplikaysyon noyow coverage babaen iti Premera Blue Cross. Daytoy ket mabalang dagiti importante a pelta iti daytoy a pakdaar. Mabalang nga adda rumbang nga aramiendyo nga addag sagay dagiti partikular a naituding nga adda tayl mopap tapagatanleyido ti coverage ti salan-aywo tiyong tungol kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tungol bitooyado a pagsasao nga awan ti bayadango. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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