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>
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</tbody>
</table>
### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></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>
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### Related Information

The available evidence suggests that long-term monitoring for atrial fibrillation after cryptogenic stroke or post cardiac ablation is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not well-defined. Trials that have demonstrated improved outcomes have used either event monitors or implantable monitors. In addition, there are individual patient considerations that may make one type of monitor preferable over another.

### Table 1. Mobile Cardiac Outpatient Telemetry

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Description</th>
<th>Sample Devices</th>
</tr>
</thead>
</table>
| Mobile cardiac outpatient telemetry | Continuously recording or autotriggered memory loop devices that transmit data to a central | • CardioNetMCOT (BioTelemetry, Malvern, PA)  
• LifeStar Mobile Cardiac |
### Device Class

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Description</th>
<th>Sample Devices</th>
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</table>
|              | recording station with real-time monitoring and analysis | Telemetry (LifeWatch Services, Switzerland)  
|              |             | • SEEQ Mobile Cardiac Telemetry (Medtronic, Minneapolis, MN) |

### Evidence Review

#### Summary of Evidence

For individuals with 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 these devices is considered investigational.

#### 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. 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. Additional studies must be done to assess the benefits of real-time transmission of data and not just arrhythmia detection rates.

One RCT was identified that compared MCOT with standard event monitors. This study enrolled patients at 17 centers and involved 305 patients randomly assigned to the LOOP recorder or MCOT and were monitored for up to 30 days. Those enrolled were patients for whom the investigators had a strong suspicion of an arrhythmic cause of symptoms which included
syncope, presyncope, or severe palpitations occurring less frequently than once per 24 hours. The enrollees also all had 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 comparison of MCOT and autotrigger devices.

A diagnostic end point (confirmation/exclusion of an 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 arrhythmias (not associated with simultaneous symptoms) in the MCOT group. These symptoms consisted 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 authors did not comment on the clinical impact (changes in management) of these findings in patients for whom the rhythm disturbance was not linked to symptoms. In this study, 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% (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 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. 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 those being evaluated for efficacy of drug treatment (25%). 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 feature (ie, the real-time analysis, transmission, and notification of arrhythmia).

Studies have evaluated the use of MCOT in detecting AF. In the largest study evaluating the diagnostic yield of MCOT for AF, Favilla et al reported results of a retrospective cohort of 227 patients with cryptogenic stroke or TIA who underwent 28 days of monitoring with mobile cardiac outpatient telemetry. 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%) who were not anticoagulated, 1 had a prior history of gastrointestinal bleeding, 3 were unwilling to accept the risk of bleeding, and 1 failed to follow-up.

In an uncontrolled case series, Tayal et al retrospectively analyzed patients with cryptogenic stroke who had not been diagnosed with AF by standard monitoring. 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 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. In this series, 82.4% of patients had completed transesophageal echocardiography, cardiac magnetic resonance imaging (cMRI), or both, with negative results. The authors proposed that the use of advanced cardiac imaging may alter the underlying prevalence of AF in patients labeled as having cryptogenic stroke.

In an earlier retrospective cohort study, Miller et al retrospectively analyzed paroxysmal AF detection rates among 156 patients evaluated with MCOT within 6 months of a cryptogenic stroke or TIA. 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 8.8 days (range, 1-21 days).

**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 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. Therefore this service is considered investigational.
Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

Clinical input was obtained from 4 academic medical centers (3 reviews) and 3 physician specialty societies to provide information on mobile cardiac outpatient telemetry (MCOT) and new devices. There was no consensus whether MCOT is medically necessary. Reviewers did not agree whether real-time monitoring provides incremental benefits or improved health outcomes over ambulatory monitoring that is not being reviewed in real time.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


**History**

<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>
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<tr>
<td>02/24/17</td>
<td>Effective date revision. Policy will be effective 03/15/17.</td>
</tr>
<tr>
<td>03/15/17</td>
<td>Effective date revision. Policy will be effective 03/17/17.</td>
</tr>
<tr>
<td>03/17/17</td>
<td>Effective date revision. Policy will be effective 03/31/17.</td>
</tr>
<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>
</tr>
<tr>
<td>08/01/17</td>
<td>Annual review, approved July 11, 2017. No changes to policy statement.</td>
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Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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