Outpatient Cardiac Telemetry

Effective: August 1, 2017

Next Review: June 2018
Last Review: June 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Cardiac event monitors are used to monitor heart rhythm outside the hospital setting in patients with symptoms suspected to be related to non-lethal cardiac arrythmias.

MEDICAL POLICY CRITERIA

NOTE: This policy addresses only outpatient cardiac telemetry; it does not address Holter monitors or ambulatory event monitors (AEMs) which are considered a standard of care.

I. Outpatient cardiac telemetry, including but not limited to mobile outpatient cardiac telemetry (e.g., MCOT), is considered not medically necessary as a diagnostic alternative in patients of any age who experience symptoms suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).

II. All other uses of outpatient cardiac telemetry are considered investigational, including but not limited to:

A. Evaluation of the effectiveness of antiarrhythmic therapy
B. Detection of myocardial ischemia by detecting ST segment changes
C. Monitoring of patients with atrial fibrillation (AF), including but not limited to:
   1. Follow-up of patients following ablation procedures for atrial fibrillation
2. Measurement of rhythm and rate control in patients with atrial fibrillation
   D. Cryptogenic stroke

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES
None

BACKGROUND

Current monitoring devices include the following:

- Holter monitors provide short-term monitoring, usually 24 to 48 hours.
- Ambulatory event monitors (AEMs) provide monitoring for up to a month. These monitors may be used for patients whose symptoms may not occur during the short-term period of Holter monitoring. Autotrigger AEMs have become the standard device, replacing manual devices that the patient activates when symptoms are felt. Autotrigger devices, which may be implantable or worn externally, automatically activate electrocardiography (ECG) recording when an arrhythmia is detected. AEMs may store the ECGs for later analysis, or the ECGs can be transmitted via telephone to a receiving station for analysis.
- Outpatient cardiac telemetry (OCT) is also intended for extended monitoring periods. OCTs provide rapid ECG analysis by transmitting real-time ECGs to a receiving station that is attended 24-hours a day by trained operators.

REGULATORY STATUS

A number of OCT devices have received approval by the U.S. Food and Drug Administration including, but not limited to the following:

- Mobile Cardiac Outpatient Telemetry™ (MCOT™) (CardioNet Inc., now owned by BioTelemetry, Inc.)
- eCardio Verite™ system (eCardio)
- HEARTLink II™ system (Cardiac Telecom Corp.)
- Heartrak ECAT (External Cardiac Ambulatory Telemetry) (AMI Cardiac Monitoring)
- VST™ (Vital Signs Transmitter, Biowatch Medical)
- NUVANT™ Mobile Cardiac Telemetry (MCT) System (Corventis, Inc.,)
- Lifestar Ambulatory Cardiac Telemetry (ACT) system (Card Guard Scientific Survival Ltd, a subsidiary of LifeWatch®).
- SEEQ™ Mobile Cardiac Telemetry System (Medtronic)
- TruVue™ Wireless Ambulatory ECG (Biomedical Systems)

EVIDENCE SUMMARY

Evaluating the effectiveness of outpatient cardiac telemetry (OCT) for the detection of cardiac arrhythmias requires large, well-designed randomized controlled trials (RCTs) comparing OCT with standard auto-trigger event monitors, the current gold standard for detecting infrequent arrhythmias. Of specific interest is the benefit of real-time monitoring in an ambulatory
population who are presumably considered to be at a lower level of risk from significant arrhythmia (such that an electrophysiologic study or inpatient telemetry may not be required).

**SUSPECTED ARRHYTHMIAS**

**Randomized Controlled Trials**

One randomized, controlled trial was identified that compared OCT to standard event monitors.\(^1\) This multicenter study involved 305 patients who were randomized to a patient-activated loop recorder or OCT and who were monitored for up to 30 days. The unblinded study enrolled patients 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. Most 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 OCT and autotrigger devices.

A diagnostic endpoint (confirmation/exclusion of arrhythmic cause of symptoms) was found in 88% of OCT patients and in 75% of loop recorder patients (p = 0.008). The difference in rates was due primarily to detection of asymptomatic (not associated with simultaneous symptoms) arrhythmias in the OCT group consisting of rapid atrial fibrillation and/or flutter (15 patients vs. 1 patient) and ventricular tachycardia defined as more than three beats and rate greater than 100 (14 patients vs. 2 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 OCT group and 9 days in the loop recorder group.

**Nonrandomized Studies**

A number of uncontrolled case series have reported on outcomes of OCT.\(^2-6\) However, data from these studies do not permit conclusion due to methodological limitations, including but not limited to the lack of randomized treatment allocation and the lack of an appropriate comparison group.

**CRYPTOGENIC STROKE OR TRANSIENT ISCHEMIC ATTACK (TIA)**

**Randomized Controlled Trials**

One small pilot study randomized 40 patients with either cryptogenic stroke or high-risk transient ischemia attack (TIA) to one of two groups, a 21-day telemetry monitoring period or routine clinical follow-up which included no cardiac monitoring.\(^7\) Follow-up was at three months and one year, consisting of indirect contact with patients and their physicians for any reported atrial fibrillation (AF) or recurrent stroke or TIA. The authors reported a lower than expected rate of detection of AF, having found no AF in either study arm. Compliance was reported to be suboptimal, with 25% of monitoring patients completely noncompliant, and the remainder of patients wearing monitors for only 64% of the assigned days. This pilot study does not permit conclusions due to methodological limitations, including but not limited to the small number of participants and the lack of an adequate AEM comparison group.
**Nonrandomized Studies**

Kalani (2015) reported a detection rate for AF of 4.7% (95% CI, 1.5% to 11.9%) in a series of 85 patients with cryptogenic stroke.[8] 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% LifeStar ACT ambulatory cardiac telemetry, 41% LifeStar AF Express auto-detect looping monitor, and 25% Cardiomedix cardiac event monitor. While the authors reported that there was a system in place to send the data for review, it is not clear if data were transmitted “real-time.”

Favilla (2015) 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.[9] 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 a retrospective cohort study, Miller (2013) analyzed paroxysmal AF detection rates among 156 patients who were evaluated with MCOT within six months of a cryptogenic stroke or TIA.[10] Over a median period of MCOT monitoring of 21 days (range: 1 to 30 days), AF was detected in 17.3% of patients. The mean time to first occurrence of AF was 8.8 days (range: 1 to 21 days).

Tayal (2008), reported on a retrospective analysis of a case series of patients with cryptogenic stroke, who had not been diagnosed with AF by standard monitoring.[5] In this study, 13 (23%) of 56 patients with cryptogenic stroke were found to have AF with MCOT. Twenty-seven asymptomatic AF episodes were detected in the 13 patients, 23 of these were shorter than 30 seconds in duration.

**PRACTICE GUIDELINE SUMMARY**

**AMERICAN COLLEGE OF CARDIOLOGY (ACC), AMERICAN HEART ASSOCIATION (AHA), AND HEART RHYTHM SOCIETY (HRS)[11-16]**

Joint evidence-based ACC/AHA guidelines on arrhythmia and heart disease management, some of which also include input from the HRS, include information on monitoring with conventional ambulatory event monitors, but outpatient cardiac telemetry was not specifically addressed.

The 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients with Syncope lists mobile cardiac outpatient telemetry as one of several possible approaches for monitoring select ambulatory patients with syncope that is suspected to be due to arrhythmia.[17]

**HEART RHYTHM SOCIETY (HRS), EUROPEAN HEART RHYTHM ASSOCIATION (EHRA, EUROPEAN SOCIETY OF CARDIOLOGY (ESC), AND EUROPEAN CARDIAC ARRHYTHMIA SOCIETY (ECAS)[18]**

A HRS/EHRA/ESC/ECAS consensus document on catheter and surgical ablation for atrial fibrillation was published in 2012 in collaboration with the ACC, AHA, the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). This document did not contain formal clinical practice guidelines, but provided general recommendations based on
literature review and expert consensus. The document also stated that, for post-ablation patients, four-week autotrigger event monitors, mobile cardiac outpatient telemetry, or implantable subcutaneous monitors may identify less frequent AF not found with short-term Holter monitors.

SUMMARY

There is enough research to show that for patients with cardiac arrhythmia symptoms, outpatient cardiac telemetry (OCT) does not improve health outcomes compared with conventional monitors such as the auto-trigger device. Therefore, OCT is considered not medically necessary for these patients. OCT is considered investigational in patients with all other conditions because there is not enough research to show that this technology improves health outcomes for these patients.

REFERENCES


2. Joshi, AK, Kowey, PR, Prystowsky, EN, et al. First experience with a Mobile Cardiac Outpatient Telemetry (MCOT) system for the diagnosis and management of cardiac arrhythmia. Am J Cardiol. 2005 Apr 1;95(7):878-81. PMID: 15781022


## CODES

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<th>Number</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<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>
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<td></td>
<td>93229</td>
<td>; 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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<td>HCPCS</td>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
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*Date of Origin: April 2010*