PURPOSE:
Define current and up-to-date policy guidelines for the authorization MCOT.

POLICY STATEMENT:
There is sufficient evidence in the published peer-reviewed medical literature supporting the clinical utility of home-based, real-time surveillance systems for a specific subset of individuals.

AUTHORITIES AND REFERENCES:
Literature review and bibliography – see attachment A and B.

DEFINITIONS:
Real-Time Continuous Attended Cardiac Monitoring Systems: 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. is a company that offers mobile cardiac outpatient telemetry. In this system, the patient wears a 3-lead sensor, which constantly communicates with the CardioNet monitor, a lightweight unit that can be carried in a pocket or 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 VST (Vital Signs Transmitter,
Biowatch Medical), and the Lifestar ambulatory cardiac telemetry (ACT) system (Card Guard Scientific Survival Ltd). The CardioNet system has a built-in cellular telephone that automatically transmits signals when the patient is away from home.

**OPERATING PROTOCOL:**

**Clinical Indications for MCOT:**
Care1st/ONECare cover an external home-based, real-time continuous attended cardiac monitoring system (CPT code 93228, 93299) as medically necessary when ALL of the following criteria are met:

- clinical suspicion of a significant arrhythmia
- symptoms of syncope, presyncope, or severe palpitations occurring less frequently than once per 24 hours are present
- non-diagnostic 24-hour Holter or non-real-time monitoring (e.g., event monitor, pacemaker telephonic telemetry, post-symptom patient-activated recorder or auto-trigger) within 45 days prior to consideration of the use of a home-based, real-time continuous attended cardiac monitoring system
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Applies to:
- Arizona Health Care Cost Containment System (AHCCCS)-Acute
- Department of Economic Securities, Division of Developmental Disabilities (DES/DDD)
- Medicare

**Corporate Approval:**

| Signature on file | Scott Cummings  
| Chief Administrative Officer |
| Signature on file | Deena Sigel  
| Chief Financial Officer |
| Signature on file | Susan Cordier  
| Chief Operating Officer |
| Signature on file | Albena Baharieva, MD  
<p>| Chief Medical Officer |</p>
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Department: Medical Management
LITERATURE REVIEW

Kadish et al. (2010) retrospectively analyzed patient characteristics, diagnostic yield, and diagnoses of patients in a large commercial database (LifeWatch Services, Inc., Rosemont, Illinois). All patients (n=26,438) who underwent monitoring from April to December 2008 at a single service provider formed the patient population of this study. Arrhythmic events noted in these patients were defined as those requiring physician notification and those that represented potentially life-threatening arrhythmias. Of the 26,438 patients included in the study, 5,459 (21%) had arrhythmic events meeting physician notification criteria during a mean monitoring period of 21 days. Of these, 262 patients (1%) had arrhythmic events that could potentially be classified as emergent. Limitations of the study include lack of a comparison group, no information on patient outcomes and detailed information on the patient population was not reported.

In a case series study, Tayal et al. (2008) analyzed 56 patients with cryptogenic transient ischemic attack (TIA) or stroke after diagnostic evaluation and Mobile MCOT for up to 21 days. Demographic, radiographic, echocardiographic, and MCOT results were reviewed. Predictors of AF detection by MCOT were determined by univariate analysis including Student t test and Fisher exact tests and multivariate analysis. The inclusion criteria were: age greater than 18 years; ischemic stroke or TIA within the last three months; and diagnosis of cryptogenic TIA/stroke. TIA was defined as sudden-onset focal neurologic symptoms or signs that resolved within 24 hours and was not associated with high-intensity abnormality in the diffusion-weighted sequence. TIA symptoms and signs included hemiplegia/hemiparesis, monoplegia/monoparesis, aphasia, transient monocular blindness, vertigo, dysarthria, and isolated sensory symptoms. The exclusionary criteria included: history of AF; admission ECG, inpatient cardiac telemetry monitoring, or 24-hour Holter data that demonstrated AF prior to initiation of MCOT; and prothrombotic state. The median MCOT monitoring duration was 21 (range 5–21) days resulting in an AF detection rate of 23% (13/56). AF was first detected after a median of 7 (range 2–19) days of monitoring. Twenty-seven asymptomatic AF episodes were detected in the 13 patients, of which 85% (23/27) were <30 seconds and the remaining 15% (4/27) were 4–24 hours in duration. Diabetes was predictive of AF detection by both univariate (p=0.024) and multivariate analysis (OR 6.15; 95% CI 1.16–32.73; p=0.033). A reported potential limitation of this study was the absence of an age-matched control group without a history of TIA/stroke. In addition, not all patients underwent a transesophageal echocardiography (TEE) in this cohort.

In a retrospective study, Saarel et al. (2008) reported on the use of the MCOT system for evaluation of children and adolescents with suspected cardiac arrhythmia. Patients older than 21 years and those with previously documented arrhythmia were excluded. A total of 59 MCOT studies were performed. Five patients met exclusion criteria leaving 54 subjects (mean age 12.4+/–4.5 years; range 3.2–19.7 years; 46% male) for inclusion. Half of the subjects had been previously monitored with a Holter (n=24), transtelephonic electrocardiographic event monitors (n=1), or both (n=2). Among these subjects, the diagnostic yield for MCOT was similar to the overall study population (59%, n=16/27).
Twenty-one subjects (39%) did not experience symptoms during MCOT, yielding a diagnostic rate of 61% (N = 33). Of the 33 diagnostic studies, 9% (n= 3; mean age 16.9 +/- 0.6 years; range 16.2 – 17.3 years; one male) showed supraventricular tachycardia and 9% (n=3; mean age 11.1 +/- 2.7 years; range 8.2 – 13.5 years; one male) showed supraventricular or ventricular ectopy. Minor skin irritation at sites of electrode placement was the only complication of MCOT (n=5). The reported limitations of this study include small sample size, retrospective data analysis, and nonrandomized design.

Rothman et al. (2007) conducted a multicenter, randomized, nonblinded controlled trial evaluating the CardioNet system versus a patient-activated external loop event monitor for symptoms thought to be due to a cardiac arrhythmia. The study included 305 patients at 17 centers. The inclusion criteria were: a high clinical suspicion of a malignant arrhythmia; symptoms of syncope, presyncope, or severe palpitations occurring less frequently than once per 24 hours (presyncope was defined as transient dizziness, lightheadedness, unsteadiness, or weak spells without loss of consciousness; severe palpitations were defined as palpitations that would warrant referral for cardiac monitoring); and a nondiagnostic 24-hour Holter or telemetry monitor within 45 days prior to enrollment. Exclusion criteria were New York Heart Association (NYHA) Class IV heart failure, myocardial infarction within the prior three months, unstable angina, candidate for or recent valvular cardiac surgery, history of sustained ventricular tachycardia or ventricular fibrillation, complex ectopy defined as ventricular premature depolarizations ≥ 10/hour with a documented ejection fraction ≤ 35%, patients < 18 years of age, and a concomitant condition prohibiting completion of or compliance with the protocol. The primary endpoint was the confirmation or exclusion of a probable arrhythmic cause of the patient’s symptoms (e.g., syncope, presyncope, or palpitations). Arrhythmias were classified as either clinically significant or clinically insignificant, and then the investigators evaluated the temporal relationship of any symptoms and the likelihood that a clinically significant arrhythmia caused the patient’s presenting symptoms.

The patients were randomized to 30 days of monitoring with MCOT (MCOT Group n=134) or with an external loop monitor (Loop Group n=132). Out of the 305 randomized patients, 266 patients completed a minimum of 25 days of monitoring. The most common reason for not completing the protocol was patient noncompliance (13 MCOT patients and seven LOOP patients). Seven patients found the devices too difficult or cumbersome to use; seven patients had an allergic reactions or skin irritation to the electrodes; and six patients stated the monitors interfered with their work or travel. Most of the patients in the Loop Group were required to activate the recorder when they experienced symptoms; however, 49 (18%) patients were at centers that had autotriggered recording of cardiac events. During monitoring, clinically significant arrhythmias were detected in 55 (41%) patients in the MCOT Group versus 19 (14%) patients in the Loop Group, a statistically significant difference (p<0.001). For patients who had syncope or presyncope, clinically significant arrhythmias were detected in 52% of patients with MCOT and in 15% of patients with loop recorders. In most cases, the arrhythmias detected were AF, atrial flutter, or ventricular tachycardia. A subgroup analysis was performed at the institutions that used autotriggered loop monitoring rather than patient-activated monitoring. A definitive diagnosis was obtained in this subgroup for 88% of MCOT Group patients versus 46% of Loop Group patients (p<0.0025). However, this subgroup analysis involved a relatively small number of patients, and the autotriggered devices may have had single ECG leads, whereas the
CardioNet system uses double ECG leads. The authors state the proportion of patients reporting symptoms was similar in both groups (79% in MCOT and 76% in LOOP), suggesting equal compliance during the early portion of the monitoring period when most transmissions and reported symptoms occurred.

In a case series study, Olson et al. (2007) evaluated the records of 122 consecutive patients using MCOT for palpitations, presyncope/syncope, or to monitor the efficacy of a specific antiarrhythmic therapy. Ten of 17 patients (59%) studied for resyncope/syncope had a diagnosis made with MCOT. Eight of these 17 patients had a previous negative evaluation for presyncope/syncope (e.g., holter or event monitor) and five had an event correlated with the heart rhythm during the monitoring period. Nineteen patients monitored for palpitations or presyncope/syncope were asymptomatic during monitoring but had a prespecified arrhythmia detected. When MCOT was used as the first ambulatory monitoring system to evaluate palpitations (n = 18), 73% of patients correlated their symptoms with the underlying cardiac rhythm. Seven of 21 patients monitored for medication titration had dosage adjustments during outpatient monitoring. A limitation of this study is the uncontrolled study design. There is no comparison to other ambulatory monitoring systems.

In a small uncontrolled study, Vasamreddy et al. (2006) used the CardioNet monitoring system to assess the efficacy of cardiac tissue ablation procedures for treatment of atrial fibrillation. A total of 19 patients with highly symptomatic drug refractory AF underwent catheter ablation. Each was provided with an MCOT monitor and was asked to wear it five days immediately before the ablation, and five days per month starting with the ablation for six consecutive months. When patients experienced any symptoms, they were asked to activate the system and to record associated symptoms. Out of the total 390 events triggered by patient’s symptoms, 40% were confirmed as AF events (156) and 60% were confirmed as non-AF events (234). Only shortness of breath and chest discomfort were highly associated with AF (p < 0.05). At the end of six months of follow-up, out of 10 patients who completed the study, seven (70%) patients were free of symptomatic AF recurrences, whereas only five (50%) patients achieved success when asymptomatic AF recurrences were included in the outcome. Poor patient compliance with a very intensive monitoring protocol was reported as an important limitation of using the CardioNet monitoring system.

In a case series study, Joshi et al. (2005) reported data from the first 100 consecutive patients monitored by an MCOT system who were undergoing treatment for known arrhythmias or who were suspected to have arrhythmias based on symptoms such as palpitations, dizziness, or syncope. A clinically significant arrhythmia was detected in 51 patients, but 25 (49%) did not have any symptoms during the arrhythmia. Thirteen of the 17 patients (76%) found to have atrial flutter/fibrillation had no symptoms during the arrhythmia. Thirty patients had been previously monitored by either an HM or an event recorder. MCOT detected an arrhythmia in 16 of the patients that was not found by a previous monitoring system. One patient had sustained ventricular tachycardia who required an implantable cardioverter-defibrillator.
BIBLIOGRAPHY:

• Joshi AK, Kowey PR, Prystowsky EN, Benditt DG, Cannom DS, Pratt CM, 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.