Medical Coverage Policy | Mobile Cardiac Outpatient Telemetry (MCOT)

EFFECTIVE DATE: 09|27|2007
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OVERVIEW
There are a wide variety of devices available for outpatient cardiac rhythm monitoring. The primary purpose of these devices is the evaluation of suspected arrhythmias that have not been detected by office or hospital-based 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 delivery of the information from patient to clinician. This policy addresses Mobile Cardiac Outpatient Telemetry (MCOT).

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
MCOT is considered medically necessary.

Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products
MCOT is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
There are a wide variety of devices 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. This policy addresses Mobile Cardiac Outpatient Telemetry (MCOT).

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 risks of sudden cardiac death, the evaluation of the second factor requires studies that directly assess outcomes, not just arrhythmia detection rates.

One RCT was identified that compared MCOT with standard event monitors. This 2007 trial involved 305 patients randomly assigned to the LOOP recorder or MCOT and monitored for up to 30 days. The unblinded study enrolled patients at 17 centers; those enrolled were 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 comparison of MCOT and autotrigger devices.

A diagnostic end point (confirmation/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 authors 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 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 (2010) 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% (5459) 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 (2005) 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 (2015) 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%) 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 (2008) 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; 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. 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."

In an earlier retrospective cohort study, 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.27 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).

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 not medically necessary for Commercial products.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are covered for BlueCHIP for Medicare only and not medically necessary for Commercial products:

93228 Wearable 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; physician review and interpretation with report

93229 Wearable 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 physician prescribed transmission of daily and emergent data reports

RELATED POLICIES

None

PUBLISHED

Provider Update, July 2018
Provider Update, August 2017
Provider Update, January 2017
Provider Update, October 2015
Provider Update, January 2014
Provider Update, January 2013
Provider Update, January, 2012
Provider Update, January 2011

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