Medical Coverage Policy | Mobile Cardiac Outpatient Telemetry (MCOT)

EFFECTIVE DATE: 09|27|2007
POLICY LAST UPDATED: 07|20|2022

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
Medicare Advantage Plans
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 Medicare Advantage Plan policies. Therefore, Medicare Advantage Plan policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans 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 that the technology results in an improvement in the net health outcome.

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

The purpose of outpatient cardiac telemetry in patients with signs or symptoms suggestive of arrhythmia is to provide an alternative method of transmitting electrical cardiac activity data to healthcare providers.

A randomized control trial (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. Patients were recruited from 17 centers. Investigators and patients were not blinded to randomization assignment. Monitor strips and diagnoses were reviewed by an electrophysiologist blinded to the monitoring device assignment. Most patients in the LOOP recorder group had a patient-triggered event monitor. Only a subset of patients (n=50) had autotrigger devices, thus precluding comparison between MCOT and autotrigger devices. Analyses were conducted on patients completing at least 25 days of monitoring. The primary endpoint was either confirmation or exclusion of arrhythmic cause of the patient's symptoms. Arrhythmias were classified as either clinically significant or clinically insignificant. The diagnostic end point (confirmation or exclusion of arrhythmic cause of symptoms) was significantly different between the 2 groups. 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. 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. 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.

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% (5459) 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. One study (Joshi et al [2005]) described the outcomes of a consecutive case series of 100 patients. Included patients had the following symptoms: palpitations (47%), dizziness (24%), or syncope (19%). Patients being evaluated for the 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 (ie, 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. 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 related to the use of anticoagulants, 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. 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).

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 detected by MCOT. Twenty-seven asymptomatic AF episodes were detected in the 13 patients; 23 of them 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, 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."

Narasimha et al (2018) published results of a study in which 33 patients wore both an ELR and a Kardia monitor to screen for AF during a period of 14 to 30 days.[49] Patients were 18 years or older, had palpitations less often than daily but more frequently than several times per month, and prior nondiagnostic ECGs. Exclusion criteria included myocardial infarction within the last 3 months, history of ventricular tachycardia/fibrillation, unstable angina, and syncope. Study personnel viewed the Kardia monitor recordings once daily and a physician was contacted if a serious or sustained arrhythmia was detected. Patients were also monitored by the ELR company, which notified a physician on call when necessary. All 33 patients had a diagnosis using the Kardia monitor and 24 patients received a diagnosis using the ELR ($p=0.001$).

Dorr et al (2019) compared the diagnostic accuracy of a smartwatch system with cardiologists' interpretation of an ECG in the diagnostic accuracy to detect AF. The smartwatch system uses an algorithm to enable rhythm analysis of the photoplethysmographic (PPG) signals. The population consisted of 508 hospitalized patients who had interpretable ECG and PPG recordings. The PPG algorithm compared with the cardiologists' diagnoses had a sensitivity of 94% and a specificity of 98%. A limitation of the study was that many of the recordings were excluded due to insufficient signal quality (148 of 672). The investigators concluded that detection of AF is feasible with a smartwatch, though signal quality issues need to be resolved and a broader population needs to be tested.

For individuals who have signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes RCT and nonrandomized studies evaluating rates of arrhythmia detection using outpatient cardiac telemetry. Relevant outcomes are OS 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 that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following codes are covered for Medicare Advantage Plans 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

Not applicable

PUBLISHED

Provider Update, September 2022
Provider Update, July 2021
Provider Update, August 2020
Provider Update, August 2019
Provider Update, July 2018

REFERENCES

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Electrocardiographic Services (20.15). 2004; https://www.cms.gov/medicare-coverage-database/details/ncd- details.aspx?MCDId=16&ExpandComments=n&McdName=Thomson+Micromedex+DrugDex+%C2%AE+Comp e ndium+Revision+Request+-+CAG-00391&NCDId=179. Accessed May 6, 2020.
2. Bolourchi M, Batra AS. Diagnostic yield of patch ambulatory electrocardiogram monitoring in children (from a national registry). Am J Cardiol. Mar 1 2015; 115(5):630-634. PMID 25591894
3. Podoleanu C, DaCosta A, Defaye P, et al. Early use of an implantable loop recorder in syncope evaluation: a randomized study in the context of the French healthcare system (FRESH study). Arch Cardiovasc Dis. Oct 2014; 107(10):546-552. PMID 25241220
4. Edvardsson N, Garutti C, Rieger G, et al. Unexplained syncope: implications of age and gender on patient characteristics and evaluation, the diagnostic yield of an implantable loop recorder, and the subsequent treatment. Clin Cardiol. Oct 2014; 37(10):618-625. PMID 24890550
5. Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: a prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. J Cardiovasc Electrophysiol. Mar 2007; 18(3): 241-247. PMID 17318994
6. 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. Apr 1 2005; 95(7):878-881. PMID 15781022
7. Olson JA, Fouts AM, Padanilam BJ, et al. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitations, presyncope, syncope, and the assessment of therapy efficacy. J Cardiovasc Electrophysiol. May 2007;18(5):473-477. PMID 17343724
8. Tayal AH, Tian M, Kelly KM, et al. Atrial fibrillation detected by mobile cardiac outpatient telemetry in cryptogenic TIA or stroke. Neurology. Nov 18 2008; 71(21):1696-1701. PMID 18815386
9. DiMarco JP, Philbrick JT. Use of ambulatory electrocardiographic (Holter) monitoring. Ann Intern Med 1990; 113(1):53-68.

10. Hoefman E, Bindels PJ, van Weert HC. Efficacy of diagnostic tools for detecting cardiac arrhythmias: systematic literature search. Neth Heart J 2010; 18(11):543-51.
11. Balmelli N, Naegeli B, Bertel O. Diagnostic yield of automatic and patient-triggered ambulatory cardiac event recording in the evaluation of patients with palpitations, dizziness, or syncope. Clin Cardiol 2003; 26(4):173-6.
12. Kadish AH, Reiffel JA, Clauser J, et al. Frequency of serious arrhythmias detected with ambulatory cardiac telemetry. Am J Cardiol. May 1 2010;105(9):1313-1316. PMID 20403485
13. Miller DJ, Khan MA, Schultz LR, et al. Outpatient cardiac telemetry detects a high rate of atrial fibrillation in cryptogenic stroke. J Neurol Sci. Jan 15 2013;324(1-2):57-61. PMID 23102659
14. Saarel EV, Doratotaj S, Sterba R. Initial experience with novel mobile cardiac outpatient telemetry for children and adolescents with suspected arrhythmia. Congenit Heart Dis. Jan-Feb 2008;3(1):33-38. PMID 18373747.
15. Favilla CG, Ingala E, Jara J, et al. Predictors of finding occult atrial fibrillation after cryptogenic stroke. Stroke. May 2015;46(5):1210-1215. PMID 25851771.
16. Kalani R, Bernstein R, Passman R, et al. Low yield of mobile cardiac outpatient telemetry after cryptogenic stroke in patients with extensive cardiac imaging. J Stroke Cerebrovasc Dis. Sep 2015;24(9):2069-2073. PMID 26139455.
17. Dörr, MM, Nohturfft, VV, Brasier, NN, Bosshard, EE, Djurdjevic, AA, Gross, SS, Raichle, CC, Rhinisperger, MM, Stöckli, RR, Eckstein, JJ. The WATCH AF Trial: SmartWATCHes for Detection of Atrial Fibrillation. JACC Clin Electrophysiol, 2019 Feb 21;5(2). PMID 30784691.
18. Lazzaro MA, Krishnan K, Prabhakaran S. Detection of atrial fibrillation with concurrent holter monitoring andcontinuous cardiac telemetry following ischemic stroke and transient ischemic attack. J Stroke Cerebrovasc Dis.Feb 2012; 21(2): 89-93. PMID 20656504
19. Derkac WM, Finkelmeier JR, Horgan DJ, et al. Diagnostic yield of asymptomatic arrhythmias detected by mobile cardiac outpatient telemetry and autotrigger looping event cardiac monitors. J Cardiovasc Electrophysiol. Dec2017; 28(12): 1475-1478. PMID 28940881
20. Steinberg JS, Varma N, Cygankiewicz I, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECGand external cardiac monitoring/telemetry. Heart Rhythm. Jul 2017; 14(7): e55-e96. PMID 28495301
21. Solomon MD, Yang J, Sung SH, et al. Incidence and timing of potentially high-risk arrhythmias detected through long term continuous ambulatory electrocardiographic monitoring. BMC Cardiovasc Disord. Feb 17 2016; 16: 35. PMID 26883019
22. Kabali C, Xie X, Higgins C. Long-Term Continuous Ambulatory ECG Monitors and External Cardiac LoopRecorders for Cardiac Arrhythmia: A Health Technology Assessment. Ont Health Technol Assess Ser. 2017; 17(1):
23. Narasimha D, Hanna N, Beck H, et al. Validation of a smartphone-based event recorder for arrhythmia detection.Pacing Clin Electrophysiol. May 2018; 41(5): 487-494. PMID 29493801
Dorr M, Nohturfft V, Brasier N, et al. The WATCH AF Trial: SmartWATCHes for Detection of Atrial Fibrillation. JACCClin Electrophysiol. Feb 2019; 5(2): 199-208. PMID 30784691