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MEDICAL POLICY – 2.02.510

Mobile Cardiac Outpatient Telemetry

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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

Note: There are many cardiac rhythm ambulatory monitoring devices available. **Many of these devices are discussed briefly in this policy for informational purposes only**. For the purposes of this policy, **the scope is on the mobile cardiac outpatient telemetry alone**.

Procedure	Medical Necessity
Outpatient cardiac telemetry (aka, mobile cardiac outpatient telemetry [MCOT])	**The use of outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry, e.g., CardioNet, LifeStar, ZioAT) as a diagnostic alternative to ambulatory event monitors may be considered medically necessary when ONE of the following conditions is met:** • An individual has symptoms of a cardiac arrhythmia, such as recurrent episodes of presyncope, syncope, palpitations, or dizziness, occurring less frequently than once every 48 hours **AND** • An external ambulatory cardiac event monitoring of at least 14 continuous days was non-diagnostic, **OR** • For evaluation of an individual with suspected atrial fibrillation as a cause of cryptogenic stroke, **AND** • An external ambulatory cardiac event monitoring of at least 14 continuous days was non-diagnostic. **Note**: (See Table 1 for MCOT and other examples of ambulatory event monitors) **The use of mobile cardiac outpatient telemetry is considered not medically necessary when the above criteria have not been met, and for all other indications.**

Coding

Code	Description
CPT	
93228	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

Code	Description
	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
93229	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

Related Information

Using mobile cardiac outpatient telemetry as a diagnostic alternative to ambulatory event monitors (AEMs) in individuals who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, syncope) is unproven.

Evidence Review

Description

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 individual intervention, and the mechanism of delivering the information from individual to clinician. These devices may be used to evaluate symptoms suggestive of arrhythmias (e.g., syncope, palpitations), and may be used to detect atrial fibrillation (AF) in individuals who have undergone cardiac ablation of AF or who have a history of cryptogenic stroke.

Background

Cardiac Arrhythmias

Cardiac monitoring is routinely used in the inpatient setting to detect acute changes in heart rate or rhythm that may need urgent response. For some conditions, a more prolonged period of monitoring in the ambulatory setting is needed to detect heart rate or rhythm abnormalities that may occur infrequently. These cases may include the diagnosis of arrhythmias in individuals with signs and symptoms suggestive of arrhythmias as well as the evaluation of paroxysmal AF.

Cardiac arrhythmias may be suspected because of symptoms suggestive of arrhythmias, including palpitations, dizziness, or syncope or presyncope, or because of abnormal heart rate or rhythm noted on exam. A full discussion of the differential diagnosis and evaluation of each of these symptoms is beyond the scope of this policy, but some general principles on the use of ambulatory monitoring are discussed.

Arrhythmias are an important potential cause of syncope or near syncope, which in some cases may be described as dizziness. An electrocardiogram (ECG) is generally indicated whenever there is suspicion of a cardiac cause of syncope. Some arrhythmic causes will be apparent on ECG. However, for individuals in whom an ECG is not diagnostic, longer monitoring may be indicated. The 2009 joint guidelines from the European Society of Cardiology and 3 other medical specialty societies suggested that, in individuals with clinical or ECG features suggesting an arrhythmic syncope, ECG monitoring is indicated; the guidelines also stated that the "duration (and technology) of monitoring should be selected according to the risk and the predicted recurrence rate of syncope."[1] Similarly, guidelines from the National Institute for Health and Care Excellence (2023) on the evaluation of transient loss of consciousness, have recommended the use of an ambulatory ECG in individuals with a suspected arrhythmic cause of syncope. The type and duration of monitoring recommended is based on the individual's history, particularly the frequency of transient loss of consciousness.[2] The Holter monitor is recommended if transient loss of consciousness occurs several times a week. If the frequency of transient loss of consciousness is every one to two weeks, an external event recorder is recommended; and if the frequency is less than once every two weeks, an implantable event recorder is recommended.

Similar to syncope, the evaluation and management of palpitations is individual-specific. In cases where the initial history, examination, and ECG findings are suggestive of an arrhythmia, some form of ambulatory ECG monitoring is indicated. A position paper from the European Heart Rhythm Association (2011) indicated that, for individuals with palpitations of unknown

origin who have clinical features suggestive of arrhythmia, referral for specialized evaluation with consideration for ambulatory ECG monitoring is indicated.[3]

Atrial Fibrillation Detection

AF is the most common arrhythmia in adults. It may be asymptomatic or be associated with a broad range of symptoms, including lightheadedness, palpitations, dyspnea, and a variety of more nonspecific symptoms (e.g., fatigue, malaise). It is classified as paroxysmal, persistent, or permanent based on symptom duration. Diagnosed AF may be treated with antiarrhythmic medications with the goal of rate or rhythm control. Other treatments include direct cardioversion, catheter-based radiofrequency- or cryo-energy-based ablation, or one of several surgical techniques, depending on the individual's comorbidities and associated symptoms.

Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low flow state increases the risk of thrombosis. The area of the left atrium with the lowest blood flow in AF, and therefore the highest risk of thrombosis, is the left atrial appendage. Multiple clinical trials have demonstrated that anticoagulation reduces the ischemic stroke risk in individuals at moderate- or high-risk of thromboembolic events. Oral anticoagulation in individuals with AF reduces the risk of subsequent stroke and is recommended by the American Heart Association, American College of Cardiology, and the Heart Rhythm Society (2014) joint guidelines on individuals with a history of stroke or transient ischemic attack.[4]

Ambulatory ECG monitoring may play a role in several situations in the detection of AF. In individuals who have undergone ablative treatment for AF, if ongoing AF can be excluded with reasonable certainty, including paroxysmal AF which may not be apparent on ECG during an office visit, anticoagulation therapy could potentially be stopped. In some cases where identifying paroxysmal AF is associated with potential changes in management, longer term monitoring may be considered. There are well-defined management changes that occur in individuals with AF. However, until relatively recently the specific role of long-term (i.e., >48 hours) monitoring in AF was not well-described.

Individuals with cryptogenic stroke are often monitored for the presence of AF because AF is estimated to be the cause of cryptogenic stroke in more than 10% of individuals, and AF increases the risk of stroke.[5,6] Paroxysmal AF confers an elevated risk of stroke, just as persistent and permanent as AF does. In individuals with a high risk of stroke, particularly those with a history of ischemic stroke that is unexplained by other causes, prolonged monitoring to identify paroxysmal AF has been investigated.

Cardiac Rhythm Ambulatory Monitoring Devices

Ambulatory cardiac monitoring with a variety of devices permits the evaluation of cardiac electrical activity over time, in contrast to a static ECG, which only permits the detection of abnormalities in cardiac electrical activity at a single point in time.

A Holter monitor is worn continuously and records cardiac electrical output continuously throughout the recording period. Holter monitors are capable of recording activity for 24 to 72 hours. Traditionally, most Holter monitors have three channels based on three ECG leads. However, some currently available Holter monitors have up to 12 channels. Holter monitors are an accepted intervention in a variety of settings where a short period (24-48 hours) of comprehensive cardiac rhythm assessment is needed (e.g., suspected arrhythmias when symptoms [syncope, palpitations] are occurring daily). These devices are not the focus of this policy.

Various classes of devices are available for situations where longer monitoring than can be obtained with a traditional Holter monitor is needed. Because there may be many devices within each category, a comprehensive description of each is beyond our scope. Devices vary in how data are transmitted to the location where the ECG output is interpreted. Data may be transmitted via cellular phone or landline, or by direct download from the device after its return to the monitoring center. The device classes are described in **Table 1**.

Note: There are many cardiac rhythm ambulatory monitoring devices available. **Many of these devices are discussed briefly in this policy for informational purposes only.** For the purposes of this policy, the scope is on the **mobile cardiac outpatient telemetry alone**.

Table 1. Ambulatory Cardiac Rhythm Monitoring Devices

Device Class	Description	Device Examples
Noncontinuous devices with memory (event recorder)	Devices not worn continuously but rather activated by individual and applied to the skin in the precordial area when symptoms develop	Zio Event Card (iRhythm Technologies) REKA E100 (REKA Health)
Continuous recording devices with longer recording periods	Devices continuously worn and continuously record via ≥1 cardiac leads and store data longer than traditional Holter (14 days)	Zio Patch system and ZIO ECG Utilization Service (ZEUS) System (iRhythm Technologies)

Device Class	Description	Device Examples
External memory loop devices (individual- or autotriggered)	Devices continuously worn and store a single channel of ECG data in a refreshed memory. When the device is activated, the ECG is then recorded from the memory loop for the *preceding* 30-90 seconds and for the next 60 seconds or so. Devices may be activated by an individual when symptoms occur (individuals-triggered) or by an automated algorithm when changes suggestive of an arrhythmia are detected (autotriggered).	Individual-triggered: Explorer Looping Monitor (LifeWatch Services) Autotriggered: LifeStar AF Express Auto-Detect Looping Monitor (LifeWatch Services) Autotriggered or individual-triggered: King of Hearts Express AF (Card Guard Scientific Survival)
Implantable memory loop devices (individual- or autotriggered)	Devices similar in design to external memory loop devices but implanted under the skin in the precordial region	Autotriggered or individual-triggered: Reveal XT ICM (Medtronic) and Confirm Rx Insertable Cardiac Monitor (Abbott) Autotriggered: BioMonitor, Biotronik)
Mobile cardiac outpatient telemetry	Continuously recording or autotriggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis	CardioNet MCOT (BioTelemetry) LifeStar Mobile Cardiac Telemetry (LifeWatch Services) Zio AT(iRhythm) SmartCardia 7L (SmartCardia)

ECG: electrocardiogram.

There are also devices that combine features of multiple classes. For example, the LifeStar ACT Ex Holter (LifeWatch Services) is a 3-channel Holter monitor, but is converted to a mobile cardiac telemetry system if a diagnosis is inconclusive after 24 to 48 hours of monitoring. The BodyGuardian Heart Remote Monitoring System (Boston Scientific Cardiac Diagnostics) is an external autotriggered memory loop device that can be converted to a real-time monitoring system. The eCardio Verité system (eCardio) can switch between an individual-activated event monitor and a continuous telemetry monitor. The Spiderflash-T (LivaNova) is an example of an external autotriggered or individual-triggered loop recorder, but, like the Zio Patch, can record 2 channels for 14 to 40 days.

Summary of Evidence

Mobile Cardiac Outpatient Telemetry

This policy addresses whether the addition of real-time mobile cardiac outpatient telemetry (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. Because it is not clear which individuals comprise that subset, or whether identification of those individuals 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 individuals with signs or symptoms suggestive of arrhythmia is to provide an alternative method of transmitting electrical cardiac activity data to healthcare providers.

One RCT by Rothman et al (2007) compared MCOT with standard event monitors.[82] This trial involved 305 individuals randomized to the LOOP recorder or to MCOT (CardioNet) and monitored for up to 30 days. Individuals were recruited from 17 centers. Investigators and individuals were not blinded to randomization assignment. Monitor strips and diagnoses were reviewed by an electrophysiologist blinded to the monitoring device assignment. Most individuals in the LOOP recorder group had an individual-triggered event monitor. Only a subset of individuals (n=50) had autotrigger devices, thus precluding comparison of MCOT and autotrigger devices. Analyses were conducted on individuals completing at least 25 days of monitoring. The primary end point was either confirmation or exclusion of arrhythmic cause of the individual's symptoms. Arrhythmias were classified as either clinically significant or clinically insignificant. The diagnostic endpoint (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 individuals vs. one individual), and ventricular tachycardia defined as more than 3 beats and rate greater than 100 (14 individuals vs. two individuals). These differences were thought to be clinically significant rhythm disturbances and the likely causes of the individuals' symptoms. In this trial, median time to diagnosis in the total study population was seven days in the MCOT group and nine days in the LOOP group. The trialists did not comment on the clinical impact (changes in

management) of these findings in individuals for whom the rhythm disturbance did not occur simultaneously with symptoms.

Derkac et al (2017) retrospectively reviewed the BioTelemetry database of individuals receiving ambulatory ECG monitoring, selecting individuals prescribed MCOT (n=69,977) and individuals prescribed AT-LER, an autotrigger looping event recorder (n=8513).[83] Individuals were diagnosed with palpitations, syncope and collapse, AF, tachycardia, and/or TIA. Individuals given the MCOT were monitored for an average of 20 days and individuals 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 individuals 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.[84] Medical records from 26,438 individuals 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% (5,459) 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 individuals with wide-complex tachycardia, 100 individuals 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.[85-88] One study (Joshi et al [2005]) described the outcomes of a consecutive case series of 100 individuals.[85] Included individuals had the following symptoms: palpitations (47%), dizziness (24%), or syncope (19%). Individuals being evaluated for the efficacy of drug treatment (25%) were also included. Clinically significant arrhythmias were detected in 51% of the individuals, but half of these individuals were asymptomatic. The authors commented that the automatic detection resulted in an increased diagnostic yield, but there was no discussion of its unique features (i.e., 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 individuals with cryptogenic stroke or TIA who underwent 28 days of monitoring with MCOT.[89] AF was detected in 14% (31/227) of individuals, of whom 3 reported symptoms at the time of AF. Oral anticoagulation was initiated in 26 (84%) individuals diagnosed with AF. Of the remaining 5 (16%) not on anticoagulation therapy, one had a prior history of

gastrointestinal bleeding, three were unwilling to accept the risk of bleeding related to the use of anticoagulants, and one failed to follow up.

Miller et al (2013) retrospectively analyzed paroxysmal AF detection rates among 156 individuals evaluated with MCOT within 6 months of a cryptogenic stroke or TIA.[33] Over a median 21-day period of MCOT monitoring (range, 1-30 days), AF was detected in 17.3% of individuals. Mean time to first occurrence of AF was 9 days (range, 1-21 days).

Tayal et al (2008) retrospectively analyzed individuals with cryptogenic stroke who had not been diagnosed with AF by standard monitoring.[88] In this study, 13 (23%) of 56 individuals with cryptogenic stroke had AF detected by MCOT. Twenty-seven asymptomatic AF episodes were detected in the 13 individuals, 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 individuals with cryptogenic stroke.[90] In this series, 82.4% of individuals had completed transesophageal echocardiography, cardiac magnetic resonance imaging (cMRI), 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 individuals wore both an external loop recorder (ELR) and a Kardia monitor to screen for AF during a period of 14 to 30 days.[91] Individuals 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 three 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. Individuals were also monitored by the ELR company, which notified a physician on call when necessary. All 33 individuals had a diagnosis using the Kardia monitor and 24 individuals 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.[92] The smartwatch system uses an algorithm to enable rhythm analysis of the photoplethysmographic signals. The population consisted of 508 hospitalized individuals who had interpretable ECG and photoplethysmographic recordings. The photoplethysmographic 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.

The available evidence suggests that MCOT is likely to be 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, permitting for emergent intervention for potentially life-threatening arrhythmias. One study reported that 1% of arrhythmic events detected on MCOT during a mean monitoring period of 21 days per individual 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. Currently, the evidence does not demonstrate a clinically significant incremental benefit for MCOT.

For individuals who have signs and/or symptoms suggestive of arrhythmia who receive outpatient cardiac telemetry, the evidence includes an RCT and nonrandomized studies evaluating rates of arrhythmia detection using outpatient cardiac telemetry. 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 that the technology results in an improvement in the net health outcome. Therefore the use of this device is considered investigational.

However, even though there are not studies that address differences in management or outcomes of real-time monitoring, the Plan has determined that for the clinical scenarios stated in the policy criteria, because the results of the RCT suggested that MCOT does provide more effective detection of infrequent cardiac arrythmias than external loop monitors[82], the Plan will consider use of MCOT as medically necessary when the policy criteria are met.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05957315	Mobile Cardiac Outpatient Telemetry for Unexplained Syncope: Time to Treatment, Arrhythmia Diagnosis and Outcome	160	Oct 2025

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from three physician specialty societies and four academic medical centers (three reviews) while this policy was under review in 2014. Input was obtained to provide information on mobile cardiac outpatient telemetry and new devices. There was no consensus whether mobile cardiac outpatient telemetry is medically necessary. While reviewers agreed that mobile cardiac outpatient telemetry is comparable to event monitors for arrhythmia detection, they did not agree on whether the real-time monitoring provides incremental benefit over external event monitors or is associated with improved health outcomes compared with external event monitors. There was consensus on the medical necessity of externally worn event monitors with longer continuous recording periods as an alternative to Holter monitors or event monitors. For implantable memory loop devices that are smaller than older-generation devices, there was consensus that these devices improve the likelihood of obtaining clinically useful information due to improved ease of use, but there was no consensus that such devices improve clinical outcomes and are medically necessary.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology

In 2014 (reaffirmed 2022), the American Academy of Neurology updated its guidelines on the prevention of stroke in individuals with nonvalvular AF (NVAF).[93], These guidelines made the following recommendations on the identification of individuals with occult NVAF.

- "Clinicians might obtain outpatient cardiac rhythm studies in individuals with cryptogenic stroke without known NVAF, to identify individuals with occult NVAF (Level C).
- Clinicians might obtain cardiac rhythm studies for prolonged periods (e.g., for 1 or more weeks) instead of shorter periods (e.g., 24 hours) in individuals with cryptogenic stroke without known NVAF, to increase the yield of identification of individuals with occult NVAF (Level C)."

International Society for Holter and Noninvasive Electrocardiology/Heart Rhythm Society

The International Society for Holter and Noninvasive Electrocardiology and the Heart Rhythm Society (HRS; 2017) issued a consensus statement on ambulatory electrocardiogram and external monitoring and telemetry.[97] Below are a summary from the consensus statement, detailing advantages and limitations of ambulatory electrocardiogram techniques (see **Table 3) and recommendations for the devices that are relevant to this policy (see Table 4**).

Table 3. Advantages and Limitations of Ambulatory ECG Techniques, International Society for Holter and Noninvasive Electrocardiology/HRS

ECG Monitoring Technique	Advantages	Limitations
Holter monitoring	• Records and documents continuous 3- to 32-lead ECG signal simultaneously with biologic signals during normal daily activities • Physicians familiar with analysis software and scanning services	• Frequent noncompliance with symptom logs and event markers • Frequent electrode detachments • Signal quality issues due to skin adherence, tangled wires, dermatitis • Absence of real-time data analysis • Poor patient acceptance of electrodes
Patch ECG monitors	• Long-term recording of ≥14 days • Excellent patient acceptance	• Limited ECG from closely spaced electrodes, lacking localization of arrhythmia origin • Inconsistent ECG quality due to body type variations
External loop recorders	• Records only selected ECG segments marked as events either automatically or manually by patient • Immediate alarm generation on event detection	• Single-lead ECG, lacking localization of arrhythmia origin • Cannot continuously document cardiac rhythm • Requires patient to wear electrodes continuously
Event recorders	• Records only selected ECG segments after an event is detected by patient • Immediate alarm generation at event detected by patient • Well-tolerated by patient	• Single-lead ECG, lacking localization of arrhythmia origin • Cannot continuously document cardiac rhythm • Diagnostic yield dependent on patient ability to recognize correct symptom
Mobile cardiac telemetry	• Multilead, so higher sensitivity and specificity of arrhythmia detection • Streams data continuously; can be programmed to autodetect and autosend events at prescribed time intervals • Immediate alarm generation on event without patient interaction	• Long-term patient acceptance is reduced due to requirement of daily electrode changes

ECG: electrocardiogram; HRS: Heart Rhythm Society.

Table 4. Select Recommendations for Ambulatory ECG and External Monitoring or Telemetry, International Society for Holter and Noninvasive Electrocardiology/HRS

Recommendation	COR[a]	LOE[b]
Selection of ambulatory ECG		
Holter monitoring when symptomatic events anticipated within 48 hours	I	B-NR
Extended ambulatory ECG (15 to 30 days) when symptomatic events are not daily or are uncertain	I	B-R
Continuous monitoring (1 to 14 days) to quantify arrhythmia burden and patterns	I	B-NR
Specific conditions for use of ambulatory ECG		
Unexplained syncope, when tachycardia suspected	I	B-R
Unexplained palpitation	I	B-R
Detection of atrial fibrillation, triggering arrhythmias, and postconversion pauses	IIa	B-NR
Cryptogenic stroke, to detect undiagnosed atrial fibrillation	I	B-R

COR: class of recommendation; ECG: electrocardiogram; HRS: Heart Rhythm Society; LOE: level of evidence.

[a] COR definitions: I: strong recommendation; IIa: benefit probably exceeds risk.

[b] LOE definitions: B-NR: moderate level based on well-executed nonrandomized studies; B-R: moderate level based on randomized trials.

American Heart Association, American College of Cardiology, et al

The American College of Cardiology (ACC), the American Heart Association (AHA), the American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS) (2023) updated guidelines initially issued in 2014[4] on the management of individuals with atrial fibrillation (AF).[94] These guidelines recommended the use of Holter or event monitoring if the diagnosis of the type of arrhythmia is in question, or as a means of evaluating rate control.

The same associations (2017) collaborated on guidelines on the evaluation and management of individuals with syncope[95], and individuals with ventricular arrhythmias[96]. Cardiac monitoring recommendations are summarized below in **Tables 5 and 6**.

Table 5. Cardiac Monitoring Recommendations, AHA/ACC/HRS

Recommendation	COR[a]	LOE[b]
Choice of a specific cardiac monitor should be determined on the basis of frequency and nature of syncope events.[95]	I	C-EO
To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful: Holter monitor, transtelephonic monitor, external loop recorder, patch recorder, and mobile cardiac outpatient telemetry.[95]	IIa	B-NR
To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an implantable cardiac monitor can be useful.[95]	IIa	B-R
Ambulatory electrocardiographic monitoring is useful to evalute whether symptoms including palpitations, presyncope, or syncope, are caused by ventricular arrhythmia[96]	I	B-NR
In patients with cryptogenic stroke (i.e., stroke of unknown cause), in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF.[94]	IIa	B-R

ACC: American College of Cardiology; AF: atrial fibrillation; AHA: American Hearth Association; COR: class of recommendation; HRS: Heart Rhythm Society; LOE: level of evidence.

[a] COR definitions: I: strong recommendation; IIa: benefit probably exceeds risk.

[b] LOE definitions: B-NR: moderate level based on well-executed nonrandomized studies; B-R: moderate level based on randomized trials; C-EO: consensus of expert opinion based on clinical experience.

Table 6. Patient Selection Recommendations by Cardiac Rhythm Monitor, AHA/ACC/HRS

Type of Monitor	Patient Selection
Holter monitor	• Symptoms frequent enough to be detected within 24 to 72 hours
Patient-activated event monitor	• Frequent spontaneous symptoms likely within 2 to 6 weeks • Limited use when syncope associated with sudden incapacitation
External loop recorder (patient or auto-triggered)	• Frequent spontaneous symptoms likely to occur within 2 to 6 weeks
External patch recorder	• Alternative to external loop recorder • Leadless, so more comfortable, resulting in improved compliance • Offers only 1-lead recording
Mobile cardiac outpatient telemetry	• Spontaneous symptoms related to syncope and rhythm correlation • High-risk patients needing real-time monitoring
Implantable cardiac monitor	• Recurrent, infrequent, unexplained syncope

ACC: American College of Cardiology; AHA: American Heart Association; HRS: Heart Rhythm Society.

US Preventive Services Task Force Recommendations

In 2022, the US Preventive Services Task Force updated its recommendation on Screening for Atrial Fibrillation and concluded, "For adults 50 years or older who do not have signs or symptoms of atrial fibrillation: The current evidence is insufficient to assess the balance of benefits and harms of screening for AF (Grade: I statement)."[98]

Medicare National Coverage

The Centers for Medicare & Medicaid Services (2004) implemented a national coverage determination for electrocardiographic services.[99] This national coverage determination includes descriptions of the Holter monitor and event recorders (both external loop recorders and implantable loop recorders). Ambulatory cardiac monitors are covered when there is documentation of medical necessity. Indications for use include detection of symptomatic transient arrhythmias and determination of arrhythmic drug therapy (to either initiate, revise, or discontinue the therapy).

Regulatory Status

Some of the newer devices are described in the Background section for informational purposes. Because there may be many devices within each category, a comprehensive description of individual devices is beyond the scope of this policy. US Food and Drug Administration product codes include: DSH, DXH, DQK, DSI, MXD, MHX.

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History

Date	Comments
08/09/16	New policy, add to Cardiology section. Use of MCOT is considered investigational. Policy will be effective 01/01/17.
10/25/16	Effective date revision. Policy will be effective 03/01/17.
02/24/17	Effective date revision. Policy will be effective 03/15/17.
03/15/17	Effective date revision. Policy will be effective 03/17/17.
03/17/17	Effective date revision. Policy will be effective 03/31/17.
03/23/17	Effective date revision. Policy will be effective 03/24/17. Coding update; removed CPT codes 0295T-0298T. Minor formatting update.
08/01/17	Annual Review, approved July 11, 2017. No changes to policy statement.
08/01/18	Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 9, 16 and 17 added. Policy statement unchanged.
08/01/19	Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019, several references added. Policy statements unchanged.
08/01/20	Annual Review, approved July 2, 2020. Policy updated with literature review through May 2020; references added. Policy statements unchanged.
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through March 25, 2021; reference added. Policy statements unchanged.
06/01/22	Interim Review, approved May 9, 2022. Minor edits made for greater clarity. Policy intent unchanged.
08/01/22	Annual Review, approved July 11, 2022. Policy updated with literature review through April 8, 2022; references added. Policy statement unchanged except for a minor edit.
08/01/23	Annual Review, approved July 10, 2023. Policy updated with literature review through April 11, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization where applicable.
02/01/24	Interim Review, approved January 9, 2024. Added policy criteria for which MCOT is now considered medically necessary rather than investigational.

Date	Comments
08/01/24	Annual Review, approved July 8, 2024. Policy updated with literature review through April 9, 2024; reference added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.