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# MEDICAL POLICY – 2.02.510

# Mobile Cardiac Outpatient Telemetry and Implantable Loop Recorders

BCBSA Ref. Policy: 2.02.08

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| Effective Date: | **May 1, 2026*** |
| Last Revised: | Apr. 14, 2026 |
| Replaces: | N/A |

*This policy has been revised. Click here to view the changes effective August 7, 2026.

RELATED MEDICAL POLICIES:

11.01.525 Site of Service Ambulatory Service Center (ASC): Select Surgical Procedures in Adults

**Select a hyperlink below to be directed to that section.**

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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## Introduction

Implantable loop recorders (ILRs) and mobile cardiac outpatient telemetry (MCOT) devices are noninvasive technologies used to record and analyze a patient's heart rhythm during normal daily activities. These systems help detect intermittent or abnormal heart rhythms (arrhythmias) such as atrial fibrillation, bradycardia, or tachycardia, that may not occur during a brief in-office test. MCOT devices provide continuous heart rhythm data to remote monitoring centers, while ILRs offer long-term, automatic rhythm surveillance over months to years. Both technologies allow for extended, outpatient cardiac monitoring providing more comprehensive information than traditional event or Holter monitors. This approach supports accurate diagnoses while allowing patients to remain outside of the hospital setting. This policy describes when ILRs and MCOTs may be considered medically necessary.

**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 only on the mobile cardiac outpatient telemetry (MCOT) and implantable loop recorders (ILRs).

We will review ILRs and MCOT for medical necessity.

**The surgical procedure subject to medical necessity review for site of service addressed in this policy is limited to:**

- **ILR implantation**

Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

| Site of Service for Elective Surgical Procedures | Medical Necessity |
|---|---|
| **Medically necessary sites of service:**<br>• **Ambulatory surgical center** | **Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This is the preferred medically necessary site of service for certain elective surgical procedures.** |
| • **Off campus-outpatient hospital/medical center**<br>• **On campus-outpatient hospital/medical center** | **Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. An elective surgical procedure performed in a hospital outpatient department may be considered medically necessary if there is no access to an ambulatory surgical center due to one of the following criteria:**<br>• There is no qualifying ASC within 30 miles that can provide the necessary care due to one of the following:<br>  ○ There is no geographically accessible ASC that has the necessary equipment to perform the procedure; or |

| Site of Service for Elective Surgical Procedures | Medical Necessity |
|---|---|
| | ○ There is no geographically accessible ASC available at which the individual's physician has privileges; or<br>○ An ASC's specific guideline prohibits the use of the ASC related to the individual's health condition or weight, or<br>• The individual is aged 18 or younger, or<br>• The service being performed is in conjunction with an additional service that requires the use of a hospital outpatient department, and the procedures are being performed in the same operative session<br>**OR**<br>• The individual has a clinical condition which puts them at increased risk for complications including any of the following (this list may not be all inclusive):<br>○ **Anesthesia Risk**<br>▪ ASA classification III or higher (see definition)<br>▪ Personal history of complication of anesthesia<br>▪ Documentation of alcohol dependence or history of cocaine use<br>▪ Prolonged surgery (greater than 3 hours)<br>○ **Cardiovascular Risk**<br>▪ Uncompensated chronic heart failure (NYHA class III or IV)<br>▪ Recent history of myocardial infarction (MI) (less than 3 months)<br>▪ Poorly controlled, resistant hypertension*<br>▪ Recent history of cerebrovascular accident (less than 3 months)<br>▪ Increased risk for cardiac ischemia (drug eluting stent placed less than 1 year or angioplasty less than 90 days)<br>▪ Symptomatic cardiac arrhythmia despite medication<br>▪ Significant valvular heart disease<br>○ **Liver Risk**<br>▪ Advanced liver disease (MELD Score greater than 8)**<br>○ **Pulmonary Risk** |

| Site of Service for Elective Surgical Procedures | Medical Necessity |
|---|---|
| | ▪ Chronic obstructive pulmonary disease (COPD) (FEV1 less than 50%)<br>▪ Poorly controlled asthma (FEV1 less than 80% despite treatment)<br>▪ Moderate to severe obstructive sleep apnea (OSA)***<br>○ **Renal Risk**<br>▪ End stage renal disease (on dialysis)<br>○ **Other**<br>▪ Morbid obesity (BMI greater than or equal to 50)<br>▪ Pregnancy<br>▪ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion])<br>▪ Anticipated need for transfusion(s)<br><br>**Note**: * 3 or more drugs to control blood pressure<br>** **https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease**<br>*** Moderate-AHI greater than or equal to 15 and less than or equal to 30, Severe-AHI greater than or equal to 30<br>****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin) |
| • **Off campus-outpatient hospital/medical center**<br>• **On campus-outpatient hospital/medical center** | **These sites of service are considered not medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.** |
| • **Inpatient hospital/medical center** | **This site of service is considered not medically necessary for this elective surgical procedure** |

| Procedure | Medical Necessity |
|---|---|
| **Implantable loop recorders (ILRs)**<br><br>• **Auto-activated**<br>• **Patient activated** | **The use of either patient-activated or auto-activated ILRs may be considered medically necessary in the following situations:**<br>• In individuals who experience recurrent symptoms (i.e., palpitations, dizziness, presyncope, or syncope) so infrequently |

| Procedure | Medical Necessity |
|---|---|
| | that a prior trial of other trial of other external ambulatory cardiac event monitoring has been unsuccessful<br>**OR**<br>• In individuals who require long-term monitoring for atrial fibrillation (AF) or possible AF (see **Related Information**) |
| **Mobile cardiac outpatient telemetry (MCOT)** | **The use of MCOT, (e.g., CardioNet, LifeStar, ZioAT) may be considered medically necessary when the following criteria are met:**<br>• An external ambulatory cardiac event monitoring of at least 14 continuous days was non-diagnostic<br>**AND**<br>○ The individual has symptoms of cardiac arrhythmia, such as recurrent episodes of presyncope, syncope, palpitations, or dizziness, occurring less frequently than once every 48 hours<br>**OR**<br>○ For evaluation of an individual with suspected AF as a cause of cryptogenic stroke<br><br>**The use of mobile cardiac outpatient telemetry is considered not medically necessary when the above criteria are not met, and for all other indications.** |

| Documentation Requirements |
|---|
| **The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**<br>• Office visit notes that contain the relevant history and physical<br><br>**For ILRs (patient-activated or auto-activated) all of the following should be documented:**<br>• Previous external ambulatory cardiac event monitoring* was unsuccessful<br>**AND**<br>○ Infrequent recurrent symptoms which include at least one of the following:<br>▪ Palpitations<br>▪ Dizziness |

## Documentation Requirements

- Presyncope
- Syncope

**AND**

- Requirement for long-term monitoring for AF or possible AF

**For MCOT at least one of the following conditions should be documented:**

- Previous external ambulatory cardiac event monitoring* for at least 14 continuous days was non-diagnostic

**AND**

- Symptomatic cardiac arrhythmia occurring less frequently than once every 48 hours including at least one of the following as a recurrent episodes:
  - Palpitations
  - Dizziness
  - Presyncope
  - Syncope

**OR**

- Evaluation of suspected atrial fibrillation as a cause of cryptogenic stroke is medically necessary

*(See Related Information for other examples of ambulatory event monitors)

# Coding

| Code | Description |
|---|---|
| **CPT** | |
| 33285 | Insertion, subcutaneous cardiac rhythm monitor, including program |
| 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 |
| **HCPCS** | |
| C1764 | Event recorder, cardiac (implantable) |
| E0616 | Implantable cardiac event recorder with memory, activator, and programmer |

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

The available evidence has suggested that long-term monitoring for atrial fibrillation postablation or after cryptogenic stroke is associated with improved outcomes, but the specific type of monitoring associated with the best outcomes is not well-defined. Trials demonstrating improved outcomes have used either event monitors or implantable monitors. In addition, there are individual considerations that may make one type of monitor preferable over another.

Therefore, for the evaluation of individuals with cryptogenic stroke who have had a negative standard workup for atrial fibrillation including 24-hour Holter monitoring, or for the evaluation of atrial fibrillation after an ablation procedure, the use of long-term monitoring with an external event monitor, OR a continuous ambulatory monitor that records and stores information for periods longer than 48 hours, OR an implantable ambulatory monitor may be considered medically necessary for individuals who meet the criteria outlined above.

## 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, 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 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 only on the **mobile cardiac outpatient telemetry and implantable loop recorders.**

## 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)<br>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) |
| 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)<br>Autotriggered: LifeStar AF Express Auto-Detect Looping Monitor (LifeWatch Services)<br>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)<br>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)<br>LifeStar Mobile Cardiac Telemetry (LifeWatch Services)<br>Zio AT(iRhythm)<br>SmartCardia 7L (SmartCardia) |

* The policy criteria is for implantable loop devices and mobile cardiac outpatient telemetry
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

## Implantable Loop Recording

For individuals who have signs and/or symptoms suggestive of arrhythmia with infrequent symptoms who receive patient- or auto-activated implantable ambulatory event monitoring, the evidence includes RCTs comparing implantable loop recordings (ILRs) with shorter term monitoring, usually 24- to 48-hour Holter monitoring, and many observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. Studies assessing prolonged implantable loop recorders (ILRs) in patients have reported high rates of arrhythmia detection compared with shorter external event or Holter monitoring. These studies have supported use of a progression in diagnostics from an external event monitor to ILR when longer monitoring is needed. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

## 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.[90] 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.

**Arrhythmia Detection**

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).[91] 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.[92] 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.[93, 94, 95, 96] One study (Joshi et al [2005]) described the outcomes of a consecutive case series of 100 individuals.[93] 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).

**Atrial Fibrillation Detection**

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.[97] 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.[96] 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.[98] 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.[99] 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.[100] 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.

## Summary: MCOT for Patients with Symptoms of Arrhythmia

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 randomized 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; one observational study reported a benefit of MCOT on hospital readmission in patient with prior stroke. The addition of

real-time monitoring to outpatient ambulatory monitoring is considered an enhancement to existing technology.

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.

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[90], 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** | | | |
| NCT06542770 | Subtle Ultrasound Atrial Anomalies Predicts the Early Diagnosis of Silent Atrial Fibrillation Detected by Implantable Cardiac Monitor in Patients With Cryptogenic Stroke. A Randomized Trial (CRIPTO-FAST) | 100 | Dec 2024 |
| NCT05957315 | Mobile Cardiac Outpatient Telemetry for Unexplained Syncope: Time to Treatment, Arrhythmia Diagnosis and Outcome | 160 | Oct 2025 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT04371055 | Intensive Heart Rhythm Monitoring to Decrease Ischemic Stroke and Systemic Embolism - the Find-AF 2 Study | 5229 | Dec 2026 |
| NCT03940066 | Evaluation of Ambulatory Monitoring of Patients After High-risk Acute Coronary Syndrome Using Two Different Systems: Biomonitor-2 and Kardia Mobile | 169 | Jun 2023 (estimated) |
| **Unpublished** | | | |
| NCT02786940 | Remote Cardiac Monitoring of Higher-Risk Emergency Department Syncope Patients after Discharge (REMOSYNC) | 99 | Mar 2023 |
| NCT03541616 | Prevalence of Subclinical Atrial Fibrillation in High Risk Heart Failure Patients and Its Temporal Relationship With Hospital Readmission for Heart Failure (PROTECT-HF) | 242 | Mar 2023 |

NCT: national clinical trial. [a] Denotes industry involvement

## 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.

## 2009 Input

In response to requests, input was received from one physician specialty society and four academic medical centers (5 reviews) while this policy was under review in 2009. There were differences among reviewers on outpatient cardiac telemetry, with some reviewers concluding it had a role in certain subsets of patients (e.g., in those with sporadic atrial fibrillation [AF]). Other reviewers commented that the value of this technology should be considered in both providing a diagnosis and in making treatment decisions. At times, excluding arrhythmia as a cause of a patient's symptoms is an important finding.

## 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).[102] 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)."

## 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).[103] 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 ACC/AHA/HRS (2017) collaborated on guidelines on the evaluation and management of individuals with syncope[104], and individuals with ventricular arrhythmias[105]. Cardiac monitoring recommendations are summarized below in **Tables 3 and 4**.

## Table 3. 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.[104] | 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.[104] | IIa | B-NR |
| To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an implantable cardiac monitor can be useful.[104] | IIa | B-R |
| Ambulatory electrocardiographic monitoring is useful to evaluate whether symptoms including palpitations, presyncope, or syncope, are caused by ventricular arrhythmia[105] | I | B-NR |
| In patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an implantable loop recorder are reasonable to improve detection of AF.[106] | IIa | B-R |

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

[a] COR definitions: I: strong recommendation; IIa or 2a: benefit probably exceeds risk (moderate).

[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 4. 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<br>• 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<br>• Leadless, so more comfortable, resulting in improved compliance<br>• Offers only 1-lead recording |
| Mobile cardiac outpatient telemetry | • Spontaneous symptoms related to syncope and rhythm correlation<br>• 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.

## 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.[106] Below is a summary from the consensus statement, detailing advantages and limitations of ambulatory electrocardiogram techniques (see **Table 5)** and recommendations for the devices that are relevant to this policy **(see Table 6**).

## Table 5. Advantages and Limitations of Ambulatory Electrocardiogram 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<br>• Physicians familiar with analysis software and scanning services | • Frequent noncompliance with symptom logs and event markers<br>• Frequent electrode detachments<br>• Signal quality issues due to skin adherence, tangled wires, dermatitis<br>• Absence of real-time data analysis<br>• Poor patient acceptance of electrodes |
| Patch ECG monitors | • Long-term recording of ≥14 days<br>• Excellent patient acceptance | • Limited ECG from closely spaced electrodes, lacking localization of arrhythmia origin<br>• 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<br>• Immediate alarm generation on event detection | • Single-lead ECG, lacking localization of arrhythmia origin<br>• Cannot continuously document cardiac rhythm<br>• Requires patient to wear electrodes continuously |
| Event recorders | • Records only selected ECG segments after an event is detected by patient<br>• Immediate alarm generation at event detected by patient<br>• Well-tolerated by patient | • Single-lead ECG, lacking localization of arrhythmia origin<br>• Cannot continuously document cardiac rhythm<br>• Diagnostic yield dependent on patient ability to recognize correct symptom |
| Mobile cardiac telemetry | • Multilead, so higher sensitivity and specificity of arrhythmia detection<br>• Streams data continuously; can be programmed to autodetect and autosend events at prescribed time intervals<br>• 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 6. Select Recommendations for Ambulatory Electrocardiogram 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.

## 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)."[107]

## Medicare National Coverage

The Centers for Medicare & Medicaid Services (2004) implemented a national coverage determination for electrocardiographic services.[108] 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. |

| Date | Comments |
|---|---|
| 02/01/24 | Interim Review, approved January 9, 2024. Added policy criteria for which MCOT is now considered medically necessary rather than investigational. |
| 08/01/24 | Annual Review, approved July 8, 2024. Policy updated with literature review through April 9, 2024; reference added. Policy statements unchanged. |
| 01/01/26 | Annual Review, approved December 23, 2025. The following policy changes are effective April 8, 2026, following 90-day provider notification. Policy updated with literature review through August 29, 2025; references added. Title changed to Mobile Cardiac Telemetry and Implantable Loop Recorders. Added implantable loop recorders as medically necessary when criteria are met. Added CPT code 33285, and HCPCS codes C1764, E0616. Added SOS ASC for implantable loop recorders. Added 11.01.525 Site of Service Ambulatory Service Center (ASC): Select Surgical Procedures in Adults to Related Policies section. |
| 05/01/26 | Annual Review, approved April 14, 2026. Policy updated with literature review through December 2, 2025; references added. Removed the term ambulatory event monitor (AEM) for clarity. Minor edits to clarify site of service review is only for implantable loop recorders (ILR) and policy statement updated with minor edits to ILR criteria for greater clarity. All other 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.