FEP Medical Policy Manual

FEP 2.02.08 Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

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Related Policies:

None

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

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

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 patients with signs and symptoms suggestive of arrhythmias as well as the evaluation of paroxysmal atrial fibrillation (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 review, 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 patients 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 (2014) 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 patient-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 (eg, 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 patient'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 patients at moderate- or high-risk of thromboembolic events. Oral anticoagulation in patients with AF reduces the risk of subsequent stroke and was recommended by American Heart Association, American College of Cardiology, and Heart Rhythm Society(2014) joint guidelines on patients 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 patients 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 patients with AF. However, until relatively recent the specific role of long-term (ie, >48 hours) monitoring in AF was not well-described.

Patients 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 patients, and AF increases the risk of stroke.[5,6,] Paroxysmal AF confers an elevated risk of stroke, just as persistent and permanent AF do. 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 (eg, suspected arrhythmias when symptoms [syncope, palpitations] are occurring daily). These devices are not the focus of this review.

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.

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 patient and applied to 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 d)	• Zio® Patch system (iRhythm Technologies) (FDA K163512)
External memory loop devices (patient- 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 s and for next 60 s or so. Devices may be activated by a patient when symptoms occur (patient-triggered) or by an automated algorithm when changes suggestive of an arrhythmia are detected (autotriggered).	• Patient-triggered: Explorer™ Looping Monitor (LifeWatch Services) • Autotriggered: LifeStar AF Express™ Auto-Detect Looping Monitor (LifeWatch Services) • Autotriggered or patient-triggered: King of Hearts Express® AF (Card Guard Scientific Survival)
Implantable memory loop devices (patient- or autotriggered)	Devices similar in design to external memory loop devices but implanted under the skin in the precordial region	• Autotriggered or patient-triggered: Reveal® XT ICM (Medtronic) and Confirm Rx Insertable™ Cardiac Monitor (Abbott) • Autotriggered: BioMonitor, Biotronik)
Mobile cardiac outpatient telemetry (MCOT)	Continuously recording or autotriggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis; commonly ordered for 14 or 30 day periods	• CardioNet MCOT (BioTelemetry) (K093288) • LifeStar Mobile Cardiac Telemetry- (Lifestar ACT) (used by LifeWatch (BioTel) Services) (K170565) • SEEQ Mobile Cardiac Telemetry (Medtronic)- discontinued 2018 • HEARTLinkII (used by Telmetry@Home) (K982803) • MCOT Patch (BioTel) (K153473)

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 (Preventice Services) 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 a patient-activated event monitor and a continuous telemetry monitor. The Spiderflash-T (LivaNova) is an example of an external autotriggered or patient-triggered loop recorder, but like the ZioÒ Patch, can record 2 channels for 14 to 40 days.

The AliveCor Kardiamobile/Kardiastation (AliveCor, Inc., San Francisco, CA) (K142743) is an iPhone-enabled heart monitor that has been known as the “iPhoneECG”. It is in a thin case with 2 electrodes that snaps onto the back of an iPhone 4 or 5. To obtain an electrocardiogram (ECG) recording, the patient just holds the device while pressing fingers from each hand onto the electrodes. The device can also obtain an ECG from the patient's chest.

The Rhythm Express RX-1 (VivaQuant) (K183704) may be worn by adult patients for a period of time as prescribed by a physician, typically 1 day to 4 weeks, and will continuously monitor ECG. RX-1 can function in one of three modes: a) Mobile Cardiac Telemetry (MCT), b) Event Recorder (ER), and Wireless Holter (WH). RX-1 incorporates a cellular modem to communicate with the RS-1 Web Service.

OBJECTIVE

The objective of this evidence review is to determine whether outpatient cardiac rhythm monitoring improves the net health outcome in individuals being monitored for arrhythmia or atrial fibrillation.

POLICY STATEMENT

The use of **patient-activated or autoactivated external ambulatory event monitors (AEMs) OR continuous ambulatory monitors** that record and store information for periods longer than 48 hours may be considered **medically necessary** as a diagnostic alternative to Holter monitoring in the following situations:

- Patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope).
- Patients with atrial fibrillation (AF) who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered.
- Patients with cryptogenic stroke who have a negative standard workup for AF including a 24-hour Holter monitor (see Policy Guidelines section).

The use of **implantable AEMs**, either patient-activated or autoactivated, may be considered **medically necessary** in the following situations:

- In the small subset of patients who experience recurrent symptoms so infrequently that a prior trial of other external AEMs has been unsuccessful.
- In patients who require long-term monitoring for AF or possible AF (see Policy Guidelines section).

Mobile cardiac outpatient telemetry (MCOT) (with real-time monitoring and analysis) is limited to a select population and may be considered **medically necessary** when **ALL** of the following are met:

- The individual has failed the following:
  - 48 hour Holter monitor **AND/OR** it is felt that longer monitoring is necessary; **and**
  - ZIO patch; **or**
  - Individual-triggered event monitor; **or**
- The individual's condition is such that a Holter monitor **OR** an event monitor **OR** a Zio Patch is **NOT** adequate to make a diagnosis. An explanation must be provided as to why ONLY the MCOT would be sufficient; **and**
- There is low likelihood of a malignant cardiac event; **and**
- Individuals who experience infrequent symptoms (less than every 24-48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, pre-syncope, or syncope); **and**
- It is anticipated that the results of this service would provide diagnostic and treatment information; **and**

ANY of the following:

- Individuals who require monitoring for known, non-life-threatening arrhythmias, such as AF, other supra-ventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block; **or**
- Individuals recovering from cardiac surgery who have documented atrial arrhythmias; **or**
- Individuals with symptomatic underlying structural disease; **or**
- Individuals with no structural heart disease but have recurrent severe symptoms (i.e., recurrent syncope), all testing is negative and an implantable event recorder is contemplated; **or**
- Individuals with unexplained syncope, near syncope, or episodic dizziness; **or**
- Individuals with unexplained recurrent palpitations; **or**
- Individuals with unexplained recurrent shortness of breath; **or**
- Individuals with unexplained recurrent chest pain; **or**
- Individuals with a history of acute myocardial infarction (MI); **or**
- Individuals who require evaluation of antiarrhythmic drug therapy.

Contraindications

- Real-time outpatient cardiac monitoring is contraindicated for individuals at high risk of developing sustained ventricular tachycardia or ventricular fibrillation and/or would be more appropriately cared for in a hospital setting.
- The MCOT is not indicated for individuals with mild to moderate symptoms of "palpitations" or "weakness."
- This system is also not indicated for use as a screening tool.

The use of AEMs or MCOT is considered **not medically necessary** outside the criteria listed above.

MCOT is considered **not medically necessary** when more than one (1) monitoring episode is reported in a 30 day period.

MCOT is considered **not medically necessary** when more than two (2) monitoring episodes are reported in a (12) month period.

Use of cardiac surveillance and Holter or event monitoring for the same individual on the same day is considered **not medically necessary**.

Mobile (smartphone) applications are considered **investigational.**

POLICY GUIDELINES

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 patient considerations that may make 1 type of monitor preferable over another.

Therefore, for the evaluation of patient 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, or for the detection of arrhythmias in individuals who experience infrequent symptoms suggestive of cardiac arrhythmias (i.e. palpitations, dizziness, pre-syncope, or syncope, 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 OR real-time mobile cardiac outpatient monitoring may be considered medically necessary for the patients who meet the criteria of the policy statements. The physician documentation should support the choice of the monitoring.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Aside from the hook-up and disconnection of the device, which is frequently performed by the provider, the actual monitoring and analysis of the electrocardiogram are frequently performed by a monitoring service. If this is the case, the various components of the ambulatory event monitors will be unbundled.

The MCOT provider must ensure the physician prescription is for MCOT; providing MCOT without a prescription for MCOT is not medically necessary. The medical record documentation must support the physician prescribed order of the use of MCOT.

FDA REGULATORY STATUS

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

RATIONALE

Summary of Evidence

Ambulatory Event Monitoring

For individuals who have signs and/or symptoms suggestive of arrhythmia(s) who receive patient- or autoactivated external ambulatory event monitoring or continuous ambulatory monitoring storing information for more than 48 hours, the evidence includes 1 randomized controlled trial (RCT) and prospective and retrospective studies reporting on the diagnostic yield. Relevant outcomes are overall survival (OS) and morbid events. The RCT and the observational studies have consistently shown that continuous monitoring with longer recording periods detects more arrhythmias than 24- or 48-hour Holter monitoring. Particularly for patients who, without the more prolonged monitoring, would only undergo shorter term monitoring, the diagnostic yield is likely to identify arrhythmias that may have therapeutic implications. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have atrial fibrillation (AF) following ablation who receive long-term ambulatory cardiac monitoring, the evidence includes one RCT comparing ambulatory event monitoring with standard care and several observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. The RCT evaluating a long-term monitoring strategy after catheter ablation for AF reported significantly higher rates of AF detection. The available evidence has suggested that long-term monitoring for AF post-ablation is associated with improved outcomes. However, the specific type of monitoring associated with the best outcomes is not established, because different long-term monitoring devices were used across the studies. Trials demonstrating improved outcomes have used event monitors or implantable monitors. In addition, there are individual patient considerations that may make one type of monitor preferable over another. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cryptogenic stroke with a negative standard workup for AF who receive long-term ambulatory cardiac monitoring, the evidence includes systematic reviews of RCTs comparing ambulatory event monitoring with standard care. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. RCTs evaluating a long-term AF monitoring strategy post-stroke have reported significantly higher rates of AF detection with longer term ambulatory monitoring. The available evidence has suggested that long-term monitoring for AF after cryptogenic stroke is associated with improved

outcomes, but the specific type of monitoring associated with the best outcomes is not established, because different long-term monitoring devices were used across the studies. Trials demonstrating improved outcomes have used event monitors or implantable monitors. In addition, there are individual patient considerations that may make one type of monitor preferable over another. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic with risk factors for AF who receive long-term ambulatory cardiac monitoring, the evidence includes an RCT and observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. The studies showed use of the ambulatory monitors would result in higher AF detection compared with routine care. However, the RCT followed patients for one year and did not detect a difference in stroke occurrence between the monitored group and the standard of care group. The other studies did not discuss changes in patient management or health outcomes based on monitoring. Studies reporting on improved outcomes with longer follow-up are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Implantable Loop Recording

For individuals who have signs and/or symptoms suggestive of arrhythmia with infrequent symptoms who receive patient- or autoactivated implantable ambulatory event monitoring, the evidence includes RCTs comparing implantable loop recorders (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 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 a meaningful improvement in the net health outcome.

Mobile Outpatient Cardiac Telemetry

For individuals who have signs and/or symptoms suggestive of arrhythmia who receive mobile outpatient cardiac telemetry (MCOT), the evidence includes RCTs and observational studies evaluating rates of arrhythmia detection using outpatient cardiac telemetry. Relevant outcomes are detection of arrhythmias and treatment, 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. The evidence is sufficient to determine the effects of the technology on health outcomes results in a meaningful improvement in the net health outcome in a select population.

Mobile Phone Enabled Applications

There is currently a lack of evidence to support the clinical value of mobile phone enabled applications. Prospective, randomized controlled studies are needed to ascertain how the use of the mobile phone enabled applications would improve clinical outcomes in patients with cardiovascular diseases/disorders.The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

International Society for Holter and Noninvasive Electrocardiology et al

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.[88], Below are two summary tables from the consensus statement, detailing advantages and limitations of ambulatory electrocardiogram techniques (see Table 2) and recommendations for the devices that are relevant to this evidence review (see Table 3).

Table 2. 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 d • 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 3. 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 h	I	B-NR
Extended ambulatory ECG (15-30 d) when symptomatic events are not daily or are uncertain	I	B-R
Continuous monitoring (1-14 d) to quantify arrhythmia burden and patterns	!	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

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

The American College of Cardiology, the American Heart Association, and HRS (2019) updated guidelines initially issuedin 2014[4,] on the management of patients with atrial fibrillation (AF).[89,] 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 patients with syncope[90,]and patients with ventricular arrhythmias[91,]. Cardiac monitoring recommendations are summarized below in Tables 4 and 5.

Table 4. 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.[90,]	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.[90,]	IIa	B-NR
To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an implantable cardiac monitor can be useful.[90,]	IIa	B-R
Ambulatory electrocardiographic monitoring is useful to evalute whether symptoms including palpitations, presyncope, or syncope, are caused by VA[91,]	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.[89,]	IIa	B-R

ACC: American College of Cardiology; AHA: American Hearth Association; COR: class of recommendation; HRS: Heart Rhythm Society; LOE: level of evidence; VA: ventricular arrhythmia.
[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 5. 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 h
Patient-activated event monitor	• Frequent spontaneous symptoms likely within 2 to 6 wk • 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 wk
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.

Heart Rhythm Society et al

A consensus document on catheter and surgical ablation for AF was published in 2012 by HRS, the European Heart Rhythm Association, and the European Cardiac Arrhythmia Society[92], and updated in 2017.[93], This document did not contain formal practice guidelines, but provided general recommendations based on literature review and expert consensus. Use of ambulatory event monitors postablation was addressed in two sections of the document. First, in the section discussing use of anticoagulation following ablation, the following statement was made:

"Patients in whom discontinuation of systematic anticoagulation is being considered based on patient values and preferences should consider undergoing continuous or frequent ECG [electrocardiogram] monitoring to screen for AF recurrence."

In the section on postoperative rhythm monitoring of patients who are postablation, the following statements were made:

"The success of AF ablation is based in large part on freedom from AF recurrence based on ECG monitoring. Arrhythmia monitoring can be performed with the use of noncontinuous or continuous ECG monitoring tools."

The statement referenced a table of ambulatory cardiac monitoring devices (Holter, patch, external loop, implantable loop, wearable multisensors, Smartphone monitors), describing unique features of each. The table did not evaluate the safety or efficacy of these devices, nor recommend one over another.

European Heart Rhythm Association

The European Heart Rhythm Association (2009) published guidelines on the use of diagnostic implantable and external loop recorders.[94], For the indications that the Association considered established at the time of publication, the guidelines made the following statements about indications for implantable and external recorders (see Table 6).

Table 6. Guidelines on Use of Diagnostic ILRs and ELRs

Recommendation	COR	LOE
"ILR [implantable loop recorder] is indicated: • "In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have: • "absence of high-risk criteria that require immediate hospitalization or intensive evaluation..."; and • "a likely recurrence within battery longevity of the device."	I	A
"ELRs are indicated in patients with recurrent palpitations, undocumented by conventional ECG techniques, who have: inter-symptom interval <4 weeks and absence of high-risk criteria...which require immediate hospitalization or intensive evaluation."	I	B
"ILR may be indicated to assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes."	IIa	B
"ILRs may be indicated in selected cases with severe infrequent symptoms when ELRs and other ECG monitoring systems fail to document the underlying cause."	IIa	B
"ELRs [external loop recorder] may be indicated in patients with recurrent (pre)syncopes who have: • "inter-symptom interval of ≤4 weeks, and • "suspicion of arrhythmic origin and • "absence of high-risk criteria that require immediate hospitalization or intensive evaluation...."	IIa	B

COR: class of recommendations; ECG: electrocardiogram; ELR: external loop recorder; ILR: implantable loop recorder; LOE: level of evidence.

American Academy of Neurology

The American Academy of Neurology updated its guidelines on the prevention of stroke in patients with nonvalvular AF (NVAF).[95] These guidelines made the following recommendations on the identification of patients with occult NVAF:

A1. "Clinicians might obtain outpatient cardiac rhythm studies in patients with cryptogenic stroke without known NVAF, to identify patients with occult NVAF (Level C).

A2. 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 patients with cryptogenic stroke without known NVAF, to increase the yield of identification of patients with occult NVAF (Level C)."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (2004) implemented a national coverage determination for electrocardiographic services.[98] 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).

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
March 2013	Replace policy	Policy updated with literature search, reference numbers 17-24, 25 added. Medically necessary indication for use of event monitors in patients with atrial fibrillation treated with catheter ablation revised for clarity and for working to be consistent with recent guidelines. Not medically necessary indication for MCOT changed to reflect revised language for not medically necessary technologies. Additional investigational indications added for use of continuous monitor that record for periods longer than 72 hours, and for monitoring patients with cryptogenic stroke.

Date	Action	Description
March 2014	Replace policy	Policy updated with literature review. References 3, 10, 28 and 29 added. Medically necessary criteria for implantable loop monitors revised from ".a prior trial of Holter monitor and other external ambulatory event monitors has been unsuccessful" to "...a prior trial of other external ambulatory event monitors has been unsuccessful." Investigational indications have been changed to not medically necessary to align with FDA approved status.
March 2015	Replace policy	Policy updated with results of clinical input. Policy statements changed to indicated that continuous monitors with longer recording periods may be medically necessary with conditions.
September 2016	Replace policy	Policy updated with literature review through March 29, 2016; references 1-3, 13, 15-16, 21, 33, 43-53, 61, and 65 added. Rationale revised and rewritten. Policy statements edited for simplicity to group continuous ambulatory monitors with longer recording periods with external event monitors, and to move language regarding the use of long-term outpatient monitoring for AF to "Policy Guidelines."
September 2018	Replace policy	Policy updated with literature review through March 5, 2018; references 17, 40-46, 47, 49-50, 60-61, 68, 75, 77, and 83 added. The last policy statement was edited (1) to include the use of mobile apps as an example of an ambulatory event monitor and (2) to include the monitoring of patients who are asymptomatic as an example of an "other use," which is still considered not medically necessary.
September 2019	Replace policy	Policy updated with literature review through March 26, 2019, several references added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through May 1, 2020; references added. MCOT policy statement changed to medically necessary with criteria. MCOT benefit application requirements added. Smartphone applications considered investigational to align with FDA 510(k) status.