BlueCross BlueShield Federal Employee Program.

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

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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 (e.g., 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 1 to 2 weeks, an external event recorder is recommended; and if the frequency is less than once every 2 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 1 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 is 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 recently 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 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 3 channels based on 3 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 to 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 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.

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 auto-activated 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:

- Individuals who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (ie, palpitations, dizziness, presyncope, or syncope).
- Individuals with atrial fibrillation (AF) who have been treated with catheter ablation, and in whom discontinuation of systemic anticoagulation is being considered.
- Individuals 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 auto-activated, may be considered **medically necessary** in the following situations:

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

The use of outpatient cardiac telemetry (also known as mobile cardiac outpatient telemetry) as a diagnostic alternative to AEMs in individuals who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, syncope) is considered **investigational**.

Other uses of AEMs, including outpatient cardiac telemetry and mobile applications, are considered **investigational**, including but not limited to monitoring asymptomatic individuals with risk factors for arrhythmia, monitoring the effectiveness of antiarrhythmic medications, and detection of myocardial ischemia by detecting ST-segment changes.

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 brady arrhythmias 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 with a history of cryptogenic stroke; 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.

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 considerations that may make 1 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.

BENEFIT APPLICATION

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

Plans may consider requiring the use of CPT code 93268, when possible, to avoid unbundling of services. However, 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.

For contracts that do not use this definition of medical necessity, other contract provisions may apply. For example, benefit or contract language describing the "least costly alternative" may also be applicable for this choice of testing.

FDA REGULATORY STATUS

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 the skin in the precordial area when symptoms develop	• Zio® Event Card (iRhythm Technologies) • REKA E100™ (REKA Health)
Continuous recording devices with longer recording periods	Devices continuously worn and continuously record via ≥1 cardiac leads and store data longer than traditional Holter (14 days)	• Zio®XT Patch and ZIO ECG Utilization Service (ZEUS) System (iRhythm Technologies)
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 seconds and for next 60 seconds 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 (auto-triggered).	• Patient-triggered: Explorer™ Looping Monitor (LifeWatch Services) • Auto-triggered: LifeStar AF Express™ Auto-Detect Looping Monitor (LifeWatch Services) • Auto-triggered or patient-triggered: King of Hearts Express® AF (Card Guard Scientific Survival)
Implantable memory loop devices (patient- or auto-triggered)	Devices similar in design to external memory loop devices but implanted under the skin in the precordial region	• Auto-triggered or patient-triggered: Reveal® XT ICM (Medtronic) and Confirm Rx Insertable™ Cardiac Monitor (Abbott) • Auto-triggered: BioMonitor, Biotronik)
Mobile cardiac outpatient telemetry	Continuously recording or auto-triggered memory loop devices that transmit data to a central recording station with real-time monitoring and analysis	• CardioNet MCOT™ (BioTelemetry) • LifeStar Mobile Cardiac Telemetry (LifeWatch Services) • Zio AT(iRhythm)

RATIONALE

Summary of Evidence

Ambulatory Event Monitoring

For individuals who have signs and/or symptoms suggestive of arrhythmia(s) who receive patient- or auto-activated external ambulatory event monitoring or continuous ambulatory monitoring storing information for more than 48 hours, the evidence includes prospective and retrospective studies reporting on the diagnostic yield. Relevant outcomes are overall survival (OS) and morbid events. The randomized controlled trial (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 an 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 1 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 postablation 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 1 type of monitor preferable over another. The evidence is sufficient to determine that the technology results in an 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 poststroke 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 1 type of monitor preferable over another. The evidence is sufficient to determine that the technology results in an 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 RCTs and observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. Multiple observational studies showed that use of ambulatory monitors would result in higher AF detection compared with routine care. Randomized controlled trials found higher AF detection and initiation of anticoagulants with monitoring, but no impact on health outcomes. The only RCT (LOOP Trial) with sufficient statistical power and duration to evaluate health outcomes found no difference between monitoring and standard care on the primary endpoint of combined stroke or systemic arterial embolism (HR 0.80; 95% CI 0.61 to 1.05; p=.11) or any secondary endpoints after 6 years of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 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 the 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.

Outpatient Cardiac Telemetry

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 OS and morbid events. The available evidence has suggested that outpatient cardiac telemetry is at least as good at detecting arrhythmias as ambulatory event monitoring. However, studies have not evaluated whether the real-time monitoring feature of outpatient cardiac telemetry leads to reduced cardiac events and mortality. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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, the American Academy of Neurology updated its guidelines on the prevention of stroke in patients with nonvalvular AF (NVAF).[93,] These guidelines made the following recommendations on the identification of patients with occult NVAF:

- "Clinicians might obtain outpatient cardiac rhythm studies in patients with cryptogenic stroke without known NVAF, to identify patients 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 patients with cryptogenic stroke without known NVAF, to increase the yield of identification of patients with occult NVAF (Level C)."

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 issued in 2014[4,] on the management of patients with atrial fibrillation (AF).[94,] These guidelines recommended the use of Holter or event monitoring if the diagnosis of the type of arrhythmia is in question, or as a means of evaluating rate control.

The same associations (2017) collaborated on guidelines on the evaluation and management of patients with syncope[95,] and patients with ventricular arrhythmias[96,]. Cardiac monitoring recommendations are summarized below in Tables 2 and 3.

Table 2. Cardiac Monitoring Recommendations, AHA/ACC/HRS

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

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

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

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

Table 3. Patient Selection Recommendations by Cardiac Rhythm Monitor, AHA/ACC/HRS

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

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

International Society for Holter and Noninvasive Electrocardiology/Heart Rhythm Society

The International Society for Holter and Noninvasive Electrocardiology and the HRS (2017) issued a consensus statement on ambulatory electrocardiogram and external monitoring and telemetry.[97], Below are 2 summary tables from the consensus statement, detailing advantages and limitations of ambulatory electrocardiogram techniques (see Table 4) and recommendations for the devices that are relevant to this evidence review (see Table 5).

Table 4. 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	• Frequent noncompliance with symptom logs and event markers • Frequent electrode detachments

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

ECG: electrocardiogram; HRS: Heart Rhythm Society.

Table 5. Select Recommendations for Ambulatory ECG and External Monitoring or Telemetry, International Society for Holter and Noninvasive Electrocardiology/HRS

Recommendation	**COR[a]**	**LOE[b]**
Selection of ambulatory ECG		
Holter monitoring when symptomatic events anticipated within 48 hours	I	B-NR
Extended ambulatory ECG (15 to 30 days) when symptomatic events are not daily or are uncertain	I	B-R

Continuous monitoring (1 to 14 days) to quantify arrhythmia burden and patterns	I	B-NR
Specific conditions for use of ambulatory ECG		
Unexplained syncope, when tachycardia suspected	I	B-R
Unexplained palpitation	I	B-R
Detection of atrial fibrillation, triggering arrhythmias, and postconversion pauses	IIa	B-NR
Cryptogenic stroke, to detect undiagnosed atrial fibrillation	I	B-R

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

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

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

U.S. Preventive Services Task Force Recommendations

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

Medicare National Coverage

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

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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.
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.
September 2021	Replace policy	Policy updated with literature review through March 25, 2021; reference added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through April 8, 2022; references added. Terminology in policy statements and policy guidelines revised from "patients" to "individuals"; cryptogenic shock added to MCOT indications.
September 2023	Replace policy	Policy updated with literature review through April 11, 2023; references added. Policy statements unchanged.