# Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

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*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

# When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of individual-activated or autoactivated external ambulatory event monitors (AEMs) OR continuous ambulatory monitors that record and store information for periods longer than 48 hours as a diagnostic alternative to Holter monitoring in the following situations to be **eligible for coverage:****

Patient Selection Criteria
Coverage eligibility will be considered when any of the following is met:

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

Based on review of available data, the Company may consider the use of mobile cardiac outpatient telemetry for individuals who meet all of the criteria below to be **eligible for coverage:****

- The individual has one of the following conditions:
    - Individuals who have symptoms suggestive of cardiac arrhythmias (e.g., unexplained syncope or near syncope, unexplained episodic dizziness, or unexplained recurrent palpitations) less frequently than once every 48 hours; **OR**

  - For the detection of suspected paroxysmal atrial fibrillation following cryptogenic stroke when the monitoring is intended to guide medical management with anticoagulants; **AND**
- The individual has had a non-diagnostic external ambulatory cardiac event monitoring trial of not less than 14 continuous days.

Based on review of available data, the Company may consider the use of implantable ambulatory event monitoring to be **eligible for coverage****in the following situations:

- For individuals with a history of cryptogenic stroke and a previous non-diagnostic trial of external ambulatory event monitoring; **OR**
- For individuals who require long-term monitoring for atrial fibrillation after an ablation procedure who had a previous non-diagnostic trial of external ambulatory event monitoring; **OR**
- For individuals with recurrent syncope who meet all the following:
  - Age greater than or equal to 40; **AND**
  - History of multiple (three or more) syncopal episodes of undetermined etiology in the past 2 years; **AND**
  - Previous diagnostic evaluation, including history, physical examination, electrocardiogram, orthostatic blood pressure measurements and echocardiogram, has not yielded a diagnosis; **AND**
  - The individual has had a non-diagnostic external ambulatory cardiac event monitoring trial of not less than 14 continuous days.

# When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers other uses of AEMs, including outpatient cardiac telemetry and mobile applications, 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 to be **investigational.***

Based on review of available data, the Company considers the use of mobile cardiac telemetry and implantable ambulatory event monitoring when the above criteria have not been met, and for all other indications to be **investigational.***

# Policy Guidelines

The available evidence has suggested that long-term monitoring for atrial fibrillation post ablation 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.

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.

Examples of devices:

- Autotriggered or patient-triggered: Reveal®‡ XT ICM (Medtronic) and Confirm Rx Insertable™‡ Cardiac Monitor (Abbott)
- Autotriggered: BioMonitor, Biotronik)

This section discusses the use of ILR, with a focus on clinical situations when use of an ILR at the beginning of a diagnostic pathway is indicated. It is expected that a longer period of monitoring with any device category is associated with a higher diagnostic yield. A progression in diagnostics, from an external event monitor to ILR, in cases where longer monitoring is needed is considered

appropriate. However, there may be situations where it is sufficiently likely that long-term monitoring will be needed and that an ILR as an initial strategy may be reasonable.

The purpose of ILRs in individuals with signs or symptoms suggestive of arrhythmia with infrequent symptoms is to provide an alternative method of arrhythmia detection.
ILRs store electrical cardiac activity data. When activated (by individual or automatically), the cardiac activity is recorded from the memory loop. ILRs are implanted under the skin in the precordial area.

Several RCTs have reported high rates of arrhythmia detection with the use of ILRs compared with external event monitoring or Holter monitoring. These studies support the use of a progression in diagnostics from an external event monitor to ILR when longer monitoring is needed. Some available trials evaluating the detection of AF after ablation procedures or in individuals with cryptogenic stroke used ILRs as an initial ambulatory monitoring strategy, after a negative Holter monitor. Many observational studies reported the initiation of treatment (for example, anticoagulation therapy or pacemaker implantation) following the confirmation of diagnoses with the ILR. Because these treatments are known to be effective, it can be concluded that long-term monitoring with ILRs will improve health outcomes.

# Background/Overview

**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 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 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." 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. 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.

**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 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 American Heart Association, American College of Cardiology, and Heart Rhythm Society (2014) joint guidelines on individuals with a history of stroke or transient ischemic attack.

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 (ie, >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. 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 (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 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®‡ 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 | • Patient-triggered: Explorer™‡ Looping Monitor (LifeWatch Services)<br>• Auto-triggered: LifeStar AF Express™‡ Auto- |

| | | |
|---|---|---|
| | activated by a individual when symptoms occur (patient-triggered) or by an automated algorithm when changes suggestive of an arrhythmia are detected (auto-triggered). | Detect Looping Monitor (LifeWatch Services)<br>• 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)<br>• 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)<br>• LifeStar Mobile Cardiac Telemetry (LifeWatch Services)<br>• Zio AT(iRhythm) |

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 auto-triggered 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 auto-triggered or patient-triggered loop recorder, but like the Zio Patch, can record 2 channels for 14 to 40 days.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

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 review. U.S. Food and Drug Administration product codes include: DSH, DXH, DQK, DSI, MXD, MHX.

# Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

As discussed previously, mobile cardiac telemetry is an externally worn type of ambulatory event monitor with the added feature of real-time transmission of data. There has been interest in the use of ambulatory event monitors devices to further characterize AF in the following clinical situations:

- Detection of AF in individuals with cryptogenic stroke;
- Following catheter or surgical ablation for the treatment of AF to detect persistent or recurrent AF.

**Cryptogenic Stroke Evaluation**

Cryptogenic stroke describes stroke without an identifiable cause, specifically a cardioembolic source, such as a patent foramen ovale or AF. When potential cardiovascular etiologies have been ruled out during an initial workup consisting of various imaging studies and EKGs, then it is considered a "cryptogenic" stroke. It is estimated that some 36% of stroke survivors have cryptogenic stroke. It has been suggested that additional monitoring may identify AF in stroke initially categorized as cryptogenic (Tayal, 2008).

In 2007, Liao conducted a systematic review of noninvasive cardiac monitoring in the post-stroke setting where the authors specifically sought to determine the frequency of occult AF detected by noninvasive methods of continuous cardiac rhythm monitoring in consecutive individuals with ischemic stroke; a total of five prospective case series were included in the analysis. Five studies evaluated Holter monitor for 24 to 72 hours in the inpatient setting and are not considered further. The results of two studies that focused on loop recorders following a negative Holter monitor are relevant to this discussion (Barthelemy, 2003; Jaboudon, 2004). New AF was identified in 5.7% and 7.7% of subjects, respectively (Liao, 2007). In the study by Jaboudon, oral anticoagulation was started in 2 of the 7 subjects with new onset AF. The authors concluded that increased duration of monitoring appears to be associated with increased rates of detection of AF; however, the authors also comment that it is uncertain whether any type of monitoring, including Holter monitor, should be routinely performed given the low incidence of AF.

Additional published evidence includes a systematic review and meta-analysis which was conducted by Kishore to determine the frequency of newly detected AF using noninvasive or invasive cardiac monitoring after ischemic stroke or transient ischemic attack (TIA). Prospective observational studies or randomized controlled trials of individuals with ischemic stroke, TIA, or both, who underwent any cardiac monitoring for a minimum of 12 hours, were included after electronic searches of multiple databases. The primary outcome was detection of any new AF during the monitoring period. A total of 32 studies were analyzed. The overall detection rate of any AF was 11.5% (95% confidence interval [CI], 8.9%-14.3%), although the timing, duration, method of monitoring, and reporting of diagnostic criteria used for paroxysmal AF varied. Results showed that detection rates were higher in subjects selected for increased risk on the basis of age, stroke pathogenesis, and prescreening for AF (13.4%; 95% CI, 9.0%-18.4%), as compared to unselected subjects (6.2%; 95% CI, 4.4%-8.3%). The authors noted the presence of substantial heterogeneity even within specified subgroups and concluded that detection of AF was highly variable. This review was limited by small sample sizes and marked heterogeneity (Kishore, 2014).

In a 2015 meta-analysis by Sposato and colleagues, the authors looked at studies to estimate the proportion of individuals who were diagnosed with atrial fibrillation after a stroke or transient ischemic attack after undergoing four phases of serial cardiac monitoring. Phase 1 consisted of acute assessment in the emergency room and admission EKG, phase 2 was an acute inpatient stay which included serial EKGs, continuous EKG monitoring and cardiac telemetry, and Holter monitoring. Phase 3 was the first ambulatory period and consisted of ambulatory Holter monitoring. Phase 4 was

the second ambulatory period and consisted of mobile cardiac outpatient telemetry, external loop recording and implantable loop recording. A total of 50 studies were analyzed and reviewed. During phase 1, 7.7% of individuals were diagnosed with post-stroke AF. During phase 2, 5.6% of individuals were diagnosed with post-stroke AF after serial EKG, 7.0% were diagnosed after continuous inpatient ECG monitoring, 4.1% were diagnosed after continuous inpatient cardiac telemetry, and 4.5% were diagnosed after inpatient Holter monitoring. During phase 3, 10.7% of individuals were diagnosed with post-stroke AF. During phase 4, 15.3% of individuals were diagnosed with post-stroke AF by mobile cardiac outpatient telemetry, 16.2% were diagnosed following external loop recording, and 16.9% were diagnosed following implantable loop recording. This analysis has limitations that include the subjective stratification into the four phases of cardiac monitoring. Also, only about 40% of individuals continued past phase 3 into phase 4 for continued monitoring. Age and risk factors for post-stroke AF varied across the 50 studies reviewed. While this analysis concludes that extended cardiac monitoring on an outpatient basis detects post-stroke AF, the proportion of individuals who were diagnosed in phase 4 by implantable loop recording did not differ significantly from those individuals diagnosed by mobile cardiac outpatient telemetry or external loop recording.

The 30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation after a Cerebral Ischemic Event (EMBRACE) trial enrolled 572 subjects with cryptogenic stroke or transient ischemic attack of undetermined cause within the previous 6 months and no history of AF. Trial subjects were randomized to receive noninvasive ambulatory electrocardiogram monitoring with either a 30-day event-triggered loop recorder (intervention group) or a conventional 24-hour Holter monitor (control group). The primary outcome was newly detected AF lasting 30 seconds or longer within 90 days after randomization. Secondary outcomes included episodes of AF lasting 2.5 minutes or longer and anticoagulation status at 90 days. At 30 days, results indicated that AF lasting 30 seconds or longer was detected in 45 of 280 subjects (16.1%) in the intervention group, as compared with 9 of 277 (3.2%) in the control group (absolute difference, 12.9 percentage points; 95% CI, 8.0 to 17.6; $p<0.001$; number needed to screen, 8). Episodes of AF lasting 2.5 minutes or longer were present in 28 of 284 subjects (9.9%) in the intervention group, as compared with 7 of 277 (2.5%) in the control group (absolute difference, 7.4 percentage points; 95% CI, 3.4 to 11.3; $p<0.001$). By 90 days, oral anticoagulant therapy had been prescribed for more individuals in the intervention group than in the control group (52 of 280 [18.6%] vs. 31 of 279 [11.1%]; absolute difference, 7.5 percentage points; 95% CI, 1.6 to 13.3; $p=0.01$). Despite remaining questions regarding the clinical relevance of subclinical AF and what therapeutic benefit is associated with anticoagulation therapy in this

population, the trial results have demonstrated that noninvasive ambulatory electrocardiogram monitoring for 30 days is superior to short-term 24-hour monitoring for the detection of AF in individuals with a history of stroke or transient ischemic attack labeled as cryptogenic (Gladstone, 2015).

The presence or absence of AF has a significant impact on post-stroke management. For example, the ACC guidelines addressing AF recommend careful consideration of warfarin, due to its superior efficacy for stroke prevention (Fuster, 2006). Guidelines published by the American College of Chest Physicians (ACCP) also recommend anti-platelet therapy, (for example, aspirin) in individuals with cryptogenic stroke, while anticoagulation therapy is recommended in individuals with AF (Lansberg, 2012). However, none of these guidelines specifically recommend extended EKG monitoring in individuals with cryptogenic stroke.

A 2011 ACCF/AHA/HRS focused update to the ACC/AHA/ESC Guidelines on the Management of AF includes Holter monitor and longer term event recording in its recommendations for initial clinical evaluation if the diagnosis or type of arrhythmia is in question and also in subsequent treatment monitoring as a means of evaluating rate control and individual risk for thromboembolic events. This document reviews the major clinical trials of various treatment strategies for AF and notes, “The optimum method for monitoring antiarrhythmic drug treatment varies with the agent involved, as well as with individual factors.” The following is excerpted:

Ambulatory ECG recordings and device-based monitoring have revealed that an individual may experience periods of both symptomatic and asymptomatic AF. …Prolonged or frequent monitoring may be necessary to reveal episodes of asymptomatic AF, which may be a cause of cryptogenic stroke (Fuster, 2011).

In 2021, the AHA and the American Stroke Association jointly published guidelines for the prevention of stroke in individuals with a prior stroke or TIA with guidance on heart rhythm monitoring for occult atrial fibrillation if no other cause of stroke is discovered. The authors note that an improvement in outcomes with long-term rhythm monitoring has not been established. The document includes the following recommendation:

In individuals with cryptogenic stroke who do not have a contraindication to anticoagulation, long-term rhythm monitoring with mobile cardiac outpatient telemetry, implantable loop recorder, or other approach is reasonable to detect intermittent AF.

Evaluation of Symptoms Suggestive of Cardiac Arrhythmia
Mobile cardiac telemetry has also been studied for use in those with infrequent symptoms suggestive of cardiac arrhythmia (for example syncope). In 1999, the American College of Cardiology (ACC), in conjunction with other organizations, published clinical guidelines for ambulatory electrocardiography with the following Class I recommendations (Crawford, 1999):

- Individuals with unexplained syncope, near syncope, or episodic dizziness in whom the cause is not obvious;
- Individuals with unexplained recurrent palpitation;
- To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been characterized as reproducible and of sufficient frequency to permit analysis.

There were two Class IIa recommendations as follows:

- To detect proarrhythmic responses to antiarrhythmic therapy in individuals at high risk;
- Individuals with suspected variant angina.

These guidelines describe both Holter monitors and ambulatory event monitor devices, but the recommendations do not distinguish between the different types of monitors. These guidelines also predate the commercial availability of external loop recorders with auto-triggered capability or implantable loop recorders. However, these guidelines are helpful to define the indications for ambulatory EKG in general, with the choice of specific device to be based on the frequency of symptoms. Of the Class I and IIa recommendations listed above, only the assessment of unexplained symptoms, such as syncope and palpitation, would occur infrequently enough to warrant the use of an ambulatory event monitor. The other indications could be adequately assessed with short-term monitoring with a Holter monitor. Additionally, in 2001, the ACC published a clinical competence statement on EKG and ambulatory EKG (Kadish, 2001) which reiterated that the indications for ambulatory EKG had been addressed in the 1999 clinical guidelines (Crawford, 1999). The competence statement noted:

There are no specific guidelines that distinguish individuals for whom it is appropriate to perform continuous monitoring, (i.e., Holter monitor) from those for whom intermittent ambulatory monitoring is adequate. However, when monitoring is performed to evaluate the cause of intermittent symptoms, the frequency of the symptoms should dictate the type of recording (Kadish, 2001).

In 2006, the American Heart Association (AHA), in conjunction with the ACC, the American College of Cardiology Foundation (ACCF) and other organizations, published a scientific statement on the evaluation of syncope (Strickberger, 2006). This scientific statement did not provide specific recommendations, but reviewed the role of "non-invasive ECG monitoring" in different clinical situations. Ambulatory event monitoring use was specifically identified as an accepted technique in individuals with syncope with an otherwise normal history and physical exam, as follows:

The type and duration of ambulatory ECG monitoring is dictated by the frequency of symptoms. A Holter monitor is appropriate for episodes that occur at least every day. Event monitoring is ideal for episodes that occur at least once a month. An implantable loop monitor allows the correlation of symptoms with the cardiac rhythm in individuals in whom the symptoms are infrequent.

Two studies published in 2007 evaluated mobile cardiac telemetry monitoring for persons with symptoms thought to be due to arrhythmias. In a retrospective chart review by Olson and colleagues, the authors evaluated the diagnostic utility of mobile cardiac telemetry in individuals with palpitations and presyncope/syncope and the ability to assist in titration of medication. The records of 122 consecutive individuals were reviewed. Mobile cardiac telemetry detected arrhythmias associated with symptoms in 96 individuals, including 14 with previous non-diagnostic work-ups. The authors report that mobile cardiac telemetry provided useful information for 21 subjects undergoing titration of medications for ventricular rate control in atrial fibrillation and for 8 individuals following radiofrequency ablation for atrial fibrillation.

Rothman and colleagues (2007) reported the results of a multicenter trial that randomized 266 participants to undergo monitoring with either a mobile cardiac telemetry monitoring system or "standard" loop event monitoring. The participants were monitored for up to 30 days with the primary endpoint being the confirmation or exclusion of an arrhythmic cause for syncope, presyncope or severe palpitations. Of the 266 participants analyzed, a diagnosis was made in 88% of the mobile cardiac telemetry group, compared to 75% of the loop event monitoring group. The authors noted that the ability to detect or exclude an arrhythmia at the time of symptoms was similar

in both groups. The authors also point out that the study was not designed to evaluate autotriggered loop recorders such as those now commonly available.

# Supplemental Information

**Clinical Input 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 3 physician specialty societies and 4 academic medical centers (3 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 1 physician specialty society and 4 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 individuals (eg, in those with sporadic atrial fibrillation). 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 an individual's symptoms is an important finding.

**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 individuals with nonvalvular AF (NVAF). 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, and Heart Rhythm Society**
The American College of Cardiology, the American Heart Association, and HRS (2019) updated guidelines initially issued in 2014 on the management of individuals with atrial fibrillation (AF). These guidelines recommended the use of Holter or event monitoring if the diagnosis of the type of arrhythmia is in question, or as a means of evaluating rate control.

The same associations (2017) collaborated on guidelines on the evaluation and management of individuals with syncope and individuals with ventricular arrhythmias. 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. | I | C-EO |

| | | |
|---|---|---|
| To evaluate selected ambulatory individuals 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. | IIa | B-NR |
| To evaluate selected ambulatory individuals with syncope of suspected arrhythmic etiology, an implantable cardiac monitor can be useful. | IIa | B-R |
| Ambulatory electrocardiographic monitoring is useful to evaluate whether symptoms including palpitations, presyncope, or syncope, are caused by ventricular arrhythmia | I | B-NR |
| In individuals 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. | 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<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 individuals 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. 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<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 individual acceptance of electrodes |
| Patch ECG monitors | • Long-term recording of ≥14 days<br>• Excellent individual 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 individual<br>• Immediate alarm generation on event detection | • Single-lead ECG, lacking localization of arrhythmia origin<br>• Cannot continuously document cardiac rhythm<br>• Requires individual to wear electrodes continuously |
| Event recorders | • Records only selected ECG segments after an event is detected by individual<br>• Immediate alarm generation at event detected by individual<br>• Well-tolerated by individual | • Single-lead ECG, lacking localization of arrhythmia origin<br>• Cannot continuously document cardiac rhythm<br>• Diagnostic yield dependent on individual 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 individual interaction | • Long-term individual 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)."

**Medicare National Coverage**
The Centers for Medicare & Medicaid Services (2004) implemented a national coverage determination for electrocardiographic services. 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).

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 6.

**Table 6. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| NCT03072693 | Daily Ambulatory Remote Monitoring System vs Conventional Therapy for the Post-Discharge Management of Acute Decompensated Heart Failure | 876 | Apr 2023 |

| | | | |
|---|---|---|---|
| NCT04126486[a] | GUARD-AF: reducing Stroke by Screening for Undiagnosed atrial Fibrillation in Elderly individuals | 11,931 | Jun 2023 |
| NCT02786940 | Remote Cardiac Monitoring of Higher-Risk Emergency Department Syncope Individuals after Discharge (REMOSYNC) | 99 | March 2023 |
| NCT03541616 | Prevalence of Subclinical Atrial Fibrillation in High Risk Heart Failure Individuals and Its Temporal Relationship With Hospital Readmission for Heart Failure | 242 | Mar 2023 |
| NCT04306978 | Impact of the CareLink Express Remote Monitoring System on Early Detection of Atrial Fibrillation and Cardiovascular Risk Reduction in Individuals With Implantable Cardiac Pacemakers | 200 | Jan 2023 |
| NCT04371055 | Intensive Heart Rhythm Monitoring to Decrease Ischemic Stroke and Systemic Embolism - the Find-AF 2 Study | 5200 | Dec 2026 |
| NCT03940066 | Evaluation of Ambulatory Monitoring of Individuals After High-risk Acute Coronary Syndrome Using Two Different Systems: Biomonitor-2 and Kardia Mobile | 169 | Jun 2023 |
| *Unpublished* | | | |
| NCT03221777 | Atrial Fibrillation Occurring Transiently With Stress (AFOTS): Understanding the Risks of Recurrent AF. Study in Non-cardiac Surgery and in Medical Illness Individuals | 281 | Nov 2022 (Completed; last update Jan 2023) |

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

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# Policy History

Original Effective Date: 11/01/2019
Current Effective Date: 08/14/2023
08/01/2019 Medical Policy Committee review

Policy # 00682
Original Effective Date: 11/01/2019
Current Effective Date: 08/14/2023

| | |
|---|---|
| 08/21/2019 | Medical Policy Implementation Committee approval. New policy. |
| 08/06/2020 | Medical Policy Committee review |
| 08/12/2020 | Medical Policy Implementation Committee approval. Clarified criteria. |
| 08/05/2021 | Medical Policy Committee review |
| 08/11/2021 | Medical Policy Implementation Committee approval. No change to coverage. |
| 08/04/2022 | Medical Policy Committee review |
| 08/10/2022 | Medical Policy Implementation Committee approval. No change to coverage. |
| 07/06/2023 | Medical Policy Committee review |
| 07/12/2023 | Medical Policy Implementation Committee approval. Coverage statement for mobile cardiac outpatient telemetry revised. Added an investigational statement for how to deny if criteria are not met. |

Next Scheduled Review Date: 07/2024

# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

Policy # 00682
Original Effective Date: 11/01/2019
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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 33285, 93228, 93229 |
| HCPCS | C1764, E0616 |
| ICD-10 Diagnosis | All related Diagnoses |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.