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

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  - 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 who experience infrequent and recurrent symptoms suggestive of cardiac arrhythmias (e.g., unexplained syncope or near syncope, unexplained episodic dizziness, or unexplained recurrent palpitations) after a non-diagnostic external ambulatory cardiac event monitoring trial of not less than 14 continuous days; **OR**
- 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

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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.

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 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

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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." Similarly, guidelines from the National Institute for Health and Care Excellence (2023) on the evaluation of transient loss of consciousness, have recommended the use of an ambulatory ECG in individuals with a suspected arrhythmic cause of syncope. The type and duration of monitoring recommended is based on the individual's history, particularly the frequency of transient loss of consciousness. 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

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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.

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. 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.

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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 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	• Patient-triggered: Explorer™‡ Looping Monitor (LifeWatch Services)

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	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).	• 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) • SmartCardia 7L (SmartCardia)

ECG: electrocardiogram.

There are also devices that combine features of multiple classes. For example, the LifeStar ACT Ex Holter (LifeWatch Services) is a 3-channel Holter monitor, but is converted to a mobile cardiac telemetry system if a diagnosis is inconclusive after 24 to 48 hours of monitoring. The

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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.

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.

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.

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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 AF following ablation who receive long-term ambulatory cardiac monitoring, the evidence includes one randomized controlled trial (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 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. Randomized controlled trials 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 an improvement in the net health outcome.

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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 the 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 recordings (ILRs) with shorter term monitoring, usually 24- to 48-hour Holter monitoring, and many observational studies. Relevant outcomes are OS, morbid events, medication use, and treatment-related morbidity. Studies assessing prolonged ILRs in patients have reported high rates of arrhythmia detection compared with shorter external event or Holter monitoring. These studies have supported use of a progression in diagnostics from an external event monitor to ILR when longer monitoring is needed. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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.

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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 patients (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 a patient's symptoms is an important finding.

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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 (reaffirmed 2022), the American Academy of Neurology updated its guidelines on the prevention of stroke in patients with nonvalvular AF (NVAF). 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, et al
The American College of Cardiology (ACC), the American Heart Association (AHA), the American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS) (2023) updated guidelines initially issued in 2014 on the management of patients with atrial fibrillation (AF).] Table 2 summarizes guideline-recommended monitoring.

The ACC/AHA/HRS (2017) collaborated on guidelines on the evaluation and management of patients with syncope and patients with ventricular arrhythmias. Cardiac monitoring recommendations are summarized below in Tables 2 and 3.

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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 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.	IIa	B-NR
To evaluate selected ambulatory patients 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 patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an implantable loop recorder are reasonable to improve detection of AF.	2a	B-R

ACC: American College of Cardiology; AF: atrial fibrillation; AHA: American Heart Association; COR: class of recommendation; HRS: Heart Rhythm Society; LOE: level of evidence; TIA: transient ischemic attack.
[a] COR definitions: I: strong recommendation; IIa or 2a: benefit probably exceeds risk (moderate).
[b] LOE definitions: B-NR: moderate level based on well-executed nonrandomized studies; B-R: moderate level based on randomized trials; C-EO: consensus of expert opinion based on clinical experience.

Table 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

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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. 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

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ECG Monitoring Technique	Advantages	Limitations
Holter monitoring	• Records and documents continuous 3- to 32-lead ECG signal simultaneously with biologic signals during normal daily activities • Physicians familiar with analysis software and scanning services	• Frequent noncompliance with symptom logs and event markers • Frequent electrode detachments • Signal quality issues due to skin adherence, tangled wires, dermatitis • Absence of real-time data analysis • Poor patient acceptance of electrodes
Patch ECG monitors	• Long-term recording of ≥14 days • Excellent patient acceptance	• Limited ECG from closely spaced electrodes, lacking localization of arrhythmia origin • Inconsistent ECG quality due to body type variations
External loop recorders	• Records only selected ECG segments marked as events either automatically or manually by patient • Immediate alarm generation on event detection	• Single-lead ECG, lacking localization of arrhythmia origin • Cannot continuously document cardiac rhythm • Requires patient to wear electrodes continuously
Event recorders	• Records only selected ECG segments after an event is detected by patient	• Single-lead ECG, lacking localization of arrhythmia origin • Cannot continuously document cardiac rhythm

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	• Immediate alarm generation at event detected by patient • Well-tolerated by patient	• 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

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Unexplained palpitation	I	B-R
Detection of atrial fibrillation, triggering arrhythmias, and post conversion 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.

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Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05957315	Mobile Cardiac Outpatient Telemetry for Unexplained Syncope: Time to Treatment, Arrhythmia Diagnosis and Outcome	160	Oct 2025
NCT03072693	Daily Ambulatory Remote Monitoring System vs Conventional Therapy for the Post-Discharge Management of Acute Decompensated Heart Failure	876	Apr 2023
NCT04306978	Impact of the CareLink Express Remote Monitoring System on Early Detection of Atrial Fibrillation and Cardiovascular Risk Reduction in Patients With Implantable Cardiac Pacemakers	200	Jan 2023 (unknown status)
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 Patients After High-risk Acute Coronary Syndrome Using Two Different Systems: Biomonitor-2 and Kardia Mobile	169	Jun 2023 (estimated)
Unpublished			
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 Patients after Discharge (REMOSYNC)	99	Mar 2023

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NCT03541616	Prevalence of Subclinical Atrial Fibrillation in High Risk Heart Failure Patients and Its Temporal Relationship With Hospital Readmission for Heart Failure	242	Mar 2023

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

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details.aspx?MCDId=16&ExpandComments=n&McdName=Thomson+Micromedex+DrugDex+%C2%AE+Compe ndium+Revision+Request+-+CAG-00391&NCDId=179.

Policy History

Original Effective Date: 11/01/2019
Current Effective Date: 08/12/2024

08/01/2019	Medical Policy Committee review
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 MCOT rewritten.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Added "For individuals who experience infrequent and recurrent symptoms suggestive of cardiac arrhythmias (e.g., unexplained syncope or near syncope, unexplained episodic dizziness, or unexplained recurrent palpitations) after a non-diagnostic external ambulatory cardiac event monitoring trial of not less than 14 continuous days" to the coverage criteria.

Next Scheduled Review Date: 07/2025

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 2023 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.

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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

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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.

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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.

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Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

Policy # 00682
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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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