

MEDICAL POLICY



MEDICAL POLICY DETAILS	
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Product Disclaimer	<ul style="list-style-type: none"> • <i>Services are contract dependent; If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i> • <i>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</i> • <i>If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</i> • <i>If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i> • <i>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</i>

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, use of external memory-recording ambulatory event monitors (AEMs), either patient-activated or auto-activated, that record and store information for periods longer than 48 hours and up to 14 days have been proven to be medically effective and, therefore, are considered **medically appropriate** as an alternative to Holter monitoring in patients who experience infrequent symptoms, when used for **ANY** of the following indications:
 - A. to assess signs or symptoms possibly related to rhythm disturbances (e.g., palpitations, serious or significant syncope, near syncope);
 - B. to assess anti-arrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well-characterized as reproducible and of sufficient frequency to permit analysis;
 - C. in patients with atrial fibrillation (AF) who have been treated with catheter ablation and in whom discontinuation of systemic anticoagulation is being considered.

- II. Based upon our criteria and assessment of the peer-reviewed literature, use of implanted AEMs (implanted loop recorder (ILR)), either patient-activated or auto-activated, have been proven to be medically effective for infrequent and recurrent syncopal episodes, infrequent and recurrent palpitations, infrequent and recurrent near syncope, or to monitor paroxysmal AF and, therefore, are considered **medically appropriate** in patients that meet the following criteria:
 - A. failure of 30-day AEM; **or**
 - B. when AEMs is contraindicated (i.e., severe skin conditions or obesity); **or**
 - C. clear documentation over 90days showing infrequent presentation of symptoms; **AND**
 - D. documentation supporting that an ILR will significantly change the plan of care and that patient understands and agrees with all aspects of implantation of an ILR.

Medical Policy: AMBULATORY EVENT MONITORS

Policy Number: 2.01.03

Page: 2 of 10

- III. Based upon our criteria and assessment of the peer-reviewed literature, use of an ILR, either patient-activated or auto-activated, ILR evaluation for AF may be considered **medically necessary** in patients with cryptogenic stroke who meet **BOTH** of the following criteria:
- A. 48-72 hours of EKG monitoring with failure to demonstrate an arrhythmia, when an arrhythmia is the suspected etiology of the cryptogenic stroke;
 - B. received a thorough stroke evaluation with imaging performed by neurologist or qualified provider from a certified stroke center.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, use of an ILR, either patient-activated or auto-activated, after a cardiac ablation may be considered **medically necessary** in patients who meet **ALL** of the following criteria:
- A. failure of 30day AEM OR when AEMs is contraindicated (i.e., severe skin conditions or obesity);
 - B. documentation supporting that an ILR will significantly change the plan of care and that patient understands and agrees with all aspects of implantation of an ILR.
- V. Based upon our criteria and assessment of the peer-reviewed literature, home-based, real-time cardiac surveillance systems (mobile cardiac outpatient telemetry (MCOT)) have not been medically proven to improve patient outcomes over standard memory-recording devices and, therefore, are considered **not medically necessary**.
- VI. Based upon our criteria and assessment of the peer-reviewed literature, standard memory-recording AEMs have not been medically proven to improve patient outcomes and, therefore, are considered **investigational** for all other indications, including but not limited to, the following:
- A. to measure heart rate variability in the assessment of patients at risk for future cardiac events without symptoms of arrhythmia; **or**
 - B. to monitor patients for myocardial ischemia by detecting ST segment changes.

This policy does not address Holter Monitoring.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

- I. Requests for cardiac event monitoring that do not meet the above criteria or repeat studies within one year of a previous study are subject to medical necessity review.
- II. The replacement of an ILR or battery for an ILR will be considered for medical necessity review if:
- A. The device is malfunctioning; and
 - B. The device has exceeded the warranty period; and
 - C. Continue to meet the above policy criteria, or
 - D. There have been irreparable changes in the device condition or in a part of the device, due to normal wear and tear.
- III. A thorough stroke evaluation should consist of, at a minimum, CT or MRI of brain, arterial imaging, CTA, MRA or ultrasound of carotid circulation, echocardiography (ECG), extended rhythm monitoring, and key laboratory studies such as a lipid profile and hemoglobin A1c [HbA1c]) per 2021 AHA/ASA guidelines for the secondary prevention of ischemic stroke.

DESCRIPTION

Ambulatory Holter electrocardiography (ECG), which is a noninvasive test used to continuously record an ECG over a specified period of time, usually 24 to 48 hours, is used to evaluate symptoms suggestive of cardiac arrhythmias. It is particularly useful if symptoms occur on a daily or near daily basis. However, Holter monitoring may be ineffective if the patient experiences infrequent symptoms.

AEMs were developed for longer periods of monitoring and may be useful when the initial evaluation by Holter monitoring is non-diagnostic or when symptoms are infrequent. AEMs are intermittent recorders that can be used for longer periods (weeks to months) of monitoring, to gather briefer, intermittent recordings in order to investigate events

Medical Policy: AMBULATORY EVENT MONITORS

Policy Number: 2.01.03

Page: 3 of 10

that occur infrequently. AEMs are either worn continuously and activated when the patient experiences symptoms or applied by the patient only when symptoms occur. Some AEM recorders are implanted under the skin for long-term recordings.

AEMs are useful in patients whose symptoms are quite brief or involve little to patient incapacitation, making it too difficult for the patient or a companion to activate the recorder. Cardiac event monitors have been developed with automatic trigger capabilities, which are designed to automatically record when certain preset conditions occur and avoid the need for the patient to activate the device. These devices are often capable of downloading data trans telephonically.

Types of Available AEMs include:

Noncontinuous Devices with Memory

These devices are carried by the patient and applied to the precordial area when symptoms occur or, alternatively, may be worn on the wrist and activated when symptoms are present. The limitations are that an arrhythmia may be of short duration and not captured by the device, or the patient may be incapacitated and unable to apply the device while symptomatic.

Continuous Memory Loop Devices

These devices are worn continuously, collecting ECG data continuously. When symptoms occur, the patient activates the device, and the ECG is recorded from the memory loop for the preceding 30-90 seconds and approximately one minute after activation. The ZioPatch is capable of continuously recording a single-lead ECG for up to 14 days. The device adheres to the pectoral region and uses a single vector to obtain continuous, single-lead ECG data. The patch is equipped with an event button that patients activate when experiencing symptoms, highlighting the ECG recording for 45 seconds before and after activation. After monitoring is complete, the patients mail the device to a processing center, where the data are analyzed using the manufacturer's algorithm and undergo technical review, physician over-read, and report generation. The ZIO Event Card (iRhythm Technologies Inc, San Francisco, CA) is a prescription-only, single-use, disposable looping ECG monitor that can be worn for up to 30 days and can hold up to two ECG recordings before the patient transmits data via the phone. When the patient feels a symptom, the patient presses the RECORD button, and the recording is stored in the device. The patient then calls into iRhythm Clinical Centers (iCC) to transmit the data, and the recording is reviewed while the patient is still on the phone. A report is generated and posted to a secure site, and, in certain instances, when the report meets account-specific notification criteria, the physician is contacted.

Implantable Continuous Memory Loop Devices

These devices are inserted under the skin in the chest area during an outpatient surgical procedure. When symptoms occur, the patient presses the hand-held activator over the recorder, to activate the storage of cardiac rhythms. The device may be used for more than a year, having a projected battery life of 14 months, at which time the device must be surgically removed. Other ILRs or insertable cardiac monitors (ICMs) (e.g., Reveal LINQ (Medtronic, Inc) and Confirm Rx (Abbott)) are implantable, patient-activated, or automatically activated monitoring systems that record subcutaneous ECG and provide continuous, long-term monitoring for up to three years. The devices are inserted under the skin and close to the sternum, usually between the first and fourth rib.

Auto-triggered Devices

Second-generation continuous memory loop devices have an auto-activation component, which allows the device to record rhythms automatically when the heart rate exceeds or goes below a preset limit.

Home-based, Real-time Cardiac Surveillance Systems

Also referred to as mobile cardiac outpatient telemetry (MCOT), these systems are automatically activated devices that require no patient intervention to capture or transmit an ECG when the cardiac rhythm violates certain preset alarm limits. Five such systems are currently commercially marketed: the CardioNet system (CardioNet, Inc.), the HEARTLink II system (Cardiac Telecom Corp), the VST (Vital Signs Transmitter, Biowatch Medical), the Lifestar ambulatory cardiac telemetry (ACT) system (Card Guard Scientific Survival Ltd.), and the SEEQ Mobile Cardiac Telemetry (MCT) Device (Medtronic). These systems provide automatic wireless transmission of abnormal ECG waveforms at the time of event

Medical Policy: AMBULATORY EVENT MONITORS

Policy Number: 2.01.03

Page: 4 of 10

occurrence from the patient's home to an attended monitoring center. The CardioNet system also has a built-in cellular telephone that automatically transmits arrhythmic signals to the monitoring center when the patient is away from home. The SEEQ Mobile Cardiac Telemetry (MCT) Device is wireless and is intended for patients who are experiencing frequent symptoms that require short-term monitoring for up to 30 days.

- I. Cryptogenic stroke is defined as imaging-confirmed stroke with unknown source despite thorough diagnostic assessment (including, at a minimum, arterial imaging, echocardiography, extended rhythm monitoring, and key laboratory studies such as a lipid profile and hemoglobin A1c [HbA1c]).
- II. Embolic stroke of undetermined source (ESUS) is defined as:
 - A. The detection of a non-lacunar infarct on brain CT/MRI;
 - B. Exclusion of >50% atherosclerotic stenosis proximal to the infarct with any imaging modality;
 - C. Exclusion of a major risk cardioembolic source with echocardiography and cardiac monitoring for >24h;
 - D. No other specific causes (e.g., arteritis, dissection, migraine, and drug misuse).

RATIONALE

AEMs utilize well-established technology and are typically used to evaluate episodes of cardiac symptoms (palpitations, dizziness, syncope) that would escape detection on a standard 24- or 48-hour Holter monitor. AEMs assist in the clinical decision-making process for treatment of patients experiencing symptoms of cardiac arrhythmia in whom the arrhythmia may not otherwise have been detected, potentially decreasing the risk of morbidity. The diagnostic evaluation of syncope is determined by many factors, and, unfortunately, the yield of AEMs in situations involving patients with this clinical condition is relatively low, according to published peer-reviewed literature.

Other proposed uses of AEMs include evaluating ST segment changes as an indication of myocardial ischemia and assessing asymptomatic patients at risk for future cardiac events. The routine monitoring of asymptomatic patients after myocardial infarction is controversial, and, while Holter monitoring has been used to detect ST segment changes, it is unclear whether an AEM can reliably detect ST segment changes. The interpretation of ST segment change is limited by instability of the isoelectric line, which, in turn, depends on meticulous attention to skin preparation, electrode attachment, and measurements to reduce cable movement.

The 2023 American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Pharmacy (ACCP)/Heart Rhythm Society (HRS) Guidelines for the Diagnosis and Management of Atrial Fibrillation have the following recommendations regarding monitoring of AF by AEM or ILR:

- In patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an implantable loop recorder is reasonable to improve detection of AF. (2a [moderate] class of recommendation [COR]).
- Among individuals without a known history of AF, it is recommended that an initial AF diagnosis be made by a clinician using visual interpretation of the electrocardiographic signals, regardless of the type of rhythm or monitoring device. (1 COR)
- In patients with an intracardiac rhythm device capable of a diagnosis of AF, such as from an atrial pacemaker lead, a diagnosis of AF should only be made after it is visually confirmed by reviewing intracardiac tracings to exclude signal artifacts and other arrhythmias. (1 COR).
- For patients who have had a systemic thromboembolic event without a known history of AF and in whom maximum sensitivity to detect AF is sought, an implantable cardiac monitor is reasonable. (2a COR).
- Among patients with a diagnosis of AF, it is reasonable to infer AF frequency, duration, and burden using automated algorithms available from electrocardiographic monitors, implantable cardiac monitors, and cardiac rhythm devices with an atrial lead, recognizing that periodic review can be required to exclude other arrhythmias. (2a COR).
- Among patients with AF in whom cardiac monitoring is advised, it is reasonable to recommend use of a consumer-accessible electrocardiographic device that provides a high-quality tracing to detect recurrences. (2a COR). (Jogler et al., 2023)

Medical Policy: AMBULATORY EVENT MONITORS

Policy Number: 2.01.03

Page: 5 of 10

The 2017 ACC/AHA/HRS Guidelines for the Evaluation and Management of Patients with Syncope have the following recommendations regarding cardiac monitoring for patients with syncope:

- The choice of a specific cardiac monitor should be determined on the basis of the frequency and nature of syncope events. I COR (strong) (expert opinion).
- 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, MCOT. (IIa COR [moderate]).
- To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful. (IIa COR). (Shen et al., 2017)

Randomized studies, including two large, randomized, controlled trials, have demonstrated that long-term monitoring is associated with higher rates of AF detection, compared with Holter monitors, among patients with cryptogenic stroke. Because most patients with a history of stroke in whom AF has been detected will be treated with anticoagulation, and because anticoagulation is an effective treatment for stroke prevention, it can be concluded that longer-term monitoring of patients with cryptogenic stroke will improve outcomes. Because different long-term monitoring devices were used across the studies, the specific type of monitoring associated with the best outcomes is not established.

Single-center studies have reported on the diagnostic yield and timing of detection of arrhythmias in patients monitored with the Zio Patch for a variety of arrhythmias. These studies generally have reported greater numbers of arrhythmias detected during extended follow-up, compared to 24- or 48-hour Holter monitoring.

Published studies regarding mobile cardiac outpatient telemetry (MCOT), such as CardioNet's Mobile Outpatient Cardiac Telemetry Service, have not demonstrated the incremental value of this system over existing AEM devices. The role of this device in the diagnosis and treatment strategy of patients with possible cardiac arrhythmias is unknown. Additionally, there are no evidence-based guidelines from professional organizations regarding MCOT. Rothman, et al. (2007) reported a study of 305 patients who were randomized to a LOOP recorder or MCOT for up to 30 days. Results from 266 patients who completed at least 25 days of monitoring, 132 in the LOOP group and 134 in the MCOT group, were analyzed. Of the 39 patients who did not complete the protocol, 20 (13 MCOT and 7 LOOP) did not complete the study due to non-compliance with (non-wearing of) the device. A diagnostic endpoint (confirmation/ exclusion of arrhythmic cause of symptoms) was found in 88% of MCOT patients and 75% of LOOP patients ($p = 0.008$). The difference in rates was due primarily to detection of asymptomatic arrhythmias in the MCOT group, consisting of rapid AF and/or flutter and ventricular tachycardia. These were thought to be clinically significant rhythm disturbances and the likely causes of the patients' symptoms. The paper does not comment on the clinical impact (changes in management) of these findings in patients for whom the rhythm disturbance did not occur simultaneously with symptoms. In this study, the median time to diagnosis in the total study population was seven days in the MCOT group and nine days in the LOOP group. A subset of only 50 patients received auto trigger loop recorders. In this subset, a diagnostic endpoint was found in 46% of the auto trigger LOOP group. The lower yield of the auto trigger loop recorder noted in this study is surprising; others have reported increased yield with this feature (Reiffel JA, et al). Since the auto trigger loop recorders have become a part of the standard diagnostic approach to patients who have infrequent symptoms that are thought likely to be due to arrhythmias, this is the test to which newer technologies must be compared. Further study of MCOT is needed, to compare MCOT with the auto trigger loop recorder. MCOT is also being studied in the evaluation of patients who have had ablation procedures (Vasamreddy, et al.), and as a method to measure rhythm and rate control in patients with atrial fibrillation (Prystowsky, et al). Neither of these papers compares MCOT with standard approaches. Based on this analysis and the increased cost of this device, mobile cardiac telemetry is considered not medically necessary.

CRYSTAL -AF was a randomized clinical trial comparing ILR with conventional follow-up, in found that there were two limitations when using and ILR for long-term monitoring. First, the positive predictive value is low in this population, which generates a high number of false-positive detections. Second, there is no data that defines the minimal duration of detected A Fib that identifies patients who benefit from anticoagulation (Mittal et al., 2021).

The PER DIEM randomized clinical trial (Buck et al., 2021) was conducted to determine whether 12 months of ILR monitoring detects more occurrences of A Fib compared to 30-day monitoring with a conventional external loop recorder. It included 300 patients within six months of ischemic stroke and without known A Fib. Participants were randomly

Medical Policy: AMBULATORY EVENT MONITORS**Policy Number: 2.01.03****Page: 6 of 10**

assigned 1:1 to prolonged electrocardiographic (ECG) monitoring with either and ILR or External loop recorder. It resulted in a significantly greater proportion of patients with A Fib detected over 12 months, however, further research is needed to compare clinical outcomes associated with their monitoring strategies.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal, subcutaneous cardiac rhythm monitor
93228 (NMN)	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or qualified health care professional
93229 (NMN)	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	recording (includes connection and initial recording)
93243	scanning analysis with report
93244	review and interpretation
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	recording (includes connection and initial recording)
93247	scanning analysis with report
93248	review and interpretation

Medical Policy: AMBULATORY EVENT MONITORS**Policy Number: 2.01.03****Page: 7 of 10**

Code	Description
93268	External patient- and, when performed, auto-activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30-days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional
93270	recording (includes connection, recording, and disconnection)
93271	transmission and analysis
93272	review and interpretation by a physician or other qualified health care professional
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; subcutaneous cardiac rhythm monitor system
93290	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of one or more recorded physiologic cardiovascular data elements from all internal and external sensors.
93291	subcutaneous cardiac rhythm monitor system, including heart rhythm derived data analysis.
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional.
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional
0525T (E/I)	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)
0526T (E/I)	electrode only; electrode only
0527T (E/I)	implantable monitor only
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional

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Code	Description
C1764	Event recorder, cardiac (implantable)

Medical Policy: AMBULATORY EVENT MONITORS**Policy Number: 2.01.03****Page: 8 of 10**

Code	Description
C1833 (E/I)	Monitor, cardiac, including intracardiac lead and all system components (implantable) (e.g., The Guardian).
E0616	Implantable cardiac event recorder with memory, activator and programmer

ICD10 Codes

Code	Description
I45.6	Pre-excitation syndrome
I45.89	Other specified conduction disorders
I45.9	Conduction disorder, unspecified
I47.0-I47.9	Paroxysmal tachycardia (code range)
I48.0-I48.92	Atrial fibrillation and flutter (code range)
I49.01-I49.02	Ventricular fibrillation and flutter (code range)
I49.2	Junctional premature depolarization
I49.40	Unspecified premature depolarization
I49.8-I49.9	Other specified and unspecified cardiac arrhythmias (code range)
I63.9	Cerebral infarction, unspecified
R00.1	Bradycardia, unspecified
R00.2	Palpitations
R06.00	Dyspnea, unspecified
R06.09	Other forms of dyspnea
R06.3	Periodic breathing
R06.83	Snoring
R06.89	Other abnormalities of breathing
R55	Syncope and collapse
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter

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Medical Policy: AMBULATORY EVENT MONITORS

Policy Number: 2.01.03

Page: 9 of 10

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Medical Policy: AMBULATORY EVENT MONITORS

Policy Number: 2.01.03

Page: 10 of 10

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*Key Article

KEY WORDS

Ambulatory Electrocardiographic (AECG) devices, Cardiac Event Detection (CED), CardioNet, Loop devices, Mobile Cardiac Outpatient Telemetry (MCOT), Ziopatch.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Electrocardiographic (EKG) Services (#20.15). Please refer to the following NCD website for Medicare Members: [<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=179&ncdver=2&bc=AgAAgAAAAAA&>] accessed 08/15/24.