

Ambulatory Cardiac Event Monitoring

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Irregular heart rhythms, known as arrhythmias, can present with symptoms such as dizziness, fainting, palpitations, chest pain, or with no symptoms at all. The Plan members with a suspected arrhythmia may require ambulatory monitoring to help make an accurate diagnosis when hospital or office-based evaluations have not revealed any abnormalities. A traditional electrocardiogram (ECG) evaluates the heart over a single point in time, providing only a short interval to detect an abnormal rhythm. Cardiac event monitors address this limitation by recording the cardiac activity over longer periods of time to detect abnormalities that may occur infrequently. There are several different types of portable cardiac monitoring devices. Some of these devices record the heart rhythm from outside the body using small electrodes placed over the chest, while others are implanted just under the skin. They also vary based on the level of patient interaction required and the method of recording or transmitting data. This guideline discusses the clinical criteria for external and internal loop recorders, continuous ambulatory monitors, and mobile cardiac telemetry.

This guideline does not outline Holter monitoring; please refer to MCG A-0120 clinical criteria for medical necessity.

Definitions

"Cardiac Arrhythmia" refers to an abnormal or irregular heart rhythm (e.g., atrial fibrillation, heart block, etc.).

“Holter Monitor” refers to an external device that continuously records the heart rhythm for 24-48 hours (up to 2 weeks with newer models) with 12 leads similar to an ECG, typically in the setting of arrhythmias or symptoms that occur at least daily.

“Continuous Ambulatory Monitor (e.g., Zio by iRhythm)” refers to a device that records the heart rhythm continuously, similar to a Holter monitor, but for durations of time up to 14 days and with only a single lead.

“External Loop Recorder” refers to a device that is worn continuously but only records data when triggered by patient interaction (often via pushing a button on the device) or a built-in algorithm that detects an abnormal rhythm. Patients are instructed to activate the device when they experience symptoms of the arrhythmia, resulting in recording of a few minutes prior to, during, and after the triggering. This device can be used for up to 6 weeks days. External loop recorders can also have a real-time data transmission and analysis function when triggered, and differ from “mobile cardiac telemetry” in that the recording and data transmission is not continuous.

“Implantable Loop Recorder” or “Insertable Cardiac Monitor” refers to a device similar to an external loop recorder except that it is implanted just under the skin for longer term monitoring and to allow the patient to resume daily activities. This device can be left in place for up to 3 years in some cases.

“Mobile Cardiac Telemetry” refers to continuous recording or automatically-triggered recording devices that transmit the cardiac rhythm in real-time to a data center for evaluation typically up to 30 days. The real-time data transmission allows the rhythm to be immediately analyzed and the treating physician to be notified for intervention.

**Note: There are also devices that combine multiple classes of event monitors, such as functioning as a Holter monitor for the first 24-48 hours and then being automatically converted to a mobile cardiac telemetry device if the initial period was non-diagnostic.*

“Atrial Fibrillation” (AF) is the most common arrhythmia in adults and can be classified as permanent, persistent, or paroxysmal. Paroxysmal AF is unique in that the rhythm alternates between atrial fibrillation and another rhythm, often spontaneously and at unpredictable intervals. Because of the risk of thrombus and subsequent embolism, potentially leading to stroke, cardiac monitoring may be indicated in some individuals with suspected paroxysmal AF.

“Cryptogenic Stroke” refers to ischemia infarct of the brain without a known etiology or cerebrovascular risk factors. Roughly one third of ischemic strokes are cryptogenic and may be due to paroxysmal atrial fibrillation.

Clinical Indications

External Loop Recorders (External Event Monitor)

The Plan considers external loop recorders medically necessary for cardiac event monitoring when any ONE of the following criteria are met:

1. To document an arrhythmia or to evaluate symptoms suggestive of cardiac arrhythmia (e.g., syncope, presyncope, lightheadedness, and/or palpitations) in:
 - a. Members with non-diagnostic Holter monitoring; *or*
 - b. Members with symptoms that occur so infrequently (i.e., less often than every 48 hour) or the suspected arrhythmia is such that Holter monitor would be unlikely to be diagnostic.
2. Members with cryptogenic stroke who have had a negative workup for atrial fibrillation including at least a 24-hour non-diagnostic Holter monitor, and where results are intended to guide anticoagulation decisions.

Continuous Ambulatory Recorders (e.g., Zio monitor, Zio patch by iRhythm)

The Plan considers continuous ambulatory recorders medically necessary for cardiac event monitoring when ALL of the following criteria are met:

1. Members 18 years of age or older; *and*
2. The recorder is needed for ONE of the following situations:
 - a. To document an arrhythmia or to evaluate symptoms suggestive of cardiac arrhythmia (e.g., syncope, presyncope, lightheadedness, and/or palpitations) in:
 - i. Members with non-diagnostic Holter monitoring within the last 60 days; *or*
 - ii. Members with symptoms that occur so infrequently (i.e., less often than every 48 hour) or the suspected arrhythmia is such that Holter monitor would be unlikely to be diagnostic; *or*
 - iii. Members with hospitalization-based telemetry monitoring within the last 60 days that failed to identify a diagnosis.
 - b. Members with cryptogenic stroke who have had a negative workup for atrial fibrillation including at least a 48-hour non-diagnostic Holter monitor, and where results are intended to guide anticoagulation decisions.
3. There is no current use of any devices that may impact electrical signal detection, including but not limited to:
 - a. Wearable external defibrillator/cardioversion
 - b. Neurostimulator

Implantable Loop Recorders / Insertable Cardiac Monitors

The Plan considers implantable loop recorders medically necessary for cardiac event monitoring when ALL of the following criteria are met:

1. The procedure and monitoring are ordered by a licensed cardiologist; *and*
2. The member meets at least ONE of the following criteria:

- a. Members with cryptogenic stroke who have had a negative workup for atrial fibrillation including at least a 48-hour non-diagnostic Holter monitor or inpatient telemetry, and where the results are intended to guide anticoagulation decisions; *or*
- b. To evaluate recurrent, unexplained symptoms suggestive of cardiac arrhythmia (e.g., syncope, presyncope, lightheadedness, and/or palpitations) in ONE of the following:
 - i. Members with structural heart disease, prior myocardial infarction, or significant clinical or ECG features* when noninvasive ambulatory monitoring with 30-day external loop recorder or mobile cardiovascular telemetry has been non-diagnostic; *or*
 - ii. Members without structural heart disease, prior myocardial infarction, or significant clinical or ECG changes* when the symptoms occur so unpredictably or infrequently (i.e., less often than once per month) or the suspected arrhythmia is such that noninvasive ambulatory monitoring with 30-day external loop recorder or mobile cardiovascular telemetry has been non-diagnostic.
 1. Symptoms must be frequent enough to have a high likelihood of capture within the battery longevity of the device (typically 2 - 3 years).

* Significant clinical or ECG features defined as any one or more of the following:

- Exertional syncope or syncope upon standing
- Syncope associated with palpitations
- Family history of sudden cardiac death
- Short QTc interval: < 370 ms or long QTc interval: > 440 ms (men) or >460 ms
- Heart rate < 50 beats per minute or sinoatrial block in the absence of influencing medications/substances or athletic lifestyle
- Non-sustained ventricular tachycardia
- Bifascicular block or other intraventricular conduction abnormalities
- Brugada pattern with ST elevations in V1-V3 and RBBB pattern

Removal/Replacement for Implantable Loop Recorders/Insertable Cardiac Monitors

The Plan considers the removal or replacement of implantable loop recorders as medical necessary if ONE of the following are met and include, but not limited to:

1. Infection at the surgical site, device sensitivity, device migration, erosion of the device; *or*
2. Device malfunction or past warranty.

Mobile Cardiac Telemetry

The Plan considers mobile cardiac telemetry medically necessary for cardiac event monitoring when ALL of the following criteria are met:

1. The device and monitoring are ordered by a licensed cardiologist; *and*
2. The member meets at least ONE of the following criteria:

- a. To document an arrhythmia or to evaluate symptoms suggestive of cardiac arrhythmia (e.g., syncope, presyncope, lightheadedness, and/or palpitations) in members with non-diagnostic Holter monitoring, continuous ambulatory monitor, and/or 48 hours of continuous telemetry; *or*
- b. For evaluation of members with suspected atrial fibrillation as the cause of cryptogenic stroke who have had non-diagnostic Holter monitor, ambulatory event monitor and/or 48 hours of continuous telemetry.

Mobile cardiac telemetry for greater than 30 days requires documentation of continued medical necessity and is subject to review.

Experimental or Investigational / Not Medically Necessary

Cardiac event monitoring for any other indication not meeting the above criteria is **NOT** considered medically necessary by the Plan, as it is considered experimental, investigational, or unproven.

Non-covered indications include, but are not limited to, the following:

1. Applicable to all cardiac event monitors:
 - a. Monitoring for asymptomatic episodes of atrial fibrillation in assessment of response to pharmacologic treatment
 - b. Monitoring for arrhythmias without any suggestive symptoms or when other potential causes have not been ruled out and/or treated appropriately
 - c. Monitoring for ST segment depression and/or suspected myocardial ischemia
 - d. Monitoring for effectiveness of pharmacologic treatment of arrhythmias
 - e. Monitoring for recurrence of arrhythmias after discontinuation of pharmacologic treatment
2. Applicable to implantable loop recorders only:
 - a. Monitoring for episodes (symptomatic or asymptomatic) of atrial fibrillation (AF) after catheter or surgical ablation
 - i. *Rationale:* The current data is contradictory, with some studies suggesting a significant benefit in the rate of AF detection and others finding no net benefit. The ABACUS study (2013) looked at 44 patients undergoing ablation for AF who received an implantable loop recorder (ILR) simultaneous to conventional monitoring. While the ILR detected significantly more events of AF, 51% of episodes were false positives. This high rate of false positives has been documented in several other studies. The authors conclude that further research is needed to guide clinical management. At this time, the available evidence is insufficient to determine whether the benefits of implantable loop recorder placement outweigh the risks for this indication.⁵³⁻⁵⁷
3. Applicable to mobile cardiac telemetry (MCT) only:
 - a. Monitoring for effectiveness of pharmacologic treatment of arrhythmias
 - i. *Rationale:* Olson et al (2007) conducted a case series evaluating the mobile cardiac telemetry for efficacy of antiarrhythmic control of arrhythmias. The study

was limited by a small sample size (n=29 for this specific subgroup), and it was uncontrolled with no comparison to other monitoring devices. The current literature is insufficient to determine the benefit of MCT in this population.³⁶

- b. Monitoring for persistent atrial fibrillation after cardiac ablation
 - i. *Rationale:* Vasamreddy et al (2006) examined 19 patients, who used a mobile cardiac telemetry system 5 days per month for 6 months to evaluate for persistent AF. Only 10 patients completed the study and it was limited by a lack of long-term follow-up and now comparison to other monitoring devices. The current literature is insufficient to determine the benefit of MCT in this population.⁵²

The following devices or monitoring technologies are NOT considered medically necessary by the Plan, as they are considered experimental, investigational, or unproven due to lack of peer-reviewed clinical evidence. Non-covered devices include, but are not limited to, the following:

1. eCardio eVolution
2. Mobile phone or mobile applications based cardiac monitoring platforms, including but not limited to:
 - a. AliveCor Heart Monitor (iPhoneECG)⁵⁹
 - b. iHeart/Kardia Mobile
 - c. Any other mobile phone based device or “app” used to record or monitor cardiac rhythm
3. ViSi Mobile Monitoring System
4. Biotronik BioMonitor⁵⁸
5. BodyGuardian Remote Monitoring System
6. CardioPatch
7. CardioKey⁶⁰
8. LifeWatch LifeStar ACT Ex service
9. AngelMed Guardian implantable device for intracardiac ischemia monitoring
 - a. *Rationale:* Study terminated after safety concerns and voted against unanimously by FDA board of advisors.

Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)

<i>External loop recorders, continuous ambulatory recorders, and mobile cardiac telemetry</i>	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
93228	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 other qualified healthcare professional
93229	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
92342	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; 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	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
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 healthcare professional
93270	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; recording (includes connection, recording, and disconnection)
93271	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; transmission and analysis
93272	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; review and interpretation by a physician or other qualified health care professional
ICD-10 codes considered medically necessary if criteria are met, but not limited to:	
<i>Code</i>	<i>Description</i>
I44.0 - I45.9	Atrioventricular and left bundle-branch block and other conduction disorders
I47.0 - I49.9	Paroxysmal tachycardia, atrial fibrillation and flutter, and other cardiac arrhythmias
I63.00 - I63.9	Cerebral infarction [inc. cryptogenic stroke]
R00.0	Tachycardia, unspecified
R00.1	Bradycardia, unspecified
R00.2	Palpitations
R42	Dizziness and giddiness
R55	Syncope and collapse [inc. presyncope]
Z82.41	Family history of sudden cardiac death
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits

<i>Implantable loop recorder</i>	
CPT/HCPCS codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal, subcutaneous cardiac rhythm monitor
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 healthcare professional; implantable loop recorder system

93291	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 loop recorder 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; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified healthcare professional
C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator and programmer

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