

CARDIAC EVENT MONITORING

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[Instructions for Use](#) ⓘ

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Community Plan Policy

- [Cardiac Event Monitoring](#)

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COVERAGE RATIONALE

Cardiac event monitoring is proven and medically necessary for evaluating suspected cardiac arrhythmias as outlined below:

- [Ambulatory Event Monitoring](#)
 - Holter monitor
 - Event monitor
 - Patch-type monitor
- [Outpatient Cardiac Telemetry](#) for **any** of the following indications:
 - Suspected cardiac arrhythmia and non-diagnostic Ambulatory Event Monitoring after a minimum of 4 weeks
 - Cryptogenic stroke with suspected occult atrial fibrillation as the cause of the stroke
 - Monitoring arrhythmia status following an ablation procedure
- [Implantable Loop Recorder](#) in certain circumstances. For medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Loop Recorder (Cardiac Event Monitor), Implantable, A-0122 (AC).

DEFINITIONS

Ambulatory Event Monitoring/Electrocardiography (ECG): Non-implantable cardiac monitors that record cardiac events for days, weeks or months. Monitoring must be of sufficient duration to detect a cardiac arrhythmia under consideration.

- **Holter Monitor:** Portable device that records heart rhythms continuously for up to 72 hours. Newer patch-type devices record for longer periods of time.
- **Event Monitor (including External Loop Recorder):** Portable device that records and stores heart rhythms continuously for 14-30 days or longer. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias. These devices capture ECG data before, during and after the time of activation. Some models transmit triggered data automatically over a wireless network to a remote monitoring system.

(Shen et al., 2017)

Attended Surveillance: The American Medical Association (AMA) defines attended surveillance as the immediate availability of a remote technician to respond to rhythm or device alert transmissions from an individual, either from an implanted or external (wearable) monitoring or therapeutic device, as they are generated and transmitted to the remote surveillance location or center (AMA, 2011).

Implantable Loop Recorder: Implantable device that records and stores heart rhythms continuously. The device is programmed to detect arrhythmias in symptomatic and asymptomatic individuals. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias (Hayes, 2019).

Outpatient Cardiac Telemetry: Portable device that records heart rhythms continuously from external electrodes placed on the body. Segments of the ECG data are automatically (i.e., without human intervention) transmitted to a

remote surveillance location by cellular or landline telephone signal. The transmitted events are triggered automatically by preprogrammed algorithms or by the individual during a symptomatic episode. There is continuous, real-time data analysis in the device and [Attended Surveillance](#) of the transmitted rhythm segments by a surveillance center technician. The surveillance center technician reviews the data and notifies the physician depending on the prescribed criteria (AMA, 2011).

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

CPT Code	Description
Patch-Type Monitor	
0295T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report
0298T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation
Holter Monitor	
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional
Outpatient Cardiac Telemetry	
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 health care 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
Event Monitor	
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

CPT Code	Description
Event Monitor	
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
Implantable Loop Recorder	
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 health care professional; subcutaneous cardiac rhythm monitor 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; subcutaneous cardiac rhythm monitor system, including heart rhythm derived data analysis
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
93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

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HCPCS Code	Description
E0616	Implantable cardiac event recorder with memory, activator, and programmer

DESCRIPTION OF SERVICES

Cardiac arrhythmias are disorders of the heart's rate or rhythm. Some individuals with arrhythmias may experience palpitations, weakness, dizziness or fainting, while others may have no symptoms at all. Effective treatment requires an accurate diagnosis, often using ambulatory electrocardiography (ECG) monitoring. The type and duration of ambulatory ECG monitoring is dictated by the frequency of symptoms. Refer to the [Definitions](#) section for information on types of ambulatory ECG devices.

CLINICAL EVIDENCE

Ambulatory Event Monitoring

In a guideline on the management of atrial fibrillation (AF), the National Institute for Health and Care Excellence (NICE) recommends the following in patients with suspected paroxysmal AF undetected by standard ECG recording:

- A 24-hour ambulatory ECG monitor should be used in those with suspected asymptomatic episodes or symptomatic episodes less than 24 hours apart.
- An event recorder ECG should be used in those with symptomatic episodes more than 24 hours apart (NICE, 2014).

Mittal et al. (2011) evaluated ambulatory external ECG technologies, looking at their utility, limitations and role in the diagnosis and evaluation of patients with AF.

Outpatient Cardiac Telemetry

A large multicenter randomized, controlled trial was conducted by Rothman et al. (2007) who evaluated the CardioNet system in 266 patients who had palpitations, presyncope, syncope or a combination of these symptoms. All patients had undergone 24 hours of monitoring with a Holter monitor, which failed to provide diagnostic information. These patients were randomized to 30 days of monitoring with MCOT (MCOT Group) or with an external loop monitor (Loop Group). Most of the patients in the Loop Group were required to activate the recorder when they experienced symptoms; however, 49 (18%) patients were at centers that had autotriggered recording of cardiac events. During monitoring, clinically significant arrhythmias were detected in 55 (41%) patients in the MCOT Group versus 19 (14%) patients in the Loop Group, a statistically significant difference. For patients who had syncope or presyncope, clinically significant arrhythmias were detected in 52% of patients with MCOT and in 15% of patients with loop recorders. In most cases, the arrhythmias detected were AF, atrial flutter, or ventricular tachycardia. A subgroup analysis was performed at the institutions that used autotriggered loop monitoring rather than patient-activated monitoring. A definitive diagnosis was obtained in this subgroup for 88% of MCOT Group patients versus 46% of Loop Group patients. However, this subgroup analysis involved a relatively small number of patients and the autotriggered devices may have had single ECG leads whereas the CardioNet system uses double ECG leads.

In a retrospective analysis of 26,438 patients with a LifeWatch ambulatory cardiac telemetry device, Kadish et al. (2010) evaluated the frequency with which potentially life-threatening events were detected using ambulatory telemetry for routine clinical indications. Arrhythmic events were defined as those requiring physician notification and those that represented potentially life-threatening arrhythmias. The authors found that 21% of the patients had arrhythmic events meeting physician notification criteria and 1% of patients experienced life-threatening arrhythmic events. The mean monitoring period was 21 days. Study limitations include its retrospective nature, lack of randomization and no follow-up on patient outcomes.

Olson et al. (2007) reviewed the records of 122 consecutive patients evaluated using MCOT for palpitations, presyncope/syncope, or to monitor the efficacy of a specific antiarrhythmic therapy. Ten of 17 patients (59%) studied for presyncope/syncope had a diagnosis made with MCOT. Eight of these 17 patients had a previous negative evaluation for presyncope/syncope and five had an event correlated with the heart rhythm during the monitoring period. Nineteen patients monitored for palpitations or presyncope/syncope were asymptomatic during monitoring but had a prespecified arrhythmia detected. When MCOT was used as the first ambulatory monitoring system to evaluate palpitations (n = 18), 73% of patients correlated their symptoms with the underlying cardiac rhythm. Seven of 21 patients monitored for medication titration had dosage adjustments during outpatient monitoring.

Joshi et al. (2005) evaluated MCOT retrospectively for 100 consecutive patients who were undergoing treatment for known arrhythmias or who were suspected to have arrhythmias based on symptoms such as palpitations, dizziness, or syncope. These patients underwent MCOT for 2 to 28 days with a mean monitoring time of 9.9 days. For this study, the effectiveness of MCOT was assessed based on detection of arrhythmias and changes in patient management after MCOT. Arrhythmias were detected in 51% of patients with 17% having supraventricular tachycardia and another 17% having AF or atrial flutter. Less common arrhythmias detected with MCOT were ventricular tachycardia, sinus node disease, long QT syndrome, second degree atrioventricular block, symptomatic sinus bradycardia, complete heart block, junctional rhythm, symptomatic premature ventricular complexes, and Wolff-Parkinson-White syndrome. Following MCOT, physicians prescribed the following changes in treatment on a per-patient basis: drug treatment started (14%), permanent pacemaker inserted (5%), cardiac tissue ablated (4%), drug treatment changed (3%), cardioverter defibrillator implanted (2%), anticoagulation stopped (2%), pacemaker replaced (1%), and drug treatment stopped (1%). Although these treatment changes were designed to address specific findings of cardiac monitoring, this study did not involve any subsequent monitoring or follow-up to determine whether patient outcomes were improved as a result of diagnostic information provided by MCOT.

Saarel et al. (2008) conducted a smaller uncontrolled study of MCOT with the CardioNet system that differed from the other available studies in its enrollment of pediatric patients. A total of 54 patients were enrolled with a mean age of 12 years (range 3 to 20). The primary indication for cardiac monitoring was chest pain or palpitations with or without syncope for 42 (78%) patients and isolated chest pain, syncope, or presyncope for the other 12 (22%) patients. Patients were monitored for a mean of 25.7 days (range 9 to 32) and during this time 33 (61%) patients experienced symptoms that corresponded with arrhythmias. Of these 33 patients, 6 (18%) had supraventricular tachycardia or significant supraventricular or ventricular ectopy while the other 27 (82%) had benign conditions. Compared with a historical control group of 495 patients who underwent transtelephonic echocardiographic monitoring, MCOT had a higher diagnostic yield; however, this increase in diagnostic yield was not statistically significant.

In a small uncontrolled study (n=19), Vasamreddy et al. (2006) used the CardioNet monitoring system to assess the efficacy of cardiac tissue ablation procedures for treatment of AF. This study found that, based on MCOT, 70% of patients were free of symptomatic AF and 50% of patients were free of asymptomatic AF. However, only 10 patients completed the study and patients underwent six 5-day periods of MCOT monitoring over 6 months rather than 30 days of monitoring before treatment, after treatment, and at 6 months follow-up.

Cryptogenic Stroke

Although not specific to outpatient telemetry, two randomized controlled trials have shown that prolonged monitoring can aid in the detection of cryptogenic stroke due to underlying occult AF (Sanna et al., 2014; Gladstone et al., 2014).

Favilla et al. (2015) analyzed a retrospective cohort of consecutive patients who underwent 28-day MCOT after cryptogenic stroke or transient ischemic stroke. Of 227 patients with cryptogenic stroke (179) or transient ischemic stroke (48), 14% had AF detected on MCOT, 58% of which was ≥ 30 seconds in duration. Age >60 years and prior cortical or cerebellar infarction seen on neuroimaging were independent predictors of AF.

Kishore et al. (2014) conducted a systematic review and meta-analysis to determine the frequency of newly detected AF using noninvasive or invasive cardiac monitoring after ischemic stroke or transient ischemic attack. Prospective observational studies or randomized controlled trials of patients with ischemic stroke, transient ischemic attack or both, who underwent any cardiac monitoring for a minimum of 12 hours, were included. A total of 32 studies were analyzed. The primary outcome was detection of any new AF during the monitoring period. The investigators performed a subgroup analysis of selected (prescreened or cryptogenic) versus unselected patients and according to duration of monitoring. The overall detection rate of any AF was 11.5%, although the timing, duration, method of monitoring and reporting of diagnostic criteria used for paroxysmal AF varied. Detection rates were higher in selected (13.4%) than in unselected patients (6.2%). In cryptogenic strokes, the new AF detection rate was 15.9%. The authors concluded that detection of AF was highly variable and that the results support initial inpatient telemetry and suggest that prolonged noninvasive monitoring (>24 hours) is likely to increase yield of AF detection.

Observational studies indicate that outpatient cardiac monitoring detects previously undiagnosed AF in 5% to 20% of patients with recent stroke. However, it remains unknown whether the yield of monitoring exceeds that of routine clinical follow-up. In a pilot trial, Kamel et al. (2013) randomly assigned 40 patients with cryptogenic ischemic stroke or high-risk transient ischemic attack to wear a Cardionet mobile cardiac outpatient telemetry monitor for 21 days or to receive routine follow-up alone. The study excluded patients with documented AF or other apparent stroke pathogenesis. Patients and their physicians were contacted at 3 months and at 1 year to ascertain any diagnoses of AF or recurrent stroke or transient ischemic attack. The baseline characteristics of this cohort broadly matched those of previous observational studies of monitoring after stroke. In the monitoring group, patients wore monitors for 64% of the assigned days, and 25% of patients were not compliant at all with monitoring. No patient in either study arm received a diagnosis of AF. Cardiac monitoring revealed AF in zero patients (0%), brief episodes of atrial tachycardia in 2 patients (10%) and nonsustained ventricular tachycardia in 2 patients (10%). In the first reported randomized trial of cardiac monitoring after cryptogenic stroke, the rate of AF detection was lower than expected, incidental arrhythmias were frequent and compliance with monitoring was suboptimal. The authors reported that these findings highlight the challenges of prospectively identifying stroke patients at risk for harboring paroxysmal AF and ensuring adequate compliance with cardiac monitoring.

The etiology of cerebral ischemia is undetermined in one-third of patients upon discharge. Occult paroxysmal AF is considered a potential etiology. Miller et al. (2013) performed a retrospective analysis on 156 patients evaluated by MCOT monitoring (CardioNet) within 6 months of a cryptogenic stroke or TIA. Paroxysmal AF occurred in 27 of 156 (17.3%) patients during MCOT monitoring of up to 30 days. The rate of paroxysmal AF detection significantly increased from 3.9% in the initial 48 hours, to 9.2% at 7 days, 15.1% at 14 days and 19.5% by 21 days. Female gender, premature atrial complex on ECG, increased left atrial diameter, reduced left ventricular ejection fraction and greater stroke severity were independent predictors of paroxysmal AF detection with strongest correlation seen for premature atrial complex on ECG. The authors concluded that length of monitoring is strongly associated with detection of paroxysmal AF, with an optimal monitoring period of at least 21 days.

Bhatt et al. (2011) investigated a cohort of cryptogenic stroke patients to determine the percentage of patients who had paroxysmal AF on prolonged non-invasive cardiac monitoring (CardioNet). Sixty-two consecutive patients with stroke and TIA in a single center with a mean age of 61 years were analyzed. Paroxysmal AF was detected in 15 (24%) patients. The majority (93%) of paroxysmal AF was detected within the first 21 days. A total of 73 episodes of paroxysmal AF were detected among these 15 patients, and the majority of these (97%) were asymptomatic. The presence of PVCs (ventricular premature beats) lasting more than 2 minutes and strokes (high signal on Diffusion Weighted Imaging (DWI)) predicted paroxysmal AF. Patients with multiple DWI signals were more likely than solitary signals to have paroxysmal AF. The authors concluded that the data suggests that up to one in five patients with suspected cryptogenic strokes and TIAs have paroxysmal AF, especially if they have PVCs and multiple high DWI signals on MRI.

Professional Societies

American Academy of Neurology (AAN)

An AAN practice parameter on stroke prevention analyzed the evidence of various technologies used to identify undetected non-valvular AF in patients with cryptogenic stroke. The most common technique used was Holter

monitoring, followed by serial ECG, event loop recorders, inpatient continuous telemetry, outpatient transtelephonic monitoring and mobile cardiac outpatient telemetry. In patients with recent cryptogenic stroke, AAN recommends outpatient cardiac rhythm monitoring with a nonimplanted device to detect unsuspected non-valvular AF. Longer monitoring periods (e.g., one or more weeks) are associated with a greater yield (Culebras et al., 2014).

Level C - Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population.

American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS)

Joint guidelines for the management of patients with AF state that the diagnosis of AF is based on clinical history and physical examination and is confirmed by electrocardiogram, ambulatory rhythm monitoring (e.g., telemetry, Holter monitor event recorders), implanted loop recorders, pacemakers or defibrillators or, in rare cases, by electrophysiological study. Prolonged or frequent monitoring may be necessary to reveal episodes of asymptomatic AF (January et al., 2014). A focused update of these guidelines has a new section on device detection of AF and atrial flutter (January et al., 2019).

Class I – Procedure should be performed.

Level of evidence C – Based on expert opinion, case studies or standard of care.

ACC/AHA/HRS guidelines (Shen et al., 2017) on the evaluation and management of patients with syncope address several ambulatory ECG monitoring options. The guidelines recommend that the choice of a specific monitoring system and duration should be determined on the basis of the frequency and nature of syncope events. 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
- Mobile cardiac outpatient telemetry

Class IIA – It is reasonable to perform procedure.

Level of evidence B-NR – Based on moderate-quality evidence from one or more well-designed, well-executed nonrandomized, observational or registry studies.

AHA/ACC/HRS guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death state that a 24-hour continuous Holter recording is appropriate when symptoms occur at least once a day or when quantitation of premature ventricular complex/nonsustained ventricular tachycardia is desired to assess possible ventricular arrhythmia-related depressed ventricular function. For sporadic symptoms, event or “looping” monitors are more appropriate because they can be activated over extended periods of time and increase diagnostic yield. When the suspicion of ventricular arrhythmia is high, outpatient ambulatory monitoring is inappropriate, as prompt diagnosis and prevention of ventricular arrhythmia are warranted (Al-Khatib et al., 2017).

American Heart Association (AHA)/American Stroke Association (ASA)

A joint scientific statement on the prevention of stroke in patients with silent cerebrovascular disease recommends that, for patients with an embolic-appearing pattern of infarction, prolonged rhythm monitoring for AF be considered (Smith et al., 2017).

Joint guidelines for the early management of patients with acute ischemic stroke state that continuous cardiac monitoring is indicated for at least the first 24 hours after a stroke. Outpatient event monitoring may be indicated in patients with cryptogenic stroke and suspected paroxysmal arrhythmias, especially in those patients with short hospitalizations in which monitoring was brief. Ongoing monitoring of cardiac rhythm on telemetry or by Holter monitoring may detect AF or other serious arrhythmias (Jauch et al., 2013). A focused update of these guidelines did not present any changes to the recommendations for continuous cardiac monitoring (Powers et al., 2015).

European Society of Cardiology (ESC)

ESC guidelines for the management of AF state that prompt recording of an ECG is an effective method to document chronic forms of AF. The technology to detect paroxysmal, self-terminating AF episodes is rapidly evolving. There is good evidence that prolonged ECG monitoring enhances the detection of undiagnosed AF (e.g., monitoring for 72 hours after a stroke, or even longer periods). Daily short-term ECG recordings increase AF detection in populations over 75 years of age. Ongoing studies will determine whether such early detection alters management (e.g., initiation of anticoagulation) and improves outcomes. Regarding prolonged monitoring for paroxysmal AF, the guidelines state that several patient-operated devices and extended continuous ECG monitoring using skin patch recorders have been

validated for the detection of paroxysmal AF. Prolonged ECG monitoring is also reasonable in survivors of ischemic stroke without an established diagnosis of AF (Kirchhof et al., 2016).

ESC guidelines for the diagnosis and management of syncope state that as a general rule, ECG monitoring is indicated only when there is a high pre-test probability of identifying an arrhythmia associated with syncope. Some studies have shown that implementing remote monitoring increases the diagnostic yield and achieves diagnosis earlier than without remote monitoring (Brignole et al., 2018).

Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) et al.

In a consensus statement on ablation of AF, the HRS, in collaboration with several other organizations, states that arrhythmia monitoring can be performed with the use of noncontinuous or continuous ECG monitoring tools. Choice of either method depends on individual needs and consequences of arrhythmia detection. More intensive monitoring is associated with a greater likelihood of detecting both symptomatic and asymptomatic AF. No specific guidelines are provided regarding the optimal monitoring system (Calkins et al., 2017).

Heart Rhythm Society (HRS)/International Society for Holter and Noninvasive Electrocardiology (ISHNE)

The HRS, in collaboration with the ISHNE, published a consensus statement on ambulatory ECG and external cardiac monitoring. The document summarizes the advantages and limitations of various ambulatory ECG techniques (Steinberg et al., 2017).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

For information on ambulatory ECG devices, cardiac telemetry or implantable loop recorders, see the following website (use product codes DSI, MXD and DXH): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed May 9, 2019)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers ambulatory cardiac event monitoring (including Holter, Event and Patch-type) when criteria are met; see the National Coverage Determination (NCD) for [Electrocardiographic Services \(20.15\)](#). Local Coverage Determinations (LCDs) exist; see the LCDs for [Cardiac Event Detection](#), [Cardiac Event Detection Monitoring](#), [Electrocardiographic \(EKG or ECG\) Monitoring \(Holter or Real-Time Monitoring\)](#), [Category III Codes](#), [Non-Covered Services](#), and [Long-Term Wearable Electrocardiographic Monitoring \(WEM\)](#).

Medicare covers outpatient cardiac telemetry when criteria are met; see the NCD for [Electrocardiographic Services \(20.15\)](#). LCDs exist; see the LCDs for [Cardiac Event Detection](#), [Electrocardiographic \(EKG or ECG\) Monitoring \(Holter or Real-Time Monitoring\)](#), [Real Time, Outpatient Cardiac Telemetry](#), and [Long-Term Wearable Electrocardiographic Monitoring \(WEM\)](#).

Medicare does not have an NCD for the use of implantable loop recorders used in cardiac event monitoring. LCDs do not exist at this time. (Accessed May 10, 2019)

REFERENCES

- Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2018 Oct 2;72(14):e91-e220.
- American Medical Association (AMA). Cardiovascular monitoring services. *CPT Assistant*. October 2011, p. 5.
- Bhatt A, Majid A, Razak A, et al. Predictors of occult paroxysmal atrial fibrillation in cryptogenic strokes detected by long-term noninvasive cardiac monitoring. *Stroke Res Treat*. 2011 Feb 22;2011:172074.
- Brignole M, Moya A, de Lange FJ, et al.; ESC Scientific Document Group. 2018 ESC guidelines for the diagnosis and management of syncope. *Eur Heart J*. 2018 Jun 1;39(21):1883-1948.
- Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm*. 2017 Oct;14(10):e275-e444.
- Culebras A, Messé SR, Chaturvedi S, et al. Summary of evidence-based guideline update: prevention of stroke in nonvalvular atrial fibrillation: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2014 Feb 25;82(8):716-24. Erratum in: *Neurology*. 2014 Apr 22;82(16):1481. Dosage error in article text.

Favilla CG, Ingala E, Jara J, et al. Predictors of finding occult atrial fibrillation after cryptogenic stroke. *Stroke*. 2015 May;46(5):1210-5.

Gladstone DJ, Spring M, Dorian P, et al.; EMBRACE Investigators and Coordinators. Atrial fibrillation in patients with cryptogenic stroke. *N Engl J Med*. 2014 Jun 26;370(26):2467-77.

Hayes, Inc. Hayes Product Comparison. Implantable cardiac loop recorders. Lansdale, PA: Hayes, Inc.; March 2019.

January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS Guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2014 Dec 2;64(21):e1-e76.

Jauch EC, Saver JL, Adams HP Jr, et al.; American Heart Association Stroke Council; Council on Cardiovascular Nursing; Council on Peripheral Vascular Disease; Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2013 Mar;44(3):870-947.

Joshi AK, Kowey PR, Prystowsky EN, et al. First experience with a mobile cardiac outpatient telemetry (MCOT) system for the diagnosis and management of cardiac arrhythmia. *Am J Cardiol*. 2005;95(7):878-881.

Kadish AH, Reiffel JA, Clauser J, et al. Frequency of serious arrhythmias detected with ambulatory cardiac telemetry. *Am J Cardiol*. 2010 May 1;105(9):1313-6.

Kamel H, Navi BB, Eljovich L, et al. Pilot randomized trial of outpatient cardiac monitoring after cryptogenic stroke. *Stroke*. 2013 Feb;44(2):528-30.

Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Eur Heart J*. 2016 Oct 7;37(38):2893-2962.

Kishore A, Vail A, Majid A, et al. Detection of atrial fibrillation after ischemic stroke or transient ischemic attack: a systematic review and meta-analysis. *Stroke*. 2014 Feb;45(2):520-6.

Miller DJ, Khan MA, Schultz LR, et al. Outpatient cardiac telemetry detects a high rate of atrial fibrillation in cryptogenic stroke. *J Neurol Sci*. 2013 Jan 15;324(1-2):57-61.

Mittal S, Movsowitz C, Steinberg JS. Ambulatory external electrocardiographic monitoring: focus on atrial fibrillation. *J Am Coll Cardiol*. 2011 Oct 18;58(17):1741-9.

Moya A, Sutton R, Ammirati F, et al.; Task Force for the Diagnosis and Management of Syncope; European Society of Cardiology (ESC); European Heart Rhythm Association (EHRA); Heart Failure Association (HFA); Heart Rhythm Society (HRS). Guidelines for the diagnosis and management of syncope (version 2009). *Eur Heart J*. 2009 Nov;30(21):2631-71.

National Institute for Health and Care Excellence (NICE). CG180. Atrial fibrillation: management. June 2014.

Olson JA, Fouts AM, Padanilam BJ, Prystowsky EN. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitations, presyncope, syncope, and the assessment of therapy efficacy. *J Cardiovasc Electrophysiol*. 2007 May;18(5):473-7.

Powers WJ, Derdeyn CP, Biller J, et al.; American Heart Association Stroke Council. 2015 American Heart Association/American Stroke Association focused update of the 2013 guidelines for the early management of patients with acute ischemic stroke regarding endovascular treatment: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2015 Oct;46(10):3020-35.

Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: A prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. *J Cardiovasc Electrophysiol*. 2007;18(3):241-247.

Saarel EV, Doratotaj S, Sterba R. Initial experience with novel mobile cardiac outpatient telemetry for children and adolescents with suspected arrhythmia. *Congenit Heart Dis*. 2008;3(1):33-38.

Sanna T, Diener HC, Passman RS, et al.; CRYSTAL AF Investigators. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. 2014 Jun 26;370(26):2478-86.

Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2017 Aug 1;70(5):e39-e110.

Smith EE, Saposnik G, Biessels GJ, et al.; American Heart Association Stroke Council; Council on Cardiovascular Radiology and Intervention; Council on Functional Genomics and Translational Biology; and Council on Hypertension. Prevention of stroke in patients with silent cerebrovascular disease: a scientific statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2017 Feb;48(2):e44-e71.

Steinberg JS, Varma N, Cygankiewicz I, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. *Heart Rhythm*. 2017 Jul;14(7):e55-e96.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2019	<p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Outpatient Cardiac Telemetry</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to indicate: <ul style="list-style-type: none"> Ambulatory Event Monitoring (Holter Monitor, Event Monitor, and patch-type monitor) is proven and medically necessary for evaluating suspected cardiac arrhythmias Implantable Loop Recorder is proven and medically necessary for evaluating suspected cardiac arrhythmias in certain circumstances; for medical necessity clinical coverage criteria, see MCG™ Care Guidelines, 23rd edition, 2019, Loop Recorder (Cardiac Event Monitor), Implantable, A-0122 (AC) Revised coverage criteria for outpatient cardiac telemetry; replaced criterion requiring “suspected cardiac arrhythmia and non-diagnostic Ambulatory Event Monitoring after a minimum of <i>30 days</i>” with “suspected cardiac arrhythmia and non-diagnostic Ambulatory Event Monitoring after a minimum of <i>4 weeks</i>” <p>Definitions</p> <ul style="list-style-type: none"> Added definition of “Implantable Loop Recorder” Revised definition of “Event Monitor (including external loop recorder)” <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT codes 0295T, 0296T, 0297T, 0298T, 33285, 33286, 93224, 93225, 93226, 93227, 93268, 93270, 93271, 93272, 93285, 93291, 93298, and 93299 Added HCPCS code E0616 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i>, <i>FDA</i>, <i>CMS</i>, and <i>References</i> sections to reflect the most current information Archived previous policy version 2019T0489S

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.