Cardiac Event Monitoring

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➲ Instructions for Use

Table of Contents **Page**

Community Plan Policy

- Cardiac Event Monitoring

Medicare Advantage Coverage Summary

- Cardiovascular Diagnostic and Therapeutic Procedures

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

The following are proven and medically necessary for evaluating suspected cardiac arrhythmias:

- Ambulatory Event Monitoring
  - Holter monitor
  - Event monitor
  - Patch-type monitor
- Outpatient Cardiac Telemetry
- Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias:
  - When noninvasive cardiac event recording is contraindicated or yielded non-diagnostic results after at least 2 weeks of monitoring in one or more of the following circumstances:
    - Suspected paroxysmal atrial fibrillation in the setting of a cryptogenic stroke or another documented systemic thromboembolic event
    - Suspected or known ventricular arrhythmia
    - High risk for arrhythmia secondary to structural or infiltrative heart disease such as aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease, family history, dilated ischemic or nonischemic cardiomyopathy, or use of medications known to cause malignant arrhythmias such as those prolonging the QT interval
    - Recurrent or unexplained infrequent syncope, after modification of potentially syncope-causing medications or associated with autonomic dysfunction
    - Abnormal tests such as electrophysiology study or tilt table testing

Replacement of Implantable Loop Recorders is considered medically necessary for an individual who continues to meet all initial criteria for insertion described above and the existing device is beyond its useful life span, is irreparable, or no longer operating.

Wearable heart rhythm monitors (Cardiac Self-Monitoring Devices) commercially available to the general public and purchased for home use are not medically necessary due to insufficient evidence of efficacy and are considered a convenience item. Such items include (but are not limited to):

- A self-monitoring device that includes an ECG monitor combined with a personal electronic device such as a cellular telephone or watch
- Hardware or software required for downloading ECG data to a device such as personal computer, tablet or smart phone

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT/HCPCS Codes*	Required Clinical Information
Implantable Loop Recorders	
33285 E0616 E1399	Medical notes documenting the following, when applicable: • Physician order • Pertinent diagnoses or symptoms • Conditions putting the member is high risk for arrhythmias • Result of non-invasive cardiac monitoring unless contraindicated, or non-diagnostic, to include duration of monitoring • Test results supporting cardiac etiology (e.g., electrophysiological studies, Tilt Table testing, relevant imaging results, etc.) unexplained symptoms, or unexplained syncopal episodes

*For code descriptions, refer to the Applicable Codes section.

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).

Cardiac Self-Monitoring Devices: Consumer-grade, connected electronic devices and/or software applications that members can use without a physician's prescription. These devices collect physiologic information to download onto an individual's smart phone, smartwatch, personal computer or tablet and can be worn on the body as an accessory or embedded into clothing. They have high processing power, numerous sophisticated sensors, and software algorithms that can generate a variety of measurements and data such as blood pressure, heart rate and heart rhythm through ECG (Bayoumy et al. 2021).

Implantable Loop Recorder: Device used to detect abnormal heart rhythms. It is placed under the skin and continuously records the heart's electrical activity. The recorder can transmit data to the physician's office to help with monitoring. An Implantable Loop Recorder may determine why an individual is having palpitations or fainting spells (National Institutes of Health [NIH], 2022).

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 Guidelines may apply.

CPT Code	Description
Patch-Type Monitor	
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	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
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

CPT Code	Description
Outpatient Cardiac Telemetry	
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
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	
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
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
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
Cardiac Self-Monitoring Devices	
93799	Unlisted cardiovascular service or procedure

HCPCS Code	Description
Implantable Loop Recorder	
E0616	Implantable cardiac event recorder with memory, activator, and programmer
Cardiac Self-Monitoring Devices	
E1399	Durable medical equipment, miscellaneous

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 (NIH, 2022).

Clinical Evidence

Ambulatory Event Monitoring

Eysenck et al. (2020) conducted a randomized controlled trial (RCT) to compare three cardiac rhythm monitoring devices, ZIO XT monitor (ZM), NUUBO vest (NV), and Carnation Ambulatory Monitor (CAM), with the 'gold standard' Novacor 'R' Test 4 (RT) in patients with an implanted dual chamber rate adaptive permanent pacemaker (DDDRP PPM) and known atrial fibrillation (AF). Twenty-one participants wore each of the four ECMs for 14 days in randomized order, with at least seven days between each of the ECM applications. RT AF burden was less accurate than the ZM, NV or CAM ($p < 0.05$). Probability of inaccurate AF diagnosis was higher for RT than ZM or CAM OR 12.31 and 5.85, respectively ($p = 0.025$ and $p = 0.042$). ZM wear time was longer than the RT: 307 h vs. 224 h; $p = 0.02$. Acceptability was greater for CAM than RT (1.86 ± 2.63 compared with 0.57 ±1.17 for CAM; $p = 0.024$). The authors concluded the ZM, NV and CAM are all more accurate than the standard practice RT device in AF burden assessment and the RT was more likely to give inaccurate diagnoses than ZM or CAM. Additionally, performance of all ECMs improved with longer duration AF episodes. Limitations include small sample size and all participants in the study had DDDRP PPMs in situ which may limit generalizability of findings with other cardiac pathology.

In the early prolonged ambulatory cardiac monitoring in stroke (EPACS) open-label RCT conducted by Kaura et al (2019), the authors compared a 14-day electrocardiogram (ECG) monitoring patch (Zio® Patch, iRhythm Technologies) to a short-duration Holter monitoring for the detection of paroxysmal atrial fibrillation (PAF) in patients with cryptogenic ischemic stroke or transient ischemic attack (TIA) early after the index event. The primary outcome was the detection of one or more episodes of ECG-documented PAF lasting at least 30 seconds within 90 days of the stroke or TIA in each of the study arms. The study included 116 patients from two sites in the UK who were randomly assigned in a 1:1 ratio with 56 patients in the patch-based monitoring group and 60 patients in the short-duration Holter monitoring group. All patients underwent short-term Holter monitoring for the duration determined by their treating physician (usually 24 hours) with a mean time of 2.1 ±1.2 days from time of the stroke or TIA event. The patients in the patch-based group then had the patch applied with a mean time of 38.9 ±33.6 days from the stroke or TIA event and wore the patch for 14 days. The patients were followed up on day 28 and day 90 via EMR data search and a telephonic outreach to each patient. Data collected included PAF documented on the ECG monitoring devices or detected incidentally during usual clinical practice. The rate of detection of PAF reported by the authors at 28 days was 14% in the patch-based monitoring group and 2.1% in the Holter monitoring group. All patients who were newly diagnosed with PAF were started on anticoagulation therapy by day 90. There was no difference in the rate of recurrent ischemic stroke or TIA between the two groups. The authors concluded that early, prolonged patch-based monitoring after an index stroke or TIA is superior to short-duration Holter monitoring in the detection of PAF with an associated greater use of anticoagulation. Limitations noted by the authors included a 20% drop out rate due to Holter ECG service provision, the lack of comparison to other extended monitoring systems such as implantable loop recorders and the lack of a control group with healthy individuals who had not had an ischemic stroke or TIA.

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 TIA. Prospective observational studies or RCTs of patients with ischemic stroke, TIA or both, who underwent any cardiac monitoring for a minimum of 12 hours, were included. A total of 32 studies were analyzed, the majority of which used inpatient, Holter, or external loop recorder monitoring. 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 after TIA or ischemic stroke was highly variable. The results support initial inpatient telemetry and suggest that prolonged noninvasive monitoring greater than 24 hours is likely to increase yield of AF detection. The optimal method and duration of monitoring is unclear, and future appropriately designed studies are recommended.

Outpatient Cardiac Telemetry

Jiang et al. (2022) conducted a meta-analysis and systematic review to evaluate the current modalities used for extended ECG monitoring in the detection of AF following a cryptogenic stroke. Forty-seven studies with a total of 6,448 patients with cryptogenic stroke were included in the review. The pooled AF rate for ILRs increased from 4.9% (3.0%–7.9%) at one month to 38.4% (20.4%–60.2%) at 36 months. Mobile cardiac outpatient telemetry (MCOT) had a significantly higher pooled AF detection rate of 12.8% (8.9%–17.9%) versus 4.9% (3.0%–7.9%) for ILR at one month ($p < 0.0001$). Predictors for AF detection include duration of monitoring ($p < 0.0001$) and age ($p < 0.0001$) for ILRs, but only age for MCOTs ($p < 0.020$). The authors concluded that in patients with cognitive and physical ability to use ECG monitoring daily for one month, MCOT may capture a significant proportion of AF and should be considered in place of ILRs. If MCOT fails to detect AF after one month of monitoring or if there are compliance issues, ILRs may be considered. The authors recommended further research for MCOT in the detection of AF for those with cryptogenic stroke. Limitations include significant unexplained heterogeneity, poor reporting of features of the study population, and risk underestimation of AF detection rates in MCOT studies.

Noubiap et al. (2021) conducted a systematic review and meta-analysis to evaluate data on AF detection rates and predictors comparing different rhythm monitoring strategies in patients with embolic stroke of undetermined source (ESUS) or cryptogenic stroke (CS). PubMed/MEDLINE, Excerpta Medica Database (EMBASE), and Web of Science were searched to identify all cohort studies or RCTs reporting primary data on the rates and predictors of AF detection in patients with CS or ESUS, published by July 6, 2020 and random-effects meta-analysis method was used to pool estimates. Forty-seven studies with a total of 8,215 patients with CS or ESUS were included. Using implantable cardiac monitor (ICM), the pooled rate of AF was 12.2% at 3 months, 16.0% at 6 months, 18.7% at 12 months, 22.8% at 24 months, and 28.5% at 36 months. AF rates were significantly higher in patients with ESUS vs CS (22.0% vs 14.2%; $p < 0.001$) at 6 months, and in studies using Reveal LINQ vs Reveal XT ICM (19.1% vs 13.0%; $p = 0.001$) at 12 months. Using MCOT, the pooled rate of AF was 13.7% at 1 month. Predictors of AF detection with ICM included older age, P wave maximal duration, CHA2DS2-VASc score, prolonged PR interval, and left atrial enlargement. The authors concluded more than a quarter of patient with CS or ESUS are diagnosed with AF during follow-up and about one in seven patients had AF detected within a month of MCOT, suggesting that a non-invasive rhythm monitoring strategy should be considered before invasive monitoring.

An ECRI Health Technology Assessment for outpatient cardiac telemetry monitors states that studies indicate outpatient telemetry increases arrhythmia detection, but does not necessarily translate to improved patient outcomes and clinical utility. The study notes that clinical guidelines recommend outpatient monitoring for arrhythmia diagnosis and evaluation but the choice of monitoring modality is left up to the clinician (ECRI, 2019).

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.

Sposato et al. (2015) conducted a systematic review and meta-analysis of 50 studies (n = 11,658) to estimate the proportion of individuals with newly diagnosed AF following TIA or stroke. The studies noted diagnostic methods including ECG, continuous inpatient ECG monitoring, Holter monitoring, continuous inpatient cardiac telemetry, outpatient mobile cardiac telemetry, external loop recording and implantable loop recorders. Phase one was assessment in the emergency room with ECG. Phase two (inpatient stay) comprised serial ECG, continuous ECG, inpatient cardiac telemetry and inpatient Holter monitoring. In phase three, the first ambulatory period, Holter monitoring was utilized. The fourth phase was the second ambulatory period, which consisted of mobile cardiac telemetry, external loop and implantable loop recording. Phase four revealed AF in 16.9% of patients; the overall AF detection after all four phases was 23.7%. The authors concluded that combined cardiac monitoring methods may lead to newly detected AF in nearly a quarter of patients with stroke or TIA. (Bhatt et al., 2011, Kamel et al., 2013, Miller et al., 2013, Gladstone et al., 2014, and Sanna et al., 2014, which were previously cited in this policy, were included in this systematic review and meta-analysis).

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.

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.

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 auto triggered 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 auto triggered 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 auto triggered devices may have had single ECG leads whereas the CardioNet system uses double ECG leads.

Implantable Loop Recorder (ILR)

In a randomized, multicenter, clinical trial, Bernstein et al. (2021) evaluated if long-term cardiac monitoring is more effective than usual care for detecting AF in patients who had a stroke attributed to large- or small- vessel disease. The study included 496 patients who were ≥ 60 years old or aged 50-59 with one or more additional stroke risk factor and had an index stroke due to large- or small-vessel disease within 10 days prior to ICM insertion. Two hundred and forty-two people in the intervention group received ICM insertion within 10 days of the index stroke, the control group (n = 250) received usual care which consisted of external cardiac monitoring (e.g. 12 lead ECG, Holter monitor, telemetry, event recorder). The individuals were monitored for AF incidents lasting more than 30 seconds through 12 months. Clinical and monitoring data were collected at baseline and one, six, and 12 months after randomization, and continued at six-month intervals up to 36 months or the end of ICM battery life. Among 492 patients who were randomized, 417 (84.8%) completed 12 months of follow-up. The median (interquartile range) CHA2DS2-VASc (congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or TIA, vascular disease, age 65 to 74 years, sex category) score was five (4-6). AF detection at 12 months was significantly higher in the ICM group vs the control group (27 patients [12.1%] vs four patients [1.8%]; hazard ratio, 7.4 [95% CI, 2.6-21.3]; p < .001). Among the 221 patients in the ICM group who received an ICM, four (1.8%) had ICM procedure–related adverse events (one site infection, two incision site hemorrhages, and one implant site pain). The authors concluded monitoring with an ICM detected significantly more AF over 12 months than the usual care in patients with a stroke attributed to large- or small- vessel disease. The authors recommend further research to ascertain if identifying AF in this group of patients is of clinical value. Limitations include lack of blinding and the study was industry sponsored. Additionally, the study failed to show an impact of the intervention on the risk of recurrent stroke.

Buck et al. (2021) conducted a RCT in patients with a recent ischemic stroke to evaluate if 12 months of ILR monitoring detects more occurrences of AF compared with external loop recorder monitoring for 30 days. The study included 300 patients at three hospitals between May 2015 and November 2017 who were within six months of ischemic stroke without known AF. Individuals were randomly assigned to either the external loop recorder group (n = 150) or the implantable loop recorder group (n = 150). Development of highly probably or definite AF was the primary outcome. There were eight secondary outcomes including recurrent ischemic stroke, intracerebral hemorrhage, and time to event analysis of new AF. One hundred and twenty-one of the 300 participants were female, 66.3% had a stroke of undetermined etiology, 273 completed cardiac monitoring lasting 24 hours or longer, and 259 completed both the assigned monitoring and 12-month follow-up visit. The primary outcome was observed in 15.3% (23/150) of patients in the implantable loop recorder group and 4.7% (7/150) of patients in the external loop recorder group. Of the eight specified secondary outcomes, six were not significantly different. There were five patients in the ILR group who had recurrent ischemic stroke versus eight patients in the external loop recorder group, one person in each group had intracerebral hemorrhage, three participants in each group died, and one person in the ILR group had device-related serious adverse events. The authors concluded implantable electrocardiographic monitoring for 12 months resulted in a significantly higher proportion of patients with AF

detected when compared with external monitoring for 30 days. The authors note that the study has several limitations such as the delay of two months between stroke onset and study enrollment, variability in the investigations that were completed before enrollment, and lack of a validated questionnaire to assess for new stroke event or TIA. Additionally, there was potential bias due to manufacturer sponsorship. The authors recommend further research to compare clinical outcomes related to these monitoring strategies.

Svendsen et al. (2021) conducted a RCT in four centers to investigate whether AF screening and subsequent use of anticoagulants when AF was detected can prevent strokes in high-risk individuals. The trial included participants who were 70-90 years old, without AF, with at least one additional stroke risk factor such as hypertension, diabetes, heart failure or a previous stroke. Individuals were randomized in a 1:3 ratio to ILR monitoring, or usual care (control) via an online system in permuted blocks with block sizes of four or eight stratified according to center. Anticoagulation was recommended in the ILR group if AF episodes lasted six minutes or longer. Time to first stroke or systemic arterial embolism was the primary outcome. Individuals (n = 6205) where screened for inclusion from January 2014 to May 2016. A total of 6004 were included and randomly assigned: 4503 to usual care and 1504 to ILR monitoring. No participants were lost to follow-up. During a median follow-up of 64·5 months, AF was diagnosed in 1027 participants: 477 (31·8%) of 1501 in the ILR group versus 550 (12·2%) of 4503 in the control group (hazard ratio [HR] 3·17 [95% CI 2·81-3·59]; p < 0·0001). Oral anticoagulation was initiated in 1036 participants: 445 (29·7%) in the ILR group versus 591 (13·1%) in the control group (HR 2·72 [95% CI 2·41-3·08]; p < 0·0001), and the primary outcome occurred in 318 participants (315 stroke, three systemic arterial embolism): 67 (4·5%) in the ILR group versus 251 (5·6%) in the control group (HR 0·80 [95% CI 0·61-1·05]; p = 0·11). Major bleeding occurred in 221 participants: 65 (4·3%) in the ILR group versus 156 (3·5%) in the control group (HR 1·26 [95% CI 0·95-1·69]; p = 0·11). The authors concluded that ILR screening resulted in a three-times increase in AF detection and anticoagulation initiation for individuals with stroke risk factors but no statistically significant reduction in the risk of systemic arterial embolism or risk of stroke.

Solbiati et al (2017) conducted a systematic review and meta-analysis to explore the diagnostic yield of ILRs in members with recurrent, unexplained syncope in the absence of high-risk criteria and in high-risk members after a negative assessment. Forty-nine studies consisting of adults (n = 4381) who underwent ILR implantation for unexplained syncope were included. The overall diagnostic yield, defined as the proportion of members with syncope recurrence and an ILR recording or automatic detection of a significant arrhythmia was the primary outcome. Proportions of members with specific etiologic diseases on the total of subjects and the proportion of an analyzable ECG recording during symptoms, were considered secondary outcomes. The overall diagnostic yield was 43.9% (95% CI = 40.2%, 47.6%). The authors concluded that approximately 50% of members had arrhythmias and about half of the people with unexplained syncope implanted with an ILR were diagnosed.

A Cochrane systematic review (Solbiati et al., 2016) of four RCTs (n = 579) also assessed the diagnostic yield of ILRs versus conventional diagnostic workup in people with unexplained syncope. Participants in the standard assessment group experienced lower rates of diagnosis (RR = 0.61, 95% CI 0.54 to 0.68; participants = 579; studies = 4; moderate quality evidence), as compared to participants who underwent ILR implantation. However, the included studies overlapped with Solbiati et al. (2017).

In a multicenter randomized prospective study, Da Costa et al. (2013) compared conventional testing with prolonged ILR monitoring following the first syncopal episode in individuals with bundle branch block (BBB) and a negative workup. Seventy-eight individuals were randomized to ILR (n = 41) or conventional follow up (n = 37) from January 2005 to December 2010. Those in the conventional strategy group were seen in the outpatient department at 3, 6, 12,15,18, 21, 24, 27, 30 and 33 months after randomization and at the end of the study (36 months). At each outpatient visit, arrhythmic or cardiovascular events were documented, and a 12-lead electrocardiogram was obtained. Additionally, a Holter monitor was used for 7 days. There was a significant difference noted between the ILR group (n-15/41; 36%) and the conventional follow-up group (n = 4/37; 10.8%) in detection of relevant arrhythmias. The authors concluded the ILR strategy was superior to the conventional follow-up in detecting recurrent events, which may have a potential impact on therapeutic management.

Cardiac Self-Monitoring Devices

Cardiac self-monitoring devices and/or software applications that download ECG data to a personal computer, smart phone, smart watch or tablet are considered convenience items and are unproven and not medically necessary due to a lack of quality research demonstrating safety and efficacy of the devices or applications for identifying cardiac arrhythmias.

In an Evolving Evidence Review on the clinical utility of mobile medical applications (MMAs) for the detection of cardiac arrhythmias, Hayes (2021) reported that there was no or unclear support for the clinical utility of MMAs for the detection of cardiac arrhythmias. The review noted that there were no studies or systematic reviews that clearly demonstrated a

benefit in clinical outcomes associated with the use of MMAs when compared to alternative monitoring modalities. The review noted that, while the studies included in the review reported a higher rate of detection of cardiac arrhythmia episodes in patients monitored with MMAs compared to routine care or Holter monitoring, the studies may have been too small or had inadequate follow-up periods to determine differences in patient health outcomes. One of the two systematic reviews reflected unclear benefit of MMAs to improve patient health outcomes while another systematic review reported a benefit of MMAs on management of AF for treatment initiation and a second reported benefit of MMAs on time to detection of cardiac arrhythmia episodes. The review was updated in 2023 with seven newly published studies, but there was no change to the current level of support (Hayes 2021; updated 2023).

Koh et al (2021) conducted a multicenter open label RCT to determine the diagnostic efficacy of a 30-day smartphone ECG recording compared with a 24-hour Holter monitoring for detecting AF lasting 30 seconds or more. The study, which was reviewed in the Hayes 2021 Evolving Technology Review above, included 203 participants 55 years old or older, without known AF who had experienced an ischemic stroke or TIA of undetermined cause within the previous 12 months. The participants were randomly assigned to the control group where they underwent one additional 24-hour Holter monitoring (n = 98) or to the intervention group where they participated in a 30-day smartphone ECG monitoring program using the KardiaMobile (AliveCor®) application on the smartphone 3 times a day or whenever they felt palpitations. The primary outcome was determined at 3 months after randomization to allow variation in duration from randomization to initiation of ECG monitoring. Secondary outcomes included the use of anticoagulation therapy at 3 months and the performance of the application. The authors reported that AF lasting 30 seconds or longer was detected in 10 of 105 participants in the intervention group and 2 of 98 participants in the control group (9.5% vs. 2% for an absolute difference of 7.5%). They also noted that there was a significantly higher proportion of participants from the intervention group who were on oral anticoagulation therapy at 3 months compared with baseline whereas the proportion of patients on oral anticoagulation therapy at 3 months compared with baseline in the control group was not statistically different. The authors reported that the KardioMobile application reported 13.1% ECGs as unclassified and 3.2% of the ECGs were reported as possible AF. They found that the majority of unclassified ECGs were due to signal artifacts and short (< 30 second) ECG recording. Of the 3.2% (218) possible AF ECG reporting, over 75% of them were determined to be false positive for AF. The authors noted a couple of limitations of the study including the use of a single lead ECG as multiple lead smartphone ECG devices are now available, and the behavioral bias of the physicians to the use of anticoagulation therapy as some participants were prescribed therapy despite not having AF detected while others were found to have AF but were not prescribed the anticoagulation therapy. The authors concluded that the 30-day smartphone ECG recording significantly improved the detection of AF when compared to the standard repeat 24-hour Holter monitoring in patients aged 55 or older with a recent cryptogenic stroke or TIA. It is unclear if the findings in this Malaysian population would be generalizable to a US population.

In the iPhone Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART) single-center, two-arm RCT, Caceres et al. (2020) evaluated the impact of the iHEART intervention on health-related quality of life (HRQOL) in patients with documented AF who were undergoing treatment for their AF with either direct current cardioversion or radiofrequency ablation to restore normal sinus rhythm . A total of 238 English-and Spanish-speaking adults were randomized to either the smartphone-based ECG monitoring and motivational text messaging intervention group (n = 115) or to receive usual care (n = 123) for six months. The participants were primarily male (77%) and white (76%). HRQOL was measured using the Atrial Fibrillation Effect on Quality of Life (AFEQT), the 36-item Short-Form Health survey, and the EQ-5D. The authors reported that both arms had improved scores from baseline to follow-up for AFEQT and AF symptom severity scores although there were no statistically significant differences in HRQOL, quality-adjusted life-years (QALYs) or AF symptom severity between groups. The authors felt it was likely that the improvements in atrial fibrillation-specific HRQOL and symptom severity were due to all participants having undergone treatment for AF. Limitations noted by the authors included that the study only included a single practice location in an urban setting, the propensity of the participants to be white males, the small sample size and the limited frequency and duration of follow-up assessments (baseline and at six months). Additionally, the study is limited by multiple comparisons, which could have led to statistically significant differences due to chance only. Furthermore, the study design does not allow to differentiate whether the observed difference in HRQOL were due to the arrythmia detection or to the motivational text messages. The authors recommend additional research with longer follow-up to examine the influence of smartphone-based interventions for AF management on HRQOL and to address the unique needs of patients diagnosed with different subtypes of AF.

Perez et al. (2019) conducted a prospective, open-label, single arm, site-less, pragmatic study (Apple Heart Study) to determine the proportion of participants using a smartwatch application that were ultimately identified as having AF. The 8-month study included 419,297 participants who self-reported no history of AF and self-monitored for a median of 117 days. Eligibility criteria included possession of a compatible Apple iPhone and Apple Watch, age of 22 years or older residing in the United States and proficient in English. The study app was used to verify eligibility, obtain consent, provide study education and provide direction through the study procedures. Study visits with physicians were conducted through telemedicine. There were 2,161 participants (0.52%) who received notifications via the smartwatch application of an

irregular pulse who were then sent an ECG patch (ePatch) to wear for seven days. The investigators received 450 ECG patches back that had been applied within 14 days of shipment for at least 1 hour and were returned within 45 days after the first study visit. They reported that AF was present in 153 (34%) of the participants who returned the ECG patches overall. The ECG patches worn by participants aged 65 or older had a diagnostic yield of AF of 35% whereas participants younger than 40 years of age had a diagnostic yield of AF of 18%. Participants were prompted to initiate a second telemedicine visit to discuss the ambulatory ECG findings and were then directed to follow-up care as the study-visit physicians did not initiate any treatment. Of the 2161 participants who received an irregular pulse notification, 1376 returned a 90-day survey which showed that 787 (57%) contacted a health care provider outside of the study, 28% were prescribed a new medication, 33% were referred to a specialist and 36% were recommended to have additional testing. Another survey at the end of the study with this same group had a survey return rate of 43% (929 participants) with 404 (44%) reporting a new AF diagnosis. In the analysis of survey results from participants who did not have a notification from the app, 3070 (1%) reported a new diagnosis of AF. The authors also reported that the notification subgroup self-reported a greater incidence of strokes, heart failure, and myocardial infarctions than did the non-notification group. The authors concluded that the probability of receiving an irregular pulse notification was low; however, among the participants who received notification by the application of an irregular pulse, 34% were found to have AF on subsequent ECG patch readings. They noted that the study had several limitations including a lower return/response rate from participants in initiating contact with the study provider and with returning ECG patches than anticipated, reliance on participants and their own assessments regarding their eligibility for inclusion, the younger demographic presence in the study population, substantial loss to follow-up, and the lack of physical / face-to-face contact with the participants. Lack of comparison group undergoing a different intervention to screen for AF was another limitation. The authors recommend rigorous investigation of the technology and its use in clinical settings, including how the technology can further guide evaluation and treatment to improve clinical outcomes.

Clinical Practice Guidelines

American Academy of Neurology (AAN)

An AAN practice guideline 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)/American College of Clinical Pharmacy (ACCP)/Heart Rhythm Society (HRS)

Joglar et al. (2023) developed a guideline for the diagnosis and management of patients with AF using evidence-based methodologies. Recommendations from the “2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation” and the “2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation” were updated with new evidence. Recommendations of the guideline are summarized as follows (not all-inclusive):

- 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 ICM is reasonable. (Strength of recommendation, 2A-moderate, quality of evidence, B-R-randomized)
- 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. (Strength of recommendation, 2A-moderate, quality of evidence, B-R-randomized)

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 el., 2014). A focused update of these guidelines has a new section on device detection of AF and atrial flutter. The update recommends that in patients with cryptogenic stroke in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF (January et al., 2019).

ACC/AHA/HRS guidelines on the evaluation and management of patients with bradycardia and cardiac conduction delay state that for those with daily symptoms, a 24- or 48-hour continuous ambulatory ECG (Holter monitor) is appropriate. Less frequent symptoms are best evaluated with more prolonged ambulatory ECG monitoring that can be accomplished with a broad array of modalities. In patients with infrequent symptoms (> 30 days between symptoms) suspected to be caused by bradycardia, long-term ambulatory monitoring with an ICM is reasonable if initial noninvasive evaluation is nondiagnostic (Kusumoto et al., 2019).

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/non sustained 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 College of Cardiology (ACC)

Joint guidelines on the diagnosis and treatment of hypertrophic cardiomyopathy state that in the presence of symptoms, ambulatory ECG monitoring should be continued until an individual has symptoms while wearing the monitor. In some individuals with infrequent symptoms, portable event monitors or implantable monitors may be warranted (Ommen et al., 2020).

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

The AHA and ASA released a guideline for the prevention of stroke in patients with stroke and TIA that recommends heart rhythm monitoring for occult AF if there was no other cause of stroke discovered. The authors also recommend further research to clarify the optimal duration of heart rhythm monitoring (Kleindorfer et al., 2021).

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).

Canadian Cardiovascular Society(CCS)/Canadian Heart Rhythm Society (CHRS)

The CCS and CHRS developed a guideline for the management of AF that recommends at least 24 hours of ambulatory ECG monitoring to identify AF in patients with nonlacunar cryptogenic stroke. The guideline additionally suggests monitoring for AF detection with an external loop recorder or implantable cardiac monitoring for patients with nonlacunar cryptogenic stroke in whom AF is suspected but unproven (Andrade et al., 2020).

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. The guideline noted that the overall post-stroke AF detection after all phases of cardiac monitoring is approximately 23.7% based on RCTs reviewed as part of the guideline development. The ESC made a strong recommendation (Class 1B) for short-term ECG recording for at least the first 24 hours followed by continuous ECG monitoring for at least 72 hours in patients with acute ischemic stroke or TIA whenever possible. They also recommend (Class IIa) that additional ECG monitoring using long-term non-invasive ECG monitors or insertable cardiac monitors should be considered to detect AF in selected stroke

patients without previously known AF such as patients who are elderly, who have cardiovascular risk factors or comorbidities, indices of left atrial remodeling or a high C_2HEST score. The ESC also made a strong recommendation (Class I) for opportunistic screening for AF by pulse or ECG rhythm strip in patients ≥ 65 years of age and a lower recommendation (Class IIa) for consideration of systematic ECG screening to detect AF in individuals aged ≥ 75 years, or for individuals at high risk of stroke. 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. They also note that mobile health technologies are rapidly developing for AF detection and other purposes and that caution is needed in their clinical use as many are not clinically validated. Prolonged ECG monitoring is also reasonable in survivors of ischemic stroke without an established diagnosis of AF (Hindricks, 2021).

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).

European Stroke Organisation (ESO)

The ESO guideline on screening subclinical AF after stroke or TIA of undetermined origin recommends, a prolonged cardiac monitoring instead of standard 24 hour monitoring to increase the detection of subclinical AF in adult patients. The guideline also we suggests the use of implantable devices for cardiac monitoring instead of non-implantable devices to increase the detection of subclinical AF (Rubiera, 2022).

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. The guidelines note that Holter monitors are typically worn for 24-48 hours, patch monitors are worn 7-14 days, event/loop monitors are worn for 30 days, and ambulatory cardiac telemetry monitors are worn up to 30 days. Frequency of symptoms should dictate the type of recording: longer term ECG monitoring is required for more infrequent events. The most appropriate clinical workflow may include a continuous (short-term 24 hour and up to 7 days) ambulatory ECG monitoring, which if unsuccessful, is followed by intermittent external loop recording (long term from weeks to months). For those individuals remaining undiagnosed after prolonged noninvasive monitoring, ILR may be necessary (Steinberg et al., 2017).

International Society for Holter and Noninvasive Electrocardiology (ISHNE)/Heart Rhythm Society (HRS)/ European Heart Rhythm Association (EHRA)/Asia Pacific Heart Rhythm Society (APHRS)

In a collaborative statement on mobile health technologies in arrhythmia management, the ISHNE, HRS, EHRA and APHRS describe the range of digital medical tools and heart rhythm disorders to which they may be applied. The current status, limitations and benefits of mobile health-based modalities, including wearable patches, Holter, MCOT and implantable loop recorders are reviewed (Varma et al., 2021).

National Institute for Health and Care Excellence (NICE)

In a guideline on the management of atrial AF, NICE recommends the following in patients with suspected paroxysmal AF undetected by 12-lead 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 ambulatory ECG monitor, event recorder, or other ECG technology should be used in those with symptomatic episodes more than 24 hours apart (NICE, 2021)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on ambulatory ECG devices, cardiac telemetry or implantable loop recorders, refer to the following website (use product codes DSI, MXD, and DXH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 5,2023)

The FDA classifies mobile cardiac self-monitoring devices as class II devices under the designation “transmitters and receivers, electrocardiograph, telephone.” For information on cardiac self-monitoring devices, refer to the following website (use product codes DXH, DPS and QDA): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 5, 2023)

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.

Andrade JG, Aguilar M, Atzema C, et al. The 2020 Canadian Cardiovascular Society/Canadian Heart Rhythm Society comprehensive guidelines for the management of atrial fibrillation. Can J Cardiol. 2020 Dec;36(12):1847-1948.

Bayoumy K, Gaber M, Elshafeey A, et al. Smart wearable devices in cardiovascular care: where we are and how to move forward. Nat Rev Cardiol. 2021 Aug;18(8):581-599.

Bernstein RA, Kamel H, Granger CB, et al. Effect of long-term continuous cardiac monitoring vs usual care on detection of atrial fibrillation in patients with stroke attributed to large- or small-vessel disease: The STROKE-AF randomized clinical trial. JAMA. 2021 Jun 1;325(21):2169-2177.

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.

Buck BH, Hill MD, Quinn FR, et al. Effect of implantable vs prolonged external electrocardiographic monitoring on atrial fibrillation detection in patients with ischemic stroke: The PER DIEM randomized clinical trial. JAMA. 2021 Jun 1;325(21):2160-2168.

Caceres BA, Hickey KT, Bakken SB, et al. Mobile electrocardiogram monitoring and health-related quality of life in patients with atrial fibrillation: Findings from the iPhone helping evaluate atrial fibrillation rhythm through technology (iHEART) study. J Cardiovasc Nurs. 2020 Jul/Aug;35(4):327-336.

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.

Da Costa A, Defaye P, Romeyer-Bouchard C, et al. Clinical impact of the implantable loop recorder in patients with isolated syncope, bundle branch block and negative workup: a randomized multicenter prospective study. Arch Cardiovasc Dis. 2013 Mar;106(3):146-54.

ECRI. Outpatient cardiac telemetry monitors for diagnosing and managing cardiac arrhythmias. Plymouth meeting (PA): ECRI; 2019, March. (Curated literature search). Updated January 2022.

Eysenck W, Freemantle N, Sulke N. A randomized trial evaluating the accuracy of AF detection by four external ambulatory ECG monitors compared to permanent pacemaker AF detection. J Interv Card Electrophysiol. 2020 Apr;57(3):361-369.

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. Evolving Evidence Review. Clinical utility of mobile medical applications for detection of cardiac arrhythmia episodes. Lansdale, PA: Hayes, Inc.; June 2021. Updated April 2023.

Hindricks G, Potpara T, Dagres N, et. al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. European Heart Journal, 2021 Feb;42(): 373–498.

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.

January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused update of the 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 Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2019 Jul 9;74(1):104-132.

Jiang H, Tan SY, Wang JK, et al. A meta-analysis of extended ECG monitoring in detection of atrial fibrillation in patients with cryptogenic stroke. Open Heart. 2022 Sep;9(2):e002081.

Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the diagnosis and management of atrial fibrillation: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation. 2023 Nov 30. Epub ahead of print.

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, Elijovich L, et al. Pilot randomized trial of outpatient cardiac monitoring after cryptogenic stroke. Stroke. 2013 Feb;44(2):528-30.

Kaura A, Sztriha L, Chan FK, et al. Early prolonged ambulatory cardiac monitoring in stroke (EPACS): an open-label randomized controlled trial. Eur J Med Res. 2019 Jul 26;24(1):25.

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.

Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline from the American Heart Association/American Stroke Association. Stroke. 2021 Jul;52(7):e364-e467.

Koh KT, Law WC, Zaw WM, et al. Smartphone electrocardiogram for detecting atrial fibrillation after a cerebral ischaemic event: a multicenter randomized controlled trial. Europace. 2021 Jul 18;23(7):1016-1023.

Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS Guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: 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. 2019 Aug 20;74(7):e51-e156. Erratum in: J Am Coll Cardiol. 2019 Aug 20;74(7):1016-1018.

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.

National Institutes of Health. National Heart, Lung, and Blood Institute. Arrhythmia. https://www.nhlbi.nih.gov/health/arrhythmias/diagnosis. March 24, 2022. Accessed December 5,2023.

National Institute for Health and Care Excellence (NICE). NG196. Atrial fibrillation: diagnosis and management. April 27, 2021. Updated June 30, 2021.

Noubiap JJ, Agbaedeng TA, Kamtchum-Tatuene J, et al. Rhythm monitoring strategies for atrial fibrillation detection in patients with cryptogenic stroke: A systematic review and meta-analysis. Int J Cardiol Heart Vasc. 2021 Apr 16;34:100780.

Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2020 Dec 22;142(25):e558-e631.

Perez MV, Mahaffey KW, Hedlin H, et al. Large-scale assessment of a smartwatch to identify atrial fibrillation. N Engl J Med. 2019 Nov 14;381(20):1909-1917.

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.

Rubiera M, Aires A, Antonenko K,. European Stroke Organisation (ESO) guideline on screening for subclinical atrial fibrillation after stroke or transient ischaemic attack of undetermined origin. Eur Stroke J. 2022 Sep;7(3):VI.

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.

Solbiati M, Casazza G, Dipaola F, et al. The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis. Int J Cardiol. 2017 Mar 15;231:170-176.

Solbiati M, Costantino G, Casazza G, et al. Implantable loop recorder versus conventional diagnostic workup for unexplained recurrent syncope. Cochrane Database of Systematic Reviews 2016, Issue 4. Art. No.: CD011637.

Sposato L, Cipriano L, Saposnik G, et al. Diagnosis of atrial fibrillation after stroke and transient ischaemic attack: a systematic review and meta-analysis. Lancet Neurol. 2015 Apr;14(4):377-87.

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.

Svendsen JH, Diederichsen SZ, Højberg S, et al. Implantable loop recorder detection of atrial fibrillation to prevent stroke (The LOOP Study): a randomized controlled trial. Lancet. 2021 Oct 23;398(10310):1507-1516.

Varma N, Cygankiewicz I, Turakhia M, et al. 2021 ISHNE/HRS/EHRA/APHRS collaborative statement on mHealth in arrhythmia management: digital medical tools for heart rhythm professionals: from the International Society for Holter and Noninvasive Electrocardiology/Heart Rhythm Society/European Heart Rhythm Association/Asia Pacific Heart Rhythm Society. J Arrhythm. 2021 Jan 29;37(2):271-319.

Policy History/Revision Information

Date	Summary of Changes

06/01/2024	**Coverage Rationale**
	• Replaced language indicating:
	  ○ "C*ardiac event monitoring is* proven and medically necessary for evaluating suspected cardiac arrhythmias *as outlined [in the policy]*" with "*the [listed services] are* proven and medically necessary for evaluating suspected cardiac arrhythmias"
	  ○ "Implantable Loop Recorder is proven and medically necessary for evaluating suspected cardiac arrhythmias for one or more of the [listed circumstances], *only if* noninvasive cardiac *monitoring* is contraindicated or yielded non-diagnostic results after at least ***3*** weeks of monitoring" with "Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias *when* noninvasive cardiac *event recording* is contraindicated or yielded non-diagnostic results after at least ***2*** weeks of monitoring in one or more of the [listed] circumstances
	  ○ "Replacement of implantable *ambulatory event monitors* is considered medically necessary for an individual who continues to meet all initial criteria for insertion described [in the policy] and the existing device is beyond its useful life span, is irreparable, or no longer operating" with "replacement of Implantable *Loop Recorders* is considered medically necessary for an individual who continues to meet all initial criteria for insertion described [in the policy] and the existing device is beyond its useful life span, is irreparable, or no longer operating"
	Outpatient Cardiac Telemetry
	• Removed list of proven and medically necessary indications
	Implantable Loop Recorders

Date	Summary of Changes
	• Revised list of circumstances when Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias; replaced: ○ "Suspected paroxysmal atrial fibrillation in the setting of cryptogenic stroke" with "suspected paroxysmal atrial fibrillation in the setting of a cryptogenic stroke *or another documented systemic thromboembolic event*" ○ "Recurrent or unexplained infrequent syncope, *if not diagnosed with 3 weeks of standard event monitoring and/or mobile cardiac outpatient telemetry,* after modification of potentially syncope-causing medications or associated with autonomic dysfunction" with "recurrent or unexplained infrequent syncope after modification of potentially syncope-causing medications or associated with autonomic dysfunction" **Documentation Requirements** • Updated list of HCPCS codes with associated documentation requirements; added E1399 **Applicable Codes** • Added CPT/HCPCS codes 93297, 93799, and E1399 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2024T0489EE

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 InterQual® criteria, 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.