Implantable Loop Recorders and Wearable Heart Rhythm Monitors

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Instructions for Use

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Commercial Policy

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Idaho	Cardiac Event Monitoring (for Idaho Only)
Indiana	None
Kansas	Cardiac Event Monitoring (for Kansas Only)
Kentucky	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for Kentucky Only)
Louisiana	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for Louisiana Only)
New Jersey	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for New Jersey Only)
New Mexico	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for New Mexico Only)
North Carolina	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for North Carolina Only)
Ohio	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for Ohio Only)
Pennsylvania	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for Pennsylvania Only)
Tennessee	Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for Tennessee Only)

Coverage Rationale

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 two 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 or 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

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

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, particularly if these symptoms are infrequent [National Institutes of Health (NIH), 2022].

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 federal, state, or contractual requirements 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
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

CPT Code	Description
Implantable Loop Recorder	
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	
0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device
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 (NIH, 2022).

Clinical Evidence

Implantable Loop Recorder (ILR)

Jiang et al. (2022) conducted a meta-analysis and systematic review to evaluate the current modalities used for extended electrocardiography (ECG) monitoring in the detection of atrial fibrillation (AF) following a cryptogenic stroke. Forty-seven studies with a total of 6,448 individuals 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 for individuals who have the cognitive and physical capacity to use ECG monitoring daily for one month, MCOT is effective in detecting a significant proportion of AF and should be considered in place of ILRs. However, ILRs may be considered for individuals needing extended monitoring, if MCOT does not detect AF after four weeks, or if compliance issues are expected. Limitations include significant unexplained heterogeneity, poor reporting of features of the study population, and risk underestimation of AF detection rates in MCOT studies.

In a randomized, multicenter, clinical trial (the STROKE-AF trial), Bernstein et al. (2021) evaluated if long-term cardiac monitoring is more effective than usual care for detecting AF in individuals who had a stroke attributed to large- or small-vessel disease. The study included 496 participants 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 implantable cardiac monitor (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 participants 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 (four-six). Atrial fibrillation detection at 12 months was significantly higher in the ICM group vs. the control group (27 participants [12.1%] vs. four participants [1.8%]; hazard ratio, 7.4 [95% CI, 2.6-21.3]; p < .001). Among the 221 participants 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 individuals with a stroke attributed to large- or small- vessel disease. The authors recommended further research to ascertain if identifying AF in this group of individuals 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. In 2023, Bernstein et al. reported the three-year results of the STROKE-AF trial. Out of the initial 492 participants, 314 completed the three-year follow-up. The study found that continuous cardiac monitoring with an ICM detected significantly more AF compared to usual care. Specifically, AF was detected in 21.7% (n = 46) of participants in the ICM group versus 2.4% in the control group (n = five). The authors concluded that individuals with ischemic stroke due to large artery disease or small vessel disease have a growing risk of developing AF over time. According to the authors, most AF episodes are not consistently identified by standard medical monitoring methods; therefore, a year of negative monitoring should not give clinicians confidence that individuals who had a stroke will be free of AF in the subsequent two years. Limitations included that the treatment for AF was neither randomized nor prescribed by the study protocol. Additionally, the reasons for oral anti-coagulation use or non-use were not documented, and the study was not designed to detect differences in recurrent stroke rates.

Buck et al. (2021) conducted a randomized controlled trial (RCT) in individuals 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 participants 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 ILR 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 participants in the ILR group and 4.7% (7/150) of participants in the external loop recorder group. Of the eight specified secondary outcomes, six were not significantly different. There were five participants in the ILR group who had recurrent ischemic stroke versus eight participants 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 ECG monitoring for 12 months resulted in a significantly higher proportion of individuals 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 recommended further research to compare clinical outcomes related to these monitoring strategies.

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 individuals with embolic stroke of undetermined source (ESUS) or cryptogenic stroke. 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 individuals with cryptogenic stroke 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 individuals with cryptogenic stroke or ESUS were included. Using ICM, the pooled rate of AF was 12.2% at three months, 16.0% at six months, 18.7% at 12 months, 22.8% at 24 months, and 28.5% at 36 months. Atrial fibrillation rates were significantly higher in individuals with ESUS vs. cryptogenic stroke (22.0% vs. 14.2%; p < 0.001) at six 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 one 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 individuals with cryptogenic stroke or ESUS are diagnosed with AF during follow-up and about one in seven individuals had AF detected within a month of MCOT,

suggesting that a non-invasive rhythm monitoring strategy should be considered before invasive monitoring (Sanna et al. 2014, which was previously cited in this policy, was included in this systematic review and meta-analysis).

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 = 6,205) where screened for inclusion from January 2014 to May 2016. A total of 6,004 were included and randomly assigned: 4,503 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 1,027 participants: 477 (31.8%) of 1,501 in the ILR group versus 550 (12.2%) of 4,503 in the control group (hazard ratio [HR] 3.17 [95% CI 2·81-3·59]; p < 0·0001). Oral anticoagulation was initiated in 1,036 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 = 4,381) 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 = four; 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 three, six, 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 ECG was obtained. Additionally, a Holter monitor was used for seven 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 a 2023 RCT, Ding et al. evaluated the accuracy, usability, and adherence of smartwatches for AF detection in older adults who had previously experience a stroke. The RCT, named Pulsewatch, involved 120 participants who were provided with either a smartwatch-smartphone system and an ECG patch or the patch alone for 14 days to assess the usability and accuracy of the system for AF detection (phase one). In phase two, the participants were rerandomized for an additional 30 days of system use to determine adherence to watch wear. The accuracy for AF detection was determined by comparing it to cardiologist-overread ECG patch, and the usability was assessed with the System Usability

Scale. Participants were aged 50 years or older, had a history of transient ischemic attack (TIA) or ischemic stroke within the past decade, were willing to use the Pulsewatch system for 44 days, and were proficient in English. The study found that the smartwatch system demonstrated 92.9% accuracy in detecting AF. Usability was assessed with a mean score of 65 out of 100, with participants wearing the watch for an average of 21.2 days out of 30. According to the authors, the findings suggested that while smartwatches are a viable option for long-term arrhythmia detection, strategies to improve adherence to watch wear are needed. Limitations included a relatively small sample size and a short duration of the trial.

The meta-analysis by Manetas-Stavrakakis et al. (2023) reviewed the diagnostic accuracy of artificial intelligence (AI)-based technologies for AF. The study conducted a systematic review of 31 eligible diagnostic accuracy studies, all of which employed either a case-control or cohort design. Eight studies used smartwatches and three used cell phones. The main technologies used were photoplethysmography (PPG) and single-lead ECG. Pooled sensitivity and specificity were 95.1% and 96.2% for PPG and 92.3% and 96.2% for single-lead ECG, respectively. In the PPG group, 0% to 43.2% of the tracings could not be classified using the AI algorithm as AF or not, and in the single-lead ECG group, the figure fluctuated between 0% and 38%. The authors concluded the analysis demonstrated AI-based methods for the diagnosis of AF have high sensitivity and specificity for the detection of AF. The authors note further research is needed to assess the impact of these technologies on clinical outcomes and patient care. The analysis also highlighted several limitations such as the variability in study designs and potential biases in participant selection.

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 individuals 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 three times a day or whenever they felt palpitations. The primary outcome was determined at three months after randomization to allow variation in duration from randomization to initiation of ECG monitoring. Secondary outcomes included the use of anticoagulation therapy at three 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 two 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 three months compared with baseline whereas the proportion of individuals on oral anticoagulation therapy at three months compared with baseline in the control group was not statistically different. The authors reported that the KardiaMobile 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. According to the authors, the 30-day smartphone ECG recording significantly improved the detection of AF when compared to the standard repeat 24-hour Holter monitoring in individuals 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 U.S. 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 individuals 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 remarked the likely reason for the improvements in AF-specific HRQOL and symptom severity was that all participants had received 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 recommended 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 individuals 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 eight-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 one 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, 1,376 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, 3,070 (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 recommended 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 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):

- In patients with AF-induced cardiomyopathy who have recovered LV function, long-term surveillance can be beneficial to detect recurrent AF in view of the high risk of recurrence of arrhythmia-induced cardiomyopathy. (Strength of recommendation 2a-moderate, quality of evidence, B-NR-moderate/non-randomized).
- 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-moderate/randomized).

- In patients with an onset of AF before 45 years of age without obvious risk factors for AF, referral for genetic counseling, genetic testing for rare pathogenic variants, and surveillance for cardiomyopathy or arrhythmia syndromes may be reasonable. (Strength of recommendation 2b-weak, quality of evidence, B-NR-moderate/non-randomized).
- In patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an ILR are reasonable to improve detection of AF. (Strength of recommendation, 2a-moderate, quality of evidence, B-R-moderate/randomized).
- Use and applicability of consumer-based wearable heart monitoring devices: These devices are now widespread and are used to diagnose and monitor response to therapy in individuals with AF. Validation on the accuracy of the most common available technologies is needed. How to best use these devices in practice, including for AF screening, must be better defined. (Future research needs).

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 ECG, 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 and to evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful. The authors note that while the diagnostic yield of an external loop recorder may be lower than that of an ICM, using the noninvasive strategy as an initial approach is reasonable. Furthermore, the guidelines indicate that patients with recurrent, infrequent, unexplained syncope (or suspected atypical reflex syncope) of suspected arrhythmic origin, after a nondiagnostic initial workup, with or without structural heart disease, are suitable candidates for implantable cardiac monitoring.

AHA/ACC/HRS guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death state that ICMs can be useful for detecting ventricular arrhythmias in patients with sporadic symptoms, including syncope. 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 College of Cardiology (ACC)/American Medical Society for Sports Medicine (AMSSM)/Heart Rhythm Society (HRS)/Pediatric & Congenital Electrophysiology Society (PACES)/Society for Cardiovascular Magnetic Resonance (SCMR)

Ommen et al. (2024) developed AHA/ACC/AMSSM/HRS/PACES/SCMR guidelines for the management of hypertrophic cardiomyopathy (HCM). The guidelines recommendations for heart rhythm assessment include (not all-inclusive):

- In patients with HCM, 24- to 48-hour ambulatory ECG monitoring is recommended in the initial evaluation and as part of periodic follow-up (every one-two years) to identify patients who are at risk for sudden cardiac death and to guide management of arrhythmias. (Strength of recommendation: 1-strong, level of evidence: B-NR-nonrandomized).

- In patients with HCM who develop palpitations or lightheadedness, extended (> 24 hours) ECG monitoring or event recording is recommended for arrhythmia diagnosis and clinical correlation. (Strength of recommendation: 1-strong, level of evidence: B-NR- nonrandomized).
- In patients with HCM who are deemed to be at high risk for developing AF based on the presence of risk factors or as determined by a validated risk score, and who are eligible for anticoagulation, extended ambulatory monitoring is recommended to screen for AF as part of initial evaluation and annual follow-up. (Strength of recommendation: 1-strong, level of evidence: B-NR- nonrandomized).
- In adult patients with HCM without risk factors for AF and who are eligible for anticoagulation, extended ambulatory monitoring may be considered to assess for asymptomatic paroxysmal AF as part of initial evaluation and periodic follow-up (every one-two years). (Strength of recommendation: 2B-weak, level of evidence: B-NR- nonrandomized).

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

The AHA and ASA have issued guidelines for preventing stroke in patients with a history of stroke and TIA. The guideline highlights that AF is a common and high-risk factor for secondary ischemic strokes and suggests heart rhythm monitoring for occult AF when no other cause of stroke is identified. The guideline recommended that for those with cryptogenic stroke who are not contraindicated for anticoagulation, it is reasonable to use long-term rhythm monitoring, such as mobile cardiac outpatient telemetry, ILRs, or other methods, to detect intermittent AF. The authors also recommended 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).

Nielsen et al. (2020) developed an expert consensus statement on risk assessment in cardiac arrhythmias, aiming to raise awareness about using the appropriate risk assessment tool for specific outcomes in particular populations, and to offer physicians practical recommendations that could enhance patient care. According to the authors:

- An ILR is indicated in the evaluation of patients with infrequent, recurrent syncope of uncertain origin, particularly when ambulatory monitoring has been inconclusive.
- An ILR is indicated in patients with syncope and high-risk criteria where a comprehensive evaluation has not identified a cause of syncope or led to a specific treatment, and who do not have conventional indications for primary prevention ICD or pacemaker.
- An ILR may be considered in patients experiencing palpitations, dizziness, pre-syncope, frequent premature ventricular complexes (PVCs)/non-sustained ventricular tachycardia, and in those with suspected AF, and post-AF ablation.

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 guidelines 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. Additionally, prolonged ECG monitoring is also considered 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 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)

Joglar et al. developed an HRS consensus statement regarding cardiac arrhythmia management during pregnancy. The statement recommends (not all-inclusive):

- Pregnant patients with suspected arrhythmic etiology of unexplained palpitations who have concerning symptoms or suspected electrical or structural heart disease on initial evaluation should undergo ambulatory monitoring as clinically indicated, in consultation with a cardiologist or electrophysiologist with expertise in cardiovascular diseases in pregnancy. (Strength of recommendation 1-strong, quality of evidence, B-NR-moderate/non-randomized).
- In pregnant patients with suspected arrhythmic etiology of palpitations unexplained after noninvasive cardiac evaluation, especially in the presence of syncope and/or electrical or structural heart disease, consideration of an ICM is reasonable. (Strength of recommendation 2a-moderate, quality of evidence, C-LD-limited data).
- In pregnant patients with recurrent syncope unexplained after comprehensive noninvasive evaluation, including external monitor, insertion of an ICM is recommended. (Strength of recommendation 1-strong, quality of evidence, C-LD-limited data).

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 seven-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 seven 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 ILRs 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).

A NICE guideline suggests that the Reveal LINQ ILR can be used to identify AF following a cryptogenic stroke, including TIA, but only when non-invasive ECG monitoring has been performed and a cardiac arrhythmia is still suspected as the cause of the stroke (NICE, 2020).

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 ILR, 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 11, 2024)

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 11, 2024)

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.

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.

Bernstein RA, Kamel H, Granger CB, et al.; STROKE AF investigators. Atrial fibrillation in patients with stroke attributed to large- or small-vessel disease: 3-year results from the STROKE AF randomized clinical trial. JAMA Neurol. 2023 Dec 1;80(12):1277-1283.

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.

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.

Ding EY, Tran KV, Lessard D, et al. Accuracy, usability, and adherence of smartwatches for atrial fibrillation detection in older adults after stroke: randomized controlled trial. JMIR Cardio. 2023 Nov 28;7:e45137.

Hayes, Inc. Evolving Evidence Review. Clinical utility of mobile medical applications for detection of cardiac arrhythmia episodes. 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. Correction to: 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. 2024 Jan 2;149(1):e167. Epub 2023 Dec 28. Erratum for: Circulation. 2024 Jan 2;149(1):e1-e156.

Joglar JA, Kapa S, Saarel Ev et al. 2023 HRS expert consensus statement on the management of arrhythmias during pregnancy. Heart Rhythm. 2023 Oct;20(10):e175-e264.

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.

Manetas-Stavrakakis N, Sotiropoulou IM, Paraskevas T, et al. Accuracy of artificial intelligence-based technologies for the diagnosis of atrial fibrillation: a systematic review and meta-analysis. J Clin Med. 2023 Oct 17;12(20):6576.

National Institute for Health and Care Excellence (NICE). DG41. Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke. September 02, 2020.

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

National Institutes of Health. National Heart, Lung, and Blood Institute. Arrhythmia. https://www.nhlbi.nih.gov/health/arrhythmias/diagnosis. March 24, 2022. Accessed December 4, 2024.

Nielsen JC, Lin YJ, de Oliveira Figueiredo MJ, et al. European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS) expert consensus on risk assessment in cardiac arrhythmias: use the right tool for the right outcome, in the right population. J Arrhythm. 2020 Jun 15;36(4):553-607.

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, Ho CY, Asif IM, et al.; Peer Review Committee Members. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR guideline for the management of hypertrophic cardiomyopathy: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. 2024 Jun 4;149(23):e1239-e1311. Epub 2024 May 8. Erratum in: Circulation. 2024 Aug 20;150(8):e198.

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.

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.

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.

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
07/01/2025	**Application** ***Louisiana*** and ***New Mexico*** • Updated reference link to reflect the current title for state-specific policy version

06/01/2025	**Title Change**
	• Previously titled *Cardiac Event Monitoring*
	Application
	Idaho and ***Kansas***
	• Added language to indicate this Medical Policy does not apply to the states of Idaho and Kansas; refer to the state-specific policy versions
	Coverage Rationale
	• Removed language indicating 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
	• Replaced language indicating "wearable heart rhythm monitors (Cardiac Self-Monitoring Devices) commercially available to the general public and purchased for home use are not medically necessary" with "wearable heart rhythm monitors *or* Cardiac Self-Monitoring Devices commercially available to the general public and purchased for home use are not medically necessary"
	Medical Records Documentation Used for Reviews
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews
	Definitions
	• Removed definition of:
	  ○ Ambulatory Event Monitoring/Electrocardiography (ECG)
	  ○ Attended Surveillance
	  ○ Outpatient Cardiac Telemetry
	• Updated definition of "Implantable Loop Recorder"

Date	Summary of Changes
	Applicable Codes • Removed CPT codes 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, and 93272 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS092.U

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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