# Implantable Loop Recorders and Wearable Heart Rhythm Monitors

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## Application

### UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

### UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

## Coverage Rationale

**Note**: This policy does not apply to individuals < 18 years of age.

Implantable Loop Recorders **are proven and medically necessary for evaluating suspected cardiac arrhythmias when noninvasive cardiac event recording is contraindicated or has yielded nondiagnostic 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
- Post-cavotricuspid isthmus ablation for typical atrial flutter if the individual is not on long-term anticoagulation and is at high thromboembolic risk (e.g., $CHA_2DS_2$-VASc ≥ 2 or HATCH score of at least 2)
- Atrial fibrillation detected during an acute medical illness or following surgery, particularly after noncardiac procedures and in individuals with stroke risk factors (e.g., $CHA_2DS_2$-VASc ≥ 2)
- 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 lifespan, 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 electrocardiographic monitor combined with a personal electronic device such as a cellular telephone or watch
- Hardware or software required for downloading electrocardiographic data to a device such as a personal computer, tablet, or smartphone

## Medical Records Documentation Used for Reviews

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. 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 protocol 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 physiological information to download onto an individual's smartphone, 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 electrocardiography (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, 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 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 |
|---|---|
| **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 |

| CPT Code | Description |
|---|---|
| **Implantable Loop Recorder** | |
| 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 |

*CPT® is a registered trademark of the American Medical Association*

| 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 monitoring. The type and duration of ambulatory electrocardiography monitoring are dictated by the frequency of symptoms (National Institutes of Health, 2022).

# Clinical Evidence

## Implantable Loop Recorder

Janmohamadi et al. (2025) conducted a systematic review and meta-analysis to compare implantable loop recorders (ILRs) with usual care for detecting atrial fibrillation (AF) and their impact on mortality and secondary stroke prevention in individuals with prior stroke or high-risk profiles. The review included 12 studies, four randomized controlled trials (RCTs), and eight cohort studies, encompassing 72,846 individuals. ILR use was associated with a significantly higher AF detection rate [hazard ratio (HR), 3.13; 95% CI, 1.97-4.97] compared with controls. However, reductions in embolic events were not statistically significant (HR, 0.81; 95% CI, 0.65-1.02), and mortality remained unchanged (HR, 1.01; 95% CI, 0.77-1.31). A subgroup analysis indicated greater AF detection in RCTs than in cohort studies (p = 0.035). While publication bias was minimal, heterogeneity across studies was substantial. The authors concluded that ILRs markedly improve AF diagnosis, about three-fold compared with conventional care, highlighting their potential role in guiding anticoagulation for secondary stroke prevention. Limitations include the variability in study design, stroke subtypes, control monitoring methods, lack of cause-specific mortality data, and inconsistent reporting of adjusted vs. unadjusted ratios. (Buck et al., 2021, Bernstein et al., 2021, and Svendsen et al., 2021, previously cited in this policy, were included in this systematic review and meta-analysis.)

Abideen Asad et al. (2024) conducted a systematic review and meta-analysis of RCTs to evaluate the impact of ILR monitoring on AF detection and related outcomes in individuals with stroke or a high risk for stroke. The analysis included four trials, with over 7,000 individuals. ILR use was associated with higher rates of AF detection and more frequent initiation of appropriate anticoagulation therapy. While there was some indication of reduced stroke risk (relative risk, 0.75; 95% CI, 0.59-0.95; p = 0.02), no significant benefit was observed in those with a history of stroke (relative risk, 0.83; 95% CI, 0.61-1.14; p = 0.25). The authors concluded that ILR screening improves AF detection and anticoagulation initiation, but its role in stroke secondary prevention remains uncertain. They recommended future studies focusing on those without a history of stroke to clarify the potential benefit in reducing stroke risk. Limitations include the short follow-up periods, study-level rather than individual-level analysis, and potential bias due to differences in study design and populations.

Attanasio et al. (2024) conducted the prospective observational FLUTFIB study to determine the incidence, timing, duration, and symptoms of AF after cavotricuspid isthmus (CTI) ablation using continuous monitoring with ILRs. The study enrolled 100 adults with typical atrial flutter (AFL), confirmed by 12-lead electrocardiogram (ECG), and no prior documented AF; all met $CHA_2DS_2$-VASc score thresholds (≥ 1 for men, ≥ 2 for women) and underwent CTI ablation. Participants with implanted cardiac devices or indications for anticoagulation unrelated to AF were excluded. The primary end point was AF episodes lasting more than 30 seconds, with secondary end points including AFL recurrence, arrhythmia-related symptoms, stroke, and major bleeding. Over a median follow-up of 24 months, 77% of participants developed AF, with a median time to first episode of 180 days and most episodes lasting longer than 1 hour. More than half of affected participants experienced AF-related symptoms, although baseline characteristics and risk scores did not predict AF occurrence. Oral anticoagulation was discontinued in nearly one-third of participants but restarted in 15% following AF detection. No strokes, transient ischemic attacks (TIAs), or major bleeding events were reported during follow-up. The authors concluded that after 24 months of follow-up, the majority of participants demonstrated episodes of AF, with roughly two-thirds lasting more than 1 hour and nearly half occurring without associated symptoms. The authors suggested that as forthcoming studies aim to clarify the threshold duration of AF that should prompt initiation of oral anticoagulation, these findings may offer important guidance for anticoagulation management following CTI ablation. Study limitations include the possibility of missed prior AF despite ECG review; use of a single ILR manufacturer, limiting broader applicability; underrepresentation of women; and potential overestimation of AF-related symptoms due to targeted questioning at the time of episode detection.

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. Overall, 47 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 1 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%) vs. 4.9% (3.0%-7.9%) for ILRs at 1 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 1 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 4 weeks, or if adherence 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.

Abdelmoneim et al. (2021) conducted a prospective, single-center, observational study involving 42 participants who underwent cardiac surgery, developed new-onset transient postoperative AF (POAF) during their hospitalization, and received an ILR at discharge for continuous rhythm monitoring. Participants were included if they experienced POAF during admission and reverted to normal sinus rhythm before discharge and excluded if they had preexisting AF. The primary end points were the incidence and timing of AF recurrence, all-cause mortality, and cerebrovascular accident. During an average follow-up of 1.7 years, AF recurred in 71% of the 42 monitored participants. Among those with recurrence, 59% experienced episodes lasting at least 5 minutes, with a median AF duration of 32 minutes in the first month and 15 minutes thereafter. Most recurrences happened early, and 80% of first episodes occurred in the first month. Between 1 and 12 months, 76% of participants had at least one recurrence, while beyond 1 year, 30% had AF episodes. A Kaplan-Meier analysis showed a median time to first recurrence of 0.83 months, with cumulative detection rates rising from 57% at 1 month to 73% at 24 months. During follow-up, there was one death and two cerebrovascular events. The authors reported that AF recurrence was frequent following transient POAF, with 71% of participants experiencing recurrence, most occurring in the first month and being generally brief. Recurrence continued to be common throughout the first year but became less frequent thereafter. Based on these findings, the authors emphasized the importance of close follow-up and suggested that prolonged rhythm monitoring could support anticoagulation decisions beyond the standard 30-day period. However, the optimal duration of anticoagulation remains unclear, and larger, randomized studies are needed to determine whether long-term therapy improves outcomes in this population of individuals. Limitations include the small sample size, single-center design, and lack of a control group.

Ha et al. (2021) conducted the SEARCH-AF RCT, evaluating whether 30-day continuous ECG monitoring improved detection of AF or AFL after cardiac surgery compared with usual care. The study included adults undergoing coronary artery bypass grafting (CABG) or valve surgery who had no prior AF/AFL and only brief (< 24 hours) postoperative episodes, along with elevated $CHA_2DS_2$-VASc scores and additional POAF risk factors. Participants with prior or sustained POAF/AFL, current AF/AFL at randomization, prolonged hospitalization, mechanical valves, or other indications for anticoagulation were excluded. The primary end point was the occurrence of AF or AFL lasting at least 6 minutes within 30 days, detected by continuous monitoring or a 12-lead ECG. The secondary end points included longer AF episodes (≥ 6 hours or ≥ 24 hours) as well as rates of death, myocardial infarction, ischemic stroke, non-central nervous system thromboembolism, major bleeding, and new oral anticoagulation therapy. Among the 336 randomized participants, 307 (91%) completed the study. In the intention-to-treat analysis, the primary end point occurred in 19.6% of participants

in the monitoring group compared with 1.7% in the usual-care group, with an absolute difference of 17.9% ($p < 0.001$). AF episodes lasting at least 6 hours were detected in 8.6% of monitored participants and in none of the usual-care participants (absolute difference, 8.6%; $p < 0.001$). The authors concluded that in participants who were post cardiac surgery, were at a high risk for stroke, with no prior history of AF, and experienced only brief POAF episodes lasting less than 24 hours during hospitalization, continuous monitoring identified substantially more post discharge AF than usual care. They emphasized that additional studies are needed to determine whether these participants would benefit from starting oral anticoagulation therapy. Limitations include the short 30-day follow-up, which limits the understanding of long-term POAF risk, and the incomplete characterization of AF burden due to the lack of detailed in-hospital AF duration and absence of preoperative monitoring to rule out subclinical AF.

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, 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 a random-effects meta-analysis method was used to pool estimates. Overall, 47 studies, with a total of 8,215 individuals with cryptogenic stroke or ESUS, were included. Using an 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 individuals with ESUS vs cryptogenic stroke (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, $CHA_2DS_2$-VASc score, prolonged PR interval, and left atrial enlargement. The authors concluded that more than one-quarter of individuals with cryptogenic stroke or ESUS were diagnosed with AF during follow-up, and approximately one in seven individuals had AF detected within 1 month of MCOT, suggesting that a noninvasive rhythm monitoring strategy should be considered before invasive monitoring. (Sanna et al., 2014, previously cited in this policy, was included in this systematic review and meta-analysis.)

A systematic review and meta-analysis by Lowres et al. (2018) focused on those with new-onset POAF deemed to be in stable sinus rhythm on discharge and aimed to determine the recurrence of POAF identified through active screening post discharge. The secondary aim was to determine the stroke risk with recurrence of POAF after discharge. The inclusion criteria consisted of individuals who underwent cardiac surgery, developed new-onset POAF during their hospitalization, reverted to sinus rhythm before discharge, and were actively monitored for AF recurrence after discharge. The exclusion criteria applied to those with any prior history of AF, studies that did not differentiate individuals with preexisting AF or those restored to sinus rhythm before discharge, and studies that assessed AF only during the inpatient postoperative period. Eight studies met the inclusion criteria, encompassing a total of 1,157 individuals with an average age of 66 years, of whom 73% were men. Monitoring approaches varied across studies and included short, daily telemetry during exercise sessions, 3 weeks of continuous telemetry, 20-second daily ECG recordings with wearable devices, single-lead ECG checks four times daily, and implanted continuous monitors. Noninvasive methods detected POAF recurrence in approximately 28% of those within the first 4 weeks after discharge, typically occurring around 12 days post surgery, while implanted monitors identified substantially higher recurrence rates (61%-100%) over 2 years. A large proportion of AF episodes (40%-93%) were asymptomatic, and limited data suggested that many individuals with recurrence met guideline thresholds ($CHA_2DS_2$-VASc score ≥ 2) for anticoagulation. The authors concluded that overall, post discharge monitoring reveals a significant burden of early, silent AF recurrence, with more intensive monitoring detecting more POAF; however, further research is needed to clarify the prognostic implications, including stroke and mortality risk. Limitations of this review are the small number of included studies, many of which had fewer than 100 individuals and varied widely in individuals' characteristics, cardiac procedures, and comorbidities. Study designs and monitoring methods were highly inconsistent, with only two RCTs and limited reporting on key secondary outcomes.

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. Overall, 49 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 individuals 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 approximately half of the people with unexplained syncope who were implanted with an ILR were diagnosed.

El-Chami et al. (2016) used ILRs to monitor individuals who underwent CABG and developed POAF, aiming to determine the incidence and timing of recurrent AF after surgery. The study included those with a $CHADS_2$ score of at least 1 while excluding individuals with a prior history of AF or those who had valve repair or replacement in addition to CABG. The

predefined end points were the detection of AF recurrence and the time to recurrence following POAF. The study followed up 23 individuals (mean age, ~69 years; mean $CHADS_2$ score, 1.9) who developed POAF after CABG. Recurrent AF was observed in 14 of 23 individuals (60.9%). Of them, nine individuals (39.1%) had recurrence within the first 3 months after surgery, while 10 individuals experienced AF that either began or persisted beyond 3 months. Among the 17 individuals who were monitored for at least a year, eight (47.1%) had AF recurrence more than 1 year after CABG. The average time from surgery to first recurrence was approximately 143 days. Overall, long-term monitoring indicated that a majority of those with POAF eventually develop recurrent AF. The authors concluded that POAF may reflect a predisposition to ongoing paroxysmal AF rather than a temporary postoperative phenomenon, and identifying recurrence may help determine who could benefit from continued anticoagulation. Limitations include the small sample size, absence of a control group, and device manufacturer's funding of the study.

Maskoun et al. (2016) performed a systematic review and meta-analysis to determine the true incidence of AF after successful catheter ablation of typical AFL, defined by achieving bidirectional block. The review included English-language clinical studies published as full articles or recent conference abstracts (within 2 years) involving adults who underwent AFL ablation only, with at least 30 days of follow-up and clear documentation of AF status before ablation. Studies were required to report AF episodes lasting more than 30 seconds after ablation. The exclusion criteria were inclusion of individuals with nontypical AFL, lack of bidirectional block as the ablation target, undocumented follow-up duration, studies in which all individuals had AF, and duplicate data. Additionally, the authors manually searched trial registries, reviews, meta-analyses, and reference lists to identify relevant studies not captured in the initial electronic search. The meta-analysis included 48 studies (n = 8,257) with a 96% ablation success rate and predominantly male individuals (79%). Overall, new-onset AF occurred in 29% of individuals during long-term follow-up, with incidence strongly influenced by monitoring intensity: 12.4% with symptom-driven ECG, 19% with short-term Holter monitoring, and 45% with prolonged monitoring or implanted cardiac devices. Across all individuals, AF occurred in 35.3% during an average follow-up of approximately 30 months. Prior AF significantly increased risk: in studies with < 2 years of follow-up, the AF incidence was 54% in those with prior AF vs. 13.9% without. For > 2 years of follow-up, incidence was 51.3% with prior AF vs. 26.2%. The authors concluded that AF incidence after AFL ablation is substantial and strongly affected by follow-up duration and monitoring methods. Successful AFL ablation should not alter long-term anticoagulation decisions; anticoagulation should remain guided by the $CHADS_2$-VASc score. Concomitant AF ablation is recommended for individuals with prior AF, while further research is needed for those without prior AF. The main limitations of this meta-analysis include the observational design of the included studies, which could have led to a confounding by indication; substantial heterogeneity among the included studies; and variability in follow-up duration and monitoring strategies, which introduce detection bias and limit comparability.

A Cochrane systematic review (Solbiati et al., 2016) of four RCTs (n = 579) also assessed the diagnostic yield of ILRs vs. a conventional diagnostic workup in people with unexplained syncope. Individuals in the standard assessment group experienced lower rates of diagnosis (risk ratio, 0.61; 95% CI, 0.54-0.68; 579 individuals; four studies; moderate-quality evidence) than individuals 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 participants with bundle-branch block and a negative workup. Overall, 78 participants 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 ECG 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 the detection of relevant arrhythmias. The authors concluded that 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, smartphone, smartwatch, or tablet are considered convenience items and are unproven and not medically necessary due to a lack of quality research demonstrating the safety and efficacy of the devices or applications for identifying cardiac arrhythmias.

Iqhrammullah et al. (2025) conducted a systematic review and meta-analysis comparing the diagnostic accuracy of smartwatch-based ECG interpreted automatically by algorithms vs manually by trained clinicians and evaluated overall interpretability. Studies were included if they were diagnostic, observational, or RCTs involving individuals with AF confirmed by a 12-lead ECG interpreted by trained clinicians. The diagnostic tool that was evaluated was a single-lead

smartwatch ECG, with readings analyzed either by algorithms or medical personnel. Only studies reporting diagnostic values compared with a 12-lead ECG were considered; those lacking such data were excluded. Of the 18 studies reviewed, six were cohort studies, while the rest were cross-sectional. The smartwatch ECG showed 86% sensitivity and 94% specificity with algorithmic interpretation, while manual interpretation achieved 96% sensitivity and 95% specificity. In a brand-specific analysis, algorithmic readings reached a summary area under the curve of 96%, and manual readings of other brands peaked at 98%. Manual interpretability was high (Cohen κ = 0.83), although 3% of ECGs were difficult to interpret. The authors concluded that smartwatch ECGs can detect AF with high accuracy, particularly when interpreted manually by trained clinicians. Although the technology has limitations, such as motion artifacts and restricted heart rate ranges, several brands show strong specificity for AF detection. The authors noted that further research is needed to evaluate effectiveness in low-risk populations and explore broader cardiovascular applications. Key limitations include the focus on those with known cardiovascular conditions, limiting generalizability, and the lack of information on software or algorithm versions, which may affect diagnostic performance. Furthermore, the study did not demonstrate noninferiority or superiority to conventional long-term AF screening or monitoring, such as Holter.

In a 2023 RCT, Ding et al. evaluated the accuracy and usability of as well as the adherence to smartwatches for AF detection in older adults who had previously experienced 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 1). In phase 2, 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 with a 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 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 suggest that while smartwatches are a viable option for long-term arrhythmia detection, strategies to improve adherence to watch wear are needed. Limitations include a relatively small sample size and 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 used 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 that the analysis demonstrated that AI-based methods for the diagnosis of AF have high sensitivity and specificity for the detection of AF. The authors noted that further research is needed to assess the impact of these technologies on clinical outcomes and individuals' care. The analysis also highlighted several limitations such as the variability in study designs and potential biases in the selection of individuals.

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 is no or unclear support for the clinical utility of MMAs for the detection of cardiac arrhythmias. The review noted that there are no studies or systematic reviews that clearly demonstrate a benefit in clinical outcomes associated with the use of MMAs compared with 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 with routine care or Holter monitoring, the studies may have been too small or used inadequate follow-up periods to determine differences in individuals' health outcomes. One of the two systematic reviews reflected unclear benefit of MMAs to improve individuals' health outcomes, while another systematic review reported a benefit of MMAs on the management of AF for treatment initiation; a second reported benefit of MMAs on time to detection of cardiac arrhythmia episodes. The review was updated in 2024, with 12 newly published studies and seven new or updated guidelines, but there was no change to the current level of support (Hayes, 2021; updated 2024).

Koh et al. (2021) conducted a multicenter open-label RCT to determine the diagnostic efficacy of a 30-day smartphone ECG recording compared with that of 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, in which they underwent one additional 24-hour Holter monitoring (n = 98), or to the intervention group, in which 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 3 months after randomization to allow variation in duration from randomization to initiation of ECG monitoring. The 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 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 3 months compared with baseline, whereas the proportion of participants on oral anticoagulation therapy at 3 months compared with baseline in the control group was not statistically different. The authors reported that the KardiaMobile application reported 13.1% of 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 a short (< 30 seconds) 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 limitations of the study, including the use of a single-lead ECG, as multiple-lead smartphone ECG devices are now available. Another limitation is 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 compared with the standard repeat 24-hour Holter monitoring in participants aged 55 years 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 iHEART (iPhone Helping Evaluate Atrial Fibrillation Rhythm through Technology) single-center two-arm RCT, Caceres et al. (2020) evaluated the impact of the iHEART intervention on health-related quality of life (HRQOL) in participants 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 usual care (n = 123) for 6 months. The participants were primarily male (77%) and White (76%). HRQOL was measured using the Atrial Fibrillation Effect on Quality of Life, 36-item Short-Form Health survey, and EQ-5D. The authors reported that both arms had improved scores from baseline to follow-up for Atrial Fibrillation Effect on Quality of Life and AF symptom severity scores, although there were no statistically significant differences in HRQOL, quality-adjusted life-years, or AF symptom severity between groups. The authors remarked that the improvements in AF-specific HRQOL and symptom severity were likely because all participants had received treatment for AF. Limitations noted by the authors include the inclusion of only a single practice location in an urban setting, propensity of the participants being White and male, small sample size, and limited frequency and duration of follow-up assessments (baseline and at 6 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 did not allow to differentiate whether the observed difference in HRQOL was due to the arrythmia detection or 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, siteless pragmatic study (Apple Heart Study) to determine the proportion of participants using a smartwatch application who 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, residence in the United States, and proficiency 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 7 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 of the participants (34%) who returned the ECG patches overall. The ECG patches worn by participants aged 65 years 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 2,161 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 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 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 has 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, younger demographic presence in the study population, substantial loss to follow-up, and lack of physical/face-to-face contact with the participants. A lack of a 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)

Spooner et al. (2024) developed a consensus decision pathway for the ACC regarding arrhythmia monitoring after stroke. For those with large- or small-vessel disease or cryptogenic stroke, cardiac monitoring may be considered, preferably for 14 days or more. An ICM may be considered in selected high-risk patients.

### American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Clinical Pharmacy (ACCP)/Heart Rhythm Society (HRS)

Joglar et al. (2023a) 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 left ventricular function, long-term surveillance can be beneficial to detect recurrent AF in view of the high risk of recurrence of arrhythmia-induced cardiomyopathy (class of recommendation, 2a-moderate, quality of evidence, B-NR-moderate/nonrandomized).
- 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 (class of recommendation, 2a-moderate, quality of evidence, B-R-moderate/randomized).
- Among patients with a diagnosis of AF, it is reasonable to infer AF frequency, duration, and burden using automated algorithms available from ECG monitors, ICMs, and cardiac rhythm devices with an atrial lead, recognizing that periodic review can be required to exclude other arrhythmias (class of recommendation, 2a-moderate, quality of evidence, B-NR-moderate/nonrandomized).
- Patients with typical AFL who have undergone successful CTI ablation and are deemed to be at a high thromboembolic risk, without any known previous history of AF, should receive close follow-up and arrhythmia monitoring to detect silent AF if they are not receiving ongoing anticoagulation in view of a significant risk of AF (class of recommendation, 1-stong, quality of evidence, B-NR-moderate/nonrandomized).
- 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/nonrandomized).
- In patients with AF-induced cardiomyopathy who have recovered left ventricular function, long-term surveillance can be beneficial to detect recurrent AF in view of the high risk of recurrence of arrhythmia-induced cardiomyopathy (class of recommendation, 2a-moderate, quality of evidence, B-NR-moderate/nonrandomized).
- In patients with AF who are identified in the setting of acute medical illness or surgery, outpatient follow-up for thromboembolic risk stratification and decision-making on oral anticoagulant initiation or continuation as well as AF surveillance can be beneficial given a high risk of AF recurrence (class of recommendation, 2a-moderate, quality of evidence, B-NR-moderate/nonrandomized). Of note, no randomized trials have directly compared outpatient monitoring strategies for acute AF, but studies such as CRYSTAL-AF and SEARCH-AF demonstrate that longer-term monitoring substantially improves AF detection.
- 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 (class 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 patients 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)

The 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 an initial noninvasive evaluation is nondiagnostic (Kusumoto et al., 2019).

The 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 for evaluation of selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful. The authors noted 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.

The AHA/ACC/HRS guidelines for the management of patients with ventricular arrhythmias and 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 (HCM) state that in the presence of symptoms, ambulatory ECG monitoring should be continued until a patient has symptoms while wearing the monitor. In some patients 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 the AHA/ACC/AMSSM/HRS/PACES/SCMR guidelines for the management of 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 1-2 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 a 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 an 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 an initial evaluation and periodic follow-up (every 1-2 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 recommends that for those with cryptogenic stroke who are not contraindicated for anticoagulation, it is reasonable to use long-term rhythm monitoring, such as MCOT, ILRs, or other methods, to detect intermittent AF. 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 should be considered (Smith et al., 2017).

## Canadian Cardiovascular Society (CCS)

Crean et al. (2024) developed a practice update for the CCS regarding the management of HCM. The update states that those with HCM should be routinely screened for AF and nonsustained ventricular tachycardia. Ambulatory ECG monitoring for 24 to 48 hours is recommended at diagnosis and annually thereafter. For patients at a higher risk of AF,

such as those with severe left atrial enlargement, frequent atrial ectopy, palpitations suggestive of AF, or unexplained embolic events, extended monitoring should be considered. Additionally, an ILR may be appropriate in cases of unexplained syncope when an implantable cardiac defibrillator is not indicated, offering long-term rhythm surveillance.

## 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 when 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 implantable cardioverter-defibrillator or pacemaker.
- An ILR may be considered in patients experiencing palpitations, dizziness, presyncope, or frequent premature ventricular complexes/nonsustained ventricular tachycardia and in those with suspected AF and post-AF ablation.

## European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS)/Asia Pacific Heart Rhythm Society (APHRS)/Latin American Heart Rhythm Society (LAHRS)

Tzeis et al. (2024) published a consensus statement for the European Heart Rhythm Association and Heart Rhythm Society on catheter and surgical ablation of AF, emphasizing that post ablation rhythm monitoring should be tailored to the context and routine clinical care vs. clinical research. Monitoring during routine clinical care is generally less rigorous than in clinical trials because detecting asymptomatic arrhythmia recurrences rarely influences post ablation management. Exceptions include patients being considered for anticoagulation discontinuation or those with impaired ventricular function. For routine care, rhythm status should be checked within 2 to 3 months after ablation using at least a 12-lead ECG, followed by annual evaluations if the patient remains asymptomatic. Symptomatic patients should undergo intermittent monitoring, with the intensity and method individualized based on symptom burden, tool availability, and patient preference. In clinical trials and when invasive monitoring is not used, a minimum of 24-hour Holter monitoring every 3 months during the first year is recommended, ideally combined with symptom-based monitoring. Longer continuous recordings (7-14 days) are preferred when feasible.

## European Society of Cardiology (ESC)

The 2024 ESC guideline for the management of AF in collaboration with the European Association for Cardio-Thoracic Surgery updates and replaces the previous 2020 version. The guidelines recommend that for those with an embolic stroke of unknown source, invasive or noninvasive ECG for prolonged monitoring would be appropriate. Per the guidelines, many new devices, such as fitness bands and smartwatches, have entered the market to monitor heart rhythm. While clinical evidence of their effectiveness is limited, these devices may help detect AF, but further study is required (Van Gelder et al., 2024).

The 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 pretest 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 prolonged cardiac monitoring instead of the 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 nonimplantable devices to increase the detection of subclinical AF (Rubiera et al., 2022).

## Heart Rhythm Society (HRS)

The HRS consensus statement regarding arrhythmias in the athlete by Lampert et al. (2024) includes the following recommendation (not all inclusive):

- For diagnosis and monitoring of syncope in athletes with a high suspicion of arrhythmic etiology, unexplained after initial testing, and/or whose symptoms are rare, loop recorder implantation can be useful (class of recommendation, 2a-moderate, level of evidence, B-NR-moderate, nonrandomized).

Joglar et al. (2023b) 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/nonrandomized).
- 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 an 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 to 48 hours, patch monitors are worn for 7 to 14 days, event/loop monitors are worn for 30 days, and ambulatory cardiac telemetry monitors are worn for up to 30 days. The 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 continuous (short term, 24 hours 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 patients remaining undiagnosed after prolonged noninvasive monitoring, an 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 noninvasive 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 electrocardiography 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 2, 2025)

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 2, 2025)

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 05/01/2026 | **Coverage Rationale**<br>• Added language to indicate this policy does not apply to individuals < 18 years of age<br>• Revised circumstances for which Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias when noninvasive cardiac event recording is contraindicated or has yielded nondiagnostic results after at least 2 weeks of monitoring; added:<br>  ○ Post-cavotricuspid isthmus ablation for typical atrial flutter if the individual is not on long-term anticoagulation and is at high thromboembolic risk (e.g., $CHA_2DS_2$-VASc ≥ 2 or HATCH score of at least 2)<br>  ○ Atrial fibrillation detected during an acute medical illness or following surgery, particularly after noncardiac procedures and in individuals with stroke risk factors (e.g., $CHA_2DS_2$-VASc ≥ 2)<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information<br>• Archived previous policy version 2026T0489II |

# 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, 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.