

Implantable Loop Recorders and Wearable Heart Rhythm Monitors (for Idaho Only)

Policy Number: CS092ID.B

Effective Date: December 1, 2025

[Instructions for Use](#)

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Related Policies

None

Application

This Medical Policy only applies the state of Idaho, including Idaho Medicaid Plus plans.

Coverage Rationale

State-Specific Criteria

For medical necessity clinical coverage criteria for implantable loop recorders, refer to the [Idaho Medicaid Provider Handbook, Medical Services, Chapter 5.8: Subcutaneous Cardiac Rhythm Monitor](#).

Non State-Specific Criteria

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

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).

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
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

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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).

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-Stavarakakis 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 US population.

In the iPhone Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART) single-center, two-arm RCT, Caceres et al. (2020) evaluated the impact of the iHEART intervention on health-related quality of life (HRQOL) in 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 arrhythmia 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, 1376 returned a 90-day survey which showed that 787 (57%) contacted a health care provider outside of the study, 28% were prescribed a new medication, 33% were referred to a specialist and 36% were recommended to have additional testing. Another survey at the end of the study with this same group had a survey return rate of 43% (929 participants) with 404 (44%) reporting a new AF diagnosis. In the analysis of survey results from participants who did not have a notification from the app, 3070 (1%) reported a new diagnosis of AF. The authors also reported that the notification subgroup self-reported a greater incidence of strokes, heart failure, and myocardial infarctions than did the non-notification group. The authors concluded that the probability of receiving an irregular pulse notification was low; however, among the participants who received notification by the application of an irregular pulse, 34% were found to have AF on subsequent ECG patch readings. They noted that the study had several limitations including a lower return/response rate from participants in initiating contact with the study provider and with returning ECG patches than anticipated, reliance on participants and their own assessments regarding their eligibility for inclusion, the younger demographic presence in the study population, substantial loss to follow-up, and the lack of physical / face-to-face contact with the participants. Lack of comparison group undergoing a different intervention to screen for AF was another limitation. The authors 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 al., 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 C₂HES 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)

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Policy History/Revision Information

Date	Summary of Changes
12/01/2025	<p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Cardiac Event Monitoring (for Idaho Only)</i> <p>Coverage Rationale</p> <p>State Specific Criteria</p> <ul style="list-style-type: none"> Added instruction to refer to the <i>Idaho Medicaid Provider Handbook, Medical Services, Chapter 5.8: Subcutaneous Cardiac Rhythm Monitor</i> for medical necessity clinical coverage criteria for implantable loop recorders <p>Non-State Specific Criteria</p> <ul style="list-style-type: none"> Removed language indicating the following are proven and medically necessary for evaluating suspected cardiac arrhythmias: <ul style="list-style-type: none"> Ambulatory Event Monitoring <ul style="list-style-type: none"> Holter Monitor Event Monitor Patch-type monitor Outpatient Cardiac Telemetry Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias when noninvasive cardiac event recording is contraindicated or yielded non-diagnostic results after at least 2 weeks of monitoring in one or more of the following circumstances: <ul style="list-style-type: none"> Suspected paroxysmal atrial fibrillation in the setting of a cryptogenic stroke or another documented systemic thromboembolic event; or Suspected or known ventricular arrhythmia; or 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; or Recurrent or unexplained infrequent syncope after modification of potentially syncope-causing medications or associated with autonomic dysfunction; or 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 <p>Definitions</p> <ul style="list-style-type: none"> Removed definition of: <ul style="list-style-type: none"> Ambulatory Event Monitoring/Electrocardiography (ECG) Attended Surveillance Implantable Loop Recorder Outpatient Cardiac Telemetry <p>Applicable Codes</p> <ul style="list-style-type: none"> Removed CPT codes 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, and 93272

Date	Summary of Changes
	Supporting Information <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information Archived previous policy version CS092ID.A

Instructions for Use

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