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

Policy Number: CS092KS.02
Effective Date: July 1, 2026

➲ Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Kansas.

Coverage Rationale

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

Implantable Loop Recorders are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Electrocardiography, Ambulatory (AECG).

Click here to view the InterQual® criteria.

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, 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 personal computer, tablet, or smart phone

Medical Records Documentation Used for Reviews

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

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

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 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 electrocardiography (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

HCPCS Code	Description
Cardiac Self-Monitoring Devices	
E1399	Durable medical equipment, miscellaneous

Clinical Evidence

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 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 $\kappa = 0.83$), 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 demonstrated 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 patient 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)/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).

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
07/01/2026	**Title Change** • Previously titled *Cardiac Event Monitoring (for Kansas Only)* **Coverage Rationale** • Added language to indicate this policy does not apply to individuals < 18 years of age • Replaced language indicating:

Date	Summary of Changes
	○ "*Cardiac event monitoring* is proven and medically necessary in certain circumstances" with "*implantable loop recorders are* proven and medically necessary in certain circumstances" ○ "Wearable heart rhythm monitors (Cardiac Self-Monitoring Devices) commercially available to the general public and purchased for home use are not medically necessary" with "wearable heart rhythm monitors *or* Cardiac Self-Monitoring Devices commercially available to the general public and purchased for home use are not medically necessary" **Medical Records Documentation Used for Reviews** • Added language to indicate: ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request **Definitions** • Removed definition of "Implantable Loop Recorder" **Applicable Codes** • Removed CPT codes 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, and 93272 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *Description of Services* section • Archived previous policy version CS092KS.01

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, heck the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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