Cardiac Event Monitoring (for Kentucky Only)

Policy Number: CS092KY.08
Effective Date: July 1, 2023

Instructions for Use

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Related Policies

None

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Cardiac event monitoring is 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 ambulatory event monitors is considered medically necessary for an individual who continues to meet initial criteria for insertion described above and the existing device is beyond its useful life span, is irreparable, or no longer operating.

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

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

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 the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Patch-Type Monitor	
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
Holter Monitor	
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional
Outpatient Cardiac Telemetry	
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional

CPT Code	Description
Event Monitor	
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis
93272	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified health care professional
Implantable Loop Recorder	
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
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
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

HCPCS Code	Description
E0616	Implantable cardiac event recorder with memory, activator, and programmer
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

Description of Services

Cardiac arrhythmias are disorders of the heart's rate or rhythm. Some individuals with arrhythmias may experience palpitations, weakness, dizziness or fainting, while others may have no symptoms at all. Effective treatment requires an accurate diagnosis, often using ambulatory electrocardiography (ECG) monitoring. The type and duration of ambulatory ECG monitoring is dictated by the frequency of symptoms. Refer to the Definitions section for information on types of ambulatory ECG devices.

Cardiac Self-Monitoring Devices

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

In an Evolving Evidence Review on the clinical utility of mobile medical applications (MMAs) for the detection of cardiac arrhythmias, Hayes (2021) reported that there was no or unclear support for the clinical utility of MMAs for the detection of cardiac arrhythmias. The review noted that there were no studies or systematic reviews that clearly demonstrated a benefit in clinical outcomes associated with the use of MMAs when compared to alternative monitoring modalities. The review noted that, while the studies included in the review reported a higher rate of detection of cardiac arrhythmia episodes in patients monitored with MMAs compared to routine care or Holter monitoring, the studies may have been too small or had inadequate follow-up periods to determine differences in patient health outcomes. One of the two systematic reviews reflected unclear benefit of MMAs to improve patient health outcomes while another systematic review reported a benefit of MMAs on management of AF for treatment initiation and a second reported benefit of MMAs on time to detection of cardiac arrhythmia episodes.

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 atrial fibrillation (AF) lasting 30 seconds or more. The study, which was reviewed in the Hayes 2021 Evolving Technology Review above, included 203 participants 55 years old or older, without known AF who had experienced an ischemic stroke or TIA of undetermined cause within the previous 12 months. The participants were randomly assigned to the control group where they underwent one additional 24-hour Holter monitoring (n = 98) or to the intervention group where they participated in a 30-day smartphone ECG monitoring program using the KardiaMobile (AliveCor®) application on the smartphone 3 times a day or whenever they felt palpitations. The primary outcome was determined at 3 months after randomization to allow variation in duration from randomization to initiation of ECG monitoring. Secondary outcomes included the use of anticoagulation therapy at 3 months and the performance of the application. The authors reported that AF lasting 30 seconds or longer was detected in 10 of 105 participants in the intervention group and 2 of 98 participants in the control group (9.5% vs. 2% for an absolute difference of 7.5%). They also noted that there was a significantly higher proportion of participants from the intervention group who were on oral anticoagulation therapy at 3 months compared with baseline whereas the proportion of patients on oral anticoagulation therapy at 3 months compared with baseline in the control group was not statistically different. The authors reported that the 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. The authors concluded that the 30-day smartphone ECG recording significantly improved the detection of AF when compared to the standard repeat 24-hour Holter monitoring in patients aged 55 or older with a recent cryptogenic stroke or TIA. It is unclear if the findings in this Malaysian population would be generalizable to a US population.

In the iPhone Helping Evaluate Atrial Fibrillation Rhythm through Technology (iHEART) single-center, two-arm RCT, Caceras et al. (2020) evaluated the impact of the iHEART intervention on health-related quality of life (HRQOL) in patients with documented AF who were undergoing treatment for their AF with either direct current cardioversion or radiofrequency ablation to restore normal sinus rhythm . A total of 238 English-and Spanish-speaking adults were randomized to either the smartphone-based ECG monitoring and motivational text messaging intervention group (n = 115) or to receive usual care (n = 123) for six months. The participants were primarily male (77%) and white (76%). HRQOL was measured using the Atrial Fibrillation Effect on Quality of Life (AFEQT), the 36-item Short-Form Health survey, and the EQ-5D. The authors reported that both arms had improved scores from baseline to follow-up for AFEQT and AF symptom severity scores although there were no statistically significant differences in HRQOL, quality-adjusted life-years (QALYs) or AF symptom severity between groups. The authors felt it was likely that the improvements in atrial fibrillation-specific HRQOL and symptom severity were due to all participants having undergone treatment for AF. Limitations noted by the authors included that the study only included a single practice location in an urban setting, the propensity of the participants to be white males, the small sample size and the limited frequency and duration of follow-up assessments (baseline and at six months). Additionally, the study is limited by multiple comparisons, which could

have led to statistically significant differences due to chance only. Furthermore, the study design doesn't allow to differentiate whether the observed difference in HRQOL were due to the arrythmia detection or to the motivational text messages. The authors recommend additional research with longer follow-up to examine the influence of smartphone-based interventions for AF management on HRQOL and to address the unique needs of patients diagnosed with different subtypes of AF.

Perez et al. (2019) conducted a prospective, open-label, single arm, site-less, pragmatic study (Apple Heart Study) to determine the proportion of participants using a smartwatch application that were ultimately identified as having AF. The 8-month study included 419,297 participants who self-reported no history of AF and self-monitored for a median of 117 days. Eligibility criteria included possession of a compatible Apple iPhone and Apple Watch, age of 22 years or older residing in the United States and proficient in English. The study app was used to verify eligibility, obtain consent, provide study education and provide direction through the study procedures. Study visits with physicians were conducted through telemedicine. There were 2,161 participants (0.52%) who received notifications via the smartwatch application of an irregular pulse who were then sent an ECG patch (ePatch) to wear for seven days. The investigators received 450 ECG patches back that had been applied within 14 days of shipment for at least 1 hour and were returned within 45 days after the first study visit. They reported that AF was present in 153 (34%) of the participants who returned the ECG patches overall. The ECG patches worn by participants aged 65 or older had a diagnostic yield of AF of 35% whereas participants younger than 40 years of age had a diagnostic yield of AF of 18%. Participants were prompted to initiate a second telemedicine visit to discuss the ambulatory ECG findings and were then directed to follow-up care as the study-visit physicians did not initiate any treatment. Of the 2161 participants who received an irregular pulse notification, 1376 returned a 90-day survey which showed that 787 (57%) contacted a health care provider outside of the study, 28% were prescribed a new medication, 33% were referred to a specialist and 36% were recommended to have additional testing. Another survey at the end of the study with this same group had a survey return rate of 43% (929 participants) with 404 (44%) reporting a new AF diagnosis. In the analysis of survey results from participants who did not have a notification from the app, 3070 (1%) reported a new diagnosis of AF. The authors also reported that the notification subgroup self-reported a greater incidence of strokes, heart failure, and myocardial infarctions than did the non-notification group. The authors concluded that the probability of receiving an irregular pulse notification was low; however, among the participants who received notification by the application of an irregular pulse, 34% were found to have AF on subsequent ECG patch readings. They noted that the study had several limitations including a lower return/response rate from participants in initiating contact with the study provider and with returning ECG patches than anticipated, reliance on participants and their own assessments regarding their eligibility for inclusion, the younger demographic presence in the study population, substantial loss to follow-up, and the lack of physical / face-to-face contact with the participants. Lack of comparison group undergoing a different intervention to screen for AF was another limitation. The authors recommend rigorous investigation of the technology and its use in clinical settings, including how the technology can further guide evaluation and treatment to improve clinical outcomes.

U.S. Food and Drug Administration (FDA)

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

For information on ambulatory ECG devices, cardiac telemetry or implantable loop recorders, refer to the following website (use product codes DSI, MXD and DXH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 21, 2022)

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 21, 2022)

References

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

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

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

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Policy History/Revision Information

Date	Summary of Changes
07/01/2023	**Supporting Information** ● Added *Description of Services* section ● Archived previous policy version CS092KY.07

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, check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines 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.