


MEDICAL POLICY	Cardiac: External Ambulatory Electrocardiography (All Lines of Business Except Medicare)
Effective Date: 9/1/2022	Medical Policy Number: 188
 9/1/2022	Technology Assessment Committee Approved Date: 3/07; 4/09; 3/12; 3/14; 6/16 Medical Policy Committee Approved Date: 10/10; 12/11; 3/13; 10/15; 10/16; 5/17; 12/17; 1/19; 5/19; 5/2020; 12/2020; 07/2021; 8/2022
Medical Officer	Date

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare (unless otherwise directed by a Medicare medical policy. Note that investigational services are considered “not medically necessary” for Medicare members.)

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

NOTE: See Billing Guidelines for coding guidance. Incorrect billing may affect the review process and coverage determination.

Event Monitor/External Cardiac Loop Recorder (ELR) and External Cardiac Patch Recorder

- I. A long-term (greater than 48 hours), external, ambulatory electrocardiographic (ECG) patch recorder (e.g., Zio AT from iRhythm, Cardea Solo and Carnation Ambulatory Monitor) (93241-8) or cardiac event monitor (also referred to as an external memory loop recorder [ELR]) (93268, 93270-2, 0497T and 0498T) that is patient- or auto-triggered may be considered **medically necessary and covered** when **both** of the following criteria are met (A. and B.):

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- A. A cardiac arrhythmia is suspected (e.g., cryptogenic stroke, syncope, pre-syncope, palpitations); **and**
- B. When **either** of the following are met (1.-2.):
 - 1. A Holter monitor failed to establish a diagnosis; **or**
 - 2. The patient experiences symptoms so infrequently (less than every 48 hours) that Holter monitoring is unlikely to capture a diagnostic ECG.
- II. Ambulatory ECG patch recorders and cardiac event monitors (aka, ELR) are considered **not medically necessary and not covered** when criterion I. above is not met.

Mobile Cardiac Outpatient Telemetry (MCOT)

- III. A long-term (greater than 48 hours), external, ambulatory electrocardiographic (ECG) mobile cardiac outpatient telemetry (MCOT) device which includes data transmission to a central recording station (93228-93229) may be considered **medically necessary and covered** when **all** of the following criteria are met (A.-C.):
 - A. Patient is experiencing symptoms of a non-life threatening cardiac arrhythmia (e.g., syncope, pre-syncope, dizziness, and/or palpitations); **and**
 - B. Patient has undergone ambulatory event monitoring (e.g., event monitor/loop recorder or patch recorder) for a minimum of 28 days or two trials of at least 14 days each which failed to establish a diagnosis; **and**
 - C. The MCOT device must be prescribed by a cardiologist or electrophysiology cardiologist.
- IV. Mobile cardiac outpatient telemetry is considered **not medically necessary and not covered** when criterion III. above is not met.

Link to [Policy Summary](#)

BILLING GUIDELINES

Codes specific to the ambulatory cardiac rhythm monitor device class are noted in both the Policy Criteria and CPT Codes sections of this policy. Incorrect coding, which may include billing with codes not specific to the cardiac monitor device class requested, may result in a denial of payment. The following (Table 1.) is a non-exhaustive list of classes and examples of marketed devices relevant to this policy with the proper code.

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Table 1. Long-term External Ambulatory Electrocardiography Device Classes, Coding and Examples (Non-exhaustive)

Device Class	Device Description	Coding Guideline	Example Devices
External Cardiac Patch Recorder	Adhesive patch that does not require any separate leads, attachments or batteries. Worn on the chest for more than 48 hours up to 14 or 16 days. The patch device both records and stores continuous rhythms. A report is provided after sending the device in for data retrieval and reading at a centralized location. On some patch recording devices, the patient may press a button or use a mobile application to log experiences of symptoms in order to generate event matching from the device recordings. Note that the FDA classifies these devices as loop recorders (Product Code: DSH, Medical magnetic tape recorder), and some patches maybe classified as MCOT depending on their capabilities (see below).	93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248	<ul style="list-style-type: none"> • Carnation Ambulatory Monitor (CAM) (K210036)¹ from BardyDx • Zio XT monitor (K202359)² with myZio app for symptom logging • Cardea SOLO from Cardiac Insight, Inc. (K162503)³
Event Monitor/ External Cardiac Loop Recorder	Event monitors were historically referred to as loop monitors due to the ability to continuously loop the recording tape. They are patient- or auto-activated when symptoms are present (event recording), depending upon the device. Generally, the small monitor (about the size of a pager) is clipped onto the patient’s waistband and records heart rhythms through two electrodes attached to the chest.	93268, 93270, 93271, 93272, 0497T, 0498T	<ul style="list-style-type: none"> • M5 Recorder (K202456)⁴ from Global Instrumentation, LLC • Nuubo System (K173461)⁵ • BodyGuardian MINI/ BodyGuardian MINI Plus (K182030)⁶ from Preventice Solutions, Inc.
Mobile Cardiac Outpatient Telemetry	Mobile cardiac outpatient telemetry traditionally included three leads, but is now also offered as a patch. These devices perform continuous monitoring and wireless transmission	93228, 93229	<ul style="list-style-type: none"> • Zio AT ECG Monitoring System⁷ • MCOT Patch, aka Braemar Telemetry

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	to a centralized reporting location for up to 30 days. Symptomatic events may be triggered by the patient or automatically by the device and wirelessly transmitted for physician review and interpretation. Product Code: DSI.		Patch System, Model BTPS1000 (K153473) ⁸ <ul style="list-style-type: none"> • ECG Mini System Continuous ECG Monitor and Arrhythmia Detector (K151269)⁹ • BodyGuardian Heart (K151188)¹⁰ from Preventice Solutions, Inc.
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CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
Mobile Cardiac Outpatient Telemetry (MCOT)	
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
Event Monitor/External Cardiac Loop Recorder (ELR) without Attended Monitoring	
0497T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection
0498T	External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event

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No Prior Authorization Required	
External Cardiac Patch Recorder	
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
Event Monitor/External Cardiac Loop Recorder (ELR) with Attended Monitoring	
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

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Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.	
93799	Unlisted cardiovascular service or procedure

DESCRIPTION

Cardiac Arrhythmia

A cardiac arrhythmia is an irregular heartbeat. Although arrhythmias are common, especially with increased age, some arrhythmias can be dangerous and require prompt diagnosis and management. Diagnosing arrhythmias can be difficult because some are asymptomatic or occur infrequently and unpredictably.¹¹ When a cardiac arrhythmia does cause symptoms, they typically include pre-syncope (feeling faint), syncope (fainting), palpitations, or dizziness. Due to these variations in the clinical presentation of cardiac arrhythmias, long-term ambulatory monitoring is sometimes necessary to obtain an accurate diagnosis.

Cryptogenic Stroke

A stroke is a “brain attack” and occurs when blood flow to the brain is cut off. Cryptogenic stroke is a stroke of unknown origin. Every year in the United States, about one third of all strokes are classified as cryptogenic. Atrial fibrillation (a type of cardiac arrhythmia that causes poor blood flow) is the leading preventable cause of recurrent stroke; therefore, early detection and treatment of atrial fibrillation is critical.

Holter Monitor

Ambulatory Holter electrocardiography is considered the standard of care for diagnosing a suspected cardiac arrhythmia in patients who exhibit frequent symptoms.¹² The battery powered device is the size of a small camera and monitors heart rhythms through small electrodes attached to the chest. This noninvasive test provides continuous ECG data over a 24 to 48 hour time period. After the monitoring period, the device is returned to the physician’s office where the ECG data is downloaded and reviewed. Due to the short monitoring period, Holter ECGs are not considered long-term cardiac monitors and can be ineffective for detecting infrequent or unpredictable arrhythmias.¹¹

External Ambulatory Electrocardiography (ECG)

External ambulatory ECGs are diagnostic instruments capable of recording heart rhythms while a patient is engaged in daily activities. Typically, these devices record patient-activated or auto-detected ECG data for 21 to 30 days. A diagnostic ECG is considered the gold standard for diagnosing cardiac arrhythmias;

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however, due to the infrequent nature of some arrhythmias standard 48 hour tests might not provide a diagnosis.¹³ Long-term ECG monitors can be more suitable for diagnosing an arrhythmia that is so infrequent it would not be diagnosed by a standard 12-lead EKG or Holter Monitor.¹⁴ Although there are several technologies that provide long-term ECG monitoring, this policy will address external loop recorders, external patch recorders (e.g., ZioPatch®), and mobile cardiac outpatient telemetry (e.g., CardioNet® MCOT).

External Patch Recorders

External patch recorders (e.g., Zio XT monitor from iRhythm) are small, water-resistant, adhesive one lead ECGs that attach to the chest and provide ECG monitoring for up to 16 days. The device continuously records and stores rhythm data, though many models also allow the wearer to press a button or use a mobile device app when symptoms are detected to allow for symptom-rhythm correlation. At the end of the monitoring period the patch is mailed to a central location for analysis. A diagnostic report is then provided to the patient and physician. Some patches have more technological capabilities and are loop recorders, and patch devices may also have wireless transmission capabilities to even be considered MCOT.

Event Monitor / External Loop Recorder (ELR)

Event monitors were historically termed external loop recorders due to the continuously recording tape that could loop and record multiple events over a long period of time. Event monitors are generally small, portable devices clipped onto the patient’s waistband, recording heart rhythms through two electrodes attached to the chest that provide up to 30 days of ECG data. However, there is also at least one patch version of this device class type that also includes the ability to wirelessly send event reports to a centralized monitoring location (Zio AT ECG Monitoring System from iRhythm). Event recorders can be patient activated when symptoms begin or auto-activated when the monitor detects an arrhythmia. Auto-activated event monitors are recommended for patients who experience incapacitating cardiac arrhythmia symptoms (e.g., syncope).¹⁵

Mobile Cardiac Outpatient Telemetry (MCOT)

Mobile Cardiac Outpatient Telemetry (MCOT) provides real-time, continuous heart rhythm monitoring through proprietary cardiac arrhythmia detection algorithms and wireless data transmission to a staffed central location (i.e., remote monitoring). CardioNet, Inc. first offered these devices in the early 2000’s after obtaining FDA approval as an arrhythmia detector and alarm (including ST-segment measurement and alarm) (Product Code: DSI). Initially MCOT™ included a small sensor worn as a pendant or on a belt clip with 3 electrodes attached to the chest. Ten years after the initial MCOT™ launch, the company reincorporated and merged BioTel Heart technology into the new brand, BioTelemetry, Inc. An MCOT™ Patch is also FDA approved and marketed under this suite of brands, which emerged from their research branch, Braemar Manufacturing, Inc. Numerous other devices have joined this brand group due to acquisitions and mergers, including LifeWatch which offers the ECG Mini System Continuous ECG Monitor and Arrhythmia Detector (K151269). In 2021, BioTelemetry, Inc was acquired by Philips. Other

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companies offer combination patch and lead systems with various mobile device application options and central reporting methodologies.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of long-term ECG monitors for diagnosing cardiac arrhythmias. Below is a summary of the available evidence identified through May 2022.

External Ambulatory ECG Devices to Diagnose Atrial Fibrillation after Cryptogenic Stroke

A 2015, systematic review and meta-analysis by Sposato et al. evaluated the diagnostic utility of sequential phases of cardiac monitoring for identifying atrial fibrillation in patients after cryptogenic stroke or transient ischemic attack.¹⁶ The authors systematically reviewed peer-reviewed literature related to eight AF diagnostic methods: admission ECG, serial ECG, continuous inpatient ECG, continuous inpatient telemetry, Holter monitoring, mobile cardiac outpatient telemetry (MCOT), external loop recorders (ELR), and implantable loop recorders (ILR). Based on the cardiac monitoring method used and time to monitoring, the cardiac monitoring methods were divided into 4 screening phases. Phase 1 (acute assessment in emergency room) was an admission ECG. Phase 2 (in-hospital stay) involved a serial ECG, continuous inpatient ECG, continuous inpatient cardiac telemetry, and in-hospital Holter monitoring. Phase 3 (the first ambulatory period) was the 24-48 hour ambulatory Holter monitor. Phase 4 (second ambulatory period involving the use of long-term sophisticated monitoring methods, usually after previous diagnostic attempts with similar methods) included MCOT, ELR, and ILR.

The authors included 50 studies giving a sample size of n=11,658. The percentage of patients diagnosed with post-stroke AF through the different cardiac monitoring phases was 7.7% in phase 1, 5.1% in phase 2, 10.7% in phase 3, and 16.9% in phase 4. There was no significant difference between the proportion of patients diagnosed with post-stroke AF using the phase 4 cardiac monitoring methods (MCOT 15.6%, ELR 16.2%, and ILR 16.9%). Of note, the authors indicated that the post-stroke atrial fibrillation detected with implantable loop recorders long after stroke or transient ischemic attack might be incidental and not causally associated with the initial event. Overall, the proportion of patients diagnosed with post-stroke atrial fibrillation after the four sequential screening phases was 23.7%.

Strengths of this study include the author’s use of PRISMA and Cochrane methodology for systematically reviewing literature and evaluating study quality. Another methodological strength is the large sample size and the author’s assessment of heterogeneity and publication bias before conducting the meta-analysis. The authors did not report the quality of included studies; however, they did acknowledge that of the included studies 46% have potential selection bias and 22% have potential funding bias. The division of the cardiac monitoring methods into different phases also introduces the possibility of misclassification bias. Ultimately, the authors concluded that “by sequentially combining cardiac monitoring methods, atrial fibrillation might be newly detected in nearly a quarter of patients with stroke or transient ischemic attack.”¹⁶

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Event Monitor/External Loop Recorder (ELR)

Randomized Controlled Trials (RCTs)

An RCT by Gladstone and colleagues evaluated ambulatory ECG monitoring for the diagnosis and treatment of patients with unexplained stroke (EMBRACE trial).¹⁴ The RCT enrolled 572 patients who were 55 years of age or older, without known atrial fibrillation (AF), and who had a cryptogenic stroke or transient ischemic attack (TIA) within the previous 6 months. Patients were randomized 1:1 to undergo ambulatory ECG monitoring with a 30-day event-triggered external loop recorder (ELR) or 24-hour Holter monitoring (n=286 ELR; n=285 controls). The primary outcome was ECG-detected AF episodes lasting more than 30 seconds within 90 days after randomization.

At 90 days post-randomization, 97.7% of patients were available for follow-up evaluation. The ELRs recorded 218 AF episodes lasting more than 30 seconds in 44 patients within the first 30 days of monitoring. AF was detected in 16.1% of the ELR group, compared to 3.2% of the control group. ELRs were also superior for detection of continuous AF lasting more than 2.5 minutes compared to the control group (9.9% vs. 2.5%). Also of note, the AF detection rate was significantly higher among patients who underwent randomization within 3 months after the initial stroke or TIA compared to patients who underwent randomization after more than 3 months.

Strengths of this RCT include the randomized, controlled design, large sample size, control group comparison, low attrition rates, and the use of intention-to-treat analysis. Limitations include the lack of blinding and patient non-compliance (18% of patients used the ELR for less than 3 weeks). The authors indicated another limitation is the inability to evaluate the total burden of AF per patient because of the ELRs limited recording capacity. The authors concluded “noninvasive ambulatory ECG monitoring for a target of 30 days significantly improved the detection of atrial fibrillation by a factor of more than five compared with the standard practice of short-term ECG monitoring.”¹⁴

A 2003, prospective, randomized study by Sivakumaran et al. evaluated the diagnostic yield of ELRs versus Holter monitors for identifying cardiac arrhythmias.¹⁷ They enrolled n=100 patients and randomly assigned them to receive either a 48 hour Holter or an ELR for 1 month. An arrhythmia was identified or excluded in 63% of ELR patients and 24% of Holter patients. The overall probability for symptom-rhythm correlation was 56% for ELR patients and 22% for Holter patients. Of the ELR patients, 23% failed to activate the loop recorder properly when symptoms recurred.

Methodological strengths of this study included its prospective, randomized design and recruitment from several different health centers; therefore creating similar baseline characteristics between both study arms. Limitations included the small sample size, lack of blinding, lack of power calculations, and the substantial difference in follow-up duration between the two groups (48 hours versus 1 month). The authors concluded ELR has a significantly higher diagnostic yield than Holter monitoring, but clinical utility might be limited in the user’s inability to properly operate the ELR.

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Nonrandomized Studies

In 2005, Reiffel et al. published a retrospective review of the Lifewatch (a commercial cardiac monitoring company) database records in order to compare the diagnostic yield of Holter monitoring versus patient-activated external loop recorders (ELR) versus auto-activated ELR.¹⁸ Of the database containing 100,000 records, the authors randomly selected 1,800 for review (600 records from each of the 3 different monitoring groups). The diagnostic yields were 6.2% for Holter monitoring, 17% for patient-activated ELR, and 36% for auto-activated ELR. The auto-activated ELR was also significantly better at capturing asymptomatic events compared to the patient-activated ELR (52 events versus 1 event).

Methodological strengths of this study include the large sample size, head-to-head comparison of three different cardiac monitoring methods, and randomly choosing database records for review. Limitations include its nonrandomized, retrospective design, and substantial difference in follow-up duration between the comparison groups (48 hours versus 1 month). Bias is also likely due to the selection of records from one patient database.

External Patch Recorders

Systematic Reviews

In 2020, Hayes published updated health technology assessment of the Zio Patch from IRhythm Technologies, Inc.¹⁹ The review included 10 clinical studies that evaluated the efficacy of Zio Patch for diagnosing cardiac arrhythmias (1 poor-quality RCT with subsequent cohort study; 3 poor-quality cohort studies; 6 very poor-quality registry analyses).¹⁹ The systematic review suggested that there is good correlation between Zio Patch and Holter monitoring for detection of clinically significant cardiac arrhythmias. The results also indicated that the longer monitoring time with Zio Patch can improve the detection of cardiac arrhythmias in some patients. Use of the Zio Patch was also shown to be advantageous for detection of asymptomatic cardiac events. The patch was well tolerated across study populations and had very few device-related adverse events. However, diagnostic and clinical limitations were seen in the devices ability to correlate patient symptoms with a corresponding cardiac arrhythmia; therefore limiting a symptom-rhythm correlation. Hayes gave an overall “C” rating for the use of Zio[®] Patch for long-term ambulatory electrocardiography in adults with known or suspected arrhythmias (potential but unproven benefit). Hayes gave “D2” ratings (insufficient evidence) for use of the Zio Patch in children and asymptomatic adults who are at-risk of developing an arrhythmia. Hayes concluded that “there is insufficient evidence to draw conclusions regarding the clinical validity or utility of the Zio Patch.”

In 2018, ECRI published an evidence review evaluating the efficacy of the Carnation Ambulatory Monitor (CAM) for diagnosing cardiac arrhythmias.²⁰ Having searched the literature through May 2018, ECRI identified and reviewed 2 comparative studies (n=80) and 4 conference abstracts. Studies reported evidence of some clinical utility as a primary diagnostic tool for cardiac arrhythmias. Nonetheless, investigators concluded that the limited quantity and quality of data (e.g. small sample sizes, lack of randomization, and lack of blinding) limited studies’ validity.

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In 2018, the United States Preventive Services Task Force (USPSTF) published a commissioned systematic review and meta-analysis evaluating the use of electrocardiogram (ECG) screening of asymptomatic people 65 years of age or older to identify occult atrial fibrillation (AF).²¹ Evidence regarding the diagnostic accuracy of screening tests for AF was not collected. Independent investigators systematically searched the literature through May 2018, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 17 studies were included for review (n=135,500). Investigators found that while systematic screening with ECG identified more new cases of AF than no screening, it did not identify more cases than an approach using pulse palpitation. Investigators concluded that some evidence demonstrated that screening for AF with ECG is associated with small-to-moderate harms (e.g. potential for misdiagnosis, additional testing and invasive procedures, and overtreatment) but that evidence was inadequate to determine the net benefit of screening with ECG.

In 2018, Ramkumar and colleagues published a systematic review and meta-analysis evaluating atrial fibrillation detection using single lead portable electrocardiographic monitoring compared to Holter monitoring.²² Independent investigators searched the literature through May 2017, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 18 studies using portable electrocardiography monitoring were included for review (n=117,436), as were 36 studies using Holter monitoring (n=8,498). The AF detection rate using portable ECG monitoring was 1.7% (95% CI 1.4 to 2.1), with significant heterogeneity between studies (I²=94% for single-lead ECG monitoring, 87% for Holter monitoring). There was a moderate linear relationship between total monitoring time and AF detection rate (r=0.65, p=0.003), and meta-regression identified total monitoring time (p=0.005) and body mass index (p=0.01) as potential contributors to heterogeneity. Across 8 studies, the detection rate (4.8%, 95%CI 3.6% to 6.0%), which performed multiple ECG recordings was comparable to that with 24 hours Holter (4.6%, 95%CI 3.5% to 5.7%). Study limitations included heterogeneity in patient cohorts across studies, heterogeneity of type/duration of monitoring and type of device used, both of which limit possible comparisons between ECG and Holter patient groups and undermine results' generalizability. Despite these limitations, investigators concluded that portable ECG devices may offer an efficient screening option for AF compared with Holter monitoring.

Randomized Controlled Trials (RCTs)

No RCTs were identified which compared external patch recorders (e.g., Zio[®] Patch) to other standard of care ambulatory cardiac monitors.

Nonrandomized Studies

In a 2013 self-controlled prospective cohort study Barrett et al. compared the standard of care (Holter monitor) with the new Zio[®] Patch technology.²³ Participants were recruited from referrals for ambulatory cardiac monitoring at a California hospital. In all, n=146 patients were recruited to simultaneously use both devices for the first 24 hours and only Zio[®] Patch for the remainder of the monitoring period (up to 14 days). In the first 24 hours of monitoring, Zio[®] Patch had a lower diagnostic yield for total arrhythmias compared to the Holter monitor (52 versus 61) but a similar yield for significant cardiac arrhythmias (27 versus 24 events). The longer monitoring time of Zio[®] Patch

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significantly increased the diagnostic yield of clinically relevant arrhythmias (27 events in the first 24 hours to 41 events by day 14).

Methodological strengths of this study included the head-to-head comparison of the two different technologies, power analysis to determine the sample size needed for statistically meaningful comparisons, and data from each device being analyzed by different independent investigators. Limitations include the prospective cohort design, small sample size, no measure of clinical performance (e.g., sensitivity and specificity), no comparison after 24 hours, and recruitment from only one hospital. There is also potential funding bias due to study sponsorship by the Zio® Patch manufacturers (iRhythm™). The authors concluded that the adhesive monitoring patch detects significantly more arrhythmias and may soon replace conventional Holter monitoring for the detection of cardiac arrhythmias.

In 2013, Rosenberg et al. published a self-controlled cohort study to compare the Zio® Patch with a 24-hour Holter monitor.²⁴ Participants were enrolled from a pool of patients undergoing atrial fibrillation (AF) management at a Massachusetts hospital. A total of 74 patients were recruited and given both devices to use simultaneously for the first 24 hours and only the Zio® Patch thereafter. In the first 24 hours, both devices were similar in identifying AF events and assessing AF burden. The diagnostic yield of Zio® Patch was also significantly improved with increased monitoring time (34% at 24 hours versus 58% by 14 days). The results also suggest that Zio® Patch changes the classification of AF and may detect other significant arrhythmias.

Strengths of this study included the head-to-head comparison of the two different technologies and the data being analyzed and interpreted by independent, blinded reviewers. Methodological limitations include the nonrandomized cohort design, small sample size, no head-to-head comparison beyond 24 hours, patient recruitment from only one hospital, and no measure of clinical performance (e.g., sensitivity and specificity). There is also potential funding bias due to study sponsorship by the Zio® Patch manufacturers (iRhythm™). The authors concluded that the, “Zio Patch was well tolerated, and allowed significantly longer continuous monitoring than a Holter, resulting in an improvement in clinical accuracy, the detection of potentially malignant arrhythmias, and a meaningful change in clinical management.”²⁴

Three additional nonrandomized studies (1 prospective cohort study and 2 cross-sectional studies) were identified that evaluated Zio® Patch for diagnosing cardiac arrhythmias.²⁵⁻²⁷ All three studies suggest that Zio® Patch is well tolerated and the extended monitoring period may identify or confirm significant cardiac arrhythmias not diagnosed with standard Holter monitoring.

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Mobile Cardiac Outpatient Telemetry (MCOT)

Cardiac Arrhythmias

Systematic Reviews

In 2019, ECRI conducted an evidence review of outpatient cardiac telemetry monitors for diagnosing and managing cardiac arrhythmias.²⁸ Searching the literature through February 2019, investigators reviewed the full text of three studies and abstracts of three studies reporting data on 90,590 patients. One systematic review assessing 50 studies (n = 11,658) compared the CardioNet MCOT monitor with external and implanted event recorders and reported on AF diagnostic yields after stroke or transient ischemic attack. One patient registry study (n = 78,490) compared CardioNET MCOT with the auto-trigger looping event recorder (AT-LER) and reported on diagnostic yield and time to diagnosis in patients with suspected arrhythmias. A case series (n = 100) reported on diagnostic yield with the SEEQ telemetry monitor in patients with suspected arrhythmia and negative 24-hour Holter monitoring. One diagnostic cohort study (n = 36) reported on diagnostic accuracy for automated long QT syndrome detection with the BodyGuard telemetry monitor compared with manual ECG recording review. One study (n = 152) reported on the BioMonitor implanted telemetry system's sensitivity compared with that of 48-hour Holter monitoring.

Limitations included studies' small sample sizes, inadequate follow-up and a lack of prospective studies. Evidence to date has also yet to assess clinical utility, only indirect evidence pertaining to diagnostic yield. Investigators concluded that evidence on the whole was "inconclusive."²⁸

Randomized Controlled Trials (RCTs)

In 2006 prospective, multi-center, randomized study Rothman et al. evaluated the diagnostic utility of mobile cardiac outpatient telemetry (MCOT) versus external loop recorders (ELR) for identifying suspected cardiac arrhythmias.²⁹ A total of 305 patients who had symptoms of syncope, pre-syncope, or severe palpitations were recruited across 17 health centers and randomized to receive MCOT or ELR for up to 30 days. Investigators analyzed data of 266 participants who completed a minimum of 25 days of monitoring (134 MCOT and 132 ELR). A cardiac arrhythmia was diagnosed in 88% of MCOT patients compared to 75% of ELR patients. Also, the MCOT device was able to find more asymptomatic clinically significant arrhythmias than the ELR device (41% MCOT versus 14% ELR). In a subgroup of syncope and pre-syncope patients, a cardiac arrhythmia was diagnosed in 89% of MCOT patients versus 69% of ELR patients. The ELR was superior at simultaneously recording an arrhythmia during symptoms (47% ELR versus 40% MCOT); thus allowing for symptom-rhythm correlation.

Methodological strengths of this study include the randomized design, recruitment from 17 different health centers, larger sample size, power calculations to determine the sample size needed for meaningful comparisons between groups, similar baseline characteristics between both treatment arms, and ECG data being reviewed by independent reviewers blinded to randomization and patient history. Limitations include the lack of blinding, lack of intention-to-treat analysis, and the exclusion of patients

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who did not wear the monitor for at least 25 days (potential selection bias). Also of note, noncompliance was much more common in the MCOT group than the ELR group and the authors did not indicate any reason for this. The authors concluded that, “MCOT provided significantly higher yield than standard cardiac loop recorders in patients with symptoms suggestive of a significant cardiac arrhythmia.”²⁹

Nonrandomized Studies

In 2017, Derkac and colleagues published a retrospective analysis of 69,977 patients prescribed MCOT over a consecutive 8-month period to evaluate accuracy in diagnosing asymptomatic arrhythmias. Compared to 8,513 patients prescribed an autotrigger looping event recorder (AT-LER), MCOT patients had significantly higher diagnostic yields for all 5 asymptomatic arrhythmias. The mean time to diagnosis for each asymptomatic arrhythmia evaluated was also shorter for MCOT patients compared to AT-LER patients. Limitations include the lack of information on patient comorbidities, which may have confounded results. Patients younger than 40 years of age were also underrepresented in the patient cohort, potentially limiting results’ generalizability to that population.³⁰

In 2009, Kadish et al. published a retrospective analysis of 26,438 patients who had used the LifeWatch® ambulatory cardiac telemetry device for diagnosis of cardiac arrhythmic events.²⁴ The cardiac arrhythmias were categorized as those requiring physician notification and those that were potentially life-threatening cardiac events. Over a three week monitoring period, 21% of patients had arrhythmic events meeting physician notification criteria while 1% had emergent, life-threatening arrhythmic events. Although this study includes a large sample size and shows promising results, significant limitations include its retrospective design, lack of randomization, and lack of long-term follow-up.

In 2007, Olson et al. published a retrospective records review of 122 consecutive patients which evaluated the use of MCOT for palpitations, pre-syncope, syncope, or to monitor antiarrhythmic drugs.³¹ Of the patients experiencing pre-syncope or syncope, 59% were diagnosed with a cardiac arrhythmia. Of patients with palpitations, 73% were able to correlate their symptoms with a cardiac arrhythmia after the MCOT monitoring period. Of the 21 patients using the MCOT to monitor antiarrhythmic drugs, 7 had medication dosage adjustments. Also, 19 patients who remained asymptomatic during the monitoring period had a cardiac arrhythmia detected. This study shows encouraging results for the use of MCOT to monitor syncope, palpitations, and drug dosages; however, there are significant methodological limitations in the retrospective design and small sample size.

In 2005, Joshi et al. published a retrospective analysis of the first 100 consecutive patients monitored with MCOT.³² The authors aimed to evaluate the effectiveness of MCOT based on its detection of arrhythmias and changes in patient management. The duration of MCOT monitoring varied by patient (the monitoring period is up to the discretion of the doctor), but was anywhere from 5 to 28 days. A clinically significant arrhythmia was detected in 51 patients and 25 (49%) of these patients were asymptomatic during the arrhythmia. 76% of patients found to have atrial fibrillation after MCOT monitoring also experienced no symptoms during the arrhythmia. The electrocardiogram results produced by MCOT led to a change in treatment management in 34 patients. Also, of 30 patients who had a previous non-diagnostic Holter monitor, 16 had a detected arrhythmia using MCOT. The results of

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this study were first to indicate the potential efficacy of MCOT for diagnosing cardiac arrhythmias; however, significant methodological limitations exist and future randomized controlled trials comparing MCOT to other diagnostic methods are needed.

Cryptogenic Stroke

Randomized Controlled Trials (RCTs)

In 2012, Kamel et al. published a randomized pilot trial to compare the use of mobile cardiac outpatient telemetry (MCOT) versus routine follow-up in patients with cryptogenic stroke or high-risk transient ischemic attack (TIA).³³ The investigators randomly assigned 40 patients to wear a MCOT monitor for 21 days or to receive routine follow-up alone. Patient follow-up was conducted at 3 months and 1 year by contacting the patient’s physician to ascertain any diagnoses of atrial fibrillation (AF), recurrent stroke, or TIA. No patients in either study arm received an AF diagnosis. MCOT did reveal other cardiac arrhythmias in 4 patients. Of note, patient compliance with the MCOT device was very poor with only 64% of patients wearing the monitor for the assigned days.

Strengths of this study include the randomized design and use of the intention-to-treat analysis. Significant limitations are seen in the small sample size, recruitment from only one hospital, and lack of blinding. Also, the authors did not report what diagnostic tests were involved in the “routine follow-up” patient group, so it is difficult to make a true conclusion regarding the diagnostic efficacy of MCOT versus other diagnostic methods. The results of this study indicate MCOT is not diagnostically efficacious for identifying AF, and further prospective randomized controlled trials are needed to confirm its usefulness for identifying AF after cryptogenic stroke or TIA.

Nonrandomized Studies

Additionally, five nonrandomized studies (4 retrospective cohort studies and 1 case series) were identified that evaluated the use of MCOT for diagnosing atrial fibrillation (AF) after cryptogenic stroke.³⁴⁻³⁸ Monitoring duration across the 4 studies ranged from 21-30 days. The detection rate of AF during MCOT monitoring ranged from 4.7% to 23%. Although MCOT shows a potential diagnostic utility for diagnosing AF after cryptogenic stroke, data from these studies does not permit conclusion due to the methodological limitations seen in the lack of randomization, small sample sizes, and lack of comparison groups.

CLINICAL PRACTICE GUIDELINES

U.S. Preventive Services Task Force (USPSTF)

In 2018, USPSTF commissioned a systematic review (discussed above)²¹ to evaluate the evidence on the benefits and harms of screening for atrial fibrillation with ECG in older adults, and the effectiveness of screening with ECG for detecting previously undiagnosed atrial fibrillation compared with usual care.³⁹

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The USPSTF concluded that evidence was insufficient to assess the risks and benefits of screening for atrial fibrillation with ECG.

National Institute for Health and Care Excellence (NICE)

The 2014 evidence-based NICE guidelines for managing atrial fibrillation recommended a 24-hour ambulatory ECG monitor (e.g., Holter monitor) for patients with suspected asymptomatic atrial fibrillation or for patients with symptomatic episodes less than 24 hours apart.⁴⁰ For patients with symptoms more than 24 hours apart NICE recommended an event recorder ECG.

The guidelines did not mention the Zio® Patch or mobile cardiac outpatient telemetry for managing atrial fibrillation.

American Academy of Neurology (AAN)

The 2014 evidence-based AAN guideline for atrial fibrillation recommended, “cardiac rhythm studies for prolonged periods (e.g., for 1 or more weeks) instead of shorter periods (e.g., 24 hours) in patients with cryptogenic stroke without known atrial fibrillation, to increase the yield of identification of patients with occult atrial fibrillation.”⁴¹

The guidelines did not specify the type of external ambulatory ECG to use for the prolonged monitoring period.

American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS)

The 2017 evidence-based ACC/AHA/HRS guidelines for managing patients with syncope stated, “the selection and usefulness of cardiac monitors is highly dependent on patient characteristics with regard to the frequency of syncope and the likelihood of an arrhythmic cause of syncope”.¹⁵

The guidelines suggested the following external cardiac monitors to evaluate ambulatory patients with syncope of suspected arrhythmic etiology:

1. Holter monitor
2. Transtelephonic monitor
3. External Loop Recorder
4. Patch recorder
5. Mobile cardiac outpatient telemetry

The guidelines also stated, “a monitor that requires patient activation (e.g., patient-activated external loop recorder or transtelephonic monitor) allows for symptom-rhythm correlation; however, some of these cardiac monitors are of limited use in patients who are temporarily incapacitated around the time of syncope”.

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The 2014 evidence-based ACC/AHA/HRS guidelines for managing patients with atrial fibrillation stated, “the diagnosis of atrial fibrillation is based on the patient’s clinical history and physical examination and is confirmed by ECG, ambulatory rhythm monitoring (e.g., telemetry, Holter monitor, and event recorders), implanted loop recorders, pacemakers or defibrillators, or, in rare cases, electrophysiological studies.”⁴² The guidelines also mentioned prolonged or frequent monitoring may be necessary to reveal asymptomatic atrial fibrillation.

The 2013 evidence-based ACC/AHA/HRS guidelines for early management of patients with acute ischemic stroke stated, “Holter monitoring is more effective in identifying atrial fibrillation or other serious arrhythmias after stroke. Outpatient event monitoring may be indicated in patients with cryptogenic stroke and suspected paroxysmal arrhythmias, especially in those patients with short hospitalizations in which monitoring was brief.”⁴³

POLICY SUMMARY

There is enough evidence to show that mobile cardiac outpatient telemetry (MCOT), cardiac event monitors (also known as external memory loop recorders) and patch recorders may improve overall health outcomes for those with a suspected cardiac arrhythmia when shorter term monitoring (e.g., Holter monitor) has failed to lead to a diagnosis. Clinical practice guidelines based on research recommend these types of monitors over 24-hour monitoring in select patient populations. Therefore, cardiac event monitors (also known as external memory loop recorders) and patch recorders when policy criteria are met. MCOT, cardiac event monitors (external memory loop recorders) and patch recorders are considered not medically necessary and not covered when policy criteria are not met.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Numerous examples of external ambulatory electrocardiography devices with United States FDA approval referred to in this policy are listed in Table 1. under Billing Guidelines, above.

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Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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