Ambulatory Cardiac Event Monitoring and Real-time Outpatient Cardiac Telemetry

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DESCRIPTION

The intended use of all ambulatory cardiac event monitors are for the **diagnosis** of cardiac arrhythmias. There is only one indication, atrial fibrillation, where the monitors would be considered **after** an arrhythmia diagnosis.

Ambulatory Holter electrocardiography (EKG) is a widely used noninvasive test in which the EKG is continuously recorded over an extended period of time, typically 24 to 48 hours, to evaluate symptoms suggestive of cardiac arrhythmias, e.g., palpitations, dizziness, or syncope. However, Holter monitoring will be ineffective in detecting arrhythmias for a patient that experiences infrequent symptoms (less than every 48 hours).

Continuous Monitoring Devices with Recording Periods Longer than a Holter
The Zio Patch/Zio XT (iRhythm Technologies, Inc., San Francisco, CA) is a recording device that provides continuous single-lead ECG data for up to 14 days (Mittal et al, 2011). The Zio Patch uses a patch that is placed on the left pectoral region. The patch does not require patient activation. However, a button on the patch can be pressed by the patient to mark a symptomatic episode. At the end of the recording period, the patient mails back the recorder in a prepaid envelope to a central monitoring station. A report is provided to the ordering physician within a few days. The manufacturer states that it is indicated for use in patients who may be asymptomatic or who may suffer from transient symptoms (e.g., anxiety, dizziness, fatigue, light-headedness, palpitations, pre-syncope, shortness of breath, and syncope). The Zio ECG Utilization Service (ZEUS) system is a comprehensive system that processes and analyzes received ECG data captured by long-duration, single-lead, continuous recording diagnostic devices

The Carnation Ambulatory Monitor or CAM™ is a lightweight, bandage-size cardiac patch monitor engineered to capture low amplitude, low frequency electrical signals that form the P-wave. The patch is worn for at least 7 days with continuous recording during sleep and normal activities. It is then sent to the clinician for ECG data assessment.

Continuous Monitoring Devices with Recording Periods Longer than a Holter with Additional Physiologic Data
The BodyGuardian Remote Monitoring System™ (Preventice®, Inc., Minneapolis, MN) continuously detects and records a variety of physiologic data including ECG tracing, respiratory rate, and activity level for up to 30 days. The data can be transmitted to the physician's office via a cellular telephone, and information can be viewed by the patient and physician through the internet.

CardioPatch or Multi-Sense CardioPatch is a wearable multi-sensor patch for remote heart monitoring aimed at providing a more detailed and comprehensive heart status diagnostics. The system integrates multiple sensors in a single patch for detection of both electrical (electrocardiogram, ECG) and mechanical (heart sounds, HS) cardiac activity, in addition to physical activity (PA).

Ambulatory event monitors (AEMs) were developed to provide longer periods of monitoring. In this technique, the recording device is either worn continuously or activated only when the patient experiences symptoms or is carried by the patient and applied and activated when symptoms are present. The recorded EKGs are then stored for future analysis or transmitted by telephone to a receiving station, such as a doctor's office, hospital, or cardiac monitoring service, where the EKGs can then be analyzed. AEMs can be used for extended periods of time, typically up to a month until the patient experiences symptoms.

Several different types of **Ambulatory Event Monitors** are available: These are available in self-activated and auto-activated models.

Noncontinuous Devices with Memory
These devices are carried by the patient and applied to the precordial area via non-gel electrodes when the symptoms are occurring or, alternatively, a recording device may be worn on the wrist and then activated when symptoms are present. The limitation of these devices is that an arrhythmia of very short duration would be difficult to record. In addition, noncontinuous devices require reasonable dexterity on the part of the patient to apply the device correctly during a symptomatic period. This is a particular limitation if the patient is incapacitated during symptomatic periods. (The Zio Event Card and the REKA E100)

Continuous "Memory Loop" Devices
These sophisticated devices are able to continuously store a single channel of EKG data in a refreshed memory. If the patient activates the device, the EKG is then recorded from the memory loop for the preceding 30 to 90 seconds, and for the next minute or so. Therefore, these types of devices permit recording of the onset of arrhythmias or other transient events. These devices are worn continuously.

Implantable Continuous "Memory Loop" Devices
For patients with very infrequent cardiac events requiring long term monitoring, an implantable loop recorder device is inserted just under the patient's skin in the chest area during an outpatient surgical procedure. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for more than one year. More recently, auto-triggering technology has become available which can be adapted to memory loop devices. For example, event monitors can be programmed to detect heart rates greater than 165 beats per minute, less than 40 beats per minute, or an asystole of greater than three seconds. The Reveal® Insertable Loop Recorder is an implantable memory loop device approved by the U.S. Food and Drug Administration (FDA). In February 2014, the FDA cleared for marketing the Reveal LINQ™, a miniaturized implantable memory loop device that is auto-triggered or patient-activated rhythm recording.

Mobile Cardiac Outpatient Telemetry (MCOT)
Real-time outpatient cardiac telemetry, also known as real-time remote heart monitors, and mobile cardiac outpatient telemetry, are devices that integrate standard AEM devices with automated calling features using computer activated dialing of telephone land lines or cellular communication technology and monitoring services. As with standard AEMs, real-time remote heart monitors use similar types of EKG leads and recording devices. However, when a real-time remote heart monitor detects an arrhythmia, either automatically or by the patient himself, the EKG record is transmitted to a service center, which may notify the treating physician if certain criteria are met.

There are several real-time remote heart monitors available on the market in the U.S. The CardioNet Mobile Cardiac Outpatient Telemetry Service™ (MCOT™) uses the CardioNet monitoring device, Telemetry @ Home uses the HEARTLink II™ monitoring device, Lifewatch® utilizes the Lifestar ACT (Ambulatory Cardiac Telemetry) device,

Applied Cardiac Systems, Inc (ACS) uses the Core device, and Biowatch™ uses the Vital Signs Transmitter (VST™).The VectraplexECG™ System is a real-time continuous Mobile Cardiac Outpatient Telemetry device to measure ischemic ECG changes that can be indicative of a myocardial infarction (MI). This device utilizes the Internet to communicate real-time ECG changes to the physician. TeleSense remote cardiac monitor uses wi-fi to transmit real-time data.

Practice Guidelines and Position Statements

American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS) Joint guidelines for the management of patients with Atrial Fibrillation (AF) state that the diagnosis of AF is based on clinical history and physical examination and is confirmed by electrocardiogram, ambulatory rhythm monitoring (e.g., telemetry, Holter monitor event recorders), implanted loop recorders, pacemakers or defibrillators or, in rare cases, by electrophysiological study. Prolonged or frequent monitoring may be necessary to reveal episodes of asymptomatic AF. An update of these guidelines (2019) has a new section on device detection of AF and atrial flutter.

ACC/AHA/HRS guidelines (2017) on the evaluation and management of patients with syncope address several ambulatory ECG monitoring options. The guidelines recommend that the choice of a specific monitoring system and duration should be determined on the basis of the frequency and nature of syncope events. To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful:

- Holter monitor
- Transtelephonic monitor
- External loop recorder
- Patch recorder
- Mobile cardiac outpatient telemetry

Heart Rhythm Society (HRS)/International Society for Holter and Noninvasive Electrocardiology (ISHNE) (2017) The HRS, in collaboration with the ISHNE, published a consensus statement on ambulatory ECG and external cardiac monitoring. The document summarizes the advantages and limitations of various ambulatory ECG techniques.

The National Institute for Health and Clinical Excellence (NICE)
The National Institute for Health and Clinical Excellence (NICE) diagnostics guidance on LeadI ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care stated that there is a lack of evidence to recommend the routine adoption of lead-I electrocardiogram (ECG) devices (imPulse, Kardia Mobile, MyDiagnostick and Zenicor-ECG) to detect atrial fibrillation when used for single time point testing in primary care for people with signs or symptoms of the condition and an irregular pulse. Further research is needed to determine how using lead-I ECG devices in this way affects the number of people with atrial fibrillation detected, compared with

current practice and how ECGs generated by the devices would be interpreted in practice, including staff time needed to interpret the ECG traces and associated costs

Regulatory Status
There are numerous manufacturers of external cardiac event monitoring devices which can be found on the FDA Center for Devices and Radiologic Health 510(k) database. An example of an FDA approved external loop monitor is the King of Hearts Express® AF (Card Guard Scientific Survival). The FDA approval granted 510(k) approval on 4/5/2002. It is indicated for diagnostic evaluation of patients who experience transient dizziness, palpitations, syncope or chest pain.

Multiple MCOT devices have been approved by the U. S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process. Manufacturers of MCOT devices include, but are not limited to: CardioNet ambulatory ECG monitor with arrhythmia detection (San Diego, CA), HEARTLink™ II (Greensburg, PA) and LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT

There are numerous manufacturers of Implantable Loop Recorders (ILR's) which can be found in the FDA Center for Devices and Radiologic Health 510(k) database. Manufacturers of ILR devices include Abbott (Sylmar, CA), Biotronik (Lake Oswego, OR), Boston Scientific (Natick, MA), Sorin Group (Arvada, CO), Medtronic (Minneapolis, MN), Transoma Medical (St. Paul, MN) and St. Jude Medical (Sylmar, CA).

PRIOR APPROVAL

Not applicable.

POLICY

External Event Monitors

A. The use of **external** loop ambulatory event monitor with 24-hour attended monitoring (93268, 93270, 93271, 93272) may be considered **medically necessary** for any of the following indications**:**

As a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than 48 hours) that are suggestive of cardiac arrhythmia (i.e. palpitations, syncope and presyncope [feeling of faintness/dizziness]); **OR**

1. In patients with known atrial fibrillation:
   a. Who have been treated with catheter ablation and discontinuation of systemic anticoagulation is being considered; **or**
   b. As a means of evaluating rate control; **OR**
2. Following a cryptogenic stroke for the detection of suspected paroxysmal atrial fibrillation when prior testing with Holter monitor or inpatient telemetry for at least 48 hours has yielded inconclusive results and external ambulatory

event monitoring is intended to guide medical management with anticoagulants.

B. The use of a continuous ambulatory event monitor that records and stores information for longer than 48 hours and up to 14 days (e.g. Zio Patch, CAM patch) (93241-93248) may be considered **medically necessary** for **either** of the following:
   1. As a diagnostic alternative to a Holter monitor in an individual who experiences infrequent symptoms (less frequently than 48 hours) suggestive of cardiac arrhythmia (i.e. palpitations, syncope and presyncope [feeling of faintness/dizziness); **OR**
   2. In patients with known atrial fibrillation:
      a. Who have been treated with catheter ablation an discontinuation of systemic anticoagulation is being considered; **or**
      b. As a means of evaluating rate control.

Implantable Event Monitors

Required Documentation for Implantable Event Monitors
Medical records should include **ALL** of the following:
- Patient's diagnosis; **and**
- Evidence that the patient is at a high risk for an arrhythmia; **and**
- Non-invasive cardiac monitoring was non-diagnostic, to include all dates and results of previous testing; **and**
- Episode dates and occurrence of syncope, including test results, cardiac etiology and/or unexplained episodes.

A. The use of an **implantable** ambulatory event monitor (E0616, C1764 33285, 33286) may be considered **medically necessary** for evaluation of recurrent symptoms of palpitations, syncope or presyncope (feeling of faintness/dizziness) when a cardiac arrhythmia is suspected as a cause of the patients symptoms and the medical records indicates the following applies:
   1. The symptoms occur infrequently (less frequently than 48 hours); **and**
   2. Diagnostic evaluation to include history and physical examination, electrocardiogram, orthostatic blood pressure measurements and an echocardiogram was non-diagnostic; **and**
   3. Suspected cardiac arrhythmia is not detected (non-diagnostic) with a previous trial of external ambulatory cardiac event monitoring for a minimum of 30 consecutive days.

B. The use of an implantable ambulatory event monitor (E0616, C1764, 33285, 33286) may be considered **medically necessary** in the evaluation of cryptogenic stroke when **ALL** of the following are met:
   1. Occult atrial fibrillation is suspected as the cause of the stroke; **and**

2. The suspected cardiac arrhythmia is not detected (non-diagnostic) by a previous trial of external ambulatory cardiac event monitoring for a minimum of 30 consecutive days or inpatient telemetry for at least 48 hours; **and**
3. There is no contraindication to the use of implantable cardiac event monitor listed below.

Removal of Internal Recorder
The removal of the internal recorder related to an implantable ambulatory event monitor for placement of a pacemaker is considered **medically necessary** regardless of the reason it was implanted.

Note: Given the small but higher risk associated with an implantable ambulatory cardiac monitor including but not limited to the following: infection at the surgical site, device migration, erosion of the device through the skin and/or sensitivity to the device material, it would be reasonable to consider the use of an implantable ambulatory cardiac monitoring only after a 30 day trial of an external cardiac event monitor and additional cardiac testing does not yield a definitive diagnosis.

Contraindications for the use of implantable ambulatory cardiac event monitor for a cryptogenic stroke include:

- Member's condition is already indicated for implant with a pacemaker, an Implantable Cardioverter-Defibrillator (ICD), or Cardiac Resynchronization Therapy (CRT); **or**
- The individual has a known etiology of stroke or TIA (i.e., large artery atherosclerosis, acute small artery occlusion); **or**
- Evidence of high-risk cardiac or aortic arch source of embolism (left ventricular (LV) or left atrial (LA) thrombus), emboli genic valvular lesion or tumor, patent foramen ovale (PFO) with extant source of venous thromboembolism, aortic arch plaque greater than three (3) mm thick; **or**
- History of spontaneous deep vein thrombosis (DVT); **or**
- Stroke of other determined cause such as the presence of non-atherosclerotic vasculopathy, hypercoagulable states and hematologic disorders; **or**
- Untreated hyperthyroidism; **or**
- Myocardial Infarction less than one (1) month before stroke/TIA; **or**
- Coronary bypass grafting (CABG) less than one (1) month before stroke/TIA; **or**
- Valvular disease requiring immediate surgical intervention; **or**
- Documented history of atrial fibrillation (AF) or atrial flutter; **or**
- The individual has a permanent indication for anticoagulation; **or**
- The individual has a permanent contraindication for anticoagulation.

All other uses of external loop cardiac event monitoring, continuous ambulatory cardiac event monitoring (Zio Patch, CAM) and implantable cardiac event monitoring not meeting the above criteria are considered **not medically necessary**, including but not limited to the following:

- Detection of myocardial ischemia by identifying ST segment changes;

- Measurement of heart rate variability in the assessment of a patient at risk for future cardiac events without symptoms of an arrhythmia;
- Ongoing medical management of a diagnosed arrhythmia, except for individuals with known atrial fibrillation meeting the above criteria.

External cardiac event monitoring without 24-hour attended monitoring are considered **investigational**. The evidence is insufficient to determine the effects of the technology on net health outcomes:

Real-time Outpatient Cardiac Telemetry/ Mobile Cardiac Outpatient Telemetry (MCOT)

Required Documentation for Mobile Cardiac Outpatient Telemetry (MCOT)
Medical records should include **ALL** of the following:

- Patient's diagnosis; **and**
- Evidence that the patient is at a high risk for an arrhythmia; **and**
- Ambulatory cardiac monitoring is non-diagnostic, to include all dates and results of the previous testing.

The use of real-time outpatient cardiac telemetry/mobile cardiac outpatient telemetry (MCOT) devices (93228, 93229) may be considered **medically necessary** when **ALL** of the following are met:

1. Recurrent, unexplained episodes of presyncope (feeling of faintness/dizziness) or syncope occurring less frequently than once every 30 days; **and**
2. A non-life-threatening cardiac arrhythmia is suspected as the cause of the patient's symptoms; **and**
3. The patient had a non-diagnostic ambulatory cardiac event monitoring for a minimum of 30 consecutive days prior to the consideration of the real-time outpatient cardiac telemetry/mobile cardiac outpatient telemetry (MCOT).

A. The use of real-time outpatient cardiac telemetry/mobile cardiac outpatient telemetry (MCOT) devices (93228, 93229) are considered **not medically necessary** when the criteria above are not met.

Event Monitors that Monitor Both Electrocardiogram and Activities
Use of patient activated ambulatory event monitors that monitor both electrocardiogram and also monitor activity, body fluid status, body temperature, posture, heart sounds, and respiratory rate (e.g., Body Guardian, CardioPatch, Vital Patch, BIOTRONIK, BioMonitor, and iHEART) are considered **investigational.** The evidence is insufficient to determine the effects of the technology on net health outcomes.

Event Monitors Managed Through Smartphones
The use of ambulatory event monitors managed by patients through a smartphone (i.e AliveCor, ViSi Mobile Monitoring System, Verily Study Watch) are considered **investigational,** because the accuracy of capturing cardiac events is diminished

compared to auto-activated devices and their value has not been proven over time in comparative studies. The evidence is insufficient to determine the effects of the technology on net health outcomes:

Self-Monitoring or Over the Counter ECG Devices
Self-monitoring or over the counter ECG devices for any indication are considered **not a covered benefit,** even if they are prescribed by a health care practitioner. Self-monitoring or over the counter ECG devices are also available without a prescription.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 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
- 93228 Wearable 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; physician review and interpretation with report
- 93229 Wearable 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 physician prescribed transmission of daily and emergent data reports
- 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
- 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
- C1764 Event recorder, cardiac (implantable)
- E0616 Implantable cardiac event recorder with memory, activator and programmer.
- E1399 Durable medical equipment, miscellaneous
- 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

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POLICY HISTORY		
Date	**Reason**	**Action**
May 2022	Annual Review	Policy Revised
May 2021	Annual Review	Policy Revised
December 2020	Interim Review	Policy Revised
July 2020	Interim Review	Policy Revised
May 2020	Annual Review	Policy Revised
May 2019	Annual Review	Policy Revised
May 2018	Annual Review	Policy Revised
December 2017	Interim Review	Policy Revised
May 2017	Annual Review	Policy Revised
May 2016	Annual Review	Policy Revised
June 2015	Annual Review	Policy Renewed
November 2014	Interim Review	Policy Revised
July 2014	Annual Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
April 2012	Interim Review	Criterion Update
October 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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