Ambulatory Cardiac Monitoring
Clinical Coverage Criteria

Overview

An electrocardiogram (ECG or EKG) is a graphic representation of electrical activity within the heart. The 12-lead EKG has served as the gold standard for cardiac arrhythmia diagnosis for over a hundred years. A cardiac arrhythmia is any abnormal heart rate or rhythm. However, for nearly as long, the limitations inherent to an EKG have also been recognized. Arrhythmias can be paroxysmal and asymptomatic; thus, a baseline resting EKG may be insufficient for diagnosis. Atrial fibrillation (AF) is the prototypical example of an arrhythmia in which a 12-lead EKG is insufficient to guide clinical management (Mittal et al., 2011).

Ambulatory cardiac monitoring, also known as ambulatory electrocardiographic (AECG) monitoring refers to EKG services rendered in an outpatient setting, generally while the patient is engaged in activities, including sleep. Ambulatory cardiac monitoring is intended to provide the physician with documented episodes of arrhythmia which may not be detected using a standard 12-lead EKG. Ambulatory cardiac monitoring is useful to evaluate whether symptoms, including palpitations, presyncope, or syncope, are caused by ventricular arrythmias (Al-Khatib et al., 2017).

Ambulatory cardiac monitoring devices can be categorized as either:

- Continuous monitoring and recording devices, or
- Patient- or event-activated recording devices.

Continuous monitoring and recording devices

Continuous AECG monitors are used in diagnosing suspected arrhythmias, establishing their frequency, and relating them to symptoms. As their name implies, continuous ambulatory ECG monitors, also known as Holter monitors, continuously record the patient's cardiac rhythm while the patient is engaged in daily activities. The data is stored on magnetic tape or other media. A physician does not review the gathered data until after the device is removed from the patient. Continuous AECG monitors are worn continuously for a period of time during which the patient keeps a diary of activities and symptoms. Continuous AECG monitors capable of recording cardiac rhythms for up to 48 hours have been the cornerstone of noninvasive diagnosis of cardiac arrhythmias since the 1960s (Galli, 2016). Many continuous AECG monitors have been approved by the Food and Drug Administration (FDA) under Product Codes MWJ (Electrocardiograph, Ambulatory (Without Analysis) and DSH (Recorder, Magnetic Tape, Medical).

Recently, single-use, adhesive patch AECG monitors with up to 14 days of continuous recording capability have been introduced (for example, Zio® Patch, IRhythm Technologies, San Francisco, CA; Carnation Ambulatory Monitor™ (CAM patch), Bardy Diagnostics, Inc., Vashon Island, Washington 98070). Zio® Patch is applied to the left pectoral region. CAM patch is applied along the sternum. A trigger button, integrated into the patch monitor, can be activated to create a digital time stamp to synchronize the recorded EKG rhythm with symptoms. At the end of the monitoring period, the patient removes the patch and mails it to the manufacturer (for example, iRhythm Technologies or Bardy Diagnostics) for data retrieval and analysis. A patient report is provided to the ordering physician for interpretation (Fung et al.,2015).

The major advantages of continuous AECG monitoring include the ability to continuously record EKG data and the lack of need for patient participation in the transmission of data. Disadvantages include the relatively short duration of monitoring (up to 14 days) and the impossibility of transmitting real-time data to an attended unit and frequent noncompliance with keeping a log of symptoms and using event markers. The absence of real-time data transmission to an attended unit is an important clinical limitation of these devices (Galli et al., 2016, Zimetbaum and Goldman, 2010).

Patient- or event-activated ECG recording devices

Patient- or event-activated ECG recording devices make up the largest category of devices. The technology varies among different devices. According to their specific functions they can be divided into two categories: loop recorders, which include external loop recorders and implantable loop recorders; and post-event recorders (non-looping recorders) (Zimetbaum and Goldman, 2010, Galli et al., 2016).

- **External loop recorders**
  External loop recorders have a retrospective (loop) memory that continuously records and deletes the patient's ECG. They include a patient activation function that allows the patient to activate ECG storage when he or she experiences symptoms and can reliably document a correlation between symptoms and an arrhythmia. External loop recorders are capable of monitoring for up to 30 days and can diagnose most arrhythmias that occur at least monthly. Some devices permit the patient to transmit EKG data transtelephonically to a receiving center. Newer devices automatically transmit predefined events via a Bluetooth wireless link to the receiving center. A technician is available at these centers to review transmitted data 24 hours per day. In some instances, when the EKG is determined to be outside certain pre-set criteria by a technician, a physician is available 24 hours per day to review the transmitted data and make clinical decisions regarding the patient (Brignole et al., 2009; Galli, 2016). This is known as "24-hour attended monitoring". In other instances, transmitted EKG data is reviewed at a later time and are, therefore, considered "non-attended." (Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 1, 20.15 Electrocardiographic Services).

- **Post-event recorder (non-looping recorders)**
  A less sophisticated form of event recorder is the post- event recorder. These devices are not worn continuously but instead are applied directly to the chest area once a symptom develops. They have no retrospective memory to allow recording of the rhythm before the device is activated. The diagnostic yield of post-event recorders is limited by the fact that they are unable to detect the mechanism of onset of episodes, the short-lasting episodes and by the lack of automatic detection (Brignole et al., 2009). As with external loop recorders, the data are transmitted transtelephonically to a central monitoring station.

  The major advantage of external loop recorders and post-event recorders compared with continuous ECG monitoring is that they allow monitoring for longer time periods and can provide nearly real-time data analysis when the patient transmits a recording in proximity to the symptomatic event. The major limitation of external loop recorders for diagnosis of unpredictable and infrequent symptoms such as syncope is that the patients must continuously wear external electrodes in order to activate loop memory (Brignole et al., 2009; Zimetbaum and Goldman, 2010).

- **Implantable loop recorders**
  For patients with very infrequent symptoms, neither Holter monitors nor 30-day loop recorders may yield diagnostic information. In such patients an implantable loop recorder can be used. Implantable loop recorders are surgically placed under the patient's skin in the upper chest. Implantable loop recorders may remain in place for a year or longer, before they are explanted.

Mobile cardiac telemetry
Mobile cardiac telemetry is a type of ambulatory event monitor. It relies on real-time remote monitoring that integrates standard ambulatory event monitor devices with automated calling features using computer dialing of land lines or cellular communication technology and monitoring services. As with standard ambulatory event monitors, real-time remote heart monitors use similar types of electrocardiographic leads and recording devices. However, when an arrhythmia is detected using external mobile cardiac telemetry, either automatically or by the individual himself/herself, the EKG is reviewed, and the treating physician may be notified when certain criteria are met. Real-time transmission of recordings is the unique feature of external mobile cardiac telemetry, and evaluation of this aspect of the technology requires consideration of the final health outcome. The use of real-time monitoring implies that there is a subset of individuals where immediate intervention is required when designated arrhythmias are noted.

Guidelines and Recommendations

In 1999, the American College of Cardiology (ACC) and the American Heart Association (AHA), in conjunction with other organizations, published clinical guidelines for AECG with the following Class I recommendations (Crawford et al., 1999):

- Individuals with unexplained syncope, near syncope, or episodic dizziness in whom the cause is not obvious,
- Individuals with unexplained recurrent palpitation, and
- To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been characterized as reproducible and of sufficient frequency to permit analysis.

These guidelines predate the commercial availability of external loop recorders with auto-triggered capability and implantable loop recorders. However, these guidelines are helpful to define the indications for AECG in general, with the choice of specific device to be based on the frequency of symptoms.

In 2001, the ACC/AHA published a clinical competence statement on electrocardiography and AECG (Kadish et al., 2001) which reiterated that the indications for AECG had been addressed in the 1999 clinical guidelines (Crawford, 1999). The competence statement noted: "*There are no specific guidelines that distinguish patients for whom it is appropriate to perform continuous monitoring, (i.e., Holter monitor) from those for whom intermittent ambulatory monitoring is adequate. However, when monitoring is performed to evaluate the cause of intermittent symptoms, the frequency of the symptoms should dictate the type of recording. Continuous recordings are indicated for the assessment of frequent symptoms that may be related to disturbances of heart rhythm, for the assessment of syncope or near syncope, and for patients with recurrent unexplained palpitations* (Kadish et al., 2001)."

The selection of the most appropriate monitor is based on the anticipated frequency of symptoms. In 2010, Hoefman published a systematic review on diagnostic tools for detecting cardiac arrhythmias. This analysis included studies of subjects presenting with palpitations and compared the yield of remote monitoring for several classes of devices: Holter monitors; self-activated event recorders; auto-triggered event recorders; and implantable loop recorders. The yield varied among devices, with the auto-trigger devices offering the highest range of detection (72-80%), followed by the self-activated devices (17-75%), and Holter monitors (33-35%). No combined analysis was performed due to the heterogeneity of the study population and study design. Limitations in the evidence base precluded any specific recommendations on selection of devices. The authors concluded that the choice of device should be driven largely by the presence, type, and frequency of symptoms experienced by each individual.

The 2017 International Society for Holter and Noninvasive Electrocardiology (ISHNE) and the Heart Rhythm Society (HRS) expert consensus statement on AECG and external cardiac monitoring (Steinberg, 2017) states,

"*Frequency of symptoms should dictate the type of recording: longer term ECG monitoring is required for more infrequent events. Correlation (or lack of) of symptoms and arrhythmias is key. The most appropriate clinical workflow may include a continuous (short-term 24 hours and up to 7 days) AECG monitoring, which if unsuccessful, is followed by external loop recording. For those patients remaining undiagnosed after prolonged noninvasive monitoring, implantable loop recorders (ILR) may be necessary."*

"*The type of recorder and the duration of recording should be tailored to the individual patient's history, but in general, the diagnostic yield is limited and dependent on the frequency of clinical symptoms. Extended recordings may improve diagnostic yield*."

Duration of Recording	Type of Recorder	Palpitations (%)	Syncope (%)
24-48 hours	Standard Holter	10-15	1-5
< 60 seconds	Event recorder	50-60	N/A
3-7 days	Patch/ELR/MCT	50-70	5-10
1-4 weeks	Patch/ELR/MCT	70-85	15-25
≤ 36 months	ILR	80-90	30-50

The 2017 ACC/AHA/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, 2017), recommendations for AECG and implanted cardiac monitors:

- AECG monitoring is useful to evaluate whether symptoms, including palpitations, presyncope, or syncope, are caused by ventricular arrhythmias (VA).
- In patients with sporadic symptoms (including syncope) suspected to be related to VA, implanted cardiac monitors can be useful.

Recommendation-specific supportive text:
"*AECG monitoring is often used to assess the effectiveness of treatments to suppress arrhythmias, but more robust data are needed on the clinical use of this practice. Continuous or intermittent AECG recording with a Holter monitor or an event recorder is helpful in diagnosing suspected arrhythmias, establishing their frequency, relating them to symptoms, and assessing the response to therapy. Although the yield of these tests is relatively low, VT (ventricular tachycardia) is occasionally documented. A 24-hour continuous Holter recording is appropriate when symptoms occur at least once a day or when quantitation of PVCs/NSVT (premature ventricular complexes/nonsustained ventricular tachycardia) is desired to assess possible VA-related depressed ventricular function. For sporadic symptoms, event or "looping" monitors are more appropriate because they can be activated over extended periods of time and increase diagnostic yield. Adhesive patch electrocardiographic monitors can record for weeks and allow for continuous short-term 1-lead monitoring and patient activation for symptoms. Studies have shown satisfactory patient compliance, and arrhythmia detection; however, with some monitors, detected arrhythmias are not discovered until the patch is returned for analysis. Serial evaluations with exercise testing and/or 24-hour ambulatory monitoring are also used to assess rhythm burden and response of VA to therapy. Importantly, when the suspicion of VA in a patient is high, outpatient ambulatory monitoring is inappropriate as prompt diagnosis and prevention of VA are warranted. It is important to accurately correlate the symptoms with the arrhythmias detected by ambulatory ECG monitoring*."

"*Implanted cardiac monitors provide continuous rhythm monitoring and stored recordings of electrograms based on patient activation or preset parameters, allowing a prolonged monitoring period of a few years. These devices require a minor invasive procedure with local anesthesia for implantation. In patients with sporadic symptoms, including syncope, implantable recorders are useful in diagnosing serious tachyarrhythmias (including VA) and bradyarrhythmias. They are generally reserved for patients in whom other ambulatory monitoring is nonrevealing due to the infrequency of events. A 25% added yield in diagnosis has been described after an unrevealing external ambulatory monitor. In a study of patients with syncope, the implantable monitor had a*

greater diagnostic yield than "conventional" testing with external monitoring, tilt table testing and electrophysiological study. A systematic review in patients with syncope concluded that use of these devices provide a higher rate of diagnosis and a trend toward reduction in syncope relapse after diagnosis, as compared with conventional management. A prospective study of patients after MI, with LVEF <40%, demonstrated NSVT (>16 beats long) in 13%, VT (>30 s) in 3% and VF in 3% of patients. It is important to accurately correlate the symptoms with the arrhythmias detected by implanted cardiac monitors."

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. In the absence of NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations. Fallon Health's Clinical Coverage Criteria are developed in accordance with Medicare Managed Care Manual, Chapter 4, Section 10.16 – Medical Necessity and Section 90.5 Creating New Guidance.

Medicare has an NCD for Electrocardiographic Services (20.15). National Government Services, Inc. does not have an LCD or LCA for mobile cardiac telemetry (MCD search 12/05/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. When there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria will be used for medical necessity determinations, except as otherwise provided herein. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204 and are therefore no more restrictive than MassHealth medical necessity guidelines.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as approved by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be approved by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria will be used for medical necessity determinations for MassHealth ACO members, except as otherwise provided herein. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204 and are therefore no more restrictive than MassHealth medical necessity guidelines.

Fallon Health Clinical Coverage Criteria

Prior authorization is not required for Holter monitoring (CPT 93224-93227). Prior authorization is required for all other ambulatory cardiac monitoring (CPT codes 93241-93244, 93245-93248, 93268-93272, 93228-93229, and 33285).

1. Continuous ambulatory electrocardiographic (AECG) recording for up to 48 hours (CPT codes 93224-93227), also known as Holter monitoring, is considered medically necessary for clinical situations where:
    1. the frequency of the symptoms suggestive of cardiac arrhythmias is not documented,
    2. certain actions can induce the symptoms, or
    3. symptoms are noted to occur at a frequency such that they would likely be detected with 48-hour continuous AECG monitoring.

2. Continuous AECG recording for more than 48 hours up to 7 days (CPT codes 93241-93244) or more than 7 days up to 15 days (CPT codes 93245-93248):

    a. Continuous AECG recording for more than 48 hours up to 7 days (CPT codes 93241-93244) is considered medically necessary for clinical situations where symptoms suggestive of cardiac arrhythmias with no loss of consciousness occur less frequently than every 48 hours but at least weekly (range, 3-7 days) and the symptoms are not incitable.

    b. Continuous AECG recording for more than 7 days up to 15 days (CPT codes 93245-93248) is considered medically necessary for clinical situations where symptoms suggestive of cardiac arrhythmias with no loss of consciousness occur less frequently than every 48 hours but at least once every 2 weeks (range, 8-14 days) and the symptoms are not incitable.

    Note: CPT codes 93241-93248 are nonpayable for MassHealth ACO members in accordance with MassHealth Physician Manual Subchapter 6 (*MassHealth Transmittal Letter PHY-164*) and Acute Outpatient Hospital Manual Subchapter 6 (*MassHealth Transmittal Letter AOH 53*).

3. Patient- or event-activated ECG recording with memory loop and 24 hour attended monitoring for up to 30 days (CPT 93268-93272) is considered medically necessary for clinical situations where symptoms suggestive of cardiac arrhythmias with no loss of consciousness are noted to occur less frequently than every 48 hours but at least monthly (range, 3-30 days) and the symptoms are not incitable.

3. Mobile cardiac telemetry (CPT 93228-93229) is considered medically necessary for clinical situations where the member loses consciousness with concern for cardiac origin.

4. An implantable loop recorder (CPT 33285, HCPCS E0616) is considered medically necessary for clinical situations where the member has very infrequent symptoms suggestive of cardiac arrhythmias, such that other ambulatory cardiac monitoring would be unlikely to yield diagnostic information.

Exclusions

- Any use of ambulatory cardiac monitoring other than outlined above.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Continuous ambulatory electrocardiographic recording

Code	Description
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
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

Mobile Cardiac Telemetry

Code	Description
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

Memory Loop Recorder

Code	Description
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

Implantable loop recorders must be monitored continuously, and a review of all transmissions must be done at least one time per 30-day period (12 times per year.) While these devices may automatically trigger many times per month, both the technical and professional CPT codes are only billed once per 30-day period. Do not report if the monitoring period is less than 10 days. It is the standard of care for implantable loop recorders to be monitored remotely. For each 30-day period, it is expected that CPT 93298 and HCPCS code G2066 would be billed for the professional and technical components of remote monitoring, respectively, on the 31st day of monitoring.

Code	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal, subcutaneous cardiac rhythm monitor
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; subcutaneous cardiac rhythm monitor system
93291	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; subcutaneous cardiac rhythm monitor system, including heart rhythm derived data analysis
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
C1764	Event recorder, cardiac (implantable)
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 or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
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 permanent programmed values with analysis, review and report by a physician or other qualified health care professional

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Policy history

Origination date:	04/26/2005
Approval(s):	Technology Assessment Subcommittee: 04/27/2010 Technology Assessment Committee: 04/26/2005, 06/02/2010, 10/23/2013, 01/28/2015 (updated template, references), 02/24/2016 (coverage added for coders 0295T-0298T in compliance with Medicare regulations, updated references), 03/22/2017 (updated references), 09/27/2017 (removed exclusion of coverage for Commercial products, now covered when meeting criteria), 08/22/2018 (updated references), 09/10/2019 (updated references), 01/24/2023 (expanded scope to include continuous AECG monitoring and patient- or event-activated ECG recording devices, including implantable loop recorders; added criteria for continuous AECG monitoring and patient- or event-activated ECG recording devices, including implantable loop recorders; updated references).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.