Medicare Advantage Medical Policy

MA Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry

Effective 01/01/2024

Description

An electrocardiogram (EKG) is a graphic representation of electrical activity within the heart. Electrodes placed on the body in predetermined locations sense this electrical activity, which is then recorded by various means for review and interpretation. EKG recordings are used to diagnose a wide range of heart disease and other conditions that manifest themselves by abnormal cardiac electrical activity.

Holter Monitoring (24-hour ECG monitoring) is a study used to evaluate the patient's ambient heart rhythm during a full day's (24 Hours) cycle. It is a wearable EKG monitor that records the overall rhythm and significant arrhythmias.

Cardiac monitoring is routinely used in the inpatient setting to detect acute changes in heart rate or rhythm that may need urgent response. For some conditions, a more prolonged period of monitoring in the ambulatory setting is needed to detect heart rate or rhythm abnormalities that may occur infrequently. These cases may include the diagnosis of arrhythmias in patients with signs and symptoms suggestive of arrhythmias as well as the evaluation of paroxysmal atrial fibrillation (AF).

EKG services are covered diagnostic tests when there are documented signs and symptoms or other clinical indications for providing the service. Coverage includes the review and interpretation of EKGs only by a physician. There is no coverage for EKG services when rendered as a screening test or as part of a routine examination unless performed as part of the one-time, “Welcome to Medicare” preventive physical examination under section 611 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Ambulatory electrocardiography (AECG) refers to services rendered in an outpatient setting over a specified period of time, generally while a patient is engaged in daily activities, including sleep. AECG devices are intended to provide the physician with documented episodes of arrhythmia, which may not be detected using a standard 12-lead EKG. AECG is most typically used to evaluate symptoms that may correlate with intermittent cardiac arrhythmias and/or myocardial ischemia. Such symptoms include syncope, dizziness, chest pain, palpitations, or shortness of breath. Additionally, AECG is used to evaluate patient response to initiation, revision, or discontinuation of arrhythmic drug therapy.

The Centers for Medicare & Medicaid Services (CMS), through the national coverage determination (NCD) process, may create new ambulatory EKG monitoring device categories if

published, peer-reviewed clinical studies demonstrate evidence of improved clinical utility, or equal utility with additional advantage to the patient, as indicated by improved patient management and/or improved health outcomes in the Medicare population (such as superior ability to detect serious or life-threatening arrhythmias) as compared to devices or services in the currently described categories below.

Dynamic electrocardiography devices that continuously record a real-time EKG, commonly known as Holter™ monitors, typically record over a 24-hour period. The recording is captured either on a magnetic tape or other digital medium. The data is then computer-analyzed at a later time, and a physician interprets the computer-generated report. A 24-hour recording is generally adequate to detect most transient arrhythmias. Documentation of medical necessity is required for monitoring longer than 24 hours. The recording device itself is not covered as durable medical equipment (DME) separate from the total diagnostic service.

An event monitor, or event recorder, is a patient-activated or event-activated EKG device that intermittently records cardiac arrhythmic events as they occur. The EKG is recorded on magnetic tape or other digital medium.

Cardiac event monitor technology varies among different devices. For patient-activated event monitors, the patient initiates recording when symptoms appear or when instructed to do so by a physician (e.g., following exercise). For self-sensing, automatically triggered monitors, an EKG is automatically recorded when the device detects an arrhythmia, without patient intervention. Some devices permit a patient to transmit EKG data transtelephonically (i.e., via telephone) to a receiving center where the data is reviewed. A technician may be 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 or other non-physician, a physician is available 24 hours per day to review the transmitted data and to make clinical decisions regarding the patient. These services are known as “24-hour attended monitoring”. In other instances, transmitted EKG data is reviewed at a later time and are, therefore, considered “non-attended.”

Cardiac event monitors without transtelephonic capability must be removed from the patient and taken to a location for review of the stored EKG data. Some devices also permit a "time sampling" mode of operation. The "time sampling" mode is not covered under ambulatory EKG monitoring technology. Some cardiac event monitoring devices with trans-telephonic capabilities require the patient to dial the phone number of a central EKG data reception center and initiate transmission of EKG data. Other devices use Internet-based in-home computers to capture and store EKG data. When such devices detect pre-programmed arrhythmias, data is automatically sent via modem and standard telephone lines to a central receiving center, or independent diagnostic testing facility (IDTF), where the data is reviewed. Internet-based in-home computer systems may also provide the receiving center with a daily computer-generated report that summarizes 24 hours of EKG data.

Long-Term Electrocardiogram (ECG) Monitoring is defined as a diagnostic procedure, which can provide continuous recording capabilities of ECG activities of the patient's heart while the patient is engaged in daily activities. These can include continuous, patient-demand or auto-detection devices. The purpose of these tests is to provide information about rhythm disturbances and waveform abnormalities and to note the frequency of their occurrence.

Cardiac Event Detection (CED) is a 30-day service for the purpose of documentation and diagnosis of paroxysmal or suspected arrhythmias.

Policy

I. External 48-hour ECG recording may be considered medically necessary for **ANY** of the following:

A. Arrhythmias **OR**
B. Chest pain **OR**
C. Syncope (lightheadedness) or near syncope **OR**
D. Vertigo (dizziness) **OR**
E. Palpitations **OR**
F. Transient ischemic episodes **OR**
G. Dyspnea (shortness of breath) **OR**
H. Evaluation of the response to antiarrhythmic drug therapy **OR**
I. Evaluation of myocardial infarction (MI) survivors with an ejection fraction of 40% or less **OR**
J. Assessment of patients with coronary artery disease with active symptoms, to correlate chest pain with ST-segment changes **OR**
K. Other acute and subacute forms of ischemic heart disease **OR**
L. To detect arrhythmias post ablation procedures

II. External electrocardiographic recording **OR** event monitors may be considered medically necessary is the following criteria are met:

A. External electrocardiographic recording/external electrocardiographic event monitors for greater than 48 hours and up to 7 days or for greater than 7 days up to 15 days that are either patient-activated or auto-activated may be considered medically necessary as a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).

III. Long term 30-day monitoring: Telephonic Transmission of ECG involves 24 hour attended monitoring per 30-day period of time; no other EKG monitoring codes can be billed simultaneously with these codes.

A. Indications for performing a Telephonic Transmission:

    1. Arrhythmias
    2. Chest pain
    3. Syncope (lightheadedness) or near syncope
    4. Vertigo (dizziness)
    5. Palpitations
    6. Transient ischemic episodes
    7. Dyspnea (shortness of breath)
    8. To initiate, revise or discontinue arrhythmia drug therapy.
    9. Evaluation of myocardial infarction (MI) survivors.
    10. Evaluation of acute and subacute forms of ischemic heart disease.

11. Assessment of patients with coronary artery disease with active symptoms, to correlate chest pain with ST-segment changes.

IV. Implantable loop recorders in adults and children may be considered **medically necessary** for **ANY** of the following:

A. member has recurrent and unexplained symptoms suggestive of an arrhythmia such as palpitations, dizziness, near syncope or syncope that occur less frequently than once a month making it unlikely to be diagnosed by external cardiac event monitoring or when these studies are non-diagnostic **OR**

B**.** to assess the results after an ablation procedure performed for an arrhythmia OR

C. member with cryptogenic stroke with whom atrial fibrillation is suspected to be the cause and a 24-hour Holter monitor or hospital telemetry is non-diagnostic.

D. genetically based arrhythmia conditions (LongQT Syndrome, Short QT Syndrome, Brugada Syndrome, Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) in whom:

1. there is suspicion of symptoms only while sleeping **OR**
2. the family history is that of cardiac arrest while sleeping **OR**

E. patients with developmental delays precluding accurate symptom description but in whom there is sufficient reason (clinical signs/symptoms, family history) to believe the patient is at risk for an arrhythmia.

VII. Implantable loop recorders are considered **investigational** for all other indications not listed above because their effectiveness for other indications has not been established.

Recommended Medical Records

Medicare monitors for medical necessity, which can include frequency. Documentation would include a history and physical exam. The record should document the evaluation, which focuses on the cause(s) of the presenting symptoms and/or the need for this testing. Some examples are:

1. The patient record has an evaluation and management service that documents the symptoms experienced by the patient.
2. The patient has had a full workup in the past month with initial tests performed and presents with continuing symptoms that indicate the need for up to 48-hour monitoring or long-term monitoring.
3. The patient requires a change in antiarrhythmic medication. In this case, an assessment of the patient's complaints, the name of the medication stopped, and the name of the new medication should be indicated.
4. In the case of referred tests, documentation of medical necessity may be requested from the referring physician. These are considered purchased diagnostic tests.
5. Independent diagnostic testing facilities (IDTF) and suppliers must retain records that include:

a. The referring physician's written orders; and
b. The identity of the employee setting up the tracing.

Documentation should be submitted as indicated when requested or when unusual circumstances are present.

Background

Cardiac Rhythm Ambulatory Monitoring Devices Ambulatory cardiac monitoring with a variety of devices permits the evaluation of cardiac electrical activity over time, in contrast to static ECG, which only permits the detection of abnormalities in cardiac electrical activity at a single point in time. A Holter monitor is worn continuously and records cardiac electrical output continuously throughout the recording period. Holter monitors are capable of recording activity for up to about 24 to 72 hours. Traditionally, most Holter monitors had three channels based on three ECG leads. However, some currently available Holter monitors have up to 12 channels. Holter monitors are an accepted intervention in a variety of settings where a short period (24-48 hours) of comprehensive cardiac rhythm assessment is needed (e.g., suspected arrhythmias when symptoms [syncope, palpitations] are occurring daily). These devices are not the focus of this review. Various classes of devices are available for situations where longer monitoring than can be obtained with a traditional Holter monitor is needed. Specific devices may vary in how data are transmitted to the location where the ECG output is interpreted. Data may be transmitted via cellular phone or landline, or by direct download from the device after its return to the monitoring center.

Certain cardiac event monitors capture electrical activity with a single electrode attached to the skin. Other devices may employ multiple electrodes in order to record more complex EKG tracings. Additionally, devices may be individually programmed to detect patient-specific factors, electrode malfunction, or other factors. Cardiac event monitors can be further categorized as either “pre-event” or “post-event” recorders, based on their memory capabilities:

a. Pre-symptom Memory Loop Recorder (MLR)

   Upon detecting symptoms, the wearer presses a button, which activates the recorder to save (i.e., memorize) an interval of pre-symptom EKG data along with data during and subsequent to the symptomatic event. Self-sensing recorders (also known as event-activated or automatic trigger) do not require patient input to capture these data. Single or multiple events may be recorded. The device is worn at all times, usually for up to 30 days.

   - Implantable (or Insertable Loop) Recorder (ILR)

   Another type of pre-symptom MLR, it is implanted subcutaneously in a patient’s upper left chest and may remain implanted for many months. An ILR is used when syncope is thought to be cardiac-related but is too infrequent to be detected by either a Holter™ monitor or a traditional pre-symptom MLR.

b. Post-symptom Recorder

> The patient temporarily places this device against the chest when symptoms occur and activates it by pressing a button. These recorders represent old technology, as they do not include a memory loop. The device transmits EKG data telephonically in real-time and is usually used for up to 30 days.

An RCT reported by Gladstone et al (2021) evaluated screening for AF with continuous ambulatory monitoring (the Zio XT patch worn for up to 4 weeks) compared to standard care (routine clinical follow-up plus a pulse check and heart auscultation at baseline and 6 months) in 876 asymptomatic adults over age 75 with hypertension and without known AF. The primary outcome was AF detected by continuous monitoring or clinically within 6 months. At 6- month follow-up, AF was detected in 23 of 434 participants (5.3%) in the screening group, compared to 2 of 422 (0.5%) in the control group (relative risk, 11.2; 95% CI, 2.7 to 47.1; p=0.001; absolute difference, 4.8%; 95% CI, 2.6% to 7.0%; p<0.001; number needed to screen, 21). Anticoagulant treatment was initiated in 4.1% of the screening group compared to 0.9% of the control group (relative risk, 4.4; 95% CI, 1.5 to 12.8; p=0.007; absolute difference, 3.2%; 95% CI, 1.1% to 5.3%; p=0.003). During the 6-month study period, 1 participant died (control group; cardiovascular death) and 2 participants had an ischemic stroke (both in the screening group). One patient had a TIA (screening group). The trial was not powered to detect clinical outcomes and was of insufficient duration to draw conclusions on health outcomes.

Svendsen et al (2021) reported results of the LOOP trial.56, This was the only RCT that was powered to detect clinical outcomes; results are shown in Table 7. Screening resulted in an increase in AF detection and anticoagulation initiation but no significant reduction in the risk of stroke or systemic arterial embolism (Table 7). A higher-than-anticipated proportion of participants in the control group were diagnosed with atrial fibrillation (12.2% compared with anticipated 3.0%), indicating that control group participants could have been more likely to consult their physician. Additionally, atrial fibrillation episodes detected in the control group are likely to have lasted longer than atrial fibrillation detected by monitors, increasing the probability of detection, and potentially decreasing the protective effect of anticoagulant.

Codes

93268	**93270**	**93271**	**93272**	**93224**
93225	**93226**	**93227**	**93228**	**93229**
93241	**93242**	**93243**	**93244**	**93245**
93246	**93247**	**93248**	**93268**	**93270**
93271	**93272**	**93799**	**0650T**	**33285**

References

Arpocha A, Klein G, Benditt D, et al. Remote electrocardiographic monitoring with a wireless implantable loop recorder: Minimizing the Data Review Burden. Pacing and Clinical Electrophysiology. 2010;33(11):1347-1352. doi:10.1111/j.1540-8159.2010.02857.x

Kristiansen J, Korshøj M, Skotte JH, et al. Comparison of two systems for long-term heart rate variability monitoring in free-living conditions - a pilot study. BioMedical Engineering OnLine. 2011;10(1):27. doi:10.1186/1475-925x-10-27

Zimetbaum P, Goldman A. Ambulatory arrhythmia monitoring. Circulation. 2010;122(16):1629-1636. doi:10.1161/circulationaha.109.925610

Gladstone DJ, Wachter R, Schmalstieg-Bahr K, et al. Screening for Atrial Fibrillation in the Older Population: A Randomized Clinical Trial. JAMA Cardiol. May 01 2021; 6(5): 558-567. PMID 33625468

Svendsen JH, Diederichsen SZ, Hojberg S, et al. Implantable loop recorder detection of atrial fibrillation to prevent stroke (The LOOP Study): a randomised controlled trial. Lancet. Oct 23 2021; 398(10310): 1507-1516. PMID 34469766

Kaura A, Sztriha L, Chan FK, et al. Early prolonged ambulatory cardiac monitoring in stroke (EPACS): an open-label randomised controlled trial. Eur J Med Res. Jul 26 2019; 24(1): 25. PMID 31349792

Davidson KW, Barry MJ, Mangione CM, et al. Screening for Atrial Fibrillation: US Preventive Services Task Force Recommendation Statement. JAMA. Jan 25 2022; 327(4): 360-367. PMID 35076659