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Cardiac Event Monitors Policy

Indication/Usage

Cardiac event monitors are small portable EKG recording devices worn by a patient during normal activity for up to 30 days and has a recording system capable of storing several minutes of the individual's cardiac activity. The patient can initiate EKG recording during a symptomatic period of arrhythmia. These monitors are particularly useful in obtaining a record of arrhythmia that would not be discovered on a routine EKG or an arrhythmia that is so infrequent that it is not detected during a 24-hour period by a Holter monitor and used to diagnose and evaluate.

Two different types of cardiac event monitors are available. Pre-symptom (looping memory) event monitors are equipped with electrodes attached to the chest, and are able to capture EKG rhythms before the cardiac event monitor is triggered. Post-symptom event monitors do not have chest electrodes. One type of post-symptom event monitor is worn on the wrist or carried. When symptoms occur, the patient presses a button to trigger an EKG recording. Cardiac event monitors have been developed with automatic trigger capabilities, which are designed to

automatically trigger an EKG recording when certain arrhythmias occur. Cardiac event monitors may come with 24-hour remote monitoring. EKG results are transmitted over standard phone lines, e-mail, or over the internet to an attended monitoring center, where a technician screens EKG results and notifies the patient's physician of any significant abnormal results, based on predetermined notification criteria. If test results suggest a life threatening emergency, monitoring center personnel may instruct the patient to seek emergency care. The development of mobile technology may extend the use of cardiac event monitors from primarily diagnostic purposes to use primarily as an alarm system, to allow rapid intervention for the elderly and others at increased risk of cardiac events (Cox, 2003; Lloyds, 1999).

Mobile cardiac telemetry (MCT) refers to non-invasive ambulatory cardiac event monitors with extended memory capable of continuous measurement of heart rate and rhythm over several days with transmission of results to a remote monitoring center. Mobile cardiac telemetry is similar to standard cardiac telemetry used in the hospital setting.

Medical Indications for Authorization

Commercial Members

Cardiac event monitoring is considered medically necessary for evaluating suspected cardiac arrhythmias as outlined below.

Ambulatory External Cardiac Monitoring

Ambulatory external cardiac monitoring from 48 hours up to 30 days is considered medically necessary when ANY of the following criteria are met:

- Symptoms of presyncope, syncope, or severe palpitations when there is clinical suspicion of a significant arrhythmia.
- Evaluation of atrial fibrillation for rhythm and/or rate control when the results will directly impact clinical decision-making and drug therapies or suspected atrial fibrillation as cause of cryptogenic stroke
- Documentation of the results after an ablation procedure for arrhythmia
- Documentation of ST segment depression for suspect ischemia

CPT Codes 93241–93248, 93268, 93270, 93271, 93272, 0497T, 0498T

Outpatient Cardiac Telemetry

Mobile cardiac outpatient telemetry (MCOT \ MCT) is considered medically necessary when Holter monitoring is non-diagnostic or symptoms occur so infrequently and unpredictably that the length of the monitoring period would likely be inadequate to capture a diagnostic ECG rhythm disorder when EITHER of the following criteria are met:

- symptoms of presyncope, syncope, or severe palpitations when there is clinical suspicion of a significant arrhythmia

- evaluation of atrial fibrillation for rhythm and/or rate control when the results will directly impact clinical decision-making

CPT codes 93228, 93229

Ambulatory Implantable Cardiac Event Monitoring

An implantable loop recorder is considered medically necessary for the evaluation of an unexplained syncopal episode, or when a cardiac arrhythmia is suspected in patients with a diagnosis of heart failure or prior myocardial infarction and/or cryptogenic stroke, and EITHER of the following criteria are met:

- Ambulatory external cardiac monitoring using a U.S. Food and Drug Administration (FDA) approved device failed to establish a definitive diagnosis

- Ambulatory external cardiac monitoring is not expected to be diagnostic because the symptoms occur so infrequently and unpredictably that the length of the monitoring period would likely be inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder

CPT code 33285, HCPCS code C1764, E0616

Medicare Members

CMS NCD ID 20.15 Electrocardiographic Services

Description Information Benefit Category Diagnostic Tests (other)
Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories

Item/Service Description

A. General

1. 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.

   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.

2. 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.

3. 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.

Descriptions of Ambulatory EKG Monitoring Technologies

1. 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.

2. 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 inhome computer systems may also provide the receiving center with a daily computer-generated report that summarizes 24 hours of EKG data.

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:

- 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.

- 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.

Indications and Limitations of Coverage

B. Nationally Covered Indications

The following indications are covered nationally unless otherwise indicated:

1. Computer analysis of EKGs when furnished in a setting and under the circumstances required for coverage of other EKG services.
2. EKG services rendered by an IDTF, including physician review and interpretation. Separate physician services are not covered unless he/she is the patient's attending or consulting physician.

3. Emergency EKGs (i.e., when the patient is or may be experiencing a life-threatening event) performed as a laboratory or diagnostic service by a portable x-ray supplier only when a physician is in attendance at the time the service is performed or immediately thereafter.
4. Home EKG services with documentation of medical necessity.
5. Transtelephonic EKG transmissions (effective March 1, 1980) as a diagnostic service for the indications described below, when performed with equipment meeting the standards described below, subject to the limitations and conditions specified below. Coverage is further limited to the amounts payable with respect to the physician's service in interpreting the results of such transmissions, including charges for rental of the equipment. The device used by the beneficiary is part of a total diagnostic system and is not considered DME separately. Covered uses are to:

    - Detect, characterize, and document symptomatic transient arrhythmias;
    - Initiate, revise, or discontinue arrhythmic drug therapy; or,
    - Carry-out early post-hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided, see C.5. below).

Certain uses other than those specified above may be covered if, in the judgment of the local Medicare Administrative Contractor (MAC), such use is medically necessary.

Additionally, the transmitting devices must meet at least the following criteria:

- They must be capable of transmitting EKG Leads, I, II, or III; and,
- The tracing must be sufficiently comparable to a conventional EKG.

24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI is only covered if provision is made for such 24-hour attended coverage in the manner described below:

24-hour attended coverage means there must be, at a monitoring site or central data center, an EKG technician or other non-physician, receiving calls and/or EKG data; tape recording devices do not meet this requirement. Further, such technicians should have immediate, 24-hour access to a physician to review transmitted data and make clinical decisions regarding the patient. The technician should also be instructed as to when and how to contact available facilities to assist the patient in case of emergencies.

C. Nationally Non-Covered Indications

The following indications are non-covered nationally unless otherwise specified below:

1. The time-sampling mode of operation of ambulatory EKG cardiac event monitoring/recording.
2. Separate physician services other than those rendered by an IDTF unless rendered by the patient's attending or consulting physician.
3. Home EKG services without documentation of medical necessity.

4. Emergency EKG services by a portable x-ray supplier without a physician in attendance at the time of service or immediately thereafter.
5. 24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI unless provision is made for such 24-hour attended coverage in the manner described in section B.5 above.
6. Any marketed Food and Drug Administration (FDA)-approved ambulatory cardiac monitoring device or service that cannot be categorized according to the framework below.

D. Other

Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the framework below. Unless there is a specific NCD for that device or service, determination as to whether a device or service that fits into the framework is reasonable and necessary is according to local MAC discretion.

Limitations

SummaCare considers Ambulatory External Cardiac Monitoring, Outpatient Cardiac Telemetry and Ambulatory Implantable Cardiac Event Monitoring experimental and investigational for **all** other indications because their effectiveness for indications other than the ones listed above has not been established.

Plans Covered By this Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Coverage Decision

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Sources Reviewed

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