
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Transmittal 26

Department of Health & Human
Services (DHHS)
Centers for Medicare & Medicaid
Services (CMS)

Date: DECEMBER 10, 2004

CHANGE REQUEST 3590

SUBJECT: Electrocardiographic Services

I. SUMMARY OF CHANGES: The CMS nationally covers the use of electrocardiographic (EKG) services under specific criteria described in §20.15, Pub. 100-03, National Coverage Determinations (NCD) Manual. In addition, EKG technologies are now organized into an updated framework to aid in making reasonable and necessary coverage determinations as they pertain to EKG technology.

(This revision to §20.15, Pub. 100-03, is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and Administrative Law Judges (see 42 CFR §§405.732, 405.860). An NCD that expands coverage is also binding on Medicare advantage organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 26, 2004

***IMPLEMENTATION DATE: December 10, 2004**

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/20.15/Electrocardiographic Services

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-03 | Transmittal: 26 | Date: December 10, 2004 | Change Request 3590

SUBJECT: Electrocardiographic Services

I. GENERAL INFORMATION

A. Background: 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. The EKG recordings are used to diagnose a wide range of heart disease and other conditions that manifest themselves by abnormal cardiac electrical activity. Medicare covers EKG services as 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.

B. Policy: The EKG technologies are now organized into an updated framework to aid in making reasonable and necessary coverage determinations. Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the EKG framework. 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 contractor discretion.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established “medlearn matters” listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

Requirement #	Requirements	Responsibility
3590.1	Contractors shall be advised that effective 08/26/04, electrocardiographic (EKG) services performed with a marketed, Food and Drug Administration (FDA)-approved device, are eligible for coverage if they can be categorized according to the EKG Services Framework	FIs and local Part B carriers

	described in §20.15, Pub 100-03, National Coverage Determinations (NCD) Manual.	
3590.2	<p>Contractors shall note that current nationally covered EKG services are:</p> <ul style="list-style-type: none"> (1) Computer-analysis of EKGs when furnished in a setting and under circumstances required for coverage of other EKG services; (2) Those rendered by an independent diagnostic testing facility, including physician review/interpretation; (3) Emergency EKGs performed as a laboratory/diagnostic service by a portable x-ray supplier only when a physician is in attendance at the time or immediately after the service is performed; (4) Home EKGs with medical necessity documentation; <p>Trans-telephonic EKG transmissions used for the specific indications, when performed with specific equipment, subject to specific limitations and conditions.</p>	FIs and local Part B carriers
3590.3	<p>Contractors shall note that current nationally non-covered EKG services are:</p> <ul style="list-style-type: none"> (1) the time-sampling mode of operations of ambulatory EKG cardiac event monitoring/recording; (2) separate physician services other than those rendered by an IDTF unless he/she is the patient's attending/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 myocardial infarction unless provided according to specific criteria; (6) Any marketed FDA-approved ambulatory cardiac monitoring device or service that cannot be categorized 	FIs and local Part B carriers

	according to the EKG Services Framework.	
3590.4	Contractors shall be advised that unless there is a specific NCD for an EKG-related device/service, determination as to whether that device/service fits into the EKG Services Framework as reasonable and necessary is left to local contractor discretion.	FIs and local Part B carriers

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: August 26, 2004 Implementation Date: December 10, 2004 Pre-Implementation Contact(s): Stuart Caplan, 410-786-8564, Pat Brocato-Simons, 410-786-0261 Post-Implementation Contact(s): CMS ROs	These instructions shall be implemented within your current operating budget.
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Medicare National Coverage Determinations Manual

Chapter 1 – Part 1 (Sections 10 - 80.12) Coverage Determinations

Table of Contents

(Rev. 26, 12-10-04)

20.15 – Electrocardiographic Services

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(Rev. 26, Issued: 12-10-04, Effective: 08-26-04, Implementation: 12-10-04)

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 trans-telephonically (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 trans-telephonic 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.

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.

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 independent diagnostic testing facility (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. *Trans-telephonic 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:*
 - a. *Detect, characterize, and document symptomatic transient arrhythmias;*

- a. *Detect, characterize, and document symptomatic transient arrhythmias;*

- b. *Initiate, revise, or discontinue arrhythmic drug therapy; or,*
 - c. *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 contractor, such use is medically necessary.

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

- a. *They must be capable of transmitting EKG Leads, I, II, or III; and,*
- b. *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

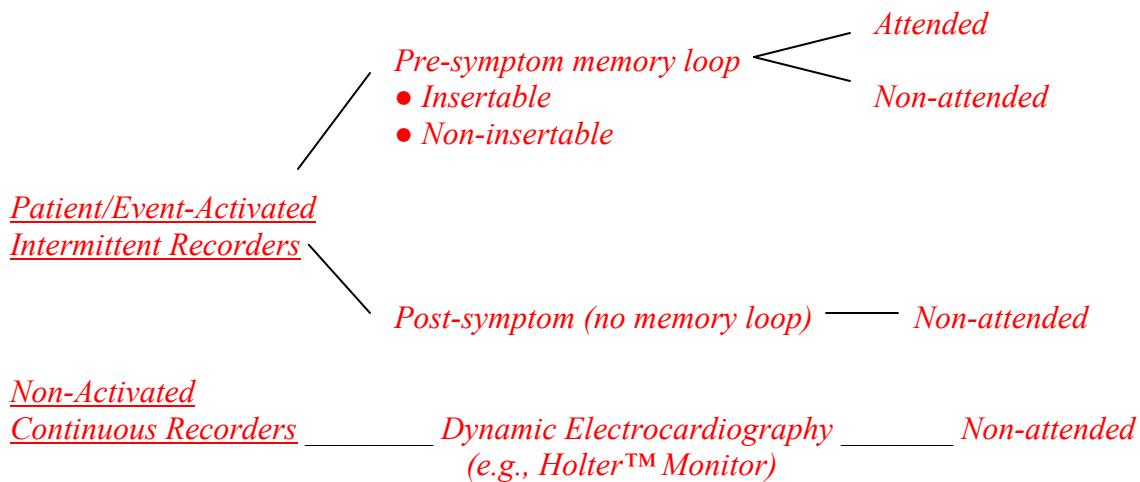
The following indications are non-covered nationally unless otherwise specified below:

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 contractor discretion.

Electrocardiographic Services Framework



(This NCD last reviewed December 2004.)