Ambulatory Cardiac Monitoring Devices

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

Type	Title	Document ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Electrocardiographic Services	20.15		

LCD LCA	Ambulatory Electrocardiograph (AECG) Monitoring	L39490 A59268	JH - Novitas Solutions, Inc. (Part A/B MAC) JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, LA, MS, NM, OK, TX DE, D.C., MD, NJ, PA
LCD LCA	Ambulatory Electrocardiograph (AECG) Monitoring	L39492 A59270	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI
LCD LCA	Cardiac Event Detection	L33952 A56452	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD LCA	Cardiac Event Detection	L34573 A56606	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring)	L34636 A57476	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MI, MO, NE IN, MI
LCD LCA	Category III Codes	L35490 A56902	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MI, MO, NE IN, MI

Description

Ambulatory cardiac monitoring devices are used by an individual at home to record the heart rhythm during daily activities. The ambulatory electrocardiograph (AECG) detects the occurrence and frequency of rhythm disturbances and waveform abnormalities to aid in diagnosing and/or managing cardiac arrhythmias and conditions such as cryptogenic (no identifiable cause) stroke, palpitations or syncope. Various devices may be used for monitoring including, but may not be limited to, continuous recorders

(also known as Holter or patch monitors), external loop monitors/recorders (also known as cardiac event monitors/recorders), implantable (insertable) loop monitors/recorders or mobile cardiac outpatient telemetry (also known as real time cardiac monitoring). In addition to symptom frequency, patient clinical condition and probability of life-threatening arrhythmia, decision-making for the selection of the appropriate ambulatory cardiac monitoring device should also consider diagnostic ability, monitoring and risk stratification accuracy, patient acceptance, availability and provider experience.[44]

Holter and Long-Term Continuous Cardiac Rhythm Monitors/Recorders

The most common cardiac monitoring device is the **Holter monitor** (also known as a continuous recorder). Holter monitors are battery operated portable devices that continuously record the electrical activity of the heart, via leads attached to the chest, during activities of daily living (ADL). A healthcare provider then analyzes the recording to identify arrhythmias. Holter monitors are usually worn for 24 to 48 hours to correlate frequent (daily or more often) symptoms with recordings of symptomatic rhythm events. Other uses include, but may not be limited to, detection of asymptomatic events (eg, nonsustained ventricular tachycardia [NSVT]) for risk stratification of hypertrophic cardiomyopathy or functional assessment of a pacemaker or implantable cardioverter defibrillator (ICD).

Newer versions of rhythm monitors, including patch recorders, may be worn for **long-term continuous cardiac rhythm monitoring** (up to 14 days) to detect arrhythmias that occur less frequently (less than daily). Patch recorders that adhere to the external chest wall without leads or wires continuously record and store rhythm data for 7 – 14 days. The choice of Holter or long-term continuous monitoring device is predicated on the frequency of symptoms or suspected arrhythmia and the degree to which symptoms incapacitate the individual.[4,5,6] Examples of long-term continuous cardiac rhythm monitors include, but may not be limited to, Cardea Solo, Carnation Ambulatory Monitor (CAM patch) and Zio XT.

External Loop Monitors/Recorders (Cardiac Event Monitors/Recorders)

External loop monitors are battery operated portable devices that record the electrical activity of the heart during ADL and are worn continuously for up to 30 days. The individual starts the recorder when symptoms begin and turns it off when symptoms end. The device captures and saves a brief period of heart rhythm activity before and after activation. After the individual activates the device, the recording can be transmitted telephonically to a 24-hour attended monitoring center for remote technician review. If the electrocardiogram (ECG) recording is outside preset criteria, a healthcare provider reviews the data and makes individualized clinical decisions. In other instances, transmitted ECG data is reviewed later and is considered nonattended.[18]

Implantable (Insertable) Loop Monitors/Recorders

Implantable (insertable) loop recorders are placed directly under the skin in the chest using a local anesthetic. Electrodes in the device sense the heart's activity, so there is no need for external electrodes or leads. When symptoms occur, the individual activates the ECG data recording for analysis by a healthcare provider. The device also has an auto-activation mode to automatically capture and record arrhythmias.

Most recorders can record and store at least 30 minutes of ECG signals during an episode of arrhythmia. The device is removed when the battery fails, or earlier, if a definitive diagnosis has been established. Examples of these devices with an estimated battery life of 3 years include, but may not be limited to, Assert-IQ, Jot Dx, LUX-Dx II and Reveal LINQ implantable cardiac monitor systems. More

recently developed versions of this device have a longer battery life and can be used to monitor and record heart rhythm and rate for 4 or more years. Examples include, but may not be limited to, Biomonitor IIIm and LINQ II implantable cardiac recorders.

Mobile Cardiac Outpatient Telemetry (Real-Time Cardiac Monitoring)

Mobile cardiac outpatient telemetry (MCOT) records, monitors and transmits an individual's ECG continuously as they go about their normal ADL. A 3-lead sensor transmits each heartbeat to a cellphone-sized monitor. If the monitor detects an arrhythmia, it transmits the individual's ECG to the monitoring center using wireless or telephone landline communication technology depending on the individual's location.

Certified cardiovascular technicians analyze the transmissions 24 hours a day. The prescribing healthcare provider selects individualized monitoring thresholds and response parameters. Routine daily telemetry reports are issued to the healthcare provider by email, fax, internet or phone. Examples of MCOT devices include, but may not be limited to, BodyGuardian Mini, MCT 3 Lead, MoMe ARC and Zio AT.

The BioFlux monitors and analyzes ECG data in real time using an ECG algorithm to detect and automatically transmit arrhythmia data to the monitoring center for review. The individual can also activate the device in the presence of any abnormal symptoms. The recorded cardiac activity is delivered via smartphone to the server where it is reviewed by a cardiovascular technician and escalated to a healthcare provider when predetermined parameters are met.

The Rhythm Express RX-1, RhythmStar and the TeleSense each function as an external use Holter monitor, event monitor and/or MCOT depending on the needs of the individual and modality that is ordered by the healthcare provider.

Self-Monitoring ECG Technologies

Self-monitoring ECG technologies, which may be obtained without a prescription, are generally activated by the touch of the individual's fingers to record and transmit data via a smartphone or watch. These hand- or wrist-held and/or smart phone-based devices are used to monitor ECG, heart rate and other noncardiac indications.

Electrocardiograph software for nonprescribed use creates, analyzes and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias, such as atrial fibrillation, bradycardia or tachycardia. This technology is not intended to provide a diagnosis.

Intracardiac Ischemia Detection Devices

The Guardian System is an implantable cardiac device suggested to measure ST elevation changes and possible impending myocardial infarction (heart attack) via real-time ECG. The system includes an **intracardiac ischemia detection device**, approximately the size of a pacemaker, with a lead placed into the heart, a pager/alerting device and a programming device that monitors the electrical activity of the heart. A healthcare provider programs the device to recognize specific changes in the heart signals which when detected, sends a signal to the pager to alert the individual to seek immediate medical attention. Information from the device can be retrieved for analysis by a healthcare provider.

Coverage Determination

iCare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

AMBULATORY ELECTROCARDIOGRAPHY MONITORING TECHNOLOGIES

While NCD 20.15 provides descriptions of ambulatory electrocardiography (AECG) monitoring technologies, it does not provide criteria specific to when the use of various types of **ambulatory AECG monitoring** will be considered medically reasonable and necessary.[18] Further, NCD 20.15 does not provide criteria specific to when the use of an **implantable loop recorder/cardiac monitor (ILR/ICM)** will be considered medically reasonable and necessary.[18]

External Cardiac Monitors

For jurisdictions without an LCD, iCare determines medical necessity for **Holter monitors (93224-93227), long-term continuous cardiac rhythm monitors (93241-93248), external loop monitors/recorders (cardiac event monitors) (93268, 93270-93272) and mobile cardiac outpatient telemetry (MCOT/MCT) (93228, 93229)** based on the criteria contained in – Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring) (L34636).

The CMS guidance above (NCD 20.15, L39490, L39492, L33952, L34573, L34636 and L35490) does not provide criteria specific to when the use of an implantable loop recorder/cardiac monitor (ILR/ICM) will be considered medically reasonable and necessary; therefore, iCare may consider the following to interpret or supplement such criteria in order to determine medical necessity consistently:

Implantable (Insertable) Loop Monitors/Recorders (0650T, 33285, 33286, 93285, 93291, 93298, C1764, E0616)

Implantable (insertable) loop monitors/recorders will be considered medically reasonable and necessary when **any** of the following requirements are met:

- Evaluation of syncope or near-syncope and longer-term (14 to 30 days) noninvasive ambulatory monitoring and routine evaluation (eg, 12-lead EKG, labs) fail to establish a definite diagnosis or when symptoms are infrequent (occur less frequently than once every 30 days) or unpredictable, and therefore prolonged testing is necessary[4,5,6,44]; **OR**

- Evaluation of palpitations when 30-day noninvasive monitoring fails to establish a definite diagnosis[5,44]; **OR**

- Individual with clinical syndromes or situations that increase the risk of cardiac arrhythmias or transient symptoms that suggest a cardiac arrhythmia requiring prolonged testing[44];

  AND either of the following:

  - Atrial fibrillation suspected as the cause of documented cryptogenic stroke[8,44,57] and noninvasive monitoring is contraindicated or nondiagnostic; **OR**

- High risk of cardiac arrhythmias (eg, Brugada syndrome, heart failure [HF], prior myocardial infarction [MI]) when external monitor is nondiagnostic[5,44]; **OR**

- Pregnant individual with recurrent syncope and/or palpitations after nondiagnostic comprehensive noninvasive evaluation that includes external monitor[46]

Note: A 24–48-hour heart monitor is most appropriate for an individual with daily or near daily symptoms. The duration of monitoring should be consistent with the individual's signs and symptoms.[19]

Replacement of implantable (insertable) loop monitors/recorders: An individual with an existing implantable (insertable) loop monitor/recorder (ILR) may receive an ILR replacement due to the end of battery life or device malfunction if the ILR continues to be medically necessary.

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, skin irritation with external monitors or allergic reaction, bleeding or infection with implantable monitors).[49] Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Intracardiac Ischemia Monitoring Devices (0525T-0532T, C1833, G2066)
For jurisdictions without an LCD, iCare determines medical necessity for **intracardiac ischemia monitoring devices** based on the criteria contained in LCD – Category III Codes (L35490).

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	
33286	Removal, subcutaneous cardiac rhythm monitor	

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	
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	
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	
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	

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	
93290	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; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors	
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	
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	
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	
93799	Unlisted cardiovascular service or procedure	
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes	
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	

CPT® Category III Code(s)	Description	Comments
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	
0526T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only	
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	
0531T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only	
0532T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only	
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	
HCPCS Code(s)	**Description**	**Comments**
C1764	Event recorder, cardiac (implantable)	
C1833	Monitor, cardiac, including intracardiac lead and all system components (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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Change Summary

01/01/2024 New Policy.
12/19/2023 Update, No Coverage Change.
08/06/2024 Annual Review, Coverage Change. Updated Coding Information
09/24/2024 Update, Coverage Change.