

Ambulatory Cardiac Monitoring Devices



INDEPENDENT CARE HEALTH PLAN

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Medical Coverage Policy

Table of Contents

[Related Medical/Pharmacy Coverage Policies](#)

[Related Documents](#)

[Description](#)

[Coverage Determination](#)

[Coverage Limitations](#)

[Coding Information](#)

[References](#)

[Appendix](#)

[Change Summary](#)

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Related Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative	Applicable States/Territories
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			Contractors (MACs)	
NCD	Electrocardiographic Services	<u>20.15</u>		
LCD (and pertinent LCA)	Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring)	<u>L34636</u> <u>A57476</u>	J5 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE
LCD (and pertinent LCA)	Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring)	<u>L34636</u> <u>A57476</u>	J8 - Wisconsin Physicians Service Insurance Corporation	IN, MI
LCD (and pertinent LCA)	Cardiac Event Detection	<u>L33952</u> <u>A56452</u>	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD (and pertinent LCA)	Ambulatory Electrocardiograph (AECG) Monitoring	<u>L39490</u> <u>A59268</u>	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCD (and pertinent LCA)	Cardiac Event Detection	<u>L34573</u> <u>A56606</u>	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCD (and pertinent LCA)	Ambulatory Electrocardiograph (AECG) Monitoring	<u>L39490</u> <u>A59268</u>	JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, D.C., MD, NJ, PA
LCD (and pertinent LCA)	Cardiac Event Detection	<u>L34573</u> <u>A56606</u>	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD (and pertinent LCA)	Ambulatory Electrocardiograph (AECG) Monitoring	<u>L39492</u> <u>A59270</u>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

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).

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.⁷ 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.²⁴

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, Confirm Rx, Jot Dx, LUX-Dx, Reveal LINQ and Reveal XT 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 III 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, LifeWatch 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 4-in-1 remote cardiac rhythm monitor 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.

Coverage Determination

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

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

External Cardiac Monitors

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) (93228, 93229) will be considered medically reasonable and necessary when **one or more** of the following requirements are met:

- Assessment for asymptomatic ventricular premature beats or nonsustained ventricular tachycardia (greater than or equal to 3 premature ventricular complexes terminating spontaneously) in an individual with arrhythmogenic right ventricular cardiomyopathy, Brugada syndrome, congenital heart disease, dilated or restrictive cardiomyopathy, hypertrophic cardiomyopathy, or long QT syndrome¹⁹; **OR**
- Assessment for silent myocardial ischemia (acute or subacute forms of ischemic heart disease) in a patient with known or suspected coronary heart disease¹⁹; **OR**
- Assessment of documented or suspected arrhythmias or bradycardia²⁰; **OR**
- Assessment of prognosis following acute coronary syndrome¹⁹; **OR**
- Assessment of the average heart rate and adequacy of rate control in an individual with atrial fibrillation (A-fib)¹⁹; **OR**
- Assessment of the effectiveness of arrhythmia therapy (e.g., post ablation)¹⁹; **OR**
- A standard 12-lead electrocardiograph (ECG), complete cardiac history and cardiac exam has not satisfactorily explained the individual's cardiac complaints and ambulatory ECG testing will provide diagnostic information that will assist in developing a treatment plan or changing a treatment plan for an individual at risk for cardiac arrhythmias¹⁹; **OR**
- Evaluation for occult atrial fibrillation as a potential cause of cardioembolism in an individual with cryptogenic stroke¹⁹; **OR**
- Evaluation of an individual with a history of myocardial infarction (MI) and an ejection fraction of less than or equal to 40%²³; **OR**
- Individual experiencing chest pain, episodic dizziness, palpitations, unexplained syncope, near syncope, shortness of breath, and/or transient ischemic episodes¹⁹; **OR**
- Individual experiencing nocturnal arrhythmias¹⁹; **OR**
- Pre/post pacemaker or implantable cardiac defibrillator reprogramming¹⁹; **OR**
- Regulation of anti-arrhythmic drug dosage¹⁹

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 patient's signs and symptoms.¹⁹

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 **either** of the following requirements are met:

- Evaluation of syncope, near-syncope or palpitations and noninvasive ambulatory monitoring fails to establish a definite diagnosis because symptoms are infrequent (occur less frequently than once every 48 hours) or unpredictable, and therefore prolonged testing is necessary; **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 (eg, suspected AF as cause of a recent [eg, within the past 90 days] cryptogenic stroke)⁷²

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 in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. 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](#)

The following **ambulatory cardiac monitoring device** indications will not be considered medically reasonable and necessary:

- Ambulatory ECG monitoring of potentially harmful ventricular arrhythmias requiring inpatient level of care¹⁹; **OR**
- Devices that do not have FDA clearance, including non-physician prescribed: hand/wrist held-smart phone-based devices¹⁹; **OR**
- Mobile cardiac telemetry that does not involve a 24-hour monitoring station¹⁹

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

Current medical literature indicates that **inpatient evaluation** for individuals at high risk for potentially life-threatening arrhythmias (eg, VT) may be more appropriate than ambulatory cardiac monitoring, particularly for those with frequent symptoms and associated syncope.⁷⁴ The literature further recommends inpatient telemetry monitoring for individuals with clinical or ECG features suggesting arrhythmic syncope or a

history of recurrent syncope with injury.²⁵ There remains a lack of randomized, sham-controlled, blinded studies regarding the safety and efficacy of using ambulatory cardiac monitoring in certain individuals with frequent symptoms, syncope and recurrent syncope with injury.

A review of the current medical literature indicates no or unclear support for the clinical utility of **non-physician prescribed hand/wrist held or smart phone-based devices** used for the measurement of physiologic parameters (eg, ECG, heart rate).³² Studies consistently reported a higher rate of detection of episodes of cardiac arrhythmia in patients monitored with these devices compared with routine care or Holter monitoring; however, the devices are considered prediagnostic and rather than a diagnostic tool.³² This low-quality body of evidence was limited by small sample size and lack of long-term randomized, sham-controlled, blinded studies. None of the currently published studies have reported that individuals consistently experience improved health outcomes when using non-prescribed hand/wrist held or smartphone-based devices to monitor for cardiac arrhythmia.⁴⁷

The available studies provide little data on arrhythmia outcomes to support conclusions on the utility of **mobile cardiac telemetry without 24-hour monitoring**. The clinical significance of detected events is variable, particularly regarding atrial fibrillation and other intermittent arrhythmias in an individual with infrequent episodes.³³ Longer-term RCTs addressing the wider intended population are necessary to validate results. Current studies are at high risk of bias from retrospective design or lack of control groups. Long-term follow-up from larger randomized, sham-controlled, blinded studies is needed to accurately assess efficacy and safety.⁵⁰

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
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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Appendix

N/A

Change Summary

- 01/01/2024 New Policy.
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