



Clinical Review Criteria

Cardiac Ambulatory Monitoring for Extended Duration

- Cardionet®
- CardioNet ECG Monitor
- eVolution
- Implantable Loop Recorder
- MCOT
- Zio®Patch

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	NCD Manual, Part 1 – Electrocardiographic Services Electrocardiographic Services (20.15)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Implantable Loop Recorder

- I. An implantable loop recorder (cardiac event monitor) may be indicated for **1 or more of the following**:
 - A. Atrial fibrillation, known or suspected, as indicated by **ALL of the following**:
 1. Cryptogenic stroke
 2. Holter monitor or other noninvasive cardiac monitor contraindicated, or results unrevealing or indeterminate
 3. Recurrent paroxysmal atrial fibrillation suspected, and test results may impact patient management
 - B. History of structural or infiltrative heart disease (eg, valvular aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease) and **ALL of the following**:
 1. Holter monitor or other noninvasive cardiac monitor contraindicated, or results unrevealing or indeterminate
 2. Patient at high risk for arrhythmias (eg, family history, symptoms, anatomy of structural heart disease)
 - C. Syncope as indicated by **ALL of the following**:
 1. Cardiac etiology of syncope, suspected, as indicated by **1 or more of the following**:
 - a) ECG results abnormal (eg, cardiac rhythm other than normal sinus, significant conduction abnormalities, Brugada ECG pattern, long QT syndrome)
 - b) Family history of sudden death
 - c) History of chronic heart failure
 - d) History of structural heart disease (eg, valvular aortic stenosis, congenital heart disease, hypertrophic cardiomyopathy) or severe coronary heart disease
 - e) Recent history of palpitations, abnormal heart rate, or symptomatic arrhythmia
 - f) Use of medication known to cause malignant arrhythmias (eg, antiarrhythmics, antidepressants, antihistamines)
 2. Recurrent syncope, suspected

3. Test results negative or inconclusive, as indicated by **1 or more of the following**:
 - a) Electrophysiologic study
 - b) Non-implantable (external) loop recorder
 - c) Tilt table testing

Service	Criteria
Cardionet® CardioNet ECG Monitor eVolution MCOT Zio®Patch	Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Cardiac rhythm abnormalities are common. Many are harmless, but some cause symptoms such as palpitation, chest pain, pre-syncope and syncope, and others may be a signal for potential stroke or cardiac arrest. Electrodiagnostic (ECG) documentation of the cardiac rhythm during symptoms is necessary for making accurate diagnosis, therapeutic decisions, assessing the effectiveness of suppression, and monitoring adverse drug effects. However, symptoms of arrhythmia are often infrequent and episodic, and the underlying heart rhythm may not be detected during physical examination and routine ECG that permits a few seconds of recording. It is thus essential to have extended periods of ECG recording while the patients are pursuing their normal routine (Kowey 2003, Naccarelli 2007, and Saarel 2008).

Devices used:

- *Holter monitors* are portable devices that record heart rhythms continuously for up to 48 hours. These devices are used to record events that occur at least once a day.
- *Non-implantable cardiac event monitors* are portable devices that record heart rhythms intermittently for up to 30 days. These devices capture ECG data before, during and after the time of activation.
- *Standard loop recorders* have just a few minutes of memory. Newer, more sophisticated devices have extended memory features that can store up to several hours of ECG data. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias. These devices are used to record infrequent or irregular events.
- *External mobile cardiovascular telemetry* consists of a monitor that continuously records the electrocardiographic rhythm from external electrodes placed on the patient's body. Segments of the ECG data are automatically (i.e., without patient intervention) transmitted to a remote surveillance location by cellular or landline telephone signal. The transmitted events are triggered automatically by preprogrammed algorithms or by the patient during a symptomatic episode. There is continuous, real-time data analysis in the device and attended surveillance of the transmitted rhythm segments by a surveillance center technician. The surveillance center technician reviews the data and notifies the physician depending on the prescribed criteria. These devices are used to record suspected asymptomatic arrhythmias.

The most commonly used method for extended ECG recording is the Holter monitor which records an ECG continuously for 24 to 48 hours via leads placed on the chest to yield 2 or 3 channels of ECG data. The Holter monitor provides complete rhythm recording and excellent quality tracing. However, it has a diagnostic yield of only 5-28% due to its limited time of recording which is usually too short to capture infrequent arrhythmias. In addition, some clinically important arrhythmias such as atrial fibrillation may be asymptomatic and pass unnoticed by the Holter recording (Kowey 2003, Naccarelli 2007, Rothman 2007, Saarel 2008).

External patient-activated loop event monitoring (LOOP) devices were found by researchers to improve the diagnostic yield of arrhythmias up to 63%. These may be used for up to 30 days; however, they have limited storage, and require appropriate patient activation during the occurrence of symptoms. Patient activation may be a difficult task for the elderly or those whose arrhythmias cause functional impairment. It was reported that one in four patients does not activate the recorder during symptomatic episodes despite the education received on operating the device. Developments are continuously being made to improve the diagnostic yield of the rhythm monitors. Newer loop recorders continually record and erase so that data gathered from 1 to 4 minutes before,

and those recorded 30-60 seconds after activation of the device can be retained. Other loop monitors are automatically activated and start the recording once an abnormal rhythm of any kind is detected, without patient activation. An implantable form of continuous-loop event recorder is also currently available. It is a small device in the size of pacemaker that is implanted subcutaneously to the right or left side of the sternum, and is triggered by placing an activator over it. The device has a programmable antegrade and retrograde memory, and may be left in place for up to 18 months and can be explanted once the diagnosis is made or battery life has ended. Data from the device however, cannot be transmitted wirelessly (Zimetbaum 1999, Kowey 2003, Naccarelli 2007 Rothman 2007).

Mobile Cardiac Outpatient Telemetry (MCOT, Cardionet®, CardioNet device or recorder) was introduced in 1999 for continuous real-time ambulatory electrographic monitoring and analysis. The device consists of a three-electrode, and a two-channel sensor that transmits wirelessly to a small PDA sized portable monitor which can be clipped to the waist or worn on a strap around the neck. Rhythm strips are recorded continuously and analyzed by an automated arrhythmia analysis algorithm. When an arrhythmia is detected (according to the physicians'predesignated thresholds) the monitor can transmit the ECG data to the monitoring center utilizing a cellular modem or telephone data line. Patients are monitored for 24 hours/day for up to 30 days, by central station technicians with immediate referral to the prescribing physician for evaluation of rate and rhythm changes and their symptoms. The patient can also initiate the recording and transmission of ECG data if symptoms are felt. MCOT thus potentially improves diagnosis of arrhythmias by allowing continuous monitoring of cardiac rhythm for extended periods of time, detecting asymptomatic arrhythmias, and allowing the patients to submit their symptoms and level of activity from a menu to the device (FDA web page, Rothman 2007, Naccarelli 2007).

The CardioNet ECG monitor was approved by the Food and Drug Administration in 2002 for cardiac monitoring for non-life-threatening arrhythmia detection, its evaluation, and monitoring of antiarrhythmic therapy.

Medical Technology Assessment Committee (MTAC)

Mobile Cardiac Outpatient Telemetry (MCOT)

06/04/2008: MTAC REVIEW

Evidence Conclusion: The literature search revealed only one randomized controlled study (Rothman 2007), and several observational studies. Rothman and colleagues' study was a multicenter, randomized, controlled study that compared the diagnostic yield of the mobile cardiac outpatient telemetry (MCOT) system (CardioNet, USA) with the patient-activated external loop devices (LOOP). Patients with symptoms of syncope, pre-syncope or severe palpitations, and a nondiagnostic 24-hour Holter, were randomized to receive one of the two monitoring devices for up to 30 days. The patients and investigators were not blinded to the monitor received, but the electrophysiologist who reviewed the monitor strips and verified the diagnosis was blinded to the patient allocation. There was a higher noncompliance rate in the MCOT group, and 14% of all participants did not complete the study. The study compared the MCOT (CardioNet) system with the patient-activated external loop device and not to the auto-triggered or the implanted loop systems which are known to have better diagnostic yield. Overall, the results of the study show that diagnosis (confirmation or exclusion) of arrhythmias was made in 88% of the patients randomized to the MCOT group, vs. 75% of the patients in the LOOP group ($P < 0.001$). A significant difference was also observed for patients with syncope or presyncope, where a diagnosis was made in 89% of patients in the MCOT group vs. 69% in the LOOP group ($p = 0.008$). Conclusion: There is fair evidence from one RCT with limitations, that CardioNet system may have a higher diagnostic yield compared to the patient-activated external loop device for up to one month. There is no published evidence to date to determine that the device is superior to the auto-triggered loop system that was found to have better diagnostic yield, or to the implanted loop system. There is insufficient evidence to determine the efficacy and safety of the CardioNet system for detecting less frequent syncopal episodes. There is insufficient evidence on the efficacy of CardioNet system in assessing the safety and efficacy of antiarrhythmic agents, or outpatient monitoring for medication titration and dose adjustments.

Articles: The search yielded around 50 articles. Many were reviews, or articles that dealt with the analysis of data or feasibility of using the device. Only one randomized controlled study (Rothman 2007) that compared the diagnostic yield of MCOT to the external patient-activated loop event monitoring up to 30 days, was identified. There were a few other relatively small observational prospective and retrospective studies that evaluated the safety and diagnostic yield of the CardioNet system. Rothman and colleagues' RCT was selected for critical appraisal. Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: A prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. *J Cardiovasc Electrophysiol* 2007;18:241-247. See [Evidence Table](#).

The use of Mobile Cardiac Outpatient Telemetry (MCOT) in the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/03/2009: MTAC REVIEW

Mobile Cardiac Outpatient Telemetry (MCOT)

Evidence Conclusion: There is no new published evidence that would alter the conclusion of the previous MTAC review. The only published RCT (Rothman 2007) that compared mobile cardiac outpatient telemetry to LOOP event monitoring was reviewed earlier in 2008. The study was randomized, controlled and multicenter. However, it was not blinded, had a 14% drop-out rate, non-compliance was more common in the MCOT group, and analysis was not based on intention to treat. Moreover, the mobile cardiac outpatient telemetry (MCOT) system (CardioNet, USA) was compared with the patient-activated external looping event recorders. The study did not compare MCOT with the implanted loop recorders, and was not designed to compare it with the auto-trigger loop recorders which were used in only 16% of the patients in the LOOP group. Both the implanted and auto-trigger loop recorders are reported to have higher diagnostic yield than the patient activated loop recorders. Overall the results of the study indicate that MCOT was superior to loop recordings with a diagnosis made in 88% MCOT patients vs. 75% LOOP patients ($p=0.008$). A significant difference in the diagnostic yield was also observed for patients with syncope or presyncope (89% vs. 69% respectively, $p=0.008$). More recently only retrospective case series (Saarel 2008, and Tayal 2008) on the use of MCOT for the detection of suspected arrhythmias were published. Saarel and colleagues (2008) reported on the use of MCOT among 54 children and adolescents with suspected arrhythmia. Thirty three subjects transmitted ECGs during symptoms yielding a diagnostic rate of 61%. The remaining 21 (39%) failed to transmit ECG while experiencing symptoms. Comparing the diagnostic yield of MCOT with historical data from transtelephonic electrocardiographic event monitors (TTMs) showed no significant differences between the two systems. Tayal and colleagues (2008) performed a retrospective analysis of 56 patients with cryptogenic stroke (undetermined cause). This showed that MCOT detected 27 asymptomatic atrial fibrillation in thirteen patients (23%). 23 (85%) of these episodes were less than 30 seconds in duration, and the remaining 4 (15%) were 4-24 hours in duration. None of the published studies to date indicate that the MCOT (CardioNet system) is superior to the auto-trigger LOOP device currently used, or that it leads to an improvement in net health outcome. Conclusion: There is fair evidence from one RCT with limitations, that CardioNet system may have a higher diagnostic yield compared to the patient-activated external loop device for up to one month. There is insufficient evidence however to determine that the device is superior to the auto-triggered or the implanted loop systems that were found to have better diagnostic yield than the patient-activated external loop monitors. There is insufficient evidence to determine that CardioNet system improves the management of patients e.g. monitoring for medication titration and dose adjustments. There is insufficient evidence to determine that CardioNet system improves patients' health outcomes.

Articles: The search did not reveal any controlled trial on MCOT published after the RCT reviewed earlier in MTAC. Only two relatively small retrospective case series were identified; one reported on the use of MCOT among adult patients with stroke, and the other evaluated its use among children and adolescents with suspected arrhythmias. None were selected for critical appraisal.

The use of Mobile Cardiac Outpatient Telemetry (MCOT) in the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Zio®Patch

12/16/2013: MTAC REVIEW

Evidence Conclusion: There is a lack of published literature on the use of Zio®Patch for detecting atrial fibrillation and other arrhythmias in asymptomatic or symptomatic patients. A pilot study conducted by Rosenberg and colleagues (2013) compared the Zio®Patch with the traditional 24 hours Holter monitor in 74 patients with paroxysmal atrial fibrillation who were referred to Holter monitoring for evaluation. The Zio®Patch was well tolerated and had a mean monitoring period of 10.8 +2.8 days (range 4-14 days). During the simultaneous 24 hour recording time when the patients wore both devices, there was a strong correlation between the Zio®Patch and the Holter monitor ($r=0.96$) for identifying AV events and estimation AF burden. 18 additional cardiac events were recorded with the Zio®Patch due to longer duration of use. Other clinically relevant cardiac events recorded by the Zio®Patch after the 24 hours of monitoring, including symptomatic ventricular pauses, led to change in medications or referrals for pacemaker placement. Overall clinical management was changed in 28.4% of the patients as a result of the Zio®Patch findings. The authors concluded that the Zio®Patch was well tolerated and allowed longer monitoring that resulted in meaningful changes in clinical management. They indicated that more studies are needed to examine the long-term impact of the device in AF management. The other published study (Turakhia et al, 2013) was only a retrospective analysis of data obtained from the device manufacturer. No comparison was made with Holter monitor or any other ambulatory cardiac rhythm monitor. There are no published studies, to date, that compared the Zio®Patch to any of the other longer-term outpatient ambulatory

cardiac rhythm monitors. Conclusion: There is weak evidence from one small single-center pilot study that Zio@Patch was well tolerated and allowed longer monitoring than Holter monitoring. This resulted in the detection of more AF episodes and cardiac events in symptomatic patients and making changes in the clinical management among more than one fourth of the study participants. There is insufficient published evidence on the use of Zio@Patch for detecting atrial fibrillation and other arrhythmias in asymptomatic patients with AF. There is insufficient evidence to determine the equivalence or superiority of Zio@Patch to any of the other longer-term outpatient ambulatory cardiac rhythm monitors.

Articles: The literature search revealed only two published studies on the use of Zio@Patch as a noninvasive monitoring device for arrhythmias in general in one study, and for atrial fibrillation in the other. A retrospective study among 285 patients seen in emergency departments was identified from a review article, but it was not published in a peer review journal; it was only presented in a conference. The two published studies were critically appraised. Rosenberg MA, Samuel M, Thosani A, et al. Use of a noninvasive continuous monitoring device in the management of atrial fibrillation: a pilot study. *Pacing Clin Electrophysiol.* 2013;36:328-333. [See Evidence Table](#), Turakhia MP, Hoang DD, Zimetbaum P, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. *Am J Cardiol.* 2013;112:520-524. [See Evidence Table](#).

The use of Zio@Patch the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Implantable Loop Recorder

BACKGROUND

Syncope has a complex differential diagnosis. Syncope that remains unexplained after standard evaluation does not appear to be associated with excess mortality (Savage et al., 1985) or serious adverse cardiovascular events (Kapoor, 1990). However, syncope recurrences are associated with fractures, automobile accidents and other complications (Kapoor, 1987).

Standard techniques for diagnosing syncope include history and physical examination, laboratory testing, exercise stress testing, Holter monitoring, tilt table testing and external loop recording. External loop recorders ("King of Hearts" model) store ECG data up to 4 minutes prior to and 1 minute after activation by a patient. They are worn on the wrist or around the waist, generally for up to 1 month.

The implantable loop recorder (ILR) is a new diagnostic tool for unexplained infrequent syncope. The ILR is a 61x19x8mm, recording device produced by Medtronic Reveal. It stores an ECG signal in a circular buffer capable of retaining 21 minutes of uncompressed signal or 42 minutes of compressed signal (can be divided into 1-3 parts). The ILR requires the patient or family member to use a hand-held pager-sized activator to "freeze" the memory buffer during or immediately following an episode of syncope. The device is implanted into the left infraclavicular region. Using local anesthesia, a 2 cm incision is made, a pocket the size and shape of the device is made and the ILR is placed in the pocket. The ILR can monitor patients for up to 14 months. The device is removed after a diagnosis of syncope is made or at the end of battery life.

Medicare approved coverage for this implantable device effective 10/1/1999. Kaiser Permanente added it to the medical criteria subject area at that time.

MTAC reviewed this device at the February 2000 meeting and found the technology appears to be promising and safe for patients whose syncope is undiagnosed but there is not enough evidence to draw conclusions regarding reproducibility, safety and accuracy. The Health Plan Medical Director Group at their February 2000 meeting reviewed the MTAC findings and determined that there was good reason to recommend coverage for patients who had infrequent, undiagnosed episodes of syncope.

02/10/1999: MTAC REVIEW

Evidence Conclusion: The one study evaluating the potential of the ILR to diagnose unexplained syncope obtained a diagnostic yield of 59% during a mean of 10.5 months of recording. Possible selection bias, conflict of interest on the part of the investigators and a lack of comparison with external loop recorders limit the ability of this study to determine efficacy of the ILR. Two studies evaluating the external loop recorders found point estimates for diagnostic findings of 25% and 36% after approximately one month of recording.

Articles: Krahn D, Klein G, Yee R, Takle-Newhouse T, Norris C. Use of an extended monitoring strategy in patients with problematic syncope. *Circulation* 1999; 99: 406-410. [See Evidence Link](#).

The use of implantable loop recorder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
07/17/08	06/04/2008, 08/03/2009, 5/4/2010 ^{MDCRPC} , 3/1/2011 ^{MDCRPC} , 1/03/2012 ^{MDCRPC} , 11/06/2012 ^{MDCRPC} , 09/03/2013 ^{MPC} , 03/04/2014 ^{MPC} , 11/03/2015 ^{MPC} , 09/06/2016 ^{MPC} , 07/11/2017 ^{MPC} , 05/01/2018 ^{MPC}	03/06/2018

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
04/05/2016	Added "Following a cryptogenic stroke" as an indication
08/09/2016	Merged Implantable Loop Recorder into one policy as External Loop Recorder
02/01/2017	Medical management approved medical necessity no longer required
03/06/2018	MPC approved commercial criteria for Implantable Loop Recorder effective date 7/1/2018

Codes

Ziopatch: 0295T, 0296T, 0297T, 0298T

External Loop Recorder: 93228, 93229, 93268, 93270, 93271, 93272

Implantable Loop Recorder: 33282, 33284, C1764, E0616

External Patient Activated EKG: 0497T, 0498T