Medica Coverage Policy

Policy Name:	**Cardiac Event Monitors**
Effective Date:	**5/15/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Ambulatory Event Monitors:
The following ambulatory event cardiac event monitors are **COVERED** for the detection of cardiac arrhythmias:
1. Holter monitor
2. External loop recorder/External intermittent cardiac event monitor
3. Patch cardiac rhythm monitor.

Real-Time Mobile Cardiac Outpatient Telemetry:
Real-time mobile cardiac outpatient telemetry ***requires prior authorization***.

Note: See Medica Utilization Management policy, *Outpatient Mobile Cardiac Real-Time Telemetry*, for specific medical necessity criteria.

Implantable Loop Cardiac Recorders:
Implantable loop cardiac recorders are **COVERED** for a select population of individuals for one of the following indications:
1. Unexplained symptoms suggestive of cardiac arrhythmias (e.g., unexplained syncope, presyncope, palpitations, or dizziness)
2. Post-cardiac ablation monitoring
3. History of cryptogenic stroke or transient ischemic attach (TIA) with suspected unconfirmed occult atrial fibrillation.

Implantable loop cardiac recorders are investigative and unproven and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

A cardiac event monitor is a portable device used to record the heart's electrical activity when symptoms of cardiac arrhythmia have been observed. It records the same information as an electrocardiogram (ECG), but for longer durations of time. Event monitors can record continuously, be programmed to record intermittently, or be triggered by the individual when an abnormal heart rhythm is experienced. Results may lead to additional diagnostic testing, changes in medication or medical management, or in a cardiac procedure (e.g., pacemaker insertion, cardioversion).

Holter Monitor

A Holter monitor is a small, wearable, battery-operated device that continuously records heart rhythm through electrode lead attached to the chest. The number of leads depends on the Holter device selected by the provider. It is worn for 24 to 48 hours or longer, and is normally performed after a traditional ECG has failed to provide enough information about cardiac arrhythmias. Holter monitoring is most practical for patients with daily or near daily symptoms. The Holter monitor is returned for evaluation and results are used to assist in ascertaining a possible heart rhythm problem.

External Loop Recorder/External Intermittent Cardiac Event Monitor

An external loop recorder (ELR) is a type of ECG monitoring system that continuously records cardiac activities for a long period of time, and is used when heart palpitations are not frequent and are of nonspecific characteristics. The design of an ELR includes the ECG electrodes, instrumentation amplifier, analog to digital converter, and signal processing unit. The ELR is smaller than Holter monitor and is attached through chest electrodes. It records the data when it is activated by the patient or by an automatic trigger programmed to detect irregular heart rates. It is used for monitoring up to 14 to 30 days. The data is sent to a central monitoring facility where the data is loaded in a computer, analyzed, and reported to clinician.

Patch Cardiac Rhythm Monitors

Long term recording devices that provide continuous, single-lead data are also available. These devices are usually placed over the left pectoral region of the chest and do not require external lead placement. One available device for long term ambulatory cardiac monitoring, the Zio® XT-Patch system (iRhythm Technologies), utilizes a small, lightweight, water-resistant patch that is designed to store up to 14 days of continuous data. A button on the patch can be activated by the wearer to mark a symptomatic episode. The Zio® Event Card is available as a single-use, disposable, looping ECG monitor that may be worn up to 30 days. When symptoms occur, the individual depresses a button, and the device records 45 seconds of data. The device can store up to two events. At the end of the recording period, these devices are mailed to iRhythm for processing, analysis, and reporting to the ordering physician. Multiple other long term ambulatory cardiac rhythm monitors are available, including but not limited to, iRhythm Zio® Patch, CardioNet CardioKey Cardiac Event Recorder, and BodyGuardian System.

Real-Time Mobile Cardiac Outpatient Telemetry

Real-time mobile cardiac outpatient telemetry (RT-MCOT), also known as outpatient mobile cardiac real-time telemetry, allows clinicians to conduct *real-time* outpatient monitoring of an individual's cardiac rhythms via electrocardiographic recordings. The individual can perform normal daily activities, while the clinician monitors the electrocardiographic recordings for suspected cardiac arrhythmias using concurrent computerized real time data analysis. With this technology, physicians can monitor a patient's cardiac rhythms for weeks at a time and purportedly be able to more accurately detect arrhythmias that occur infrequently.

When using this technology, the patient wears a portable electrocardiogram (ECG) sensor with leads attached to the patient's skin for continuous monitoring of cardiac rhythms during daily activities. If the algorithm of the monitoring system detects an arrhythmic event, the system will automatically transmit the ECG data wirelessly or through a telephone line to a service center attended 24-hours per day/365 days per year. Experienced monitoring specialists analyze the data, respond to events, and report results as prescribed by the physician. Data can also be sent manually by pressing a button when experiencing a symptom.

Implantable Loop Cardiac Recorders

An implantable loop recorder (ILR) is a subcutaneous, single-lead, ECG monitoring device used for diagnosis in patients with recurrent unexplained episodes of palpitations or syncope. The device is normally implanted in the left pectoral region of the chest, and is typically done in the physician's office under local anesthetic. These devices can be worn for up to three years. Risks of the procedure include infection or a reaction to the device that causes redness

at the incision site.

The device records the heart's electrical impulses and transmits them automatically to the physician using the internet and wireless technology. The individual can also activate data transmission when symptoms are observed. An implantable loop recorder can provide information regarding arrythmias that other heart-monitoring devices do not provide, as it allows for longer-term heart rhythm monitoring.

FDA Approval

Holter Monitor

The first wearable Holter monitor was released for commercial production in 1962, and was based on work in radio telemetery started in 1949. Many companies manufacture Holter monitors and associated supplies, including but not limited to: (1) Morgara Instruments, (2) MidMark Holter Monitoring Company, (3) Phillips Healthcare, and (4) and Scott Care Holter Monitoring.

External Loop Recorder/External Intermittent Cardiac Event Monitor

Multiple external loop recorders/external intermittent cardiac event monitors have received FDA clearance. One example of an external loop recorder is the eCardio eVolution Cardiac Monitor.

Patch Cardiac Rhythm Monitors

Multiple long term ambulatory cardiac rhythm monitors have received FDA approval, including but not limited to:

1. The Zio™ Event Card (iRhythm Technologies)
2. The Zio® XT-Patch (iRhythm Technologies)
3. The ZP model N100 (iRhythm Technologies)
4. CardioNet CardioKey Cardiac Event Recorder (CardioNet, Inc.)
5. The BodyGuardian Remote Monitoring System™ (Preventice®, Inc.)
6. CardioPAL SAVI (PM410) (Medicomp, Inc.)

Real-Time Mobile Cardiac Outpatient Telemetry

There are numerous FDA 510(k) marketing clearances for RT-MCOT devices and associated supplies and accessories. Examples of current manufacturers and products include, but are not limited to:

1. BioMedical Systems (St. Louis, MO)
    a. TruVue® Wireless Ambulatory ECG Monitoring system
    b. TruVue® Wireless ECG Ambulatory Monitoring system
2. BioTelemetry, Inc. (Malvern, PA)
    a. BioTel MCOT
3. CardioNet (Malvern, PA)
    a. CardioNet MCOT™ system
4. Corventis, Inc. (San Jose, CA)
    a. NUVANT Mobile Cardiac Telemetry (MCT) system
5. Cardiac Telecom Corp. (Greensburg, PA)
    a. HEARTLink II™ system
6. Mednet Healthcare Technologies, Inc. (Trenton, NJ)
    a. Heartrak Smart ECAT (External Cardiac Ambulatory Telemetry)
7. LifeWatch, a subsidiary of Card Guard Scientific (Rosemount, IL)
    a. LifeStar™ ACT Ambulatory Cardiac Telemetry system
8. Biowatch Medical (Columbia, SC)
    a. VST™ (Vital Signs Transmitter).

Implantable Loop Cardiac Recorders

Multiple implantable cardiac monitors and associated supplies have received FDA approval, including but not limited to:

1. Medtronic, Inc.
    a. Reveal LINQ ICM Model LNQ11 and Reveal XTi Patient Assistant Model 9538

   b. Reveal XT ICM System, consisting of: Reveal XT Model 9529, and Reveal XT Patient Assistant Model 9539
   c. Reveal DX ICM System, consisteing of: Reveal DX ICM Model 9528, and Reveal Patient Assistant Model 9538
   d. Reveal Plus Insertable Loop Recorder (ILR) System, consisting of: Model 9526 implanted recorder, and Model 6191 activator
2. Transoma Medical, Inc.
   a. The Transoma Medical Sleuth Implantable ECG Monitoring System, consisting of: Model 2010 Implantable Monitoring Device, Model 4000 Activator, and Model 5000 Base Station
3. St. Jude Medical, Inc.
   a. SJM Confirm ICM Model DM2102
4. Biotronik
   a. BioMonitor 2-AF
   b. BioMonitor 2-S.

Prior Authorization

Prior authorization is not required with the exception of Real-Time Mobile Cardiac Outpatient Telemetry. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

Implantable Loop Cardiac Recorders

- **33285** - Insertion, subcutaneous cardiac rhythm monitor, including programming
- **33286** - Removal, subcutaneous cardiac rhythm monitor
- **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
- **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
- **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
- **E0616** - Implantable cardiac event recorder with memory, activator, and programmer
- **C1764** - Event recorder, cardiac (implantable)
- **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

Ambulatory Event Monitors:

- **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
- **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
- **0295T** - External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
- **0296T** - External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
- **0297T** - External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report
- **0298T** - External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation
- **0497T** - External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recorder without 24 hour attended monitoring; in-office connection
- **0498T** - External patient-activated, physician- or other qualified health care professional-prescribed, electrocardiographic rhythm derived event recording without 24 hour attended monitoring; review and interpretation by a physician or other qualified health care professional per 30 days with at least one patient-generated triggered event

Real-Time Mobile Cardiac Outpatient Telemetry

- **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

Document History:

Real-Time Mobile Cardiac Outpatient Telemetry (RT-MCOT)
Original Effective Date: 5/1/2012
Re-review Date(s): 2/25/2014
2/28/2017
2/25/2020

Long Term Ambulatory Cardiac Rhythm Monitors (e.g., Patch monitors):
Original Effective Date: 4/1/2013
Re-review Date(s): 10/25/2014
3/21/2018
2/17/2020

Cardiac Even Monitors
Original Effective Date: 5/18/2020
6/16/2020 – administrative update; MD requirements added for RT-MCOT
1/1/2121 – administrative update; code update
7/1/2021 – administrative update; code update
3/22/2023 – Clinical Review Reserve