Page: 1 of 10

MEDICAL POLICY



| MEDICAL POLICY DETAILS | | |
|--------------------------------|---|--|
| Medical Policy Title | Ambulatory Event Monitors | |
| Policy Number | 2.01.03 | |
| Category | Technology Assessment | |
| Original Effective Date | 10/18/01 | |
| Committee Approval | 10/18/01, 07/18/02, 06/19/03, 06/17/04, 04/21/05, 02/16/06, 12/21/06, 10/18/07, 11/20/08, | |
| Date | 10/29/09, 10/28/10, 10/20/11, 09/16/21 | |
| Current Effective Date | 03/15/23 | |
| Archived Date | 10/18/12 | |
| Archive Review Date | 10/17/13, 09/18/14, 09/17/15, 10/20/16, 10/21/17, 08/16/18, 09/19/19, 9/17/20, 01/12/21, 09/16/21, 11/17/22 | |
| Product Disclaimer | If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line. | |

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, use of external memory-recording ambulatory event monitors (AEMs), either patient-activated or auto-activated, that record and store information for periods longer than 48 hours and up to 14 days have been proven to be medically effective and, therefore, are considered **medically appropriate** as an alternative to Holter monitoring in patients who experience infrequent symptoms, when used:
 - A. to assess signs or symptoms possibly related to rhythm disturbances (e.g., palpitations, serious or significant syncope, near syncope); **OR**
 - B. to assess anti-arrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well-characterized as reproducible and of sufficient frequency to permit analysis; **OR**
 - C. in patients with atrial fibrillation (AF) who have been treated with catheter ablation and in whom discontinuation of systemic anticoagulation is being considered.
- II. Based upon our criteria and assessment of the peer-reviewed literature, use of implanted AEMs (implanted loop recorder (ILR)), either patient-activated or auto-activated, have been proven to be medically effective for infrequent and recurrent syncopal episodes, infrequent and recurrent palpitations, infrequent and recurrent near syncope, or to monitor paroxysmal A Fib, therefore, are considered **medically appropriate** in patients that meet the following criteria:
 - A. Failure of 30day AEM **OR** when AEMs is contraindicated (i.e., severe skin conditions or obesity) **OR**
 - B. Clear documentation over 90days showing infrequent presentation of symptoms AND
 - C. Documentation supporting that an ILR will significantly change the plan of care and that patient understands and agrees with all aspects of implantation of an ILR.

Policy Number: 2.01.03

Page: 2 of 10

III. Based upon our criteria and assessment of the peer-reviewed literature, use of implanted AEMs (implanted loop recorder (ILR)), either patient-activated or auto-activated, ILR evaluation for AF may be considered **medically necessary** in patients with **cryptogenic stroke** who meet **BOTH** of the following criteria:

- A. 48-72 hours of EKG monitoring with failure to demonstrate an arrhythmia, when an arrhythmia is the suspected etiology of the cryptogenic stroke **AND**
- B. Received a thorough stroke evaluation with imaging performed by neurologist or qualified provider from a certified stroke center.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, use of implanted AEMs (implanted loop recorder (ILR)), either patient-activated or auto-activated, the implantation of an ILR **after a cardiac ablation** may be considered **medically necessary** in patients who meet all of the following criteria:
 - A. Failure of 30day AEM OR when AEMs is contraindicated (i.e., severe skin conditions or obesity) AND
 - B. Documentation supporting that an ILR will significantly change the plan of care and that patient understands and agrees with all aspects of implantation of an ILR.
- V. Based upon our criteria and assessment of the peer-reviewed literature, standard memory-recording AEMs have not been medically proven to improve patient outcomes and, therefore, are considered **investigational** for all other indications, including but not limited to, the following:
 - A. To measure heart rate variability in the assessment of patients at risk for future cardiac events without symptoms of arrhythmia, **OR**
 - B. To monitor patients for myocardial ischemia by detecting ST segment changes.
- VI. Based upon our criteria and assessment of the peer-reviewed literature, home-based, real-time cardiac surveillance systems (mobile cardiac outpatient telemetry (MCOT)) have not been medically proven to improve patient outcomes over standard memory-recording devices and, therefore, are considered **not medically necessary**.

This policy does not address Holter monitoring.

POLICY GUIDELINES

- I. Requests for cardiac event monitoring that do not meet the above criteria or repeat studies within one year of a previous study are subject to medical necessity review.
- II. The replacement of an ILR or battery for and ILR will be considered for medically necessity review if:
 - A. The device is malfunctioning; **AND**
 - B. The device has exceeded the warranty period: **AND**
 - C. Continue to meet the above criteria, **OR**
 - D. There have been irreparable changes in the device condition or in a part of the device, due to normal wear and tear.
- III. A thorough stroke evaluation should consist of, at a minimum, CT or MRI of brain, arterial imaging, CTA, MRA or ultrasound of carotid circulation, echocardiography(ECG), extended rhythm monitoring, and key laboratory studies such as a lipid profile and hemoglobin A1c [HbA1c]) per 2021 AHA/ASA guidelines for the secondary prevention of ischemic stroke.

DESCRIPTION

Ambulatory Holter electrocardiography (ECG), which is a noninvasive test used to continuously record an ECG over a specified period of time, usually 24 to 48 hours, is used to evaluate symptoms suggestive of cardiac arrhythmias. It is particularly useful if symptoms occur on a daily or near daily basis. However, Holter monitoring may be ineffective if the patient experiences infrequent symptoms.

AEMs were developed for longer periods of monitoring and may be useful when the initial evaluation by Holter

Policy Number: 2.01.03

Page: 3 of 10

monitoring is non-diagnostic or when symptoms are infrequent. AEMs are intermittent recorders that can be used for longer periods (weeks to months) of monitoring, to gather briefer, intermittent recordings in order to investigate events that occur infrequently. AEMs are either worn continuously and activated when the patient experiences symptoms or applied by the patient only when symptoms occur. Some AEM recorders are implanted under the skin for long-term recordings.

AEMs are useful in patients whose symptoms are quite brief or involve little to patient incapacitation, making it too difficult for the patient or a companion to activate the recorder. Cardiac event monitors have been developed with automatic trigger capabilities, which are designed to automatically record when certain preset conditions occur and avoid the need for the patient to activate the device. These devices are often capable of downloading data trans telephonically.

There are several types of AEMs available:

- I. *Noncontinuous devices with memory*. These devices are carried by the patient and applied to the precordial area when symptoms occur or, alternatively, may be worn on the wrist and activated when symptoms are present. The limitations are that an arrhythmia may be of short duration and not captured by the device, or the patient may be incapacitated and unable to apply the device while symptomatic.
- II. Continuous memory loop devices. These devices are worn continuously, collecting ECG data continuously. When symptoms occur, the patient activates the device, and the ECG is recorded from the memory loop for the preceding 30-90 seconds and approximately one minute after activation. The ZioPatch is capable of continuously recording a single-lead ECG for up to 14 days. The device adheres to the pectoral region and uses a single vector to obtain continuous, single-lead ECG data. The patch is equipped with an event button that patients activate when experiencing symptoms, highlighting the ECG recording for 45 seconds before and after activation. After monitoring is complete, the patients mails the device to a processing center, where the data are analyzed using the manufacturer's algorithm and undergo technical review, physician over-read, and report generation. The ZIO Event Card (iRhythm Technologies Inc, San Francisco, CA) is a prescription-only, single-use, disposable looping ECG monitor that can be worn for up to 30 days and can hold up to two ECG recordings before the patient transmits data via the phone. When the patient feels a symptom, the patient presses the RECORD button, and the recording is stored in the device. The patient then calls into iRhythm Clinical Centers (iCC) to transmit the data, and the recording is reviewed while the patient is still on the phone. A report is generated and posted to a secure site, and, in certain instances, when the report meets account-specific notification criteria, the physician is contacted.
- III. *Implantable continuous memory loop devices*. These devices are inserted under the skin in the chest area during an outpatient surgical procedure. When symptoms occur, the patient presses the hand-held activator over the recorder, to activate the storage of cardiac rhythms. The device may be used for more than a year, having a projected battery life of 14 months, at which time the device must be surgically removed. Other implantable loop devices (ILRs) or insertable cardiac monitors (ICMs) (e.g., Reveal LINQ (Medtronic, Inc) and Confirm Rx (Abbott)) are implantable, patient-activated, or automatically activated monitoring systems that record subcutaneous ECG and provide continuous, long-term monitoring for up to three years. The devices are inserted under the skin and close to the sternum, usually between the first and fourth rib.
- IV. *Auto-triggered devices*. Second-generation continuous memory loop devices have an auto-activation component, which allows the device to record rhythms automatically when the heart rate exceeds or goes below a preset limit.
- V. Home-based, real-time cardiac surveillance systems. Also referred to as mobile cardiac outpatient telemetry (MCOT), these systems are automatically activated devices that require no patient intervention to capture or transmit an ECG when the cardiac rhythm violates certain preset alarm limits. Five such systems are currently commercially marketed: the CardioNet system (CardioNet, Inc.), the HEARTLink II system (Cardiac Telecom Corp), the VST (Vital Signs Transmitter, Biowatch Medical), the Lifestar ambulatory cardiac telemetry (ACT) system (Card Guard Scientific Survival Ltd.), and the SEEQ Mobile Cardiac Telemetry (MCT) Device (Medtronic). These systems provide automatic wireless transmission of abnormal ECG waveforms at the time of event occurrence from the patient's home to an attended monitoring center. The CardioNet system also has a built-in cellular telephone that automatically transmits arrhythmic signals to the monitoring center when the patient is away from home. The SEEQ

Policy Number: 2.01.03

Page: 4 of 10

Mobile Cardiac Telemetry (MCT) Device is wireless and is intended for patients who are experiencing frequent symptoms that require short-term monitoring for up to 30 days.

- VI. Cryptogenic stroke is defined as imaging-confirmed stroke with unknown source despite thorough diagnostic assessment (including, at a minimum, arterial imaging, echocardiography, extended rhythm monitoring, and key laboratory studies such as a lipid profile and hemoglobin A1c [HbA1c]).
- VII. Embolic stroke of undetermined source (ESUS) is defined as:
 - 1. The detection of a non-lacunar infarct on brain CT/MRI;
 - 2. Exclusion of >50% atherosclerotic stenosis proximal to the infarct with any imaging modality;
 - 3. Exclusion of a major risk cardioembolic source with echocardiography and cardiac monitoring for >24h;
 - 4. No other specific causes (e.g., arteritis, dissection, migraine, and drug misuse).

RATIONALE

AEMs utilize well-established technology and are typically used to evaluate episodes of cardiac symptoms (palpitations, dizziness, syncope) that would escape detection on a standard 24- or 48-hour Holter monitor. AEMs assist in the clinical decision-making process for treatment of patients experiencing symptoms of cardiac arrhythmia in whom the arrhythmia may not otherwise have been detected, potentially decreasing the risk of morbidity. The diagnostic evaluation of syncope is determined by many factors, and, unfortunately, the yield of AEMs in situations involving patients with this clinical condition is relatively low, according to published peer-reviewed literature.

Other proposed uses of AEMs include evaluating ST segment changes as an indication of myocardial ischemia and assessing asymptomatic patients at risk for future cardiac events. The routine monitoring of asymptomatic patients after myocardial infarction is controversial, and, while Holter monitoring has been used to detect ST segment changes, it is unclear whether an AEM can reliably detect ST segment changes. The interpretation of ST segment change is limited by instability of the isoelectric line, which, in turn, depends on meticulous attention to skin preparation, electrode attachment, and measurements to reduce cable movement.

In 1999, the American College of Cardiology (ACC), in conjunction with the American Heart Association (AHA), published guidelines for the use of ambulatory ECG. These guidelines did not make an explicit distinction between Holter and AEM monitoring. Regarding the effectiveness of antiarrhythmic therapy, the ACC guidelines list one Class I* indication: "To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been well-characterized as reproducible and of sufficient frequency to permit analysis." The guidelines do not specify whether Holter monitoring or AEMs are more likely to be used. However, the accompanying text notes that intermittent monitoring (AEM) may be used to confirm the presence of an arrhythmia during symptoms. There were no Class I indications for detection of myocardial ischemia. In addition, there were no Class I indications for ambulatory monitoring to assess risk for future cardiac events in patients without symptoms of arrhythmia. This latter category would suggest that routine monitoring of patients after myocardial infarction, to detect nonsustained ventricular tachycardia as a risk factor for sudden cardiac death, is not routinely recommended. (*Class I is defined as conditions for which there is evidence and/general agreement that a given procedure or treatment is useful and effective.)

The American Heart Association/American College of Cardiology Foundation (AHA/ACCF) Scientific Statement on the evaluation of syncope (2006) notes that the major limitation for the use of an event recorder is the complexity of its use: Patient error interferes with the acquisition and transmission of data. The introduction of continuously recording monitors that have both patient-activated and automatic triggers appears to have improved the diagnostic yield of event monitors. Implantable loop recorders are capable of recording bipolar ECG signals for approximately 14 months. The patient may use an activator to record the rhythm at the time of symptoms, and the device automatically records bradycardia and tachycardia. In patients with unexplained syncope, use of an implantable loop recorder for one year yielded diagnostic information in more than 90% of patients. This approach is more likely to identify the mechanism of syncope than is a conventional approach that uses Holter or event monitors, and electrophysiological testing and is cost-effective.

The updated AHA/ACCF Scientific Statement on the evaluation of syncope (2018) included additional statements for implantable loop recorders. ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes (Class IIA; LOE: B). ILR may be considered in patients in whom epilepsy was

Policy Number: 2.01.03

Page: 5 of 10

suspected but the treatment has proven ineffective (Class IIb; LOE:B). ILR may be considered in patients with unexplained falls (Class IIb: LOE: B). Instead of an ICD, ILR should be considered in HCM/ARVC/long QT syndrome or Brugada syndrome patients with recurrent episodes of unexplained syncope who are at low risk of Sudden Cardiac Death (SCD).

Randomized studies, including two large, randomized, controlled trials, have demonstrated that long-term monitoring is associated with higher rates of AF detection, compared with Holter monitors, among patients with cryptogenic stroke. Because most patients with a history of stroke in whom AF has been detected will be treated with anticoagulation, and because anticoagulation is an effective treatment for stroke prevention, it can be concluded that longer-term monitoring of patients with cryptogenic stroke will improve outcomes. Because different long-term monitoring devices were used across the studies, the specific type of monitoring associated with the best outcomes is not established.

Single-center studies have reported on the diagnostic yield and timing of detection of arrhythmias in patients monitored with the Zio Patch for a variety of arrhythmias. These studies generally have reported greater numbers of arrhythmias detected during extended follow-up, compared to 24- or 48-hour Holter monitoring.

Published studies regarding mobile cardiac outpatient telemetry (MCOT), such as CardioNet's Mobile Outpatient Cardiac Telemetry Service, have not demonstrated the incremental value of this system over existing AEM devices. The role of this device in the diagnosis and treatment strategy of patients with possible cardiac arrhythmias is unknown. Additionally, there are no evidence-based guidelines from professional organizations regarding MCOT. Rothman, et al. (2007) reported a study of 305 patients who were randomized to a LOOP recorder or MCOT for up to 30 days. Results from 266 patients who completed at least 25 days of monitoring, 132 in the LOOP group and 134 in the MCOT group, were analyzed. Of the 39 patients who did not complete the protocol, 20 (13 MCOT and 7 LOOP) did not complete the study due to noncompliance with (non-wearing of) the device. A diagnostic endpoint (confirmation/ exclusion of arrhythmic cause of symptoms) was found in 88% of MCOT patients and 75% of LOOP patients (p = 0.008). The difference in rates was due primarily to detection of asymptomatic arrhythmias in the MCOT group, consisting of rapid AF and/or flutter and ventricular tachycardia. These were thought to be clinically significant rhythm disturbances and the likely causes of the patients' symptoms. The paper does not comment on the clinical impact (changes in management) of these findings in patients for whom the rhythm disturbance did not occur simultaneously with symptoms. In this study, the median time to diagnosis in the total study population was seven days in the MCOT group and nine days in the LOOP group. A subset of only 50 patients received auto trigger loop recorders. In this subset, a diagnostic endpoint was found in 46% of the auto trigger LOOP group. The lower yield of the auto trigger loop recorder noted in this study is surprising; others have reported increased yield with this feature (Reiffel JA, et al). Since the auto trigger loop recorders have become a part of the standard diagnostic approach to patients who have infrequent symptoms that are thought likely to be due to arrhythmias, this is the test to which newer technologies must be compared. Further study of MCOT is needed, to compare MCOT with the auto trigger loop recorder. MCOT is also being studied in the evaluation of patients who have had ablation procedures (Vasamreddy, et al.), and as a method to measure rhythm and rate control in patients with atrial fibrillation (Prystowsky, et al). Neither of these papers compares MCOT with standard approaches. Based on this analysis and the increased cost of this device, mobile cardiac telemetry is considered not medically necessary.

The 2019 American College of Cardiology/American Heart Association Task Force and the Heart Rhythm Society (AHA/ACC/HRS) Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation stated that, in patients with cryptogenic shock (i.e., stroke of unknown cause) in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF. (Class IIa, LOE: B-R). The cause of ischemic stroke remains unknown in 20-40% of patients, leading to a diagnosis of cryptogenic stroke. Prolonged electrocardiogram monitoring with an implantable cardiac monitor in these patients (age greater than 40 years) has the advantage of increasing the likelihood of detecting silent AF that would escape detection with short-term monitoring.

CRYSTAL -AF was a randomized clinical trial comparing ILR with conventional follow-up, in found that there were two limitations when using and ILR for long-term monitoring. First, the positive predictive value is low in this population, which generates a high number of false-positive detections. Second, there is no data that defines the minimal duration of detected A Fib that identifies patients who benefit from anticoagulation (Mittal et al., 2021).

Policy Number: 2.01.03

Page: 6 of 10

The PER DIEM randomized clinical trial (Buck et al., 2021) was conducted to determine whether 12 months of ILR monitoring detects more occurrences of A Fib compared to 30day monitoring with a conventional external loop recorder. It included 300 patients within six months of ischemic stroke and without known A Fib. Participants were randomly assigned 1:1 to prolonged electrocardiographic(ECG) monitoring with either and ILR or External loop recorder. It resulted in a significantly greater proportion of patients with A Fib detected over 12months, however, further research is needed to compare clinical outcomes associated with their monitoring strategies.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

CPT Codes

| Code | Description |
|----------------------|--|
| 33285 | Insertion, subcutaneous cardiac rhythm monitor, including programming |
| 33286 | Removal, subcutaneous cardiac rhythm monitor |
| 93228 (NMN) | 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; physician review and interpretation with report |
| 93229 (NMN) | 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 physician prescribed transmission of daily and emergent data reports |
| 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) |

Medical Policy: AMBULATORY EVENT MONITORS Policy Number: 2.01.03 Page: 7 of 10

| Code | Description |
|----------------------|---|
| 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 | recording (includes connection, recording, and disconnection) |
| 93271 | transmission and analysis |
| 93272 | 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 value with physician analysis, review and report; implantable loop recorder 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 monitor system, including analysis of one 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; implantable loop recorder system, including heart rhythm derived data analysis. |
| 93297 | Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular 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; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional |
| 93299 | Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results |
| 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 recorder 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 |
| 0525T (E/I) | 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) (Effective 01/01/22) |

Policy Number: 2.01.03 Page: 8 of 10

| Code | Description |
|----------------------|--|
| 0526T (E/I) | 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; electrode only (Effective 01/01/22) |
| 0527T (E/I) | 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; implantable monitor only (Effective 01/01/22) |
| 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 (effective 07/01/21) |
| 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 |

Copyright © 2022 American Medical Association, Chicago, IL

HCPCS Codes

| Code | Description |
|----------------------|---|
| C1764 | Event recorder, cardiac (implantable) |
| C1833 (E/I) | Monitor, cardiac, including intracardiac lead and all system components (implantable) |
| | (e.g., The Guardian). |
| E0616 | Implantable cardiac event recorder with memory, activator and programmer |

ICD10 Codes

| Code | Description |
|---------------|---|
| I45.6 | Pre-excitation syndrome |
| I45.89 | Other specified conduction disorders |
| I45.9 | Conduction disorder, unspecified |
| I47.0-I47.9 | Paroxysmal tachycardia (code range) |
| I48.0-I48.92 | Atrial fibrillation and flutter (code range) |
| I49.01-I49.02 | Ventricular fibrillation and flutter (code range) |
| I49.2 | Junctional premature depolarization |
| I49.40 | Unspecified premature depolarization |
| I49.8-I49.9 | Other specified and unspecified cardiac arrhythmias (code range) |
| I63.9 | Cerebral infarction, unspecified |
| R00.1 | Bradycardia, unspecified |
| R00.2 | Palpitations |
| R06.00 | Dyspnea, unspecified |
| R06.09 | Other forms of dyspnea |
| R06.3 | Periodic breathing |
| R06.83 | Snoring |
| R06.89 | Other abnormalities of breathing |
| R55 | Syncope and collapse |
| T50.905A | Adverse effect of unspecified drugs, medicaments and biological substances, initial |
| | encounter |

Policy Number: 2.01.03

Page: 9 of 10

REFERENCES

Agency for Healthcare Research and Quality (AHRQ). Remote cardiac monitoring. Technology Assessment. Contract No. 290-02-0019. Rockville, MD: AHRQ; December 12, 2007

[https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id51ta.pdf] accessed 10/28/2022.

Aggarwal G, et al. Subcutaneouscardiac Rhythm Monitors: A Comprehensive Review. <u>J Atr Fibrillation</u> 2021 Feb 28;13(5):2387.

Aguilar M, et al. Influence of monitoring strategy on assessment of ablation success and postablation atrial fibrillation burden assessment: Implications for practice and clinical trial design. Circulation 2022 Jan 4;145(1):21-30.

Ahluwalia, et al. Contemporary practice and optimizing referral pathways for implantable cardiac monitoring for atrial fibrillation after cryptogenic stroke. <u>J of Stroke and Cerebrovascular Disease</u> 2022 Jul;31(7):1-6.

Brignole M, et al. 2018 ESC Guidelines for the Diagnosis and Management of Syncope. Eur Heart J 2018;39(21):1883-1948.

*Brignole M, et al. Early application of an implantable loop recorder allows effective specific therapy in patients with recurrent suspected neurally mediated syncope. Eur Heart J 2006 May;27(9):1085-92.

Buck BH, et al. Effect of implantable vs prolonged external electrocardiographic monitoring on atrial fibrillation detection in patients with ischemic stroke: The PER DIEM randomized clinical trial. JAMA 2021 Jun 1;325(21):2160-2168.

Bun SS, Taghji P, Deharo JC. Cardiac events monitoring. Ann Cardiol Angeiol (Paris). 2021 Feb 25:S0003-3928(21)00001-9.

*Crawford MH, et al. ACC/AHA guidelines for ambulatory electrocardiography: executive summary and recommendations. A report of the American College of Cardiology/American Heart Association task force on practice guidelines (committee to revise the guidelines for ambulatory electrocardiography). Circ 1999 Aug 24;100(8):886-93.

Eisenberg EE, et al. Chronic ambulatory monitoring: results of a large single-center experience. <u>J Innovations Cardiac Rhythm Manage</u>. Nov 2014;5:1818-1823.

Giada F, et al. Recurrent unexplained palpitations (RUP) study comparison of implantable loop recorder versus conventional diagnostic strategy. <u>J Am Coll Cardiol</u> 2007 May 15;49(19):1951-6

Goldberger ZD, et al. ACC/AHA/HRS Versus ESC Guidelines for the Diagnosis and Management of Syncope: JACC Guideline Comparison. J Am Coll Cardiol 2019 Nov 12;74(19):2410-2423.

January CT, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration with the Society of Thoracic Surgeons. <u>Circ</u> 2019;140(2):-e151.

Kadish AH, et al. Frequency of serious arrhythmias detected with ambulatory cardiac telemetry. <u>Am J Cardiol</u> 2010;105:1313-6.

Kato and Takahashi. Atrial cardiopathy and cryptogenic stroke. Fontiers in Neurology 2022 Feb;13:839398.

Kleindorfer DO, et al. 2021 guideline for the preventions of stroke in patients with stroke and transient ischemic attack: A guideline from the AHA/ASA. 2021 Jul;52(7):e364-e467.

Ko D, et al. Meta-analysis of randomized clinical trials comparing the impact of implantable loop recorder versus usual care after ischemic stroke for detection of atrial fibrillation and stroke risk. <u>Am L Cardiol</u> 2022 Jan;162:100-104.

*Krahn AD, et al. Randomized assessment of syncope trial – conventional diagnostic testing versus a prolonged monitoring system. <u>Circ 2001</u>:104(1):46-51.

Leshem-Rubinow E, et al. New real-time loop recorder diagnosis of symptomatic arrhythmia via telemedicine. <u>Clin</u> Cardiol 2011 Jul;34(7):420-425.

Policy Number: 2.01.03

Page: 10 of 10

Mittal S. Implantable Loop Recorders-Syncope, Cryptogenic Stroke, Atrial Fibrillation. <u>Card Electrophysiol Clin</u> 2021 Sep;13(3):439-447.

Quan KJ. Palpitation. Extended electrocardiogram monitoring: Which tests to use and when. Med Clin North Am 2019;103(5):785-791.

Rothman SA, et al. The diagnosis of cardiac arrhythmias: a prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. <u>J Cardiovasc Electrophysiol</u> 2007 Mar;18(3):241-7.

Sakhi R, et al. Insertable cardiac monitors: current indications and devices. <u>Expert Rev Med Devices</u> 2019 Jan;16(1):45-55.

Sana F, et al. Wearable devices for ambulatory cardiac monitoring: JACC State-of-the-Art Review. <u>J Am Coll Cardiol</u>. 2020 Apr 7;75(13):1582-1592.

Steinberg JS, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. Heart Rhythm 2017 Jul;14(7):e55-e96.

*Strickberger SA, et al. AHA/ACCF Scientific Statement on the evaluation of syncope: from the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation: in collaboration with the Heart Rhythm Society: endorsed by the American Autonomic Society. Circulation 2006 Jan 17;113(2):316-27.

Varma N, et al. 2021 ISHNE/ HRS/ EHRA/ APHRS collaborative statement on mHealth in Arrhythmia Management: Digital Medical Tools for Heart Rhythm Professionals: From the International Society for Holter and Noninvasive Electrocardiology/Heart Rhythm Society/European Heart Rhythm Association/Asia Pacific Heart Rhythm Society. <u>Ann Noninvasive Electrocardiol</u> 2021 Mar;26(2):e12795.

*Key Article

KEY WORDS

Ambulatory Electrocardiographic (AECG) devices, Cardiac Event Detection (CED), CardioNet, Loop devices, Mobile Cardiac Outpatient Telemetry (MCOT), Ziopatch.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Electrocardiographic (EKG) Services. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=179&ncdver=2&bc=AgAgAAAAAA&.