Clinical UM Guideline

Subject:	Implantable Ambulatory Event Monitors and Mobile Cardiac Telemetry		
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Description

This document addresses ambulatory cardiac event monitors. Specifically:

- External ambulatory event monitors with real-time transmission capability (also referred to as real-time remote heart monitors or mobile outpatient cardiac telemetry). The external mobile outpatient cardiac telemetry monitors have an additional feature that uses cellular telephone communications technology to communicate heart rhythms in real-time to a central monitoring station.
- Implantable ambulatory event monitors.

This document does not address interrogation of implantable ambulatory event monitors. Device interrogation refers to checking on the status of batteries and leads in monitoring devices which are implanted inside the body.

Note: Please see the following related documents for additional information:

- CG-MED-40 External Ambulatory Cardiac Monitors

Clinical Indications

Mobile Cardiac Telemetry

Medically Necessary:

The use of mobile cardiac telemetry is considered **medically necessary** for individuals who meet criterion A and criterion B below:

A. The individual has one of the following conditions:
   1. Individuals who have symptoms suggestive of cardiac arrhythmias less frequently than once every 48 hours; **or**
   2. For the detection of suspected paroxysmal atrial fibrillation following cryptogenic stroke when the monitoring is intended to guide medical management with anticoagulants; **and**

B. Previous non-diagnostic trial of external ambulatory cardiac event monitoring consisting of 14 continuous days or more.

Not Medically Necessary:

The use of mobile cardiac telemetry is considered **not medically necessary** when the above criteria have not been met, and for all other indications.

Implantable Ambulatory Event Monitor

Medically Necessary:

The use of implantable ambulatory event monitors is considered **medically necessary** for:

A. Individuals who have a history of cryptogenic stroke; **and**
B. Had a previous non-diagnostic trial of external ambulatory event monitoring.

The use of implantable ambulatory event monitors is considered **medically necessary** for individuals with recurrent syncope who have all of the following:

A. Age greater than or equal to 40; **and**
B. History of multiple (three or more) syncopal episodes of undetermined etiology in the past 2 years; **and**
C. Previous diagnostic evaluation, including history, physical exam, electrocardiogram, orthostatic blood pressure measurements and echocardiogram, has not yielded a diagnosis; **and**
D. Previous non-diagnostic trial of external ambulatory cardiac event monitoring consisting of 14 continuous days or more.

Replacement of implantable ambulatory event monitors is considered **medically necessary** when the device is not operating and criteria for initial insertion continue to be met.

Not Medically Necessary:

The use of implantable ambulatory event monitors is considered **not medically necessary** when the above criteria have not been met, and for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

External mobile cardiac telemetry:
When services may be Medically Necessary when criteria are met:

CPT	
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

ICD-10 Diagnosis

I47.0-I47.9	Paroxysmal tachycardia
I48.0-I48.92	Atrial fibrillation and flutter
I49.01-I49.9	Other cardiac arrhythmias
I63.9	Cerebral infarction, unspecified
I69.30-I69.398	Sequelae of cerebral infarction
R00.0-R00.9	Abnormalities of heart beat
R42	Dizziness and giddiness
R55	Syncope and collapse
R94.30-R94.39	Abnormal results of cardiovascular function studies
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Implantable monitors:
When services may be Medically Necessary when criteria are met:

CPT

33285	Insertion, subcutaneous cardiac rhythm monitor, including programming

HCPCS

C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator and programmer

ICD-10 Diagnosis

I63.9	Cerebral infarction, unspecified
I69.30-I69.398	Sequelae of cerebral infarction
R55	Syncope and collapse

Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

Arrhythmias are deviations from the normal cadence of the heartbeat which can cause the heart to pump improperly. More than four million Americans have an arrhythmia, most of which pose no significant health threat. The probability of experiencing an arrhythmia increases as people age. In the United States, arrhythmias are the primary cause of sudden cardiac death, accounting for more than 350,000 deaths each year. The standard initial testing for the presence of arrhythmias involves the use of electrocardiogram (ECG) testing which records the electrical activity of the heart.

Types of Devices
Standard ECGs are simple tests that are available in many clinical settings including physician offices and emergency departments. They are an initial study indicated for the evaluation of suspected myocardial ischemia or cardiac rhythm disturbance. Since the period of observation with a standard ECG is brief, typically 10 seconds, it may not detect changes that occur intermittently.

Holter monitors record the heart's electrical activity over a period of several days. During this test, electrodes are placed externally on an individual's chest to record the electrical activity of the heart. Tested individuals maintain a diary of activities and symptoms while wearing the Holter monitor. The information from the Holter ECG and the diary are interpreted by a physician to determine a diagnosis and a treatment plan.

In some cases, the 24–48-hour recording period allowed by a Holter monitor is insufficient. Longer monitoring periods using different types of monitors may be required for intermittent arrhythmias. Ambulatory event monitors (AEMs), also referred to as external loop recorders (ELRs), may be indicated in this setting. ELRs are like Holter monitors but allow data collection over a few days up to a month. Unlike Holter monitors, these devices usually do not continuously record data but do so when activated by a symptomatic individual. They may also be autotriggered by an arrhythmia. Most event monitors can allow the collected data to be manually transmitted via telephone to monitoring centers attended by technicians 24 hours a day, 7 days a week. The data can be available to the provider within moments of an event. Most event recorders can be worn on an individual's belt or carried in some other manner.

This document does not address the medical necessity for standard ECGs and for the use of external (nonimplanted) AEMs that are not equipped for real-time physician notification. Criteria for the use of AEMs that are not equipped for real-time physician notification can be found in the clinical UM guideline CG-MED-40 External Ambulatory Cardiac Monitors.

Mobile cardiac telemetry (sometimes referred to as Mobile Cardiac Outpatient Telemetry [MCOT]) is a type of ambulatory event monitor. Mobile cardiac telemetry devices are worn in a manner similar to a standard AEM; however, when a mobile cardiac telemetry device detects an arrythmia or when the individual has symptoms a rhythm tracing is sent to a central monitoring station in real time and the treating physician is notified when certain criteria are met.

Real-time transmission and interpretation of recordings is the unique feature of external mobile cardiac telemetry. Determining the need for this feature requires consideration of whether real-time interpretation will affect the final health outcome. The use of real-time monitoring should be reserved for a subset of individuals for whom immediate intervention is required when specific arrhythmias are noted. Mobile cardiac telemetry is typically only used for up to a 1-month duration due to compliance limitations.

Ambulatory cardiac event monitors may also be surgically implanted to facilitate longer term monitoring. Implanted loop recorders (ILRs) are inserted subcutaneously in the chest area during an outpatient surgical procedure. The device may remain implanted and can record data for up to 36 months. ILRs have the ability to record events either automatically (auto-activated) or by manual activation (self-activated).

The type of monitoring device most likely to provide diagnostic information is related to the anticipated frequency of symptoms. In 2010, Hoefman published a systematic review on diagnostic tools for detecting cardiac arrhythmias. This analysis compared the yield of remote monitoring for several classes of devices reported in studies of individuals who presented with palpitations. Devices included in the studies included Holter monitors, self-activated event recorders, auto-triggered event recorders, and ILRs. The yield varied among devices, with the auto-trigger devices offering the highest range of detection (72-80%), followed by the self-activated devices (17-75%), and Holter monitors (33-35%). No combined analysis was performed due to the heterogeneity of the study populations and study designs. Limitations in the evidence base precluded any specific recommendations on selection of devices. The authors concluded that the choice of device should be driven largely by the presence, type, and frequency of symptoms experienced by each individual.

In 2017 the International Society for Holter and Noninvasive Electrocardiology (ISHNE) and the Heart Rhythm Society (HRS) published an expert consensus statement for ambulatory ECG (AECG) and external cardiac monitoring. In their recommendations, they do not distinguish between the different types of AECG monitors for specific conditions, but they offer Class I recommendations to use AECG monitoring for the following conditions: unexplained syncope when a tachycardic or bradycardic etiology is suspected; unexplained palpitations; monitoring for runs of atrial fibrillation (AF); cryptogenic stroke in detection of undiagnosed AF; and newly diagnosed nonischemic cardiomyopathy. (Steinberg, 2017).

A 2022 systematic review by Jiang and colleagues sought to identify the rate of detection of AF by ILRs and mobile cardiac telemetry following cryptogenic stroke. The systematic review included 47 studies. For mobile cardiac telemetry, the pooled rate of AF detection was 9.4% in 14 days or less and was 12.8% after 28 days or less. For ILRs, the pooled rate of AF detection at 1 month was 4.9%. The detection rate by ILR rose to 38.4% at 36 months. The design of this review does not permit conclusions to be drawn about the comparability of mobile

cardiac telemetry or ILR monitoring to monitoring using AEMs that are not equipped for real-time physician notification. Unexplained heterogeneity limited the comparability of results from the included studies. The study's discussion noted that publication bias may have led to underestimation of AF detection rates in the mobile cardiac telemetry studies. The authors concluded that: "In patients with sufficient cognitive and physical ability to carry out ECG monitoring daily, a 1-month duration of MCOT can capture a significant proportion of AF and should be considered in place of ILRs."

Mobile Cardiac Telemetry
There has been interest in the use of mobile cardiac telemetry to further characterize AF in the following clinical situations:

- Detection of AF in individuals with cryptogenic stroke;
- Following catheter or surgical ablation for the treatment of AF to detect persistent or recurrent AF.

Cryptogenic Stroke Evaluation
The expression "cryptogenic stroke" describes a brain infarction whose cause is not determined after a thorough cardiovascular and serologic evaluation. It is estimated that up to 36% of strokes are cryptogenic. The standard evaluation of ischemic stroke includes brain imaging to determine the location and extent of the infarct. Imaging of the heart and the arteries leading to and within the brain may reveal a cause for the stroke. Blood tests including markers of myocardial injury and blood clotting abnormalities may be helpful. When the standard evaluation does not show the stroke's cause, additional monitoring may identify AF in stroke initially categorized as cryptogenic (Tayal, 2008).

In 2007, Liao performed a systematic review of noninvasive cardiac monitoring in the post-stroke setting (Liao, 2007). The authors specifically sought to determine the frequency of occult AF detected by noninvasive methods of continuous cardiac rhythm monitoring to detect paroxysmal AF in individuals with ischemic stroke. Five prospective case series were included in the analysis. Two of these five studies focused on loop recorders following a negative Holter monitor and allow a comparison between these two monitoring methods (Barthelemy, 2003; Jaboudon, 2004). These two studies reported that the loop recorders detected AF in 5.7% and 7.7% of participants whose Holter monitoring did not detect AF . In the study by Jaboudon, oral anticoagulation was started in 2 of the 7 participants with new onset AF. The authors concluded that increased duration of monitoring appears to be associated with increased rates of detection of AF; however, the authors also comment that it is uncertain whether any type of monitoring, including Holter monitor, should be routinely performed given the low incidence of AF.

A systematic review and meta-analysis was conducted by Kishore in 2014 to determine the frequency of new AF detected by noninvasive or invasive cardiac monitoring after ischemic stroke or transient ischemic attack (TIA). After electronic searches of multiple databases, Kishore and colleagues found 32 prospective observational studies or randomized controlled trials of individuals who had experienced ischemic stroke, TIA, or both, and who underwent any cardiac monitoring for a minimum of 12 hours. The primary outcome was detection of any new AF during the monitoring period. The overall detection rate of any AF was 11.5% (95% confidence interval [CI], 8.9%-14.3%), although the timing, duration, method of monitoring, and reporting of diagnostic criteria used for paroxysmal AF varied. Results showed that detection rates were higher in participants selected based on increased

risk due to their age, stroke pathogenesis, or prescreening for AF. The overall detection rate for such high-risk individuals was 13.4% (95% CI, 9.0%-18.4%), whereas the overall detection rate for the general unselected populations in the included studies was 6.2% (95% CI, 4.4%-8.3%). The authors noted the presence of substantial heterogeneity even within specified subgroups and concluded that detection of AF was highly variable. This review was limited by small sample sizes and marked heterogeneity.

In a 2015 meta-analysis by Sposato and colleagues, the authors looked at 50 studies to estimate the proportion of individuals who had experienced a stroke or TIA and were diagnosed with AF after undergoing four phases of serial cardiac monitoring. Phase 1 consisted of acute assessment in the emergency room including an admission ECG. Phase 2 included an acute inpatient stay with serial ECGs, continuous ECG monitoring and cardiac telemetry, and Holter monitoring. Phase 3 was the first ambulatory period and consisted of ambulatory Holter monitoring. Phase 4 was the second ambulatory period and consisted of mobile cardiac telemetry, ELR and ILR. During phase 1, 7.7% of individuals were diagnosed with post-stroke AF. During phase 2, 5.6% of individuals were diagnosed with post-stroke AF after serial ECG, 7.0% were diagnosed after continuous inpatient ECG monitoring, 4.1% were diagnosed after continuous inpatient cardiac telemetry, and 4.5% were diagnosed after inpatient Holter monitoring. During phase 3, 10.7% of individuals were diagnosed with post-stroke AF. During phase 4, 15.3% of individuals were diagnosed with post-stroke AF by mobile cardiac telemetry, 16.2% were diagnosed following ELR, and 16.9% were diagnosed following ILR. This analysis has limitations that include the subjective stratification into the four phases of cardiac monitoring. This stratification may not have reflected the sequence in which individuals received their testing. Also, only about 40% of individuals continued past phase 3 into phase 4 for continued monitoring. Age and risk factors for post-stroke AF varied across the 50 studies reviewed. While this analysis concludes that extended cardiac monitoring on an outpatient basis detects post-stroke AF, the proportion of individuals who were diagnosed in phase 4 by ILR did not differ significantly from those individuals diagnosed by mobile cardiac telemetry or ELR.

The 30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation after a Cerebral Ischemic Event (EMBRACE) trial enrolled 572 individuals with cryptogenic stroke or TIA of undetermined cause within the previous 6 months and no history of AF. Trial participants were randomized to receive noninvasive AECG monitoring with either a 30-day event-triggered loop recorder (intervention group) or a conventional 24-hour Holter monitor (control group). The primary outcome was newly detected AF lasting 30 seconds or longer within 90 days after randomization. Secondary outcomes included episodes of AF lasting 2.5 minutes or longer and anticoagulation status at 90 days. At 30 days, results indicated that AF lasting 30 seconds or longer was detected in 45 of 280 participants (16.1%) in the intervention group, as compared with 9 of 277 (3.2%) in the control group (absolute difference, 12.9 percentage points; 95% CI, 8.0 to 17.6; $p<0.001$; number needed to screen, 8). Episodes of AF lasting 2.5 minutes or longer were present in 28 of 284 participants (9.9%) in the intervention group, as compared with 7 of 277 (2.5%) in the control group (absolute difference, 7.4 percentage points; 95% CI, 3.4 to 11.3; $p<0.001$). By 90 days, oral anticoagulant therapy had been prescribed for more individuals in the intervention group than in the control group (52 of 280 [18.6%] vs. 31 of 279 [11.1%]; absolute difference, 7.5 percentage points; 95% CI, 1.6 to 13.3; $p=0.01$). Despite remaining questions regarding the clinical relevance of subclinical AF and potential therapeutic benefits associated with anticoagulation therapy in this population, the trial results demonstrated that noninvasive AECG monitoring for 30 days is superior to short-term 24-hour monitoring for the

detection of AF in individuals with a history of stroke or TIA labeled as cryptogenic. The authors noted that shorter term monitoring could be considered as an initial screen before proceeding to a 30-day test. An important limitation of this study is that its outcomes of interest were the intermediate markers of detected AF and use of anticoagulation treatment. The study did not evaluate patient-centered outcomes such as recurrent cerebral ischemia or bleeding from anticoagulation (Gladstone, 2015). An accompanying editorial (Kamel, 2014) noted that the randomized controlled trials showing benefit from anticoagulation for individuals with AF involved participants who had clinically recognized AF that did not require extended monitoring to detect. The editorial went on to state: "Whether the proven benefit of anticoagulation in this population extends to patients with subclinical atrial fibrillation must be answered in future trials."

The presence or absence of AF has a significant impact on post-stroke management. The American College of Cardiology (ACC) guidelines addressing the diagnosis and management of AF recommend oral anticoagulation with non-vitamin K oral anticoagulants (NOACs) or with warfarin if moderate-to-severe mitral stenosis or a mechanical heart valve are present (Joglar 2024). Guidelines published by the American College of Chest Physicians (ACCP) also recommend anti-platelet therapy such as aspirin for individuals with cryptogenic stroke, while anticoagulation therapy is recommended in individuals with AF (Lansberg, 2012).

In 2021, the American Heart Association (AHA) and the American Stroke Association jointly published guidelines for the prevention of stroke in individuals with a prior stroke or TIA (Kleindorfer, 2021) with guidance on heart rhythm monitoring for occult atrial fibrillation if no other cause of stroke is discovered. The authors note that it has not been established whether long-term rhythm monitoring leads to an improvement in outcomes. The document includes the following recommendation:

> In patients with cryptogenic stroke who do not have a contraindication to anticoagulation, long-term rhythm monitoring with mobile cardiac outpatient telemetry, implantable loop recorder, or other approach is reasonable to detect intermittent AF.

In a 2024 systematic review by Ho and colleagues, the authors report the use of wearable devices following cryptogenic stroke. The wearable devices reported in this review included wearable belts and vests that record the individual's ECG (for example Holter monitors or the Nuubo vest), mobile cardiac telemetry, patch-based ECG devices such as the Zio patch, handheld devices such as the Coala heart monitor, smart watches, and photoplethysmography devices. The meta-analysis did not find an overall increase in AF detection by wearable devices when compared to Holter monitoring. The authors noted that there are very few studies comparing wearable ECG devices to Holter or ILR monitoring and that the high heterogeneity among existing studies limits the reliability of pooled estimates. They also noted that there is "no evidence to suggest that AF detected by wearable devices results in increase in recurrent stroke, and RCTs such as the LOOP study showed that increased AF detection and anticoagulation rates on ILR did not translate to a reduction in the risk of stroke and systemic embolism."

Evaluation of Symptoms Suggestive of Cardiac Arrhythmia

In 1999, the ACC), in conjunction with other organizations, published clinical guidelines for ambulatory electrocardiography (Crawford, 1999). These guidelines describe both Holter monitors and AEM devices, but the recommendations do not distinguish between these different types of monitors. These guidelines also predate the commercial availability of ELRs with auto-triggered capability or ILRs.

In 2006, the AHA, in conjunction with the ACC, the American College of Cardiology Foundation (ACCF) and other organizations, published a scientific statement on the evaluation of syncope (Strickberger, 2006). This scientific statement did not provide specific recommendations but reviewed the role of "non-invasive ECG monitoring" in different clinical situations. Use of AEM was specifically identified as an accepted technique in individuals with syncope with an otherwise normal history and physical exam, as follows:

> The type and duration of ambulatory ECG monitoring is dictated by the frequency of symptoms. A Holter monitor is appropriate for episodes that occur at least every day. Event monitoring is ideal for episodes that occur at least once a month. An implantable loop monitor allows the correlation of symptoms with the cardiac rhythm in patients in whom the symptoms are infrequent.

Mobile cardiac telemetry has also been studied for use in those with infrequent symptoms suggestive of cardiac arrhythmia (for example syncope). Two studies published in 2007 evaluated mobile cardiac telemetry monitoring for persons with symptoms thought to be due to arrhythmias.

In a 2007 retrospective chart review by Olson and colleagues, the authors evaluated the diagnostic utility of mobile cardiac telemetry in individuals with palpitations and presyncope or syncope and the ability to assist in titration of medication. The records of 122 consecutive individuals were reviewed. The report does not include inclusion or exclusion criteria or the methods used to recruit participants. Mobile cardiac telemetry detected arrhythmias associated with symptoms in 96 individuals, including 14 with previous non-diagnostic work-ups. The authors report that mobile cardiac telemetry provided useful information for 21 participants undergoing titration of medications for ventricular rate control in AF and for 8 individuals following radiofrequency ablation for AF. The results of this retrospective convenience sample reported by industry representatives may have been subject to various forms of unintended biasing, including selection bias, availability bias, and confirmation bias. The design of this study does not permit conclusions to be drawn concerning the effectiveness of mobile cardiac telemetry in improving patient-centered outcomes.

Rothman and colleagues (2007) reported the results of a multicenter trial that randomized 266 participants to undergo monitoring with either a mobile cardiac telemetry monitoring system or "standard" loop event monitoring. The participants were monitored for up to 30 days with the primary endpoint being the confirmation or exclusion of an arrhythmic cause for syncope, presyncope or severe palpitations. Of the 266 participants analyzed, a diagnosis was made in 88% of the mobile cardiac telemetry group, compared to 75% of the loop event monitoring group. The authors noted that the ability to detect or exclude an arrhythmia at the time of symptoms was similar in both groups. The authors also point out that the study was not designed to evaluate autotriggered loop recorders such as those now commonly available.

Implantable Ambulatory Event Monitor

Cryptogenic Stroke Evaluation

The Cryptogenic Stroke and underlying Atrial Fibrillation (CRYSTAL-AF) trial (Sanna, 2014) was a large, prospective, randomized controlled study that used a parallel-group design to evaluate the time to first episode of AF detected by 6 months of continuous rhythm monitoring using an implanted cardiac monitor (ICM) or by noninvasive rhythm evaluation. Participants in this trial had a recent cryptogenic stroke or TIA but were without a personal history of AF. Trial participants at 50 centers in the U.S., Canada and Europe were randomized in a 1:1 fashion to standard arrhythmia monitoring (control arm) or to implantation of a long-term ICM (continuous monitoring arm). The control arm received scheduled and unscheduled physician office visits with ECG monitoring prescribed at the discretion of their physician. The intervention group received implants with REVEAL XT ICMs (Medtronic). During the study period, 447 trial participants were enrolled and 441 were randomly assigned to either the ICM group (n=221) or the control group (n=220). The rate of detection of AF at 6 months was 8.9% among those assigned to the ICM group (n=19). This can be compared with a detection rate of 1.4% among those assigned to the control group (n=3) (hazard ratio [HR], 6.4; 95% CI, 1.9 to 21.7; p<0.001). The yield of 3 detected episodes in the control group was from a total of 88 conventional ECG studies in 65 participants, 20 occurrences of 24-hour Holter monitor in 17 participants, and monitoring with an event recorder in 1 participant. The rate of detection of atrial fibrillation at 12 months was 12.4% (29 participants) in the ICM group, as compared with 2.0% (4 participants) in the control group (HR, 7.3; 95% CI, 2.6 to 20.8; p<0.001). The median time from randomization to detection of AF was 84 days (interquartile range, 18 to 265) in the ICM group and 53 days (interquartile range, 17 to 212) in the control group. Asymptomatic AF was noted in 23 of 29 first episodes in the ICM group (79%) and in 2 of 4 first episodes in the control group (50%). When monitoring continued from 6 through 12 months, an additional 10 first episodes of AF were detected in the ICM group versus 1 in the control group, despite 34 conventional electrogram studies in 33 participants and 12 uses of Holter monitoring in 10 participants. Ischemic stroke or TIA occurred in 11 participants (5.2%) in the ICM group, as compared with 18 (8.6%) in the control group during the first 6 months after randomization, and in 15 participants (7.1%) versus 19 (9.1%) during the first 12 months. Although the authors report a p- value for all other outcomes, they did not do so for the secondary outcomes of recurrent stroke or TIA. The rate of oral anticoagulant use was 10.1% in the ICM group versus 4.6% in the control group at 6 months (p=0.04) and 14.7% versus 6.0% at 12 months (p=0.007). By 12 months, 97.0% of trial participants in whom atrial fibrillation had been detected were receiving oral anticoagulants.

At closure of the CRYSTAL-AF study, 277 participants (63% of the original 441) had completed the scheduled 18-month follow-up visit. The completion rate dropped to 177/441 (40%) by the 24-month visit, 94/441 (21%) by the 30-month visit, and 48/441 (11%) at the 36-month visit. The most common adverse events associated with the ICM were infection (3 participants [1.4%]), pain (3 participants [1.4%]), and irritation or inflammation (4 participants [1.9%]) at the insertion site. The ICM remained inserted in 98.1% of participants at 6 months and in 96.6% of participants at 12 months. The authors concluded that AF was more frequently detected with an ICM than with conventional follow-up in participants with a recent cryptogenic stroke. Limitations of this study include significant attrition and a lack of comparison to currently available intermediate-term AEM such as loop recorders or mobile cardiac telemetry. The lack of reported p- values for the secondary outcomes of recurrent stroke or TIA raise the possibility that the study was underpowered to show a difference in those patient-centered outcomes. Additionally,

the study's published protocol notes that "All 95 % confidence intervals of secondary objectives before 12 months of follow-up should be considered exploratory and hypothesis-generating rather than hypothesis testing." The authors noted that they were unable to determine whether detected AF was related to the index stroke or TIA and that "the clinical significance of brief episodes of atrial fibrillation detected with the use of an ICM is unknown." (Sanna, 2014).

In a 2013 randomized controlled trial by Higgins and colleagues, the authors evaluated standard clinical practice for detection of AF to standard clinical practice plus additional cardiac-event monitoring. There were 100 participants enrolled within 7 days of presentation of ischemic stroke. Participants were in sinus rhythm with no history of AF. In the standard clinical practice plus cardiac event monitoring group, 18% of participants had sustained paroxysms of AF compared to 2% who received standard clinical practice only. Anticoagulant therapy was started in 16% of those who received the additional cardiac event monitoring compared to none in the standard clinical practice group.

A 2015 systematic review and meta-analysis by Afzal and colleagues reported on 3 randomized controlled trials and 10 observational studies which compared the effectiveness of an implantable monitor to the effectiveness of a wearable external monitor in the identification of AF for individuals with cryptogenic stroke. The randomized trials were those by Gladstone, Higgins, and Sanna which are discussed above. Afzal and colleagues reported that the aggregated detection of AF by outpatient monitoring was 17.6%. Detection of AF by implantable devices was 23.3% when compared to wearable devices which was 13.6%. The authors noted significant heterogeneity among the included observational studies. They concluded that "At present, the clinical implications of detection of subclinical AF are not known. This review highlights the need for large-scale, multicenter trials with standardized design, in order to validate the role of subclinical AF detection in general population."

A 2020 study by Riordan and colleagues sought to identify predictors of AF in individuals with ICM following cryptogenic stroke. The authors studied 293 consecutive individuals treated at a single medical center. All participants were evaluated with a workup that included ECG and telemetry monitoring including Holter or AEM, transesophageal echocardiography, an evaluation for thrombophilia, and imaging of the head and neck vasculature. Individuals whose Holter or AEM testing showed AF were excluded from the study. With a mean follow-up of 22 ± 12 months, AF was detected by implanted cardiac monitor in 74 participants. A higher rate of AF was detected in those 70 years of age or older compared to those less than 70 years of age (HR, 2.28; 95% CI, 1.39–3.76; p=0.001). The design of this study does not permit conclusions to be drawn about the relative effectiveness of implanted AEMs compared to Holter monitoring or externally worn AEMs.

In 2021, the European Society of Cardiology published guidelines for the diagnosis and management of AF. For detection of AF following cryptogenic stroke, they give a IIa recommendation and state that insertable cardiac monitors should be considered in select individuals with a previous stroke, but no previously known AF (Hindricks, 2021).

In 2021, the AHA and the American Stroke Association jointly published guidelines for the prevention of stroke in individuals with a prior stroke or TIA. These guidelines support the use of implantable monitors in individuals with

cryptogenic stroke. The document does not provide a specific recommendation for the use of ICMs in individuals who have had a TIA.

In 2024, the ACC, AHA, American College of Clinical Pharmacy (ACCP), and the Heart Rhythm Society (HRS) (Joglar, 2024) updated their guideline for the diagnosis and management of AF and gave a IIa recommendation stating that the use of an ICM is reasonable in individuals with a systemic thromboembolic event without a known history of AF. The discussion supporting this recommendation states that "Randomized trials, predominately among cryptogenic stroke patients, have revealed that implantable cardiac monitors exhibit the highest sensitivity in detecting AF in view of extended monitoring periods compared with external monitors." The two references cited for this recommendation were to the PER DIEM RCT (Buck, 2021) and the STROKE-AF RCT (Bernstein, 2021), both of which are discussed in this document. The 2024 joint guideline notes the following as a need for future research.

> What magnitude of AF burden mandates stroke prevention therapy in patients with subclinical AF must be better defined. Certainly, large general risk categories have been identified, and general guidelines exist, but extensive practice variations remain, and more precise recommendations for the community are needed. In addition, the role and impact on outcomes of AF screening in general and poststroke should be better defined.

Syncope Evaluation

A 2006 two-phase study by Brignole and colleagues assessed the efficacy of early implantation of an AEM with specific therapy started after the monitored recurrence of syncope. A total of 392 participants received ILRs and started phase I of the study. During a median follow-up of 9 months, 143 participants had recurrence of syncope. Of those 143, 103 participants were included in phase II of the study. In phase II, participants were treated according to the electrophysiologic abnormality detected by the ILR implanted in phase I: participants with asystole or bradycardia received a dual chamber pacemaker; those with tachyarrhythmias received antiarrhythmic drug therapy; and those whose ILR showed normal findings or only slight abnormalities received counselling but no specific therapy. A total of 53 participants received specific therapy as described above while 50 received no specific therapy. Among the group receiving specific therapy, 47 had pacemaker insertion, 4 had catheter ablation, 1 had an implantable defibrillator inserted and 1 was placed on an anti-arrhythmic medication. With a median follow-up of 9 months for the phase II of the study, 6 participants who were assigned to the ILR-based therapy had a total of 7 syncopal relapses while 17 people in the non-specific therapy group had 46 syncopal episodes. The authors concluded that delaying therapy for syncope until an electrophysiologic abnormality is demonstrated by an ILR appears to be safe and effective. However, the design of this study does not allow conclusions to be drawn about the relative effects of this strategy compared to other diagnostic approaches such as use of externally worn monitors.

In a 2016 prospective randomized single-center controlled trial by Sulke and colleagues, the authors randomized 246 participants to one of four treatment arms to study the use of an ILR for the evaluation of syncope. Participants received either conventional management (CONV, n=61), syncope clinic review (SC, n=60), ILR with syncope clinic review (SC+ILR, n=59), or ILR only (ILR, n=66). Most of the participants in the CONV group received an

evaluation by Holter monitoring or use of an ELR. Participants in the SC and SC+ILR groups received an assessment by a group of cardiologists and geriatricians who specialize in syncope evaluation. The primary outcome was time to ECG diagnosis. Of the participants who received an ILR, 62 achieved an ECG diagnosis within a mean of 95.2 days compared to 21 participants who received conventional management with or without syncope clinical review achieving an ECG diagnosis. Among the participants in the CONV group, 12 (19.6%) reported a first post-randomization syncopal event during the follow-up period. This compares to 24 (40%) in the SC group, 29 (43.4%) in the SC + ILR group, and 33 (55.9%) in the ILR group. Most of these syncopal events in the SC groups occurred in the course of tilt table testing, however no explanation was provided for the increased rate among the ILR group. Participants in the ILR group were less likely to experience a second post-randomization syncopal event during the follow-up period (HR 0.38, 95% CI 0.17 –0.86, P ¼ 0.02).

The 2017 ACC/AHA/HRS guideline for the evaluation and management of individuals with syncope defines syncope as "A symptom that presents with an abrupt, transient, complete loss of consciousness, associated with inability to maintain postural tone, with rapid and spontaneous recovery." An appropriate initial evaluation, which could include a thorough history, physical exam, and ECG, should be done to try to determine the cause of the syncope. According to the ACC/AHA/HRS guideline, the physical exam should include orthostatic blood pressure measurements and changes of heart rate in the lying and sitting positions, on immediate standing, and after 3 minutes of upright posture. A basic neurological exam should also be performed as part of the physical exam. The ACC/AHA/HRS guideline gives a IIa recommendation for an ambulatory event monitor for those individuals with syncope of suspected arrhythmic etiology. The guideline states the following in support of this recommendation:

> The effectiveness of any external cardiac monitoring device for syncope evaluation is related to the duration of monitoring, continuous versus intermittent monitoring, frequency of syncope, duration of prodrome, and suddenness of incapacitation. The patient activation, before or after an event, allows for symptom rhythm correlation; however, some external loop recorders are of limited use in patients who are temporarily incapacitated around the time of syncope. External loop recorders are also limited by infrequent syncopal events. The advantage of an external loop recorder over Holter monitoring stems from a longer monitoring period, which confers a higher yield than Holter monitoring and may offer a diagnosis after a negative Holter evaluation. Although the diagnostic yield of an external loop recorder may be lower than that of an implantable cardiac monitor (ICM), the noninvasive strategy is reasonable as a first approach. (Shen, 2017).

The 2018 European Society of Cardiology guideline for the diagnosis and management of syncope (Brignole, 2018) recommends ILRs for individuals with recurrent syncope of uncertain origin when there is an absence of high-risk criteria and for individuals with high-risk criteria when a comprehensive evaluation did not demonstrate a cause for the syncope or lead to a specific treatment. The guideline defined high risk as a new onset of chest discomfort, breathlessness, abdominal pain, headache, syncope during exertion or when supine, or sudden onset of palpitation immediately followed by syncope.

In a 2019 retrospective review by Padmanabhan and colleagues, the authors reported on 312 participants who had undergone insertion of implantable monitors. The primary outcome was to assess the diagnostic and therapeutic yield of cardiac monitoring with implantable monitors. A diagnosis of syncope was the most frequent indication for

implantation of the device (n=206) followed by unexplained palpitations (n=51), more than one indication (n=39), cryptogenic stroke to monitor for AF (n=27), and presyncopal symptoms (n=23). Prior to insertion of an implantable monitor, most of the participants (91.3%) had an evaluation using ambulatory monitoring including Holter monitor, tilt table test, and electrophysiology study. There were 18 participants lost to follow-up, 116 participants did not have any symptoms during monitoring with the implanted device, and 46 participants had no arrhythmia which correlated with their symptoms. A bradyarrhythmia or tachyarrhythmia was detected by the implanted monitor in 142 participants with AF being the most common diagnosis in 38 participants. There were 20 participants who had an asymptomatic arrhythmia. Multiple arrhythmias were seen in 23 participants. Of the 206 participants who had syncope, 90 had an arrhythmia detected with 71 reporting symptoms and 51 having a correlation between symptoms and arrhythmia. There were 17 participants without a correlation between their arrhythmia and their symptoms. The remaining participants were considered indeterminate. With the 51 participants who had implantable monitoring due to palpitations, 33 had an arrhythmia detected during monitoring, 30 reported symptoms, and 21 had a correlation between symptoms and arrhythmia. Of the 27 participants who had implantable monitor for cryptogenic stroke, 12 had an arrhythmia detected during monitoring with 5 reporting symptoms and 4 having a correlation between their symptoms and the arrhythmia. New AF was diagnosed in 5 participants and all were started on anticoagulant therapy. The median time to detection of AF was 2 months in this group of participants. There was a median follow-up period of 14 months, in which 48% of participants experienced an arrhythmia, 32% of participants had symptoms correlating with the arrhythmia, and a 42% of participants had a change in cardiac management based on implantable monitoring results. The study has limitations including the retrospective design and single facility design. However, within a large cohort, the implantable monitor provided diagnostic guidance for 48% of participants and therapeutic guidance in 47% of participants.

In 2021, the Pediatric and Congenital Electrophysiology Society (PACES) published an expert consensus statement on the indications for and management of cardiovascular implantable electronic devices in pediatric patients (Shah, 2021). PACES gives a level I recommendation for noninvasive cardiac rhythm monitoring before placement of an ICM. They also provide a level I recommendation for ICM use in individuals who have had syncope and risk factors for sudden cardiac death when a comprehensive evaluation has not shown a cause, however the guideline does not define these high-risk criteria. The consensus statement also gives several level IIa recommendations stating it is reasonable to use an ICM for individuals with prior syncope but no high-risk factors, for individuals with infrequent symptoms (> 30-day intervals) when non-invasive evaluations have been inconclusive, and to guide management of individuals with cardiac channelopathies or structural heart disease associated with significant rhythm abnormalities. The text supporting these recommendations includes this statement: “Several observational studies have demonstrated a benefit of ICM in establishing a diagnosis for recurrent symptoms of unclear etiology when other monitoring methods have failed to document an underlying cause.”

Detection of Atrial Fibrillation

Bernstein and colleagues (2021) reported the results of the STROKE-AF trial, a randomized trial evaluating whether long-term cardiac monitoring is more effective than usual care for AF detection in individuals with stroke attributed to large- or small-vessel disease. The study involved 492 participants with an index stroke within 10 days prior to the insertion of an ICM. Individuals randomized to the intervention group (n=242) received ICM insertion while those in the control group (n=250) received site-specific usual care consisting of external cardiac monitoring,

such as 12-lead ECG, Holter monitoring, telemetry, or event recorders. The primary outcome was AF detection lasting more than 30 seconds through the 12-month follow-up visit. Of the participants that were randomized, 223 received an ICM and 417 (84.8%) completed 12 months of follow-up. AF detection at 12 months was significantly higher in the ICM group (27 participants, 12.1%) compared to the control group (4 participants, 1.8%; HR 7.4; 95% CI, 2.6 to 21.3; p<0.001). Four participants had ICM procedure-related adverse events. In a post-hoc analysis, the investigators found few episodes of AF were detected in the ICM group during the first 30 days of follow-up (6 episodes). The incidence of recurrent ischemic or hemorrhagic stroke at 12 months was 7.2% (n=16) in the ICM group and 9.8% (n=23) in the control group (p=0.30). Of the 16 recurrent strokes in the ICM group, only 1 occurred in a participant who had AF detected prior to the stroke. Additionally, 1 participant without AF detected prior to the recurrent stroke was prescribed oral anticoagulants prior to the recurrent event. In the control group, none of the 23 recurrent strokes were in individuals with detected AF or prescribed anticoagulants. However, this study was not powered to detect a significant difference in rates of recurrent stroke. In this trial, monitoring with an ICM detected significantly more episodes of AF over 12 months than usual care. However, further research is needed to understand whether identifying AF in these individuals has an impact on clinical outcomes.

In 2023, Berstein and colleagues report the 3-year results from the STROKE-AF trial. Out of the 492 initial participants 314 (64%) completed the 3-year follow-up. AF was detected within 3 years in 21.7% (n=46) of the ICM group and 2.4% (n=5) in the control group. AF was asymptomatic in 88% of participants in the ICM group. Those in the ICM group received oral anticoagulation more often than the control group (24.4% vs. 8.0%, respectively). There were no statistically significant differences between the ICM and control groups in the incidence of first ischemic or hemorrhagic stroke (17.0% vs 14.1%; HR, 1.1; 95% CI, 0.7-1.8; p=0.71) or recurrent transient ischemic attack (5.4% vs 3.7%; HR, 1.48; 95% CI, 0.61-3.63; p=0.38). The authors proposed several explanations for this lack of observed differences for these patient-centered outcomes. They note that the study was not powered to detect a difference in these outcomes. For unknown reasons, 24% of the participants with AF detected by their ICM were not treated with anticoagulants. Treatment for AF in this study was neither randomized nor prescribed by the study protocol. The authors noted that these factors limit the conclusions that can be drawn about the clinical impacts of AF detection. Significant attrition raises the potential that survivorship bias may have confounded the results. An additional limitation is that the control group did not include individuals monitored using newer patch external monitors, so no comparison can be made between AF detection by ICM and detection by these newer monitors.

Buck and colleagues (2021) conducted a randomized clinical trial (the PER DIEM trial) to determine whether 12 months of ILR monitoring detected more occurrences of AF compared to conventional ELR monitoring for 30 days. The study involved 300 individuals within 6 months of ischemic stroke and without known AF. Participants were assigned 1:1 to prolonged monitoring for 12 months with an ILR (n=150) or an ELR for 30 days (n=150) with follow-up visits at 30 days, 6 months, and 12 months. The primary outcome was the development of definite AF or highly probably AF. Due to technical limitations for the studied ILR devices, the study only evaluated new AF lasting 2 minutes or longer within 12 months of randomization. Of participants that were randomized, 259 (86.3%) completed both the assigned monitoring and 12-month follow-up visit. The primary outcome was observed in 15.3% (13/150) of participants in the ILR group and 4.7% (7/150) of participants in the ELR group (between-group

difference, 10.7% [95% CI, 4.0% to 17.3%]; risk ratio 3.29 [95% CI, 1.45 to 7.42]; p=0.003). The study found no statistically significant differences between the ILR and ELR groups for the following secondary outcomes:

TIA (ILR 6 [4.0%]; ELR 2 [1.3%]; p=0.28)
Recurrent ischemic stroke (ILR 5 [3.3%]; ELR 8 [5.3%]; p=0.40)
Intracerebral hemorrhage (ILR 1 [0.7%]; ELR 1 [0.7%])
Death (ILR 3 [2.0%]; ELR 3 [2.0%])

One individual in the ILR group experienced a device-related serious adverse event (skin erosion requiring device removal). The results indicate that among individuals with ischemic stroke and no prior evidence of AF, ILR monitoring for 12 months resulted in a significantly greater proportion of individuals with AF detected compared to external monitoring for 30 days. Although ILR detected more AF than ELR, there were no observed differences in the patient-centered outcomes of TIA, recurrent ischemic stroke, intracerebral hemorrhage, or death. The authors acknowledged that participants who did not have holter monitoring prior to enrollment in the study may have had their AF detected by that method.

Svendsen and colleagues (2021) conducted a randomized controlled trial investigating whether AF screening and the use of anticoagulants prevented stroke in individuals at high risk. The study involved individuals without diagnosed AF, aged 70 to 90 years, with at least one additional stroke risk factor such as, hypertension, diabetes, previous stroke, or heart failure. Participants (n=6004) were randomly assigned in a 1 to 3 ratio to receive ILR monitoring (n=1501) or usual care (n=4503). In the ILR group, anticoagulation was recommended if AF episodes lasted 6 minutes or longer. The primary outcome was time to first stroke or systemic arterial embolism. AF was diagnosed in 477 participants (31.8%) in the ILR group compared with 550 (12.2%) in the control group (HR, 3.17; 95% CI, 2.81 to 3.59; p<0.0001). Oral anticoagulation was initiated in 445 participants (29.7%) in the ILR group compared to 591 (13.1%) in the control group (HR, 2.72; 95% CI, 2.41 to 3.08; p<0.0001). The primary outcome occurred in 67 participants (4.5%) in the ILR group and 251 (5.6%) in the control group (HR, 0.8; 95% CI, 0.61 to 1.05; p=0.11). Major bleeding occurred in 65 participants (4.3%) in the ILR group and 156 (3.5%) in the control group (HR, 1.26; 95% CI, 0.95 to 1.69; p=0.11). While the results demonstrate that ILR screening for AF resulted in approximately triple the amount of AF detection and anticoagulant initiation compared to usual care, there was no significant reduction in the risk of stroke or systemic arterial embolism.

Hypertrophic Cardiomyopathy
ICMs have been proposed to detect arrhythmias in individuals with hypertrophic cardiomyopathy to assist with risk stratification and intervention. A few observational studies have found that prolonged monitoring using ICMs detected a higher incidence of arrhythmias compared to Holter monitoring (Magnusson, 2021; Safabakhsh, 2021; Sakhi, 2021). However, additional study is needed to understand the impact of these results on patient-centered health outcomes.

Conclusion
Based on current literature and society recommendations, the use of mobile cardiac telemetry and implantable AEMs can be appropriate in the care of recurrent syncope following previous non-diagnostic work-up. Input from

clinicians experienced in ECG monitoring indicates that a trial of least 14 days of continuous monitoring by external ambulatory cardiac event monitoring is helpful to identify and assess clinically irrelevant arrhythmias before proceeding to more invasive or technologically advanced testing.

Definitions

Ambulatory event monitors (AEM): Also known as external cardiac event recorder. An outpatient cardiac monitor that provide extended periods of monitoring (up to a month). They are used in cases such as arrhythmias that occur infrequently. The device may be automatically or manually activated.

Arrhythmia: Abnormal heart rhythms which may be classified as either atrial or ventricular, depending on the origin in the heart. Individuals with arrhythmias may experience a wide variety of symptoms ranging from palpitations to fainting.

Atrial fibrillation: A quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications.

Automatic real-time event notification function: For the purpose of this document, automatic real-time event notification means that acquired electrocardiographic data is monitored continuously and providers are notified when pre-specified events are identified.

Autotrigger AEM: Outpatient cardiac monitors that provide extended periods of monitoring (up to 30 days), programmed to automatically capture arrhythmias (predefined tachycardia, bradycardia, atrial fibrillation). These devices may be user activated for symptomatic episodes.

Cryptogenic stroke: Cerebral infarction that despite evaluation is not attributable to other well-established singular etiologies including cardioembolism, large artery atherosclerosis, or thromboembolism, or small vessel occlusion.

Electrocardiogram (ECG or EKG): a graph showing the heart's electrical activity as voltage over time recorded over repeated cardiac cycles. The test can be abbreviated as ECG or EKG. EKG is an older abbreviation of the word electrocardiogram that reflects the fact that this test was invented in Germany. Modern terminology uses the English abbreviation ECG.

Extended memory capacity: For the purpose of this document, extended memory capacity is considered more than 24 hours of accessible data [see also definition for codes 93228 and 93229].

Holter monitor: A widely used noninvasive test in which an ECG is continuously recorded over an extended time period, usually 24 to 48 hours, to evaluate symptoms of cardiac arrhythmias, such as palpitations, dizziness, or syncope.

Syncope: A presentation of an abrupt, transient, complete loss of consciousness, that is associated with the inability to maintain postural tone, with a quick and spontaneous recovery.

Transient ischemic attack (TIA): A transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action

Revised	05/09/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN statements regarding 14 day requirement for trial of external ambulatory cardiac event monitoring. Revised formatting to criteria for implantable ambulatory event monitor for cryptogenic stroke. Revised Discussion/General Information, Definitions, References, and Index sections.
Reviewed	05/11/2023	MPTAC review. Updated Discussion/General Information and References sections.
	11/09/2022	Updated Discussion/General Information section.
Reviewed	05/12/2022	MPTAC review. Updated Discussion/General Information, References and Websites sections.
Reviewed	05/13/2021	MPTAC review. Updated Discussion/General Information and References sections. Reformatted and updated Coding section; removed 93285 not applicable.
Revised	05/14/2020	MPTAC review. Clarification of MN statement regarding mobile cardiac telemetry. Added MN statement to address replacement of implantable ambulatory event monitors. Added separate NMN statement for mobile cardiac telemetry. Updated Coding, Description, Background/Overview, Definitions, References, and Index sections.
Reviewed	06/06/2019	MPTAC review. Updated Discussion/General Information, References and Index sections.
	12/27/2018	Updated Coding section with 01/01/2019 CPT changes; added 33285, removed 33282 deleted 12/31/2018.
New	07/26/2018	MPTAC review. Initial document development. Moved content of MED.00051 Implantable Ambulatory Event Monitors and Mobile Cardiac Telemetry to new clinical utilization management guideline document with the same title.