Anthem

Clinical UM Guideline

Subject: Implantable Ambulatory Event Monitors and Mobile Cardiac Telemetry
Guideline #: CG-MED-74
Status: Reviewed
Publish Date: 06/28/2023
Last Review Date: 05/11/2023

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

I. *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. The individual has had a non-diagnostic external ambulatory cardiac event monitoring trial of not less than 14 continuous days.

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.

II. *Implantable Ambulatory Event Monitor*

Medically Necessary:

The use of implantable ambulatory event monitors is considered **medically necessary** for individuals who have a history of cryptogenic stroke and 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 of not less than 14 continuous days.

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 cause the heart to pump improperly. More than four million Americans have arrhythmias, most of which pose no significant health threat. As people age, the probability of experiencing an arrhythmia increases. 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 measure for a diagnosis of arrhythmias involves the use of electrocardiogram (EKG) testing, which allows evaluation of the electrical function of the heart.

Types of Devices
Holter monitors are self-contained recording devices that provide a graphic representation of electrical activity within the heart. Electrodes are placed externally in predetermined locations on an individual's chest to detect and record the electrical activity of the heart. Individuals maintain a diary of activities and symptoms while wearing the Holter monitor. The information from the Holter EKG is reviewed and 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. In this instance, ambulatory event monitors, also referred to as loop recorders, may be indicated. These devices are similar to 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 or may be autotriggered by an arrhythmia. Most event monitors have the ability to allow the data collected 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.

External mobile cardiac telemetry is a type of ambulatory event monitor. It relies on real-time remote heart monitoring that integrates standard ambulatory event monitor devices with automated calling features using computer dialing of land lines or cellular communication technology and monitoring services. As with standard ambulatory event monitors, real-time remote heart monitors use similar types of electrocardiographic leads and recording devices. However, when an arrhythmia is detected using external mobile cardiac telemetry, either automatically or by the individual himself/herself, the EKG is reviewed and the treating physician may be notified when certain criteria are met.

Real-time transmission of recordings is the unique feature of external mobile cardiac telemetry, and evaluation of this aspect of the technology requires consideration of the final health outcome. The use of real-time monitoring implies that there is a subset of individuals where immediate intervention is required when designated arrhythmias are noted. Mobile cardiac telemetry is typically only used for 1 month in duration due to compliance limitations.

In the most extreme cases, ambulatory cardiac event monitors may be surgically implanted under the skin. Implantable ambulatory event monitors are available for those instances where an individual experiences symptoms and extended monitoring is needed. These devices are inserted just under the skin in the chest area during an outpatient surgical procedure. The device may remain implanted and can record data for up to 36 months. Implantable loop recorders have the ability to record events either automatically

(auto-activated) or by manual activation (self-activated).

The selection of the most appropriate monitor is based on the anticipated frequency of symptoms. In 2010, Hoefman published a systematic review on diagnostic tools for detecting cardiac arrhythmias. This analysis included studies of subjects presenting with palpitations and compared the yield of remote monitoring for several classes of devices: Holter monitors; self-activated event recorders; auto-triggered event recorders; and implantable loop recorders. 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 population and study design. 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 for 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. While the document does not distinguish between the different types of monitors, it is helpful to define the indications for AECG in general (Steinberg, 2017).

A 2022 systematic review by Jiang and colleagues sought to identify the rate of detection of AF of different modalities for extended EKG monitoring and compared implantable loop recorders and mobile cardiac telemetry in the detection of AF following cryptogenic stroke. There were 47 studies included. For implantable loop recorders, the pooled rate of AF detection at 1 month was 4.9% and 38.4% at 36 months. For mobile cardiac telemetry, the pooled rate of AF detection at <14 days was 9.4% and was 12.8% at <28 days. Both devices identified the detection of AF.

Mobile Cardiac Telemetry
As discussed previously, mobile cardiac telemetry is an externally worn type of ambulatory event monitor with the added feature of real-time transmission of data. There has been interest in the use of ambulatory event monitors devices 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
Cryptogenic stroke describes stroke without an identifiable cause, specifically a cardioembolic source, such as a patent foramen ovale or AF. When potential cardiovascular etiologies have been ruled out during an initial workup consisting of various imaging studies and EKGs, then it is considered a “cryptogenic” stroke. It is estimated that some 36% of stroke survivors have cryptogenic stroke. It has been suggested that additional monitoring may identify AF in stroke initially categorized as cryptogenic (Tayal, 2008).

In 2007, Liao conducted a systematic review of noninvasive cardiac monitoring in the post-stroke setting where the authors specifically sought to determine the frequency of occult AF detected by noninvasive methods of continuous cardiac rhythm monitoring in consecutive individuals with ischemic stroke; a total of five prospective case series were included in the analysis. Five studies evaluated Holter monitor for 24 to 72 hours in the inpatient setting and are not considered further. The results of two studies that focused on loop recorders following a negative Holter monitor are relevant to this discussion (Barthelemy, 2003; Jaboudon, 2004). New AF was identified in 5.7% and 7.7% of subjects, respectively (Liao, 2007). In the study by Jaboudon, oral anticoagulation was started in 2 of the 7 subjects 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.

Additional published evidence includes a systematic review and meta-analysis which was conducted by Kishore to determine the frequency of newly detected AF using noninvasive or invasive cardiac monitoring after ischemic stroke or transient ischemic attack (TIA). Prospective observational studies or randomized controlled trials of individuals with ischemic stroke, TIA, or both, who underwent any cardiac monitoring for a minimum of 12 hours, were included after electronic searches of multiple databases. The primary outcome was detection of any new AF during the monitoring period. A total of 32 studies were analyzed. 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 subjects selected for increased risk on the basis of age, stroke pathogenesis, and prescreening for AF (13.4%; 95% CI, 9.0%-18.4%), as compared to unselected subjects (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 (Kishore, 2014).

In a 2015 meta-analysis by Sposato and colleagues, the authors looked at studies to estimate the proportion of individuals who were diagnosed with atrial fibrillation after a stroke or transient ischemic attack after undergoing four phases of serial cardiac monitoring. Phase 1 consisted of acute assessment in the emergency room and admission EKG, phase 2 was an acute inpatient stay which included serial EKGs, continuous EKG 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 outpatient telemetry, external loop recording and implantable loop recording. A total of 50 studies were analyzed and reviewed. 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 EKG, 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 outpatient telemetry, 16.2% were diagnosed following external loop recording, and 16.9% were diagnosed following implantable loop recording. This analysis has limitations that include the subjective stratification into the four phases of cardiac monitoring. 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 implantable loop recording did not differ significantly from those individuals diagnosed by mobile cardiac outpatient telemetry or external loop recording.

The 30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation after a Cerebral Ischemic Event (EMBRACE) trial enrolled 572 subjects with cryptogenic stroke or transient ischemic attack of undetermined cause within the previous 6 months and no history of AF. Trial subjects were randomized to receive noninvasive ambulatory electrocardiogram 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 subjects (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 subjects (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 what therapeutic benefit is associated with anticoagulation therapy in this population, the trial results have demonstrated that noninvasive ambulatory electrocardiogram 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 transient ischemic attack labeled as cryptogenic (Gladstone, 2015).

The presence or absence of AF has a significant impact on post-stroke management. For example, the ACC guidelines addressing AF recommend careful consideration of warfarin, due to its superior efficacy for stroke prevention (Fuster, 2006). Guidelines published by the American College of Chest Physicians (ACCP) also recommend anti-platelet therapy, (for example, aspirin) in individuals with cryptogenic stroke, while anticoagulation therapy is recommended in individuals with AF (Lansberg, 2012). However, none of these guidelines specifically recommend extended EKG monitoring in individuals with cryptogenic stroke.

A 2011 ACCF/AHA/HRS focused update to the ACC/AHA/ESC Guidelines on the Management of AF includes Holter monitor and longer term event recording in its recommendations for initial clinical evaluation if the diagnosis or type of arrhythmia is in question and also in subsequent treatment monitoring as a means of evaluating rate control and individual risk for thromboembolic events. This document reviews the major clinical trials of various treatment strategies for AF and notes, “The optimum method for monitoring antiarrhythmic drug treatment varies with the agent involved, as well as with patient factors.” The following is excerpted:

> Ambulatory ECG recordings and device-based monitoring have revealed that an individual may experience periods of both symptomatic and asymptomatic AF. …Prolonged or frequent monitoring may be necessary to reveal episodes of asymptomatic AF, which may be a cause of cryptogenic stroke (Fuster, 2011).

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 with guidance on heart rhythm monitoring for occult atrial fibrillation if no other cause of stroke is discovered. The authors note that an improvement in outcomes with long-term rhythm monitoring has not been established. 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.

Evaluation of Symptoms Suggestive of Cardiac Arrhythmia
Mobile cardiac telemetry has also been studied for use in those with infrequent symptoms suggestive of cardiac arrhythmia (for example syncope). In 1999, the American College of Cardiology (ACC), in conjunction with other organizations, published clinical guidelines for ambulatory electrocardiography with the following Class I recommendations (Crawford, 1999):

- Individuals with unexplained syncope, near syncope, or episodic dizziness in whom the cause is not obvious;
- Individuals with unexplained recurrent palpitation;
- To assess antiarrhythmic drug response in individuals in whom baseline frequency of arrhythmia has been characterized as reproducible and of sufficient frequency to permit analysis.

There were two Class IIa recommendations as follows:

- To detect proarrhythmic responses to antiarrhythmic therapy in individuals at high risk;
- Individuals with suspected variant angina.

These guidelines describe both Holter monitors and ambulatory event monitor devices, but the recommendations do not distinguish between the different types of monitors. These guidelines also predate the commercial availability of external loop recorders with auto-triggered capability or implantable loop recorders. However, these guidelines are helpful to define the indications for ambulatory EKG in general, with the choice of specific device to be based on the frequency of symptoms. Of the Class I and IIa recommendations listed above, only the assessment of unexplained symptoms, such as syncope and palpitation, would occur infrequently enough to warrant the use of an ambulatory event monitor. The other indications could be adequately assessed with short-term monitoring with a Holter monitor. Additionally, in 2001, the ACC published a clinical competence statement on EKG and ambulatory EKG (Kadish, 2001) which reiterated that the indications for ambulatory EKG had been addressed in the 1999 clinical guidelines (Crawford, 1999). The competence statement noted:

> There are no specific guidelines that distinguish patients for whom it is appropriate to perform continuous monitoring, (i.e., Holter monitor) from those for whom intermittent ambulatory monitoring is adequate. However, when monitoring is performed to evaluate the cause of intermittent symptoms, the frequency of the symptoms should dictate the type of recording (Kadish, 2001).

In 2006, the American Heart Association (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. Ambulatory event monitoring use 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.

Two studies published in 2007 evaluated mobile cardiac telemetry monitoring for persons with symptoms thought to be due to arrhythmias. In a retrospective chart review by Olson and colleagues, the authors evaluated the diagnostic utility of mobile cardiac telemetry in individuals with palpitations and presyncope/syncope and the ability to assist in titration of medication. The records of 122 consecutive individuals were reviewed. 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 subjects undergoing titration of medications for ventricular rate control in atrial fibrillation and for 8 individuals following radiofrequency ablation for atrial fibrillation.

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
There has been interest in the use of implanted ambulatory event monitors to detect AF in individuals with cryptogenic stroke. As discussed previously, cryptogenic stroke describes stroke without an identifiable cause, specifically a cardioembolic source, such as a patent foramen ovale or AF.

Cryptogenic Stroke Evaluation
The Cryptogenic Stroke and underlying Atrial Fibrillation (CRYSTAL-AF) trial was a large, prospective, randomized controlled study that utilized parallel-group design to evaluate the time to first episode of atrial fibrillation by means of 6 months of continuous rhythm monitoring versus control treatment in subjects with a recent cryptogenic stroke or TIA but without a personal history of atrial fibrillation. 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, insertable, subcutaneous cardiac monitor (ICM) (continuous monitoring arm). The purpose of this trial was to assess whether a long-term electrocardiogram monitoring strategy with an ICM is superior to conventional follow-up for the detection of atrial fibrillation in subjects with cryptogenic stroke. The primary endpoint was time to detection of atrial fibrillation within 6 months after stroke, and the clinical follow-up period was at least 12 months. Secondary endpoints included the time to first detection of atrial fibrillation at 12 months of follow-up, recurrent stroke or TIA, and the change in use of oral anticoagulant drugs. Atrial fibrillation was defined as an episode of irregular heart rhythm, without detectable P waves, lasting more than 30 seconds, with events qualifying for analysis adjudicated by an independent committee. 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 mean (± standard deviation [SD]) time between the index event and randomization was 38.1 ± 27.6 days. In 2014, results of the CRYSTAL-AF trial were published (Sanna, 2014). The rate of detection of AF at 6 months was 8.9% among the subjects assigned to the ICM group (n=19), as compared with 1.4% among subjects assigned to the control group (n=3) (hazard ratio [HR], 6.4; 95% CI, 1.9 to 21.7; p<0.001). The median time from randomization to detection of atrial fibrillation was 41 days (interquartile range, 14 to 84) in the ICM group and 32 days (interquartile range, 2 to 73) in the control group. Asymptomatic atrial fibrillation was noted in 14 of 19 first episodes in the ICM group (74%) and in 1 of 3 first episodes in the control group (33%). The yield of 3 detected episodes in the control group was from a total of 88 conventional electrocardiogram studies in 65 subjects, 20 occurrences of 24-hour Holter monitor in 17 subjects, and monitoring with an event recorder in 1 trial subject. The rate of detection of atrial fibrillation at 12 months was 12.4% (29 subjects) in the ICM group, as compared with 2.0% (4 subjects) 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 atrial fibrillation 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 atrial fibrillation 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 atrial fibrillation were detected in the ICM group versus 1 in the control group, despite 34 conventional electrogram studies in 33 subjects and 12 occurrences of Holter monitor in 10 subjects. Ischemic stroke or TIA occurred in 11 subjects (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 subjects (7.1%) versus 19 (9.1%) during the first 12 months. 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.

In subgroup analysis, the higher rate of detection of atrial fibrillation with ICM, than with conventional follow-up, was consistent across all the prespecified subgroups, defined by age, sex, race or ethnic group, type of index event, presence or absence of patent foramen ovale, and CHADS2 score at 6 months, with no significant interactions. The results of subgroup analyses at 12 months were consistent with those at 6 months. At study closure, 277 subjects had completed the scheduled 18-month follow-up visit, 177 had completed the 24-month visit, 94 had completed the 30-month visit, and 48 had completed the 36-month visit (total follow-up, 815.5 subject years). A relatively small number of subjects were followed for more than 24 months, but at 36 months of follow-up, the rate of detection of atrial fibrillation was 30.0% in the ICM group (42 subjects) versus 3.0% in the control group (5 subjects) (HR, 8.8; 95% CI, 3.5 to 22.2; p<0.001). The most common adverse events associated with the ICM were infection (3 subjects [1.4%]), pain (3 subjects [1.4%]), and irritation or inflammation (4 subjects [1.9%]) at the insertion site. The ICM remained inserted in 98.1% of subjects at 6 months and in 96.6% of subjects at 12 months. The authors concluded that results of this manufacturer sponsored trial, despite study limitations, demonstrated that AF was more frequently detected with an ICM than with conventional follow-up in subjects with a recent cryptogenic stroke. Study results also showed that AF after cryptogenic stroke was most often asymptomatic and paroxysmal and, thus, unlikely to be detected by strategies based on symptom-driven monitoring or intermittent short-term recordings (Sanna, 2014).

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 versus a wearable external monitor in the identification of AF in those individuals with cryptogenic stroke. The overall 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%.

A 2020 study by Riordan and colleagues looked at identifying predictors of AF in those with implantable cardiac monitors following cryptogenic stroke. Primary outcome was detection of AF lasting greater than 2 minutes. There were 293 subjects enrolled. 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 aged greater than or equal to 70 years of age compared to those less than 70 years of age (hazard ratio, 2.28 [95% CI, 1.39–3.76]; p=0.001).

In 2019, the American Heart Association, American College of Cardiology and the Heart Rhythm Society (AHA/ACC/HRS) updated their guideline for the management of AF and gives a IIa recommendation for the use of an implantable cardiac monitor for individuals with cryptogenic stroke when external ambulatory monitoring is inconclusive (January, 2019).

In 2021, the European Society of Cardiology published guidelines for the diagnosis and management of AF. For the search of AF in those with 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 supporting 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.

Syncope Evaluation
There has also been interest in the use of implanted ambulatory event monitors for syncope. A 2006 two-phase study by Brignole and colleagues assessed the efficacy of a diagnostic and treatment strategy of early implantation of an ambulatory event monitor and specific therapy after recurrence of syncope in participants with recurrent suspected syncope. A total of 392 participants received implantable loop recorders and started phase I of the study. The participants were at least 30 years of age and had a history of three or more episodes of syncope over the previous 2 years. During a median follow-up of 9 months, 143 participants had recurrence of syncope. Of those 143 participants with recurrent syncope, 103 participants went on to be included in phase II of the study which

included either implantable loop recorder-based therapy (n=53) or no specific therapy (n=50). For those who received the implantable loop recorder-based therapy, 47 people had pacemaker insertion, 4 people had catheter ablation, 1 person had an implantable defibrillator inserted and 1 person 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 implantable loop recorder-based therapy had a total of 7 syncopal relapses while 17 people in the non-specific therapy group had 46 syncopal episodes. This study demonstrated that, in a cohort of individuals with previous recurrent, unexplained syncope, the use of implantable loop recorders and subsequent targeted intervention was effective in reducing the further recurrence of syncope.

In a 2016 prospective randomized controlled trial by Sulke and colleagues, the authors randomized 246 participants to one of four treatment arms to study the use of an implantable loop recorder in the evaluation of syncope. Participants received either conventional management (n=61), syncope clinic review (n=60), implantable loop recorder with syncope clinic review (n=59), or implantable loop recorder only (n=66). The primary outcome was time to EKG diagnosis. Of the participants who received an implanted loop recorder, 62 achieved an EKG diagnosis within a mean of 95.2 days compared to 21 participants who received conventional management with or without syncope clinical review achieving an EKG diagnosis.

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 EKG, 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 also gives a IIa recommendation for an ambulatory event monitor for those individuals with syncope of suspected arrhythmic etiology (Shen, 2017).

The 2018 European Society of Cardiology guidelines on the diagnosis and management of syncope (Brignole, 2018) recommends implantable loop recorders in individuals with recurrent syncope of uncertain origin when there is an absence of high-risk criteria (defined 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) and in individuals with high-risk criteria when a comprehensive evaluation did not demonstrate a cause for the syncope or lead to a specific treatment.

In a 2019 retrospective review by Padmanabhan and colleagues, the authors reported on 312 subjects with 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 implantable monitor, most of the subjects (91.3%) had an evaluation using ambulatory monitoring including Holter monitor, tilt table test, and electrophysiology study. There were 18 subjects lost to follow-up, 116 subjects did not have any symptoms during monitoring with the implanted device, and 46 subjects had no arrhythmia which correlated with their symptoms. A bradyarrhythmia or tachyarrhythmia was diagnosed by implanted monitor in 142 subjects with AF being the most common diagnosis in 38 subjects. There were 20 subjects who had an asymptomatic arrhythmia with AF seen in 2 of them. Multiple arrhythmias were seen in 23 subjects. Of the 206 subjects who had syncope, 90 had an arrhythmia detected with 71 reporting symptoms and 51 having a correlation between symptoms and arrhythmia. There were 17 subjects without correlation between arrhythmia and symptoms. The remaining subjects were considered indeterminate. With the 51 subjects 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 subjects 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 subjects and all were started on anticoagulant therapy. The median time to detection of AF was 2 months in this group of subjects. 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 does have limitations including the retrospective design and single facility design. However, with the large cohort, the implantable monitor provided diagnostic guidance for 48% of subjects and therapeutic guidance in 47% of subjects.

Detection of Atrial Fibrillation

Bernstein and colleagues (2021) reported the results of a randomized trial (the STROKE-AF 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%; hazard ratio 7.4; 95% CI, 2.6 to 21.3; p<0.001). A total of 4 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.

Buck and colleagues (2021) conducted a randomized clinical trial (the PER DIEM trial) to determine whether 12 months of implantable loop recorder monitoring detected more occurrences of AF compared to conventional external loop recorder monitoring for 30 days. The study involved 300 individuals within 6 months of ischemic stroke without known AF. Participants were assigned 1:1 to prolonged monitoring for 12 months with an implantable loop recorder (n=150) or an external loop recorder 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 (adjudicated as new AF lasting ≥ 2 minutes 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 implantable loop recorder group and 4.7% (7/150) of participants in the external loop recorder 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). There were 5 participants (3.3%) in the implantable loop recorder group who had recurrent ischemic stroke compared to 8 participants (5.3%) in the external loop recorder group, 1 participant in each group who had an intracerebral hemorrhage, 3 in each group who died, and 1 individual in the implantable loop recorder group who had a device-related serious adverse event. The results indicate that among individuals with ischemic stroke and no prior evidence of AF, implantable loop recorder monitoring for 12 months resulted in a significantly greater

proportion of individuals with AF detected compared to external monitoring for 30 days. Further study is needed to evaluate the clinical outcomes associated with these strategies.

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 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 implantable loop recorder monitoring (n=1501) or usual care (n=4503). In the implantable monitoring 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 implantable monitoring group compared with 550 (12.2%) in the control group (hazard ratio [HR], 3.17; 95% CI, 2.81 to 3.59; p<0.0001). Oral anticoagulation was initiated in 445 participants (29.7%) in the implantable monitoring 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 implantable monitoring 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 implantable monitoring 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 screening for AF by implantable monitor 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 health outcomes.

Conclusion
Based on current literature and society recommendations, the use of mobile cardiac telemetry and implantable ambulatory event monitors can be appropriate in the care of recurrent syncope following previous non-diagnostic work-up. Input from clinicians experienced in electrocardiographic 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): Outpatient cardiac monitors 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.

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 EKG 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
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (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.
