Anthem

Clinical UM Guideline

Subject: External Ambulatory Cardiac Monitors
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Description

This document addresses the use of external (nonimplanted) ambulatory event monitors (AEMs) that are not equipped for real-time physician notification. Examples of devices addressed in this document include continuous 24- to 48-hour Holter monitors.

This document **does not** address *implantable* ambulatory event monitors or the use of AEMs equipped with cellular telecommunications equipment for real time physician notification. For information related to these devices, refer to:

- CG-MED-74 Implantable Ambulatory Event Monitors and Mobile Cardiac Telemetry.

Also, this document **does not** address attended, real-time electrocardiogram monitoring.

Clinical Indications

I. *Ambulatory Electrocardiograph (ECG) Holter Monitor*

Medically Necessary:

Continuous 24- to 48-hour ambulatory ECG Holter monitor use is considered **medically necessary** for *adults* with any of the following indications:

A. As a diagnostic tool to evaluate frequent, unexplained symptoms suggestive of cardiac arrhythmias such as palpitations, unexplained dizziness or syncope or near syncope; **or**
B. Evaluation of hypertrophic cardiomyopathy or dilated cardiomyopathies; **or**
C. As a diagnostic tool for detecting ventricular arrhythmias, QT interval changes, or ST changes, to evaluate risk; **or**
D. As a method to assess treatment response to antiarrhythmic therapy (efficacy; proarrhythmic effect); **or**
E. As a method to assess for paroxysmal atrial fibrillation following cryptogenic stroke; **or**
F. As a method to assess for asymptomatic atrial fibrillation three or more months after ablation of arrhythmogenic foci for atrial fibrillation; **or**
G. Assessment of the function of pacemakers or implantable cardioverter defibrillators (ICD) in individuals:
    1. with frequent symptoms of palpitation, syncope, or near syncope to assess device function to exclude myopotential inhibition and pacemaker mediated tachycardia; **or**
    2. to assist in programming parameters such as rate-responsivity and automatic mode switching; **or**
    3. to evaluate suspected component failure or malfunction when device interrogation is not definitive; **or**
    4. to assess response to adjunctive pharmacologic therapy in individuals receiving frequent ICD therapy; **or**
H. Suspected variant angina.

Continuous 24- to 48-hour ambulatory ECG Holter monitor use is considered **medically necessary** for *children* with any of the following indications:

A. As a diagnostic tool to evaluate frequent, unexplained symptoms suggestive of cardiac arrhythmias such as palpitations, unexplained dizziness or syncope or near syncope; **or**
B. Evaluation of hypertrophic cardiomyopathy or dilated cardiomyopathies; **or**
C. Evaluation of possible or documented long QT syndromes; **or**
D. As a method to assess treatment response to antiarrhythmic therapy (efficacy; proarrhythmic effect); **or**
E. Palpitations in children with prior surgery for congenital heart disease and significant residual hemodynamic abnormalities; **or**
F. Asymptomatic, unpaced, congenital complete atrioventricular (AV) block; **or**
G. Evaluation of cardiac rhythm after transient (AV) block associated with heart surgery or catheter ablation; **or**
H. Evaluation of rate-responsive or physiological pacing function in children with persistent or recurrent cardiac symptoms.

Not Medically Necessary:

Ambulatory ECG Holter monitor use is considered **not medically necessary** when the above criteria are not met.

Ambulatory ECG Holter monitor use is considered **not medically necessary** for all other indications including, but not limited to:

- Autonomic cardiac neuropathy associated with diabetes mellitus
- After a myocardial infarction when the individual has left ventricular dysfunction (ejection fraction [EF] less than or equal to 40%)

II. *External Ambulatory Event Monitor*

Medically Necessary:

The use of *external* ambulatory event monitors is considered **medically necessary** when **EITHER** of the following criteria are met (A **or** B):

A. As a diagnostic alternative to Holter monitoring, in individuals who experience infrequent symptoms (less frequently than once every 48 hours) suggestive of cardiac arrhythmias; **or**
B. Following cryptogenic stroke, for the detection of suspected paroxysmal atrial fibrillation when prior testing with Holter monitoring has yielded inconclusive results and when external ambulatory event monitoring is intended to guide medical management with anticoagulants.

Not Medically Necessary:

Other uses of *external* ambulatory event monitors and telemetry are considered**not medically necessary** including, but not limited to, the following clinical situations:

- Monitoring effectiveness of antiarrhythmic therapy and detection of myocardial ischemia by detecting ST segment changes
- Following catheter or surgical ablation of atrial fibrillation
- Monitoring for the presence of atrial fibrillation in individuals with cryptogenic stroke when the criteria are not met

Coding

The following codes for treatments and procedures applicable to this document 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.

Ambulatory ECG Holter Monitor
When services may be Medically Necessary when criteria are met:

CPT	
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording and disconnection)
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional

ICD-10 Diagnosis	
I20.1	Angina pectoris with documented spasm
I20.9	Angina pectoris, unspecified [chest pain]
I24.0-I24.9	Other acute ischemic heart diseases
I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I44.0-I45.9	Atrioventricular and left bundle-branch block, other conduction disorders
I47.0-I49.9	Paroxysmal tachycardia, atrial fibrillation and flutter, other cardiac arrhythmias
I63.9	Cerebral infarction, unspecified
I69.30-I69.398	Sequelae of cerebral infarction
Q24.6	Congenital heart block
Q24.8	Other specified congenital malformations of heart
R00.0-R00.9	Abnormalities of heart beat
R06.00-R06.09	Dyspnea
R07.1-R07.9	Pain in throat and chest
R42	Dizziness and giddiness
R55	Syncope and collapse
Z45.010-Z45.018	Encounter for adjustment and management of cardiac pacemaker
Z45.02	Encounter for adjustment and management of automatic implantable cardiac defibrillator
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
Z95.0	Presence of cardiac pacemaker
Z95.810	Presence of automatic (implantable) cardiac defibrillator

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

External Ambulatory Event Monitor
When services may be Medically Necessary when criteria are met:

CPT	
93241-93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage [includes codes 93241, 93242, 93243, 93244]
93245-93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage [includes codes 93245, 93246, 93247, 93248]
93268-93272	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring [includes codes 93268, 93270, 93271, 93272]
93799	Unlisted cardiovascular service or procedure [when specified as in-office connection or review and interpretation of an external patient-activated electrocardiographic rhythm-derived event recorder without 24-hour attended monitoring]

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

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 (ECG) testing, which allows evaluation of the electrical function of the heart.

Types of Devices

Holter monitors are self-contained, ambulatory, noninvasive, unattended ECG recording devices that provide continuous recordings of the electrical activity of the heart for up to 48 hours. 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 ECG, also known as an ambulatory ECG (AECG) device, is reviewed and interpreted by a physician to determine a diagnosis and a treatment plan.

In some cases, longer monitoring periods using different types of monitors may be required for intermittent arrhythmias. In this instance, ambulatory event monitors (AEMs), also referred to as loop recorders, may be indicated. AEMs are similar to Holter monitors but allow data collection beyond 48 hours up to 1 month. With AEM, the recording device is either continuous, automatically triggered by an arrhythmia, or activated when the individual experiences symptoms. The recorded ECGs are then stored for future analysis or transmitted over telephone lines to a receiving station, that is, a doctor's office, hospital, or to a cardiac monitoring center attended by technicians 24 hours a day, 7 days a week. Most event recorders can be worn on an individual's belt or carried in some other manner.

Holter Monitor

AECG utilizing the traditional Holter monitoring devices has been in use for many years to diagnose various heart diseases and other conditions that manifest themselves by abnormal cardiac electrical activity (Centers for Medicare & Medicaid Services, 2004). Holter monitors have a low sensitivity for detecting intermittent arrhythmias. Therefore, Holter monitors are utilized to evaluate frequently occurring symptoms (for example, daily or multiple occurrences during the day) and ECG events.

The practice of AECG using a Holter monitor over 24-48 hours has been based on clinical practice guidelines reviewed and published by multiple societies including the American College of Cardiology (ACC), American Heart Association (AHA) and the European Society of Cardiology (ESC).

Atrial Fibrillation (AF)

Huang and colleagues (2021) reported the results of a multicenter RCT evaluating whether the detection rate of new AF in individuals with acute ischemic stroke could be improved by performing serial 12-lead ECG compared with conventional 24-hour Holter monitoring. The study involved 826 participants with age ≥ 65 years and no prior history of AF who were randomized to undergo either a 12-lead ECG once daily for 5 days or 24-hour Holter monitoring. The primary outcome was newly detected AF based on intention-to-treat analysis. There was no statistical difference in detection of AF between serial ECGs (8.4%) compared to 24-hour Holter monitoring (6.9%; adjusted odds ratio, 1.17; 95% confidence interval [CI], 0.69 to 2.01). Stepwise multivariate logistic regression revealed that age ≥ 80 years and a history of heart failure were associated with the detection of AF whereas individuals with lacunar infarction had lower odds of detection. The results indicate that 12-lead ECGs once daily for 5 days and 24-hour Holter monitoring are comparable as a first-line assessment tool for the detection of AF in this population. Further evaluation is necessary to understand the long-term impact of these findings on stroke recurrence, anticoagulant therapy, and other outcomes.

Gladstone and colleagues (2014) reported on the 30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation after a Cerebral Ischemic Event (EMBRACE) randomized controlled trial that assessed noninvasive AECG monitoring with a 30-day event-triggered loop recorder (intervention group) in comparison to 24-hour Holter monitoring (control group). A total of 572 individuals without known AF, who have had a cryptogenic ischemic stroke or TIA within the previous 6 months, and who received an initial screening with 24-hour Holter monitoring were randomized to the intervention group (n=286) or the control group (n=285). The investigators were unable to assess outcomes for various reasons in 14 individuals who were excluded from the primary analysis and 10 individuals were excluded from the secondary analysis. 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. The evaluators reported the following results:

> Atrial fibrillation lasting 30 seconds or longer was detected in 45 of 280 patients (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% confidence interval [CI], 8.0 to 17.6; p<0.001; number needed to screen, 8). Atrial fibrillation lasting 2.5 minutes or longer was present in 28 of 284 patients (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 patients in the intervention group than in the control group (52 of 280 patients [18.6%] vs. 31 of 279 [11.1%]; absolute difference, 7.5 percentage points; 95% CI, 1.6 to 13.3; p=0.01) (Gladstone, 2014).

The results of the trial demonstrate that noninvasive AECG monitoring with a 30-day event-triggered loop recorder increases the diagnostic yield after initial non-diagnostic Holter monitoring for individuals with cryptogenic ischemic stroke or TIA.

The ACC/AHA Task Force on Practice Guidelines in collaboration with the HRS issued guidelines for the management of individuals with AF (January, 2014). The guidelines recommend electrocardiographic documentation, including Holter monitor, in establishing a diagnosis of AF (Level of Evidence: C), and acknowledge that paroxysmal AF increases the risk of thromboembolic ischemic stroke. The collaborating organizations subsequently published a focused update to the guidelines that did not specifically address the use of Holter monitors (January, 2019).

In 2014, the American Academy of Neurology published guidelines on the prevention of stroke in nonvalvular AF (NVAF). The guidelines were reaffirmed in 2022 and included the following Level C recommendation:

> Clinicians might obtain cardiac rhythm studies for prolonged periods (for example, for one or more weeks) instead of shorter periods (for example, 24 hours) in patients with cryptogenic stroke without known NVAF, to increase the yield of identification of patients with occult NVAF (Culebras, 2022).

The 2017 HRS/EHRA/ECAS/APHRS/Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLAECE) expert consensus statement on catheter and surgical ablation of AF recommended the following in relation to Holter monitors (Calkins, 2017):

- Minimum documentation for persistent atrial fibrillation: 24-hour Holter within 90 days of the ablation procedure showing continuous atrial fibrillation.
- Minimum documentation for early persistent atrial fibrillation: 24-hour Holter showing continuous atrial fibrillation within 90 days of the ablation procedure.
- Minimum documentation for long-standing persistent atrial fibrillation: 24-hour Holter within 90 days of the ablation procedure showing continuous atrial fibrillation.

- Documentation of atrial fibrillation-related symptoms: Documentation by a physician evaluating the patient that the patient experiences symptoms that could be attributable to atrial fibrillation. This does not require a time-stamped ECG, Holter, or event monitor at the precise time of symptoms. For patients with persistent atrial fibrillation who initially report no symptoms, it is reasonable to reassess symptom status after restoration of sinus rhythm with cardioversion.
- Minimum follow-up screening for paroxysmal atrial fibrillation recurrence: For paroxysmal atrial fibrillation, the minimum follow up screening should include (1) 12-lead ECG at each follow-up visit; (2) 24-hour Holter at the end of the follow-up period (for example, 12 months); and (3) event recording with an event monitor regularly and when symptoms occur from the end of the 3-month blanking period to the end of follow-up (for example, 12 months).
- Minimum follow-up screening for persistent or longstanding atrial fibrillation recurrence: 24-hour Holter every 6 months.

In 2021, the ESC released guidelines for the management of AF, which were developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS) (Hindricks, 2021). The guideline included the following statement regarding screening for AF:

> When AF is detected by a screening tool, including mobile or wearable devices, a single-lead ECG tracing of >_30 s or 12-lead ECG showing AF analysed by a physician with expertise in ECG rhythm interpretation is necessary to establish a definitive diagnosis of AF (devices capable of ECG recording enable direct analysis of the device-provided tracings). When AF detection is not based on an ECG recording (for example, with devices using photoplethysmography) or in case of uncertainty in the interpretation of device-provided ECG tracing, a confirmatory ECG diagnosis has to be obtained using additional ECG recording (for example, 12-lead ECG, Holter monitoring, etc.).

It also included the following recommendations in relation to the search for AF in individuals with cryptogenic stroke:

- In patients with acute ischaemic stroke or [transient ischemic attack] (TIA) and without previously known AF, monitoring for AF is recommended using a short-term ECG recording for at least the first 24 h, followed by continuous ECG monitoring for at least 72 h whenever possible. (Class I Recommendation; Level of Evidence B)
- In selected stroke patients without previously known AF, additional ECG monitoring using long-term non-invasive ECG monitors or insertable cardiac monitors should be considered, to detect AF. (Class IIa Recommendation; Level of Evidence B)

In 2022 the Untied Stated Preventive Services Task Force (USPSTF) concluded in an evidence summary that although screening can detect more cases of unknown AF, evidence regarding the effects on health outcomes is limited.

In 2023 the ACC in conjunction with the AHA, American College of Chest Physicians (ACCP) and the HRS published “Guidelines for the Diagnosis and Management of Atrial Fibrillation.” The recommendation includes the following:

> In patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an implantable loop recorder are reasonable to improve detection of AF.

The committee cited relevant studies that analyzed AF in individuals with recent stroke, including the following:

- The EMBRACE (30 Day Event Monitoring Belt for Recording Atrial Fibrillation After a Cerebral Ischemic Event) trial, which randomized 572 individuals aged 55 or older with recent cryptogenic stroke or TIA to either 30-day external loop recorder or conventional 24-hour Holter monitoring, extended monitoring was associated with higher rates of AF detection at 90 days.
- The CRYSTAL-AF (Cryptogenic Stroke and Underlying AF) trial randomized 441 individuals aged 40 years or older with recent cryptogenic stroke or TIA to cardiac monitoring with either insertable loop recorder or conventional follow-up ECGs. Implantable recorder was superior in detecting AF at 6 months (8.9% compared to 1.4%), 12 months (12.4% compared to 2.0%), and 3 years (30% compared to 3%).
- The FIND-AF (Future Innovations in Novel Detection of Atrial Fibrillation), which compared repeated sets of 10-day Holter monitoring (at baseline, 3-months, and 6-months) to conventional 24-Holter in individuals aged 60 years or older with recent stroke, higher rates of detection were associated with repeated monitoring (14% compared to 5%; absolute difference, 9.0% [95% CI, 3.4-14.5]; p=0.002).
- The PER DIEM (Post-Embolic Rhythm Detection with Implantable versus External Monitoring) RCT also showed a larger proportion of patients with AF detected at 1 year with prolonged monitoring.

The committee concluded that additional studies are needed to determine whether extended cardiac monitoring improves long-term clinical outcomes after stroke.

Other Cardiac Arrhythmias and Syncope

In 2010, Hoefman published a systematic review on diagnostic tools for detecting cardiac arrhythmias. This analysis included studies of participants presenting with palpitations and compared the yield of remote monitoring for several classes of devices: Holter monitors; patient-activated event recorders; auto-triggered event recorders; and implantable loop recorders (ILRs). The yield varied among devices, with the auto-trigger devices offering the highest range of detection (72-80%), followed by the patient-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 the 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 2011, the ACCF/AHA Foundation published guidelines for the diagnosis and treatment of hypertrophic cardiomyopathy (HCM) that included recommendations for AECG Holter monitoring. Twenty-four-hour AECG Holter monitoring was recommended in the initial evaluation of individuals with HCM to detect ventricular tachycardia (VT) and to identify candidates for implantable cardioverter defibrillator therapy and in individuals with HCM who developed palpitations or lightheadedness (Gersh, 2011).

European Heart Rhythm Association (EHRA)/HRS/Asia Pacific Heart Rhythm Society (APHRS) 2014 expert consensus document on ventricular arrhythmias (VAs) included the following recommendation for the general diagnostic work-up of non-sustained VAs:

> Prolonged ECG monitoring by Holter ECG, prolonged ECG event monitoring, or implantable loop recorders should be considered when documentation of further, potentially longer arrhythmias would change management (class IIa, level of evidence C).

The International Society for Holter and Noninvasive Electrocardiology (ISHNE) and the HRS 2017 expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry included recommendations on a variety of devices used to detect cardiac arrhythmias and/or arrhythmia patterns which cannot be easily diagnosed through standard ECG. The guidelines note:

> Ambulatory ECG (AECG) telemetry is typically used to evaluate symptoms such as syncope, dizziness, chest pain, palpitations, or shortness of breath, which may correlate with intermittent cardiac arrhythmias. Additionally, AECG is

> used to evaluate patient response to initiation, revision, or discontinuation of arrhythmic drug therapy and to assess prognosis in specific clinical contexts.

The 2017 ACC/AHA/Heart Rhythm Society (HRS) guideline on the management of syncope noted that several external cardiac monitoring approaches, including Holter monitors, may be used to evaluate syncope in a select group of ambulatory individuals with syncope of suspected arrhythmic etiology (IIa recommendation). The guideline also noted that other devices with longer monitoring periods may confer a higher yield than Holter monitoring and may be useful after a negative Holter evaluation (Shen, 2017).

In the 2017 ACC/AHA/HRS guideline on the management of VA and the prevention of sudden cardiac death (Al-Khatib, 2017), continuous 24-hour AECG Holter recording was deemed, "appropriate when symptoms occur at least once a day or when quantitation of PVCs/NSVT is desired to assess possible VA-related depressed ventricular function." Conventional standard external and implantable AEMs were considered more appropriate for sporadic episodes of palpitations, dizziness or syncope.

Another ACC/AHA/HRS guideline on the evaluation and management of individuals with bradycardia and cardiac conduction delay recommended (Kusumoto, 2019):

> In the evaluation of patients with documented or suspected bradycardia or conduction disorders, cardiac rhythm monitoring is useful to establish correlation between heart rate or conduction abnormalities with symptoms, with the specific type of cardiac monitor chosen based on the frequency and nature of symptoms, as well as patient preferences (Strength of Recommendation: Strong; Level of Evidence: Moderate-quality with nonrandomized studies).

Assessments of Other Conditions

Ole and colleagues (2012) evaluated if cardiovascular autonomic neuropathy (CAN) could be detected by simple function tests compared to heart rate variability (HRV) from 24-hour AECG recordings in individuals with type 1 and type 2 diabetes. Randomly selected individuals with diabetes were monitored for 24 hours with a Holter monitor. The participants were then put through a series of five function tests to assess the autonomic nervous system. The trained technician who edited the 24-hour AECG recordings was blinded to the participants' information. Data from participants with acceptable 24-hour AECG recordings and who had completed all five function tests were analyzed. The evaluators assessed all of the variables and determined that the Valsalva ratio (p=0.002), the 30:15 ratio (p=0.037), and the handgrip (p=0.037) function tests were significant predictors for all-cause mortality and CAN, as compared to 24-hour AECG Holter monitor recordings.

There are multiple cardiovascular monitoring devices (Holter monitors) that have received U.S. Food & Drug Administration 510(k) clearances as Class II devices. Some newer devices are continuous monitors that are similar to traditional AECG Holter monitoring in concept, but offer other features such as the ability to monitor for longer periods of time.

External Ambulatory Event Monitor

In 2010, Hoefman published a systematic review on diagnostic tools for detecting cardiac arrhythmias. This analysis included studies of participants 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 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 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 2011, Brignole published the results of a small study that investigated participants with unexplained recurrent syncope due to idiopathic paroxysmal atrioventricular (AV) block, in the absence of structural heart disease and normal standard ECG and electrophysiological findings. This observational study, which followed 18 participants for a total timeframe of 12 ± 8 years, included prolonged ECG monitoring with ILRs, as well as with Holter monitor and in-hospital telemetry, to confirm the common clinical and electrophysiological features of this distinct form of syncope. The authors acknowledged the need for larger prospective study to confirm their findings.

In 1999, the ACC, in conjunction with other organizations, published clinical guidelines for ambulatory electrocardiography with the following Class I recommendations:

- 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 monitor and AEM devices; 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 ILR. However, these guidelines are helpful to define the indications for ambulatory ECG in general, with the choice of a specific device 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 AEM. 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 ECG and ambulatory ECG, which reiterated the indications for ambulatory ECG addressed in the 1999 clinical guidelines. 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 2017, the AHA, in conjunction with the ACC, and the HRS, published a guideline on the evaluation and management of syncope. The guideline for cardiac monitoring includes the following Class I recommendation:

- The choice of a specific cardiac monitor should be determined on the basis of the frequency and nature of syncope events.

The second recommendation for ambulatory individuals is a Class IIa recommendation:

- To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful:
    1. Holter monitor
    2. Transtelephonic monitor
    3. External loop recorder
    4. Patch recorder
    5. Mobile cardiac outpatient telemetry

In 2017, the AHA/ACC/HRS published a guideline for the management of individuals with VA and prevention of sudden cardiac death. The guideline does not recommend ambulatory monitoring when suspicion of VA is high as diagnosis needs to be made quickly to prevent VA. Ambulatory monitoring is recommended in the following Class I recommendation:

- Ambulatory electrocardiographic monitoring is useful to evaluate whether symptoms, including palpitations, presyncope, or syncope, are caused by VA

In 2020, the AHA/ACC published a guideline for the diagnosis and treatment of HCM which includes recommendations for heart rhythm assessment. The following Class 1 recommendation for AEMs are:

- In patients with HCM who develop palpitations or lightheadedness, extended (>24 hours) electrocardiographic monitoring or event recording is recommended, which should not be considered diagnostic unless patients have had symptoms while being monitored.

The Class 2a and 2b (respectively) recommendations include:

- In patients with HCM who have additional risk factors for atrial fibrillation (AF), such as left atrial dilatation, advanced age, and New York Heart Association (NYHA) class III to class IV heart failure (HF), and who are eligible for anticoagulation, extended ambulatory monitoring is reasonable to screen for AF as part of initial evaluation and periodic follow-up (every 1 to 2 years).
- In adult patients with HCM without risk factors for AF and who are eligible for anticoagulation, extended ambulatory monitoring may be considered to assess for asymptomatic paroxysmal AF as part of initial evaluation and periodic follow-up (every 1 to 2 years).

Monitoring for AF in the post-cryptogenic stroke setting:

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 ECGs, 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). The presence or absence of AF has a significant impact on post-stroke management. Numerous guidelines have been published with recommendations for treatment, however there are no recommendations addressing extended ECG monitoring in individuals with cryptogenic stroke (Fuster, 2006; Lansberg, 2012; Sacco, 2006).

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. The two studies that focused on loop recorders, following a negative HM finding, are relevant to this discussion (Barthelemy, 2003; Jaboudon, 2004). New AF was identified in 5.7% and 7.7% of subjects, respectively. 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 HM, should be routinely performed given the low incidence of AF.

Buck and colleagues (2021) published the results of an open-label RCT evaluating the detection of occurrences of AF in individuals with a recent stroke by means of ILR monitoring for 12 months compared with conventional external loop recorder monitoring for 30 days. The study involved 300 participants within 6 months of ischemic stroke and without known AF across three centers. Participants were randomized 1:1 to receive either an ILR (Reveal LINQ; Medtronic, Inc., Minneapolis, MN) plus remote monitoring for 12 months or monitoring with an external loop recorder (SpiderFlash-t; Sorin Group Italia S.R.L, Burnaby, British Columbia) for 30 days with follow-up visits at 30 days, 6 months, and 12 months. The primary outcome was the development of definite AF or highly probable AF (adjudicated new AF lasting ≥ 2 minutes within 12 months of randomization). At baseline, it was determined that 66.3% of participants had an index stroke of undetermined etiology using the Trial of ORG in Acute Stroke Treatment (TOAST) classification. Of the 300 randomized participants, a total of 273 (91%) participants completed cardiac monitoring lasting 24 hours or longer and 259 (86.3%) completed both the assigned monitoring and 12-month follow-up visit. The primary outcome of development of definite or highly probable AF within 12 months was observed in 15.3% (23/150) of participants in the ILR group and 4.7% (7/150) of participants in the external loop recorder group (between-group difference, 10.7% [95% CI, 4% to 17.3%]; risk ratio, 3.29 [95% CI, 1.45 to 7.42]; p=0.003). This indicates that approximately 1 additional person was diagnosed with AF for approximately every 10 persons monitored with an ILR instead of an external loop recorder. In the first 30 days from randomization there were 7 (4.7%) new AF diagnoses in the ILR group and 5 (3.3%) in the external loop recorder group (between-group difference, 1.3% [95% CI, -3.1% to 5.8%]; p=0.77). Between 30 days and 12 months there were significantly (p=0.001) more cases of AF diagnosed in the ILR group (n=16) compared with the external loop recorder group (n=2). All AF diagnoses resulted in new prescriptions for anticoagulant therapy. The only significant features associated with AF detection were older age (p=0.002) and device group (p=0.004). There were no significant between group differences for secondary outcomes of TIA, recurrent ischemic attack, intracerebral hemorrhage, or death. In this study, although the use of an ILR over the period of 12 months led to the higher detection of AF compared to monitoring with an external loop recorder over 30 days, it remains unclear whether this results in a lower incidence of strokes for this population.

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 AF by means of 6 months of continuous rhythm monitoring versus control treatment in participants with a recent cryptogenic stroke or transient ischemic attack (TIA) but 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 (in the control arm) or to implantation of a long-term, insertable, subcutaneous cardiac monitor (ICM), the Reveal XT (Medtronic, Inc., Minneapolis, MN) (in the continuous monitoring arm). The purpose of this trial was to assess whether a long-term ECG monitoring strategy with an ICM is superior to conventional follow-up for the detection of AF in participants with cryptogenic stroke. The primary endpoint was time to detection of AF 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 AF at 12 months of follow-up, recurrent stroke or TIA, and the change in use of oral anticoagulant drugs. AF 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. The rate of detection of AF at 6 months was 8.9% among the participants assigned to the ICM group (n=19), as compared with 1.4% among participants 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 AF 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 AF 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 three detected episodes in the control group was from a total of 88 conventional ECG studies in 65 subjects, 20 occurrences of 24-hour HM in 17 subjects, and monitoring with an event recorder in 1 trial subject. The rate of detection of AF 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 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 one in the control group, despite 34 conventional ECG studies in 33 participants and 12 occurrences of HM in 10 subjects. 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. 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 AF had been detected were receiving oral anticoagulants (NCT00924638).

In subgroup analysis, the higher rate of detection of AF 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 analysis at 12 months were consistent with those at 6 months. At study closure, 277 participants 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 participants were followed for more than 24 months, but at 36 months of follow-up, the rate of detection of AF 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 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 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 participants 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).

Similar results were noted from another open-label, multi-center, randomized controlled trial, the 30-Day Cardiac Event Monitor Belt for Recording Atrial Fibrillation after a Cerebral Ischemic Event (EMBRACE) trial that enrolled 572 participants 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 ambulatory ECG monitoring with either a 30-day event-triggered loop recorder (intervention group) or a conventional 24-hour HM (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 what therapeutic benefit is associated with anticoagulation therapy in this population, the trial results have demonstrated that noninvasive ambulatory ECG 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 (Gladstone, 2014).

Additional published evidence includes a systematic review and meta-analysis conducted by Kishore in 2014 to determine the frequency of newly detected AF using noninvasive or invasive cardiac monitoring after ischemic stroke or 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% CI, 8.9%-4.3%), 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 selected participants (13.4%; 95% CI, 9.0%-18.4%), as compared to unselected participants (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 2022, a report of the Guideline Development Subcommittee of the American Academy of Neurology (AAN) issued updated Guidelines on the Prevention of Stroke in Patients with NVAF. This update to the former 1998 AAN practice parameter on stroke prevention in NVAF focuses on medical strategies to reduce risk of ischemic stroke but also provided the following regarding identification of individuals with occult NVAF:

- Clinicians might obtain outpatient cardiac rhythm studies in patients with cryptogenic stroke without known NVAF to identify patients with occult NVAF (Level C***);
- Clinicians might obtain cardiac rhythm studies for prolonged periods (for example, for 1 or more weeks) instead of shorter periods (for example, 24 hours) in patients with cryptogenic stroke without known NVAF, to increase the yield of identification of patients with occult NVAF (Level of evidence: C***);
- Clinicians should routinely offer anticoagulation to patients with NVAF and a history of TIA or stroke to reduce these patients' subsequent risk of ischemic stroke ((Level B**);
- To inform their judgments as to which patients with NVAF might benefit more from anticoagulation, clinicians should use a risk stratification scheme to help identify patients with NVAF who are at higher risk for stroke or at no clinically significant risk. However, clinicians should not rigidly interpret anticoagulation thresholds suggested by these tools as being definitive indicators of which patients require anticoagulation (Level B**);
- Specific patient considerations will inform anticoagulant selection in patients with NVAF judged to need anticoagulation (Culebras, 2022).

Levels of Evidence are provided as follows for the AAN guideline recommendations above:
**B: Data derived from a single randomized trial or nonrandomized studies;
***C: Low confidence in evidence, small benefit relative to harm (AAN, 2014).

In 2019, the AHA/ACC/HRS update the guidelines for AF and includes a Class IIa recommendation for device detection of AF and atrial flutter:

- In patients with cryptogenic stroke (for example, stroke of unknown cause) in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF.

In 2021, the AHA and American Stroke Association (Kleindorfer, 2021) updated the guidelines for the prevention of stroke in individuals with a history of stroke and TIA. The guidelines include a Class IIa recommendation for the use of long-term rhythm monitoring to detect intermittent AF:

- 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.

Monitoring for AF in the post-ablation setting:

Ablation, as a treatment of AF, is an option in individuals with symptomatic AF, in individuals who are refractory or intolerant to pharmacologic management, and in selected individuals with heart failure (HF) and/or reduced left ventricular ejection fraction (LVEF).

The ACC/AHA/ESC Guidelines on the Management of AF address the role of ablation techniques, and note:

> The long term efficacy of catheter ablation to prevent recurrent AF requires further study. Available data demonstrate 1 year or more free from recurrent AF in most (albeit, carefully selected) patients. It is important to bear in mind, however, that AF can recur without symptoms and be unrecognized by the patient or the physician. Therefore, it remains uncertain whether apparent cures represent elimination of AF or transformation into an asymptomatic form of paroxysmal AF. The distinction has important implications for the duration of anticoagulation treatment (Fuster, 2006).

A 2011 ACCF/AHA/HRS focused update to the ACC/AHA/ESC Guidelines on the Management of AF includes HM 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 2014, the AHA/ACC/HRS updated its Guidelines on the Management of Patients with Atrial Fibrillation which referred to ILR, pacemakers and defibrillators as, “Offer the possibility to report the frequency, rate, and duration of abnormal atrial rhythms including AF” (January, 2014). No additional information or recommendations for use of ILRs were provided in this document.

Based on available published evidence, there is inadequate data to support the use of AEMs in post-ablation therapy to determine the need for continued anticoagulation therapy (Chao, 2011).

Monitoring in other study populations:

Ha and colleagues (2021) published the results of an open-label, multicenter, RCT aimed at determining whether continuous cardiac rhythm monitoring enhances the detection of postoperative AF (POAF) among individuals undergoing cardiac surgery during the first 30 days following hospital discharge compared with usual care. The study involved individuals with CHA_2DS_2-VASc (a point-based tool used to stratify risk of stroke in individuals with AF) scores greater ≥ 4 or ≥ 2 with at least 1 additional risk factor for POAF, no history of preoperative AF, and POAF lasting less than 24 hours during hospitalization. The intervention group underwent continuous cardiac rhythm monitoring with a wearable, patch-based monitor for 30 days after randomization. Monitoring was not mandated in the usual care group. The primary outcome was cumulative AF and/or atrial flutter lasting 6 minutes or longer detected by continuous cardiac rhythm monitoring or 12-lead ECG within 30 days of randomization. A total of 336 individuals were randomized (163 individuals in the intervention group and 173 individuals in the usual care group), though 307 (91.4%) completed the trial. In the intent-to-treat analysis, the primary endpoint occurred in 32 participants (19.6%) in the intervention group compared to 3 participants (1.7%) in the usual care group (absolute difference, 17.9%; 95% CI, 11.5% to 24.3%; p<0.001). The majority of cumulative AF or atrial flutter in the intervention group occurred within the first 2 weeks of monitoring (n=35) compared to the last 2 weeks (n=6). In this study population, continuous monitoring detected significantly more POAF after discharge compared to usual care. However, the study was not designed to assess differences in major adverse cardiovascular outcomes, stroke rates in the presence of POAF, or the effects of anticoagulant therapy for this population.

The CARISMA study (Cardiac Arrhythmias and Risk Stratification After MyoCardial Infarction) investigated the incidence and prognostic significance of arrhythmias, documented by use of an ILR, in individuals following acute myocardial infarction (MI) with left ventricular systolic dysfunction. After exclusions, 297 participants (21%) (mean ± SD age 64.0 ± 11.0 years; LVEF 31 ± 7%) received an ILR within 11 ± 5 days of the acute MI and were followed every 3 months for an average of 1.9 ± 0.5 years. Predefined bradyarrhythmias and tachyarrhythmias were recorded in 137 participants (46%); 86% of these were asymptomatic. The ILR documented a 28% incidence of new-onset AF with fast ventricular response (≥ 125 bpm), a 13% incidence of nonsustained ventricular tachycardia (≥ 16 beats), a 10% incidence of high-degree atrioventricular block (≤ 30 bpm lasting ≥ 8 seconds), a 7% incidence of sinus bradycardia (≤ 30 bpm lasting ≥ 8 seconds), a 5% incidence of sinus arrest (≥ 5 seconds), a 3% incidence of sustained ventricular tachycardia, and a 3% incidence of ventricular fibrillation. Cox regression analysis with time-dependent covariates revealed that high-degree atrioventricular block was the most powerful predictor of cardiac death (HR, 6.75; 95% CI, 2.55 to 17.84; p<0.001). In this first study to report on long-term cardiac arrhythmias, recorded by an ILR in individuals with an LVEF ≤ 40% after MI, the authors concluded that clinically significant bradyarrhythmias and tachyarrhythmias were documented in a substantial proportion of study participants with depressed LVEF after acute MI and that intermittent high-degree atrioventricular block was associated with a very high risk of cardiac death (Bloch, 2010).

A substudy of the CARISMA investigated the incidence and risk associated with new-onset AF occurring after discharge in participants following an acute MI. This study included 271 post-MI participants with an LVEF ≤ 40% and no history of previous AF. All trial participants were implanted with an ILR and followed up every 3 months for 2 years. Major cardiovascular events were defined as reinfarction, stroke, hospitalization for HF, or death. Results showed the risk of new-onset AF is highest during the first 2 months after the acute MI (16% event rate) and decreases until month 12 post-MI, after which the risk for new-onset AF is stable. The risk of major cardiovascular events was increased in participants with AF events lasting ≥ 30 seconds (HR [95% CI] =2.73 [1.35 to 5.50], p=0.005), but not in participants with AF events lasting < 30 seconds (HR [95% CI] =1.17 [0.35 to 3.92], p=0.80). More than 90% of all recorded AF events were asymptomatic. The authors concluded that, through use of an ILR, the incidence of new-onset AF was found to be 4-

fold higher than earlier reported. In the study population in which treatment with beta-blockers was optimized, the vast majority of AF events were asymptomatic, and a duration of 30 seconds or more identified clinically important AF episodes (Jons, 2011).

Devices are becoming available with enhanced recording capability, such as the Zio®Patch (iRhythm Technologies, Inc., San Francisco, CA) which obtained FDA clearance in 2012 for, “Prescription only single patient use, continuous recording EGG monitor that can be worn for up to 14 days. It is indicated for use on patients who experience transient symptoms, such as syncope, palpitations, shortness of breath, or chest pains” (FDA, 2012). To date, the published evidence regarding these newer devices is limited regarding safety/efficacy and impact on clinical outcomes.

*The CHADS2 (cardiac failure, hypertension, age, diabetes, stroke) score is a risk assessment tool that is based on a point system, in which 2 points are assigned for a history of stroke or TIA, and 1 point each is assigned for age over 75 and a history of hypertension, diabetes or recent HF. The adjusted stroke rate can be assessed based on the CHADS2 score. For example, a CHADS2 score of 2 is associated with an adjusted stroke rate of 4% per year (Fuster, 2006).

Definitions

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.

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.

Myopotential: The electric signal originating from skeletal muscle (usually the pectoralis major), close to a pacemaker, which may be sensed by the pacemaker during activity and falsely interpreted as a depolarization.

Physiological pacing: A dual chamber or atrium-based pacing device used to maintain atrioventricular synchrony.

Rate-responsive pacing: A pacemaker that can vary the pacing rate, depending on the immediate needs of the individual using sensors of body motion or respiratory rate.

Syncope: An episode where the individual experiences loss of consciousness lasting at least several seconds. If extreme dizziness is experienced without actual loss of consciousness, this is termed "pre- syncope."

Tachycardia: An abnormally rapid heartbeat.

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Websites for Additional Information

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Cardiac Arrhythmias
Cardiac Event Monitors/Loop Recorders
Continuous Cardiac Recorder
Holter Monitor
iRhythm Zio Patch
SimplECG Nanowear

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	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References, and Websites sections.
Reviewed	02/16/2023	MPTAC review. Updated Description, Discussion, References and Websites sections.
	12/28/2022	Updated Coding section with 01/01/2023 CPT changes; added 93799 NOC replacing 0497T, 0498T deleted 12/31/2022.
Revised	02/17/2022	MPTAC) review. Updated Subject of CUMG to External Ambulatory Cardiac Monitors. Moved content from CG-MED-44 Holter Monitors to this CUMG. Added headings to organize MN criteria. Clarified language and reorganized MN criteria for Holter Monitors. Clarified language in NMN criteria for External Ambulatory Event Monitors. Added Definitions and Websites for Additional Information sections. Updated Description, Discussion/General Information, References and Index sections. Updated Coding section; added CPT codes 93224, 93225, 93226, 93227 previously addressed in CG-MED-44.
Reviewed	05/13/2021	MPTAC review. Updated Discussion/General Information and Reference sections. Reformatted Coding section.
	12/16/2020	Updated Coding section with 01/01/2021 CPT changes; added 93241-93248 replacing 0295T-0298T deleted 12/31/2020.
Reviewed	05/14/2020	MPTAC review. References were updated.
Reviewed	06/06/2019	MPTAC review. References were updated.
Revised	07/26/2018	MPTAC review. Minor grammatical edits made to the Position Statement section to remove the acronyms (AEM and AF).The Discussion and References sections were updated.
	12/27/2017	The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Coding section with 01/01/2018 CPT changes; added codes 0497T and 0498T.
Reviewed	08/03/2017	MPTAC review. References were updated.
Revised	08/04/2016	MPTAC review. Added “external” to title. Moved clinical indications and other content related to implantable event monitors to MED.00051. Added “external” to NMN statement. Updated formatting in the Clinical Indications section. Updated Discussion, Reference, and Index sections. Removed CPT codes 33282, 93285, and HCPCS code E0616 from Coding section.
Reviewed	11/05/2015	MPTAC review. References were updated. Removed ICD-9 codes from Coding section.
Revised	11/13/2014	MPTAC review. The medically necessary criteria for external ambulatory event monitors were revised to add use following cryptogenic stroke for detection of suspected paroxysmal AF when criteria are met. The Rationale and Reference sections were updated.
Reviewed	05/15/2014	MPTAC review. The Discussion and References sections were updated.
Reviewed	05/09/2013	MPTAC review. The Discussion section and References were updated.
Reviewed	05/10/2012	MPTAC review. The Discussion section, Coding and References were updated. The number changed from CG-DME-29 to CG-MED-40.
Reviewed	05/19/2011	MPTAC review. References and Websites updated.
	01/01/2011	Updated Coding section with 01/01/2011 CPT changes; removed CPT 93012, 93014 deleted 12/31/2010.
Reviewed	05/13/2010	MPTAC review. References were updated.
Revised	05/21/2009	MPTAC review. The indications considered not medically necessary for these devices have been expanded to add the following: following ablation procedures for atrial fibrillation and monitoring for atrial fibrillation in cryptogenic stroke. Discussion section, Coding and References were updated.
Reviewed	05/15/2008	MPTAC review. References were updated.
	10/01/2007	Updated Coding section with 10/01/2007 ICD-9 changes.
Reviewed	05/17/2007	MPTAC review. References and coding were updated.
Reviewed	06/08/2006	MPTAC review. References were updated to include scientific statements and guideline recommendations from the ACC/AHA. Guideline was renumbered to CG-DME-29 from former CG-MED-03.
	11/18/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. Converted into a guideline.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.			No prior document
WellPoint Health Networks, Inc.	06/24/2004	9.04.02	Ambulatory Event Monitors to Detect Cardiac Arrhythmias

Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.