OUTPATIENT CARDIOVASCULAR TELEMETRY

Policy Number: 2017T0489P  Effective Date: February 1, 2017

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies andCoverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Outpatient Cardiovascular Telemetry is proven and medically necessary for the following indications:

- Suspected cardiac arrhythmia not detected with standard cardiac event monitoring*
- Cryptogenic stroke with suspected occult atrial fibrillation as the cause of the stroke
- Monitoring arrhythmia status following an ablation procedure

*Standard cardiac event monitoring includes non-implantable cardiac event monitors that record cardiac events for days, weeks or months. Event recording may be patient activated or automatically collected. The patient then
periodically telephones events to a central collection area. Standard cardiac event monitoring must be of sufficient duration to detect a cardiac arrhythmia under consideration. Event monitors may be used for a short duration (e.g., 24-48 hours) or for a longer period (e.g., 14-30 days or longer). A physician who suspects an occult arrhythmia will order event monitoring for a longer time period; therefore, non-diagnostic 24-48 hour Holter monitoring to detect a cardiac arrhythmia would not be an indication for outpatient cardiovascular telemetry.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

Coding Clarification: The following cardiac monitoring codes should not be used to report services addressed in this policy: 0295T, 0296T, 0297T, 0298T, 93224, 93225, 93226, 93227, 93228, 93229, 93230, 93231, 93232, 93233, 93234, 93235, 93236, 93237, 93238, 93239, 93240, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93249, 93250, 93251, 93252, 93253, 93254, 93255, 93256, 93257, 93258, 93259, 93260, 93261, 93262, 93263, 93264, 93265, 93266, 93267, 93268, 93269, 93270, 93271 and 93272.

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<td>93228</td>
<td>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</td>
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<tr>
<td>93229</td>
<td>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</td>
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DESCRIPTION OF SERVICES

Cardiac arrhythmias are abnormal heart rhythms. Although some patients with arrhythmias may experience palpitations, weakness, dizziness or fainting, other patients may have no symptoms at all. Effective treatment requires an accurate diagnosis. This can be difficult since arrhythmias can occur infrequently and unpredictably and may be asymptomatic (ECRI, 2014). The type and duration of ambulatory electrocardiography (ECG) monitoring is dictated by the frequency of symptoms.

- **Holter monitors** are portable devices that record heart rhythms continuously for up to 48 hours. These devices are used to record events that occur at least once a day.
- **Non-implantable cardiac event monitors** are portable devices that record heart rhythms intermittently for up to 30 days. These devices capture ECG data before, during and after the time of activation.
- **Standard loop recorders** have just a few minutes of memory. Newer, more sophisticated devices have extended memory features that can store up to several hours of ECG data. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias. These devices are used to record infrequent or irregular events.

External mobile cardiovascular telemetry consists of a monitor that continuously records the electrocardiographic rhythm from external electrodes placed on the patient’s body. Segments of the ECG data are automatically (i.e., without patient intervention) transmitted to a remote surveillance location by cellular or landline telephone signal. The transmitted events are triggered automatically by preprogrammed algorithms or by the patient during a symptomatic episode. There is continuous, real-time data analysis in the device and attended surveillance of the transmitted rhythm segments by a surveillance center technician. The surveillance center technician reviews the data and notifies the physician depending on the prescribed criteria (American Medical Association (AMA), 2011). These devices are used to record suspected asymptomatic arrhythmias.

The American Medical Association (AMA) defines attended surveillance as the immediate availability of a remote technician to respond to rhythm or device alert transmissions from a patient, either from an implanted or external (wearable) monitoring or therapeutic device, as they are generated and transmitted to the remote surveillance location or center (AMA, 2011).
A large multicenter randomized, controlled trial was conducted by Rothman et al. (2007) who evaluated the CardioNet system in 266 patients who had palpitations, presyncope, syncope or a combination of these symptoms. All patients had undergone 24 hours of monitoring with a Holter monitor, which failed to provide diagnostic information. These patients were randomized to 30 days of monitoring with MCOT (MCOT Group) or with an external loop monitor (Loop Group). Most of the patients in the Loop Group were required to activate the recorder when they experienced symptoms; however, 49 (18%) patients were at centers that had autotriggered recording of cardiac events. During monitoring, clinically significant arrhythmias were detected in 55 (41%) patients in the MCOT Group versus 19 (14%) patients in the Loop Group, a statistically significant difference. For patients who had syncope or presyncope, clinically significant arrhythmias were detected in 52% of patients with MCOT and in 15% of patients with loop recorders. In most cases, the arrhythmias detected were atrial fibrillation, atrial flutter, or ventricular tachycardia. A subgroup analysis was performed at the institutions that used autotriggered loop monitoring rather than patient-activated monitoring. A definitive diagnosis was obtained in this subgroup for 88% of MCOT Group patients versus 46% of Loop Group patients. However, this subgroup analysis involved a relatively small number of patients and the autotriggered devices may have had single ECG leads whereas the CardioNet system uses double ECG leads.

In a retrospective analysis of 26,438 patients with a LifeWatch ambulatory cardiac telemetry device, Kadish et al. (2010) evaluated the frequency with which potentially life-threatening events were detected using ambulatory telemetry for routine clinical indications. Arrhythmic events were defined as those requiring physician notification and those that represented potentially life-threatening arrhythmias. The authors found that 21% of the patients had arrhythmic events meeting physician notification criteria and 1% of patients experienced life-threatening arrhythmic events. The mean monitoring period was 21 days. Study limitations include its retrospective nature, lack of randomization and no follow-up on patient outcomes.

Olson et al. (2007) reviewed the records of 122 consecutive patients evaluated using MCOT for palpitations, presyncope/syncope, or to monitor the efficacy of a specific antiarrhythmic therapy. Ten of 17 patients (59%) studied for presyncope/syncope had a diagnosis made with MCOT. Eight of these 17 patients had a previous negative evaluation for presyncope/syncope and five had an event correlated with the heart rhythm during the monitoring period. Nineteen patients monitored for palpitations or presyncope/syncope were asymptomatic during monitoring but had a prespecified arrhythmia detected. When MCOT was used as the first ambulatory monitoring system to evaluate palpitations (n = 18), 73% of patients correlated their symptoms with the underlying cardiac rhythm. Seven of 21 patients monitored for medication titration had dosage adjustments during outpatient monitoring.

Joshi et al. (2005) evaluated MCOT retrospectively for 100 consecutive patients who were undergoing treatment for known arrhythmias or who were suspected to have arrhythmias based on symptoms such as palpitations, dizziness, or syncope. These patients underwent MCOT for 2 to 28 days with a mean monitoring time of 9.9 days. For this study, the effectiveness of MCOT was assessed based on detection of arrhythmias and changes in patient management after MCOT. Arrhythmias were detected in 51% of patients with 17% having supraventricular tachycardia and another 17% having atrial fibrillation or atrial flutter. Less common arrhythmias detected with MCOT were ventricular tachycardia, sinus node disease, long QT syndrome, second degree atrioventricular block, symptomatic sinus bradycardia, complete heart block, junctional rhythm, symptomatic premature ventricular complexes, and Wolff-Parkinson-White syndrome. Following MCOT, physicians prescribed the following changes in treatment on a per-patient basis: drug treatment started (14%), permanent pacemaker inserted (5%), cardiac tissue ablated (4%), drug treatment changed (3%), cardioverter defibrillator implanted (2%), anticoagulation stopped (2%), pacemaker replaced (1%), and drug treatment stopped (1%). Although these treatment changes were designed to address specific findings of cardiac monitoring, this study did not involve any subsequent monitoring or follow-up to determine whether patient outcomes were improved as a result of diagnostic information provided by MCOT.

Saarel et al. (2008) conducted a smaller uncontrolled study of MCOT with the CardioNet system that differed from the other available studies in its enrollment of pediatric patients. A total of 54 patients were enrolled with a mean age of 12 years (range 3 to 20). The primary indication for cardiac monitoring was chest pain or palpitations with or without syncope for 42 (78%) patients and isolated chest pain, syncope, or presyncope for the other 12 (22%) patients. Patients were monitored for a mean of 25.7 days (range 9 to 32) and during this time 33 (61%) patients experienced symptoms that corresponded with arrhythmias. Of these 33 patients, 6 (18%) had supraventricular tachycardia or significant supraventricular or ventricular ectopy while the other 27 (82%) had benign conditions. Compared with a historical control group of 495 patients who underwent transtelephonic echocardiographic monitoring, MCOT had a higher diagnostic yield; however, this increase in diagnostic yield was not statistically significant.

In a small uncontrolled study (n=19), Vasamreddy et al. (2006) used the CardioNet monitoring system to assess the efficacy of cardiac tissue ablation procedures for treatment of atrial fibrillation. This study found that, based on MCOT, 70% of patients were free of symptomatic atrial fibrillation and 50% of patients were free of asymptomatic atrial
fibrillation. However, only 10 patients completed the study and patients underwent six 5-day periods of MCOT monitoring over 6 months rather than 30 days of monitoring before treatment, after treatment, and at 6 months follow-up.

In a guideline on the management of atrial fibrillation (AF), the National Institute for Health and Care Excellence (NICE) recommends the following in patients with suspected paroxysmal AF undetected by standard ECG recording:

- A 24-hour ambulatory ECG monitor should be used in those with suspected asymptomatic episodes or symptomatic episodes less than 24 hours apart
- An event recorder ECG should be used in those with symptomatic episodes more than 24 hours apart (NICE, 2014).

**Cryptogenic Stroke**

Although not specific to outpatient telemetry, two randomized controlled trials have shown that prolonged monitoring can aid in the detection of cryptogenic stroke due to underlying occult atrial fibrillation (Sanna et al., 2014; Gladstone et al., 2014).

Favilla et al. (2015) analyzed a retrospective cohort of consecutive patients who underwent 28-day MCOT after cryptogenic stroke or transient ischemic stroke. Of 227 patients with cryptogenic stroke (179) or transient ischemic stroke (48), 14% had AF detected on MCOT, 58% of which was ≥30 seconds in duration. Age >60 years and prior cortical or cerebellar infarction seen on neuroimaging were independent predictors of AF.

Kishore et al. (2014) conducted a systematic review and meta-analysis to determine the frequency of newly detected atrial fibrillation (AF) using noninvasive or invasive cardiac monitoring after ischemic stroke or transient ischemic attack. Prospective observational studies or randomized controlled trials of patients with ischemic stroke, transient ischemic attack or both, who underwent any cardiac monitoring for a minimum of 12 hours, were included. A total of 32 studies were analyzed. The primary outcome was detection of any new AF during the monitoring period. The investigators performed a subgroup analysis of selected (prescreened or cryptogenic) versus unselected patients and according to duration of monitoring. The overall detection rate of any AF was 11.5%, although the timing, duration, method of monitoring and reporting of diagnostic criteria used for paroxysmal AF varied. Detection rates were higher in selected (13.4%) than in unselected patients (6.2%). In cryptogenic strokes, the new AF detection rate was 15.9%. The authors concluded that detection of AF was highly variable and that the results support initial inpatient telemetry and suggest that prolonged noninvasive monitoring (>24 hours) is likely to increase yield of AF detection.

Observational studies indicate that outpatient cardiac monitoring detects previously undiagnosed atrial fibrillation (AF) in 5% to 20% of patients with recent stroke. However, it remains unknown whether the yield of monitoring exceeds that of routine clinical follow-up. In a pilot trial, Kamel et al. (2013) randomly assigned 40 patients with cryptogenic ischemic stroke or high-risk transient ischemic attack to wear a Cardionet mobile cardiac outpatient telemetry monitor for 21 days or to receive routine follow-up alone. The study excluded patients with documented AF or other apparent stroke pathogenesis. Patients and their physicians were contacted at 3 months and at 1 year to ascertain any diagnoses of AF or recurrent stroke or transient ischemic attack. The baseline characteristics of this cohort broadly matched those of previous observational studies of monitoring after stroke. In the monitoring group, patients wore monitors for 64% of the assigned days, and 25% of patients were not compliant at all with monitoring. No patient in either study arm received a diagnosis of AF. Cardiac monitoring revealed AF in zero patients (0%), brief episodes of atrial tachycardia in 2 patients (10%) and nonsustained ventricular tachycardia in 2 patients (10%). In the first reported randomized trial of cardiac monitoring after cryptogenic stroke, the rate of AF detection was lower than expected, incidental arrhythmias were frequent and compliance with monitoring was suboptimal. The authors reported that these findings highlight the challenges of prospectively identifying stroke patients at risk for harboring paroxysmal AF and ensuring adequate compliance with cardiac monitoring. This study is limited by small sample size. Clinical Trial NCT00932425.

The etiology of cerebral ischemia is undetermined in one-third of patients upon discharge. Occult paroxysmal atrial fibrillation (PAF) is considered a potential etiology. Miller et al. (2013) performed a retrospective analysis on 156 patients evaluated by MCOT monitoring (CardioNet) within 6 months of a cryptogenic stroke or TIA. PAF occurred in 27 of 156 (17.3%) patients during MCOT monitoring of up to 30 days. The rate of PAF detection significantly increased from 3.9% in the initial 48 hours, to 9.2% at 7 days, 15.1% at 14 days and 19.5% by 21 days. Female gender, premature atrial complex on ECG, increased left atrial diameter, reduced left ventricular ejection fraction and greater stroke severity were independent predictors of PAF detection with strongest correlation seen for premature atrial complex on ECG. The authors concluded that length of monitoring is strongly associated with detection of PAF, with an optimal monitoring period of at least 21 days. This study is limited by its retrospective design.

Bhatt et al. (2011) investigated a cohort of cryptogenic stroke patients to determine the percentage of patients who had paroxysmal atrial fibrillation/flutter (PAF) on prolonged non-invasive cardiac monitoring (CardioNet). Sixty-two consecutive patients with stroke and TIA in a single center with a mean age of 61 years were analyzed. PAF was
detected in 15 (24%) patients. The majority (93%) of PAF was detected within the first 21 days. A total of 73 episodes of paroxysmal PAF were detected among these 15 patients, and the majority of these (97%) were asymptomatic. The presence of PVCs (ventricular premature beats) lasting more than 2 minutes and strokes (high signal on Diffusion Weighted Imaging (DWI)) predicted PAF. Patients with multiple DWI signals were more likely than solitary signals to have PAF. The authors concluded that the data suggests that up to one in five patients with suspected cryptogenic strokes and TIAs have PAF, especially if they have PVCs and multiple high DWI signals on MRI. This study is limited by small sample size. Further studies using a larger patient population are necessary to determine if detecting PAF in cryptogenic stroke patients warrants a change in therapy.

Tayal et al. (2008) reported on a case series of 56 patients with cryptogenic TIA/stroke who were analyzed after diagnostic evaluation and Mobile Cardiac Outpatient Telemetry (MCOT). Predictors of atrial fibrillation (AF) detection by MCOT were determined by univariate analysis including Student t test and Fisher exact tests and multivariate analysis. The median MCOT monitoring duration was 21 (range 5-21) days resulting in an AF detection rate of 23% (13/56). Twenty-seven asymptomatic AF episodes were detected in the 13 patients, of which 85% (23/27) were <30 seconds and the remaining 15% (4/27) were 4-24 hours in duration. The authors concluded that there is a high rate of atrial fibrillation (AF) detection by MCOT (21 days) in patients with cryptogenic TIA/stroke that may be related to extended monitoring duration, patient selection and inclusion of all new onset AF episodes. Brief AF episodes (<30 seconds) may be biomarkers of more prolonged and clinically significant AF. Outcomes of this study however resulted in minimal changes to patient management.

**Professional Societies**

**American Academy of Neurology (AAN)**

An AAN practice parameter on stroke prevention analyzed the evidence of various technologies used to identify undetected non-valvular atrial fibrillation in patients with cryptogenic stroke. The most common technique used was Holter monitoring, followed by serial EKG, event loop recorders, inpatient continuous telemetry, outpatient transtelephonic monitoring and mobile cardiac outpatient telemetry. In patients with recent cryptogenic stroke, AAN recommends outpatient cardiac rhythm monitoring with a nonimplanted device to detect unsuspected non-valvular atrial fibrillation. Longer monitoring periods (e.g., one or more weeks) are associated with a greater yield (Culebras et al., 2014).

Level C - possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population.

**American College of Cardiology (ACC) / American Heart Association (AHA) / Heart Rhythm Society (HRS)**

Joint guidelines for the management of patients with atrial fibrillation state that the diagnosis of atrial fibrillation is based on clinical history and physical examination and is confirmed by electrocardiogram, ambulatory rhythm monitoring (e.g., telemetry, Holter monitor event recorders), implanted loop recorders, pacemakers or defibrillators or, in rare cases, by electrophysiological study. Prolonged or frequent monitoring may be necessary to reveal episodes of asymptomatic atrial fibrillation (January et al., 2014).

Class I – procedure should be performed

Level of evidence C – based on expert opinion, case studies or standard of care

An AHA/ACC scientific statement on the evaluation of syncope states that ambulatory ECG is appropriate in the absence of underlying heart disease when the diagnosis remains uncertain. A Holter monitor is appropriate for episodes that occur at least every day, and event monitoring is ideal for episodes that occur at least once a month. The introduction of continuously recording monitors that have both patient-activated and automatic triggers appears to improve the diagnostic yield of event monitors (Strickger et al., 2006).

ACC/AHA/ESC guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death state that continuous 24-48 hour Holter recordings are deemed appropriate when arrhythmias are known or suspected to occur at least once a day. Because intermittent event monitors can record over longer time periods, they are considered more appropriate when sporadic episodes produce symptoms of syncope, dizziness or palpitations. This guideline makes no mention of real-time continuous attended monitoring systems (Zipes et al., 2006).

An ACC/AHA clinical competence statement suggests that, when ambulatory cardiac monitoring is performed to evaluate the cause of intermittent symptoms, the frequency of symptoms should dictate the type of recording device used (Kadish et al., 2001).

**American Heart Association (AHA) / American Stroke Association (ASA)**

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A joint scientific statement on the prevention of stroke in patients with silent cerebrovascular disease recommends that, for patients with an embolic-appearing pattern of infarction, prolonged rhythm monitoring for AF be considered (Smith et al., 2016).

Joint guidelines for the early management of patients with acute ischemic stroke state that continuous cardiac monitoring is indicated for at least the first 24 hours after a stroke. Outpatient event monitoring may be indicated in patients with cryptogenic stroke and suspected paroxysmal arrhythmias, especially in those patients with short hospitalizations in which monitoring was brief. Ongoing monitoring of cardiac rhythm on telemetry or by Holter monitoring may detect atrial fibrillation or other serious arrhythmias (Jauch et al., 2013).

Joint guidelines for the prevention of stroke state that for patients who have experienced an acute ischemic stroke or transient ischemic attack with no other apparent cause, prolonged rhythm monitoring (approximately 30 days) for atrial fibrillation is reasonable within 6 months of the index event (Kernan et al., 2014).

Class IIa – it is reasonable to perform procedure
Level of evidence C - based on diverging expert opinion, case studies or standard of care

**European Society of Cardiology (ESC)**
ESC guidelines for the management of atrial fibrillation state that prompt recording of an ECG is an effective method to document chronic forms of AF. The technology to detect paroxysmal, self-terminating AF episodes is rapidly evolving. There is good evidence that prolonged ECG monitoring enhances the detection of undiagnosed AF (e.g., monitoring for 72 hours after a stroke, or even longer periods). Daily short-term ECG recordings increase AF detection in populations over 75 years of age. Ongoing studies will determine whether such early detection alters management (e.g., initiation of anticoagulation) and improves outcomes. Regarding prolonged monitoring for paroxysmal atrial fibrillation, the guidelines state that several patient-operated devices and extended continuous ECG monitoring using skin patch recorders have been validated for the detection of paroxysmal AF. Prolonged ECG monitoring is also reasonable in survivors of ischemic stroke without an established diagnosis of AF (Kirchhof et al., 2016).

ESC guidelines for the diagnosis and management of syncope state that as a general rule, ECG monitoring is indicated only when there is a high pre-test probability of identifying an arrhythmia associated with syncope. Initial data showed that a mobile cardiac outpatient telemetry system had a higher diagnostic yield than a patient-activated external looping event monitor in patients with syncope or pre-syncope. The potential role of these systems in the diagnostic work-up of patients with syncope needs to be further evaluated (Moya et al., 2009).

**Heart Rhythm Society (HRS) / European Heart Rhythm Association (EHRA) / European Cardiac Arrhythmia Society (ECAS)**
In a consensus statement on ablation of atrial fibrillation, the HRS, in collaboration with the ACC and other organizations, states that arrhythmia monitoring can be performed with the use of noncontinuous or continuous ECG monitoring tools. Choice of either method depends on individual need and consequence of arrhythmia detection. More intensive monitoring is associated with a greater likelihood of detecting both symptomatic and asymptomatic atrial fibrillation (AF). Available non-continuous detection tools include scheduled or symptom-initiated standard ECGs, Holter (24 hours to 7 days) and transtelephonic recordings, patient and automatically activated devices and external loop recorders. Mobile cardiac outpatient telemetry is listed as one option for follow-up ECG monitoring after an ablation procedure. The guideline states that a one to seven day Holter monitor is an effective way to identify frequent asymptomatic recurrences of AF. A four-week auto-trigger event monitor, mobile cardiac outpatient telemetry system or implantable subcutaneous monitor may identify less frequent AF. No specific guidelines are provided regarding the optimal monitoring system (Calkins et al., 2012).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**
The CardioNet device has been classified as a combined ambulatory electrocardiograph and arrhythmia detector with alarm by the U.S. Food and Drug Administration (FDA). The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection Model CN1001 (K012241) was approved for marketing by the FDA in February 2002. Additional information is available at: [http://www.accessdata.fda.gov/cdrh_docs/pdf/K012241.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/K012241.pdf). (Accessed December 16, 2016)

Several modifications have been made to the device in subsequent approvals (product code DSI). Additional information is available at: [http://www.accessdata.fda.gov/scripts/cdrh_docs/cfPMN/pmnn.cfm](http://www.accessdata.fda.gov/scripts/cdrh_docs/cfPMN/pmnn.cfm). (Accessed December 16, 2016)

LifeStar ACT (LifeWatch®, Inc., a subsidiary of Card Guard Scientific) was approved by the FDA under the name CG-6108 Arrhythmia ECG Event Recorder (K060911) as a combined telephone electrocardiograph transmitter and receiver and arrhythmia detector and alarm (product codes DXH and DSI) on August 22, 2006. Additional information is available at: [http://www.accessdata.fda.gov/cdrh_docs/pdf6/K060911.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf6/K060911.pdf). (Accessed December 16, 2016)
Additional Products
- SAVI® (Medicomp)
- TruVue® (Biomedical Systems)
- Hearttrak ECAT (External Cardiac Ambulatory Telemetry) (Mednet Healthcare Technologies)
- TeleSentry™ (ScottCare Cardiovascular Solutions)
- NUVA NT (Corventis, Inc.)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does have a National Coverage Determination (NCD) for Electrocardiographic Services (20.15). Local Coverage Determinations (LCDs) exist; see the LCD’s for Cardiac Event Detection Monitoring, Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring), Real Time, Outpatient Cardiac Telemetry, Medicine: Long-Term Wearable Electrocardiographic Monitoring (WEM) and Long-Term Wearable Electrocardiographic Monitoring (WEM).

(Accessed December 7, 2016)

REFERENCES

American Medical Association (AMA). Cardiovascular monitoring services. CPT Assistant. October 2011, p. 5.


Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design: A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. Developed in partnership with the European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) and the European Cardiac Arrhythmia Society (ECAS); and in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS) and the Society of Thoracic Surgeons (STS). Endorsed by the governing bodies of the American College of Cardiology Foundation, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, the Asia Pacific Heart Rhythm Society and the Heart Rhythm Society. Heart Rhythm. 2012 Apr;9(4):632-696.e21.


UnitedHealthcare
Outpatient Cardiovascular Telemetry

POLICY


POLICY HISTORY/REVISION INFORMATION

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<th>Date</th>
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<td>Reformatted and reorganized policy; transferred content to new template</td>
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<td>Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable</td>
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