

# Cardiac Event Monitoring (for North Carolina Only)

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[Instructions for Use](#)

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Related Policies
None

## Application

This Medical Policy only applies to the State of North Carolina.

## Coverage Rationale

### Cardiac Event Monitoring

For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy, Cardiac Procedures: 1R-4, Electrocardiography, Echocardiography, and Intravascular Ultrasound](#).

### Implantable Loop Recorders

**[Implantable Loop Recorders](#) are proven and medically necessary for evaluating suspected cardiac arrhythmias:**

- When noninvasive cardiac event recording is contraindicated or yielded non-diagnostic results after at least 2 weeks of monitoring in one or more of the following circumstances:
  - Suspected paroxysmal atrial fibrillation in the setting of a cryptogenic stroke or another documented systemic thromboembolic event
  - Suspected or known ventricular arrhythmia
  - High risk for arrhythmia secondary to structural or infiltrative heart disease such as aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease, family history, dilated ischemic, or nonischemic cardiomyopathy or use of medications known to cause malignant arrhythmias such as those prolonging the QT interval
  - Recurrent or unexplained infrequent syncope, after modification of potentially syncope-causing medications or associated with autonomic dysfunction
  - Abnormal tests such as electrophysiology study or tilt table testing

**Replacement of Implantable Loop Recorders is considered medically necessary for an individual who continues to meet all initial criteria for insertion described above and the existing device is beyond its useful life span, is irreparable, or no longer operating.**

## Definitions

**Implantable Loop Recorder:** Device used to detect abnormal heart rhythms. It is placed under the skin and continuously records the heart's electrical activity. The recorder can transmit data to the physician's office to help with monitoring. An

Implantable Loop Recorder may determine why an individual is having palpitations or fainting spells [National Institutes of Health (NIH), 2022].

## 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 federal, state, or contractual requirements 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 Guidelines may apply.

CPT Code	Description
<b>Patch-Type Monitor</b>	
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation
<b>Holter Monitor</b>	
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
<b>Outpatient Cardiac Telemetry</b>	
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional

CPT Code	Description
<b>Event Monitor</b>	
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified health care professional
93270	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; recording (includes connection, recording, and disconnection)
93271	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; transmission and analysis
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; review and interpretation by a physician or other qualified health care professional
<b>Implantable Loop Recorder</b>	
*0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal, subcutaneous cardiac rhythm monitor
93285	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; subcutaneous cardiac rhythm monitor system
93291	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; subcutaneous cardiac rhythm monitor system, including heart rhythm derived data analysis
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional
<b>Cardiac Self-Monitoring Devices</b>	
*93799	Unlisted cardiovascular service or procedure

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HCPCS Code	Description
<b>Implantable Loop Recorder</b>	
*E0616	Implantable cardiac event recorder with memory, activator, and programmer
<b>Cardiac Self-Monitoring Devices</b>	
E1399	Durable medical equipment, miscellaneous

Codes labeled with an asterisk (\*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the North Carolina Medicaid Program.

## Description of Services

Cardiac arrhythmias are disorders of the heart's rate or rhythm. Some individuals with arrhythmias may experience palpitations, weakness, dizziness, or fainting, while others may have no symptoms at all. Effective treatment requires an accurate diagnosis, often using ambulatory electrocardiography (ECG) monitoring. The type and duration of ambulatory ECG monitoring is dictated by the frequency of symptoms.

## Clinical Evidence

### Implantable Loop Recorder (ILR)

In a randomized, multicenter, clinical trial, Bernstein et al. (2021) evaluated if long-term cardiac monitoring is more effective than usual care for detecting AF in patients who had a stroke attributed to large- or small- vessel disease. The study included 496 patients who were  $\geq 60$  years old or aged 50-59 with one or more additional stroke risk factor and had an index stroke due to large- or small-vessel disease within 10 days prior to ICM insertion. Two hundred and forty-two people in the intervention group received ICM insertion within 10 days of the index stroke, the control group ( $n = 250$ ) received usual care which consisted of external cardiac monitoring (e.g., 12 lead ECG, Holter monitor, telemetry, event recorder). The individuals were monitored for AF incidents lasting more than 30 seconds through 12 months. Clinical and monitoring data were collected at baseline and one, six, and 12 months after randomization, and continued at six-month intervals up to 36 months or the end of ICM battery life. Among 492 patients who were randomized, 417 (84.8%) completed 12 months of follow-up. The median (interquartile range) CHA<sub>2</sub>DS<sub>2</sub>-VASc (congestive heart failure, hypertension, age  $\geq 75$  years, diabetes mellitus, stroke or TIA, vascular disease, age 65 to 74 years, sex category) score was five (4-6). AF detection at 12 months was significantly higher in the ICM group vs the control group [27 patients (12.1%) vs four patients (1.8%); hazard ratio, 7.4 (95% CI, 2.6-21.3);  $p < .001$ ]. Among the 221 patients in the ICM group who received an ICM, four (1.8%) had ICM procedure-related adverse events (one site infection, two incision site hemorrhages, and one implant site pain). The authors concluded monitoring with an ICM detected significantly more AF over 12 months than the usual care in patients with a stroke attributed to large- or small- vessel disease. The authors recommend further research to ascertain if identifying AF in this group of patients is of clinical value. Limitations include lack of blinding and the study was industry sponsored. Additionally, the study failed to show an impact of the intervention on the risk of recurrent stroke.

Buck et al. (2021) conducted a RCT in patients with a recent ischemic stroke to evaluate if 12 months of ILR monitoring detects more occurrences of AF compared with external loop recorder monitoring for 30 days. The study included 300 patients at three hospitals between May 2015 and November 2017 who were within six months of ischemic stroke without known AF. Individuals were randomly assigned to either the external loop recorder group ( $n = 150$ ) or the implantable loop recorder group ( $n = 150$ ). Development of highly probably or definite AF was the primary outcome. There were eight secondary outcomes including recurrent ischemic stroke, intracerebral hemorrhage, and time to event analysis of new AF. One hundred and twenty-one of the 300 participants were female, 66.3% had a stroke of undetermined etiology, 273 completed cardiac monitoring lasting 24 hours or longer, and 259 completed both the assigned monitoring and 12-month follow-up visit. The primary outcome was observed in 15.3% (23/150) of patients in the implantable loop recorder group and 4.7% (7/150) of patients in the external loop recorder group. Of the eight specified secondary outcomes, six were not significantly different. There were five patients in the ILR group who had recurrent ischemic stroke versus eight patients in the external loop recorder group, one person in each group had intracerebral hemorrhage, three participants in each group died, and one person in the ILR group had device-related serious adverse events. The authors concluded implantable electrocardiographic monitoring for 12 months resulted in a significantly higher proportion of patients with AF detected when compared with external monitoring for 30 days. The authors note that the study has several limitations such as the delay of two months between stroke onset and study enrollment, variability in the investigations that were completed before enrollment, and lack of a validated questionnaire to assess for new stroke event or TIA. Additionally, there was potential bias due to manufacturer sponsorship. The authors recommend further research to compare clinical outcomes related to these monitoring strategies.

Svensden et al. (2021) conducted a RCT in four centers to investigate whether AF screening and subsequent use of anticoagulants when AF was detected can prevent strokes in high-risk individuals. The trial included participants who were 70-90 years old, without AF, with at least one additional stroke risk factor such as hypertension, diabetes, heart failure or a previous stroke. Individuals were randomized in a 1:3 ratio to ILR monitoring, or usual care (control) via an online system in permuted blocks with block sizes of four or eight stratified according to center. Anticoagulation was recommended in the ILR group if AF episodes lasted six minutes or longer. Time to first stroke or systemic arterial embolism was the primary outcome. Individuals ( $n = 6205$ ) were screened for inclusion from January 2014 to May 2016. A total of 6004 were included and randomly assigned: 4503 to usual care and 1504 to ILR monitoring. No participants were lost to follow-up. During a median follow-up of 64.5 months, AF was diagnosed in 1027 participants: 477 (31.8%) of

1501 in the ILR group versus 550 (12.2%) of 4503 in the control group [hazard ratio (HR) 3.17 (95% CI 2.81-3.59);  $p < 0.0001$ ]. Oral anticoagulation was initiated in 1036 participants: 445 (29.7%) in the ILR group versus 591 (13.1%) in the control group [HR 2.72 (95% CI 2.41-3.08);  $p < 0.0001$ ], and the primary outcome occurred in 318 participants (315 stroke, three systemic arterial embolism): 67 (4.5%) in the ILR group versus 251 (5.6%) in the control group [HR 0.80 (95% CI 0.61-1.05);  $p = 0.11$ ]. Major bleeding occurred in 221 participants: 65 (4.3%) in the ILR group versus 156 (3.5%) in the control group [HR 1.26 (95% CI 0.95-1.69);  $p = 0.11$ ]. The authors concluded that ILR screening resulted in a three-times increase in AF detection and anticoagulation initiation for individuals with stroke risk factors but no statistically significant reduction in the risk of systemic arterial embolism or risk of stroke.

Solbiati et al. (2017) conducted a systematic review and meta-analysis to explore the diagnostic yield of ILRs in members with recurrent, unexplained syncope in the absence of high-risk criteria and in high-risk members after a negative assessment. Forty-nine studies consisting of adults ( $n = 4381$ ) who underwent ILR implantation for unexplained syncope were included. The overall diagnostic yield, defined as the proportion of members with syncope recurrence and an ILR recording or automatic detection of a significant arrhythmia was the primary outcome. Proportions of members with specific etiologic diseases on the total of subjects and the proportion of an analyzable ECG recording during symptoms, were considered secondary outcomes. The overall diagnostic yield was 43.9% (95% CI = 40.2%, 47.6%). The authors concluded that approximately 50% of members had arrhythmias and about half of the people with unexplained syncope implanted with an ILR were diagnosed.

A Cochrane systematic review (Solbiati et al., 2016) of four randomized controlled trials ( $n = 579$ ) also assessed the diagnostic yield of ILRs versus conventional diagnostic workup in people with unexplained syncope. Participants in the standard assessment group experienced lower rates of diagnosis ( $rr = 0.61$ , 95% CI 0.54 to 0.68; participants = 579; studies = 4; moderate quality evidence), as compared to participants who underwent ILR implantation. However, the included studies overlapped with Solbiati et al. (2017).

In a multicenter randomized prospective study, Da Costa et al. (2013) compared conventional testing with prolonged ILR monitoring following the first syncopal episode in individuals with bundle branch block (BBB) and a negative workup. Seventy-eight individuals were randomized to ILR ( $n = 41$ ) or conventional follow-up ( $n = 37$ ) from January 2005 to December 2010. Those in the conventional strategy group were seen in the outpatient department at 3, 6, 12, 15, 18, 21, 24, 27, 30, and 33 months after randomization and at the end of the study (36 months). At each outpatient visit, arrhythmic or cardiovascular events were documented, and a 12-lead electrocardiogram was obtained. Additionally, a Holter monitor was used for seven days. There was a significant difference noted between the ILR group ( $n=15/41$ ; 36%) and the conventional follow-up group ( $n = 4/37$ ; 10.8%) in detection of relevant arrhythmias. The authors concluded the ILR strategy was superior to the conventional follow-up in detecting recurrent events, which may have a potential impact on therapeutic management.

## **Clinical Practice Guidelines**

### ***American Academy of Neurology (AAN)***

An AAN practice guideline on stroke prevention analyzed the evidence of various technologies used to identify undetected non-valvular AF in patients with cryptogenic stroke. The most common technique used was Holter monitoring, followed by serial ECG, 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 AF. 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)/American College of Clinical Pharmacy (ACCP)/Heart Rhythm Society (HRS)***

Joglar et al. (2023) developed a guideline for the diagnosis and management of patients with AF using evidence-based methodologies. Recommendations from the “2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation” and the “2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation” were updated with new evidence. Recommendations of the guideline are summarized as follows (not all-inclusive):

- For patients who have had a systemic thromboembolic event without a known history of AF and in whom maximum sensitivity to detect AF is sought, an ICM is reasonable. (Strength of recommendation, 2A-moderate, quality of evidence, B-R-randomized).

- 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. (Strength of recommendation, 2A-moderate, quality of evidence, B-R-randomized).

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

Joint guidelines for the management of patients with AF state that the diagnosis of AF 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 AF (January et al., 2014). A focused update of these guidelines has a new section on device detection of AF and atrial flutter. The update recommends that in patients with cryptogenic stroke in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF (January et al., 2019).

ACC/AHA/HRS guidelines on the evaluation and management of patients with bradycardia and cardiac conduction delay state that for those with daily symptoms, a 24- or 48-hour continuous ambulatory ECG (Holter monitor) is appropriate. Less frequent symptoms are best evaluated with more prolonged ambulatory ECG monitoring that can be accomplished with a broad array of modalities. In patients with infrequent symptoms (> 30 days between symptoms) suspected to be caused by bradycardia, long-term ambulatory monitoring with an implantable cardiac monitor is reasonable if initial noninvasive evaluation is nondiagnostic (Kusumoto et al., 2019).

ACC/AHA/HRS guidelines (Shen et al., 2017) on the evaluation and management of patients with syncope address several ambulatory ECG monitoring options. The guidelines recommend that the choice of a specific monitoring system and duration should be determined on the basis of the frequency and nature of syncope events. To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful:

- Holter monitor
- Transtelephonic monitor
- External loop recorder
- Patch recorder
- Mobile cardiac outpatient telemetry

Class IIA – It is reasonable to perform procedure.

Level of evidence B-NR – Based on moderate-quality evidence from one or more well-designed, well-executed nonrandomized, observational or registry studies.

AHA/ACC/HRS guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death state that a 24-hour continuous Holter recording is appropriate when symptoms occur at least once a day or when quantitation of premature ventricular complex/non-sustained ventricular tachycardia is desired to assess possible ventricular arrhythmia-related depressed ventricular function. For sporadic symptoms, event or “looping” monitors are more appropriate because they can be activated over extended periods of time and increase diagnostic yield. When the suspicion of ventricular arrhythmia is high, outpatient ambulatory monitoring is inappropriate, as prompt diagnosis and prevention of ventricular arrhythmia are warranted (Al-Khatib et al., 2017).

### ***American Heart Association (AHA)/American College of Cardiology (ACC)***

Joint guidelines on the diagnosis and treatment of hypertrophic cardiomyopathy state that in the presence of symptoms, ambulatory ECG monitoring should be continued until an individual has symptoms while wearing the monitor. In some individuals with infrequent symptoms, portable event monitors or implantable monitors may be warranted (Ommen et al., 2020).

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

The AHA and ASA released a guideline for the prevention of stroke in patients with stroke and TIA that recommends heart rhythm monitoring for occult AF if there was no other cause of stroke discovered. The authors also recommend further research to clarify the optimal duration of heart rhythm monitoring (Kleindorfer et al., 2021).

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., 2017).

### ***Canadian Cardiovascular Society (CCS)/Canadian Heart Rhythm Society (CHRS)***

The CCS and CHRS developed a guideline for the management of AF that recommends at least 24 hours of ambulatory ECG monitoring to identify AF in patients with nonlacunar cryptogenic stroke. The guideline additionally suggests monitoring for AF detection with an external loop recorder or implantable cardiac monitoring for patients with nonlacunar cryptogenic stroke in whom AF is suspected but unproven (Andrade et al., 2020).

### ***European Society of Cardiology (ESC)***

ESC guidelines for the management of AF 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. The guideline noted that the overall post-stroke AF detection after all phases of cardiac monitoring is approximately 23.7% based on RCTs reviewed as part of the guideline development. The ESC made a strong recommendation (Class 1B) for short-term ECG recording for at least the first 24 hours followed by continuous ECG monitoring for at least 72 hours in patients with acute ischemic stroke or transient ischemic attack whenever possible. They also recommend (Class IIa) that additional ECG monitoring using long-term non-invasive ECG monitors or insertable cardiac monitors should be considered to detect AF in selected stroke patients without previously known AF such as patients who are elderly, who have cardiovascular risk factors or comorbidities, indices of left atrial remodeling or a high C<sub>2</sub>HES<sub>T</sub> score. The ESC also made a strong recommendation (Class I) for opportunistic screening for AF by pulse or ECG rhythm strip in patients ≥ 65 years of age and a lower recommendation (Class IIa) for consideration of systematic ECG screening to detect AF in individuals aged ≥ 75 years, or for individuals at high risk of stroke. Ongoing studies will determine whether such early detection alters management (e.g., initiation of anticoagulation) and improves outcomes. Regarding prolonged monitoring for paroxysmal AF, 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. They also note that mobile health technologies are rapidly developing for AF detection and other purposes and that caution is needed in their clinical use as many are not clinically validated. Prolonged ECG monitoring is also reasonable in survivors of ischemic stroke without an established diagnosis of AF (Hindricks, 2021).

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. Some studies have shown that implementing remote monitoring increases the diagnostic yield and achieves diagnosis earlier than without remote monitoring (Brignole et al., 2018).

### ***European Stroke Organisation (ESO)***

The ESO guideline on screening subclinical AF after stroke or TIA of undetermined origin recommends, a prolonged cardiac monitoring instead of standard 24 hour monitoring to increase the detection of subclinical AF in adult patients. The guideline also we suggests the use of implantable devices for cardiac monitoring instead of non-implantable devices to increase the detection of subclinical AF (Rubiera, 2022).

### ***Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) et al.***

In a consensus statement on ablation of AF, the HRS, in collaboration with several 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 needs and consequences of arrhythmia detection. More intensive monitoring is associated with a greater likelihood of detecting both symptomatic and asymptomatic AF. No specific guidelines are provided regarding the optimal monitoring system (Calkins et al., 2017).

### ***Heart Rhythm Society (HRS)/International Society for Holter and Noninvasive Electrocardiology (ISHNE)***

The HRS, in collaboration with the ISHNE, published a consensus statement on ambulatory ECG and external cardiac monitoring. The document summarizes the advantages and limitations of various ambulatory ECG techniques. The guidelines note that Holter monitors are typically worn for 24-48 hours, patch monitors are worn 7-14 days, event/loop monitors are worn for 30 days and ambulatory cardiac telemetry monitors are worn up to 30 days. Frequency of symptoms should dictate the type of recording: longer term ECG monitoring is required for more infrequent events. The most appropriate clinical workflow may include a continuous (short-term 24 hour and up to seven days) ambulatory ECG monitoring, which if unsuccessful, is followed by intermittent external loop recording (long-term from weeks to months).

For those individuals remaining undiagnosed after prolonged noninvasive monitoring, ILR may be necessary (Steinberg et al., 2017).

### ***International Society for Holter and Noninvasive Electrocardiology (ISHNE)/Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/Asia Pacific Heart Rhythm Society (APHRS)***

In a collaborative statement on mobile health technologies in arrhythmia management, the ISHNE, HRS, EHRA, and APHRS describe the range of digital medical tools and heart rhythm disorders to which they may be applied. The current status, limitations and benefits of mobile health-based modalities, including wearable patches, Holter, MCOT, and implantable loop recorders are reviewed (Varma et al., 2021).

### ***National Institute for Health and Care Excellence (NICE)***

In a guideline on the management of atrial AF, NICE recommends the following in patients with suspected paroxysmal AF undetected by 12-lead 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 ambulatory ECG monitor, event recorder, or other ECG technology should be used in those with symptomatic episodes more than 24 hours apart (NICE, 2021).

## **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on ambulatory ECG devices, cardiac telemetry or implantable loop recorders, refer to the following website (use product codes DSI, MXD, and DXH): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed March 14, 2024)

The FDA classifies mobile cardiac self-monitoring devices as class II devices under the designation “transmitters and receivers, electrocardiograph, telephone.” For information on cardiac self-monitoring devices, refer to the following website (use product codes DXH, DPS and QDA): <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed March 14, 2024)

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## Policy History/Revision Information

Date	Summary of Changes
08/01/2024	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"><li>Updated instruction to clarify the <i>North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy, Cardiac Procedures: 1R-4, Electrocardiography, Echocardiography, and Intravascular Ultrasound</i> should be referenced for <i>medical necessity clinical coverage criteria</i></li><li>Replaced language indicating “Implantable Loop Recorder may be indicated for one or more of the [listed circumstances], <i>only if noninvasive cardiac monitoring</i> is contraindicated or yielded non-diagnostic results after at least <b>3</b> weeks of monitoring” with “Implantable Loop Recorders <i>are proven and medically necessary for evaluating suspected cardiac arrhythmias when noninvasive cardiac event recording</i> is contraindicated or yielded non-diagnostic results after at least <b>2</b> weeks of monitoring in one or more of the [listed] circumstances</li><li>Revised list of circumstances when Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias; replaced:<ul style="list-style-type: none"><li>“Suspected paroxysmal atrial fibrillation in the setting of cryptogenic stroke” with “suspected paroxysmal atrial fibrillation in the setting of a cryptogenic stroke <i>or another documented systemic thromboembolic event</i>”</li><li>“Recurrent or unexplained infrequent syncope, <i>if not diagnosed with 3 weeks of standard event monitoring and/or mobile cardiac outpatient telemetry</i>, after modification of potentially syncope-causing medications or associated with autonomic dysfunction” with “recurrent or unexplained infrequent syncope after modification of potentially syncope-causing medications or associated with autonomic dysfunction”</li></ul></li><li>Added language to indicate replacement of Implantable Loop Recorders is considered medically necessary for an individual who continues to meet all initial criteria for insertion described [in the policy] and the existing device is beyond its useful life span, irreparable, or no longer operating</li></ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"><li>Added CPT/HCPCS codes 93297, 93799, and E1399</li><li>Removed HCPCS code G2066</li><li>Added notation to indicate CPT/HCPCS codes 0650T and E0616 are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program</li></ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"><li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li><li>Archived previous policy version CSNCT0489.03</li></ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right 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 InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.