Implantable Loop Recorders and Wearable Heart Rhythm Monitors (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 particularly if these symptoms are infrequent [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
Implantable Loop Recorder	
*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
Cardiac Self-Monitoring Devices	
*0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device
*93799	Unlisted cardiovascular service or procedure

HCPCS Code	Description
Implantable Loop Recorder	
*E0616	Implantable cardiac event recorder with memory, activator, and programmer
Cardiac Self-Monitoring Devices	
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 State of 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 (NIH, 2022).

Clinical Evidence

Implantable Loop Recorder (ILR)

Jiang et al. (2022) conducted a meta-analysis and systematic review to evaluate the current modalities used for extended electrocardiography (ECG) monitoring in the detection of atrial fibrillation (AF) following a cryptogenic stroke. Forty-seven studies with a total of 6,448 individuals with cryptogenic stroke were included in the review. The pooled AF rate for ILRs increased from 4.9% (3.0%–7.9%) at one month to 38.4% (20.4%–60.2%) at 36 months. Mobile cardiac outpatient telemetry (MCOT) had a significantly higher pooled AF detection rate of 12.8% (8.9%–17.9%) versus 4.9% (3.0%–7.9%) for ILR at one month ($p < 0.0001$). Predictors for AF detection include duration of monitoring ($p < 0.0001$) and age ($p < 0.0001$) for ILRs, but only age for MCOTs ($p < 0.020$). The authors concluded that for individuals who have the cognitive and physical capacity to use ECG monitoring daily for one month, MCOT is effective in detecting a significant proportion of AF and should be considered in place of ILRs. However, ILRs may be considered for individuals needing extended monitoring, if MCOT does not detect AF after four weeks, or if compliance issues are expected. Limitations include significant unexplained heterogeneity, poor reporting of features of the study population, and risk underestimation of AF detection rates in MCOT studies.

In a randomized, multicenter, clinical trial (the STROKE-AF trial), Bernstein et al. (2021) evaluated if long-term cardiac monitoring is more effective than usual care for detecting AF in individuals who had a stroke attributed to large- or small-vessel disease. The study included 496 participants who were ≥ 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 implantable cardiac monitor (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 participants who were randomized, 417 (84.8%) completed 12 months of follow-up. The median (interquartile range) CHA2DS2-VASc (congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or TIA, vascular disease, age 65 to 74 years, sex category) score was five (four-six). Atrial fibrillation detection at 12 months was significantly higher in the ICM group vs the control group (27 participants [12.1%] vs four participants [1.8%]; hazard ratio, 7.4 [95% CI, 2.6-21.3]; $p < .001$). Among the 221 participants 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 individuals with a stroke attributed to large- or small- vessel disease. The authors recommended further research to ascertain if identifying AF in this group of individuals 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. In 2023, Bernstein et al. reported the three-year results of the STROKE-AF trial. Out of the initial 492 participants, 314 completed the three-year follow-up. The study found that continuous cardiac monitoring with an ICM detected significantly more AF compared to usual care. Specifically, AF was detected in 21.7% (n = 46) of participants in the ICM group versus 2.4% in the control group (n = five). The authors concluded that individuals with ischemic stroke due to large artery disease or small vessel disease have a growing risk of developing AF over time. According to the authors, most AF episodes are not consistently identified by standard medical monitoring methods; therefore, a year of negative monitoring should not give clinicians confidence that individuals who had a stroke will be free of AF in the subsequent two years. Limitations included that the treatment for AF was neither randomized nor prescribed by the study protocol. Additionally, the reasons for oral anti-coagulation use or non-use were not documented, and the study was not designed to detect differences in recurrent stroke rates.

Buck et al. (2021) conducted a randomized controlled trial (RCT) in individuals 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 participants 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 ILR 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 participants in the ILR group and 4.7% (7/150) of participants in the external loop recorder group. Of the eight specified secondary outcomes, six were not significantly different. There were five participants in the ILR group who had recurrent ischemic stroke versus eight participants 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 ECG monitoring for 12 months resulted in a significantly higher proportion of individuals 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 recommended further research to compare clinical outcomes related to these monitoring strategies.

Noubiap et al. (2021) conducted a systematic review and meta-analysis to evaluate data on AF detection rates and predictors comparing different rhythm monitoring strategies in individuals with embolic stroke of undetermined source (ESUS) or cryptogenic stroke. PubMed/MEDLINE, Excerpta Medica Database (EMBASE), and Web of Science were searched to identify all cohort studies or RCTs reporting primary data on the rates and predictors of AF detection in individuals with cryptogenic stroke or ESUS, published by July 6, 2020 and random-effects meta-analysis method was used to pool estimates. Forty-seven studies with a total of 8,215 individuals with cryptogenic stroke or ESUS were included. Using ICM, the pooled rate of AF was 12.2% at three months, 16.0% at six months, 18.7% at 12 months, 22.8% at 24 months, and 28.5% at 36 months. Atrial fibrillation rates were significantly higher in individuals with ESUS vs cryptogenic stroke (22.0% vs 14.2%; $p < 0.001$) at six months, and in studies using Reveal LINQ vs Reveal XT ICM (19.1% vs 13.0%; $p = 0.001$) at 12 months. Using MCOT, the pooled rate of AF was 13.7% at one month. Predictors of AF detection with ICM included older age, P-wave maximal duration, CHA2DS2-VASc score, prolonged PR interval, and left atrial enlargement. The authors concluded more than a quarter of individuals with cryptogenic stroke or ESUS are diagnosed with AF during follow-up and about one in seven individuals had AF detected within a month of MCOT, suggesting that a non-invasive rhythm monitoring strategy should be considered before invasive monitoring (Sanna et al. 2014, which was previously cited in this policy, was included in this systematic review and meta-analysis).

Svendsen 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) where 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 RCTs (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 ECG 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 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):

- In patients with AF-induced cardiomyopathy who have recovered LV function, long-term surveillance can be beneficial to detect recurrent AF in view of the high risk of recurrence of arrhythmia-induced cardiomyopathy. (Strength of recommendation 2a-moderate, quality of evidence, B-NR-moderate/non-randomized)
- 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-moderate/randomized)
- In patients with an onset of AF before 45 years of age without obvious risk factors for AF, referral for genetic counseling, genetic testing for rare pathogenic variants, and surveillance for cardiomyopathy or arrhythmia syndromes may be reasonable. (Strength of recommendation 2b-weak, quality of evidence, B-NR-moderate/non-randomized)
- In patients with stroke or TIA of undetermined cause, initial cardiac monitoring and, if needed, extended monitoring with an ILR are reasonable to improve detection of AF. (Strength of recommendation, 2a-moderate, quality of evidence, B-R-moderate/randomized)
- Use and applicability of consumer-based wearable heart monitoring devices: These devices are now widespread and are used to diagnose and monitor response to therapy in individuals with AF. Validation on the accuracy of the most common available technologies is needed. How to best use these devices in practice, including for AF screening, must be better defined. (Future research needs)

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 ECG, 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 el., 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 ICM 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 and to evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful. The authors note that while the diagnostic yield of an external loop recorder may be lower than that of an ICM, using the noninvasive strategy as an initial approach is reasonable. Furthermore, the guidelines indicate that patients with recurrent, infrequent, unexplained syncope (or suspected atypical reflex syncope) of suspected arrhythmic origin, after a nondiagnostic initial workup, with or without structural heart disease, are suitable candidates for implantable cardiac monitoring.

AHA/ACC/HRS guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death state that ICMs can be useful for detecting ventricular arrhythmias in patients with sporadic symptoms, including syncope. 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 College of Cardiology (ACC)/American Medical Society for Sports Medicine (AMSSM)/Heart Rhythm Society (HRS)/ Pediatric & Congenital Electrophysiology Society (PACES)/Society for Cardiovascular Magnetic Resonance (SCMR)

Ommen et al. (2024) developed AHA/ACC/AMSSM/HRS/PACES/SCMR guidelines for the management of hypertrophic cardiomyopathy (HCM). The guidelines recommendations for heart rhythm assessment include (not all-inclusive):

- In patients with HCM, 24- to 48-hour ambulatory ECG monitoring is recommended in the initial evaluation and as part of periodic follow-up (every one-two years) to identify patients who are at risk for sudden cardiac death and to guide management of arrhythmias. (Strength of recommendation: 1-strong, level of evidence: B-NR-nonrandomized)
- In patients with HCM who develop palpitations or lightheadedness, extended (> 24 hours) ECG monitoring or event recording is recommended for arrhythmia diagnosis and clinical correlation. (Strength of recommendation: 1-strong, level of evidence: B-NR- nonrandomized)
- In patients with HCM who are deemed to be at high risk for developing AF based on the presence of risk factors or as determined by a validated risk score, and who are eligible for anticoagulation, extended ambulatory monitoring is recommended to screen for AF as part of initial evaluation and annual follow-up. (Strength of recommendation: 1-strong, level of evidence: B-NR- nonrandomized)
- 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 one-two years). (Strength of recommendation: 2B-weak, level of evidence: B-NR- nonrandomized)

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

The AHA and ASA have issued guidelines for preventing stroke in patients with a history of stroke and TIA. The guideline highlights that AF is a common and high-risk factor for secondary ischemic strokes and suggests heart rhythm monitoring for occult AF when no other cause of stroke is identified. The guideline recommended that for those with cryptogenic stroke who are not contraindicated for anticoagulation, it is reasonable to use long-term rhythm monitoring, such as mobile cardiac outpatient telemetry, ILRs, or other methods, to detect intermittent AF. The authors also recommended 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).

Nielsen et al. (2020) developed an expert consensus statement on risk assessment in cardiac arrhythmias, aiming to raise awareness about using the appropriate risk assessment tool for specific outcomes in particular populations, and to offer physicians practical recommendations that could enhance patient care. According to the authors:

- An ILR is indicated in the evaluation of patients with infrequent, recurrent syncope of uncertain origin, particularly when ambulatory monitoring has been inconclusive.
- An ILR is indicated in patients with syncope and high-risk criteria where a comprehensive evaluation has not identified a cause of syncope or led to a specific treatment, and who do not have conventional indications for primary prevention ICD or pacemaker.
- An ILR may be considered in patients experiencing palpitations, dizziness, pre-syncope, frequent premature ventricular complexes (PVCs)/non-sustained ventricular tachycardia, and in those with suspected AF, and post- AF ablation.

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 TIA 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_2HEST score. The guidelines 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. Additionally prolonged ECG monitoring is also considered 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 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)

Joglar et al. developed an HRS consensus statement regarding cardiac arrhythmia management during pregnancy. The statement recommends (not all-inclusive):

- Pregnant patients with suspected arrhythmic etiology of unexplained palpitations who have concerning symptoms or suspected electrical or structural heart disease on initial evaluation should undergo ambulatory monitoring as clinically indicated, in consultation with a cardiologist or electrophysiologist with expertise in cardiovascular diseases in pregnancy. (Strength of recommendation 1-strong, quality of evidence, B-NR-moderate/non-randomized)
- In pregnant patients with suspected arrhythmic etiology of palpitations unexplained after noninvasive cardiac evaluation, especially in the presence of syncope and/or electrical or structural heart disease, consideration of an ICM is reasonable. (Strength of recommendation 2a-moderate, quality of evidence, C-LD-limited data)
- In pregnant patients with recurrent syncope unexplained after comprehensive noninvasive evaluation, including external monitor, insertion of an ICM is recommended. (Strength of recommendation 1-strong, quality of evidence, C-LD-limited data)

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 ILR 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).

A NICE guideline suggests that the Reveal LINQ ILR can be used to identify AF following a cryptogenic stroke, including TIA, but only when non-invasive ECG monitoring has been performed and a cardiac arrhythmia is still suspected as the cause of the stroke (NICE, 2020).

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 ILR, refer to the following website (use product codes DSI, MXD, and DXH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed February 3, 2025)

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.
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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	**Title Change** • Previously titled *Cardiac Event Monitoring (for North Carolina Only)* **Definitions** • Updated definition of "Implantable Loop Recorder" **Applicable Codes** • Removed CPT codes 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, and 93272 **Supporting Information** • Updated *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CSNCT0489.05

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