Implantable Loop Recorders

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial (self-funded groups only)** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Implantable Loop Recorders: Diagnostic Guideline Note D2

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

This policy and the criteria therein only apply to self-funded employer groups. For all other commercial groups, please refer to the Carelon Cardiovascular Guidelines.

Note: Implantable loop recorder procedures are reviewed for both medical necessity (criteria below) and outpatient surgical site of service (see criteria in the "Outpatient Surgical Site of Service," medical policy).

Initial Placement

I. An implantable cardiac loop recorder (ICLR) may be considered **medically necessary** for the evaluation of recurrent, unexplained syncope (RUS) when **all** of the following criteria are met (A.-C.):

   A. Patient has suspected cardiac arrhythmia; **and**
   B. Either of the following criteria is met (1.- 2.):
      1. Syncope symptoms are frequent (once a month or more) and a diagnosis was not established with **both** of the following non-invasive ambulatory monitoring methods:
         a. Holter monitoring; **and**
         b. 30-day external cardiac rhythm monitoring; **or**

2. Syncope symptoms are experienced so infrequently and unpredictably (less than once per month) that noninvasive ambulatory monitoring (e.g. Holter monitoring or external cardiac rhythm monitoring) are unlikely to be diagnostic; **and**

C. The implantable loop recorder must be inserted by a cardiologist or electrophysiology cardiologist.

II. An implantable cardiac loop recorder (ICLR) may be considered **medically necessary** for the evaluation of cryptogenic stroke when **all** of the following criteria are met (A.-C.):

A. Atrial fibrillation is the suspected cause of cryptogenic stroke; **and**
B. A diagnosis was not established after 30-day external cardiac rhythm monitoring (e.g., external loop recorder or external patch recorder); **and**
C. The implantable loop recorder must be inserted by a cardiologist or electrophysiology cardiologist.

III. An implantable cardiac loop recorder is considered **not medically necessary** when criteria I. or II. above is not met, including but not limited to: monitoring post-catheter ablations.

Device Replacement

IV. Replacement of implantable cardiac loop recorders may be considered **medically necessary** when criteria I. or II. is met and **any** of the following criteria are met (A.- C.):

A. The device is nonfunctioning; **or**
B. The electric replacement indicator signals device replacement is necessary; **or**
C. Replacement is needed in accordance with the device manufacturer instructions.

V. Replacement of implantable cardiac loop recorders is considered **not medically necessary** when criterion IV. is not met.

Device Removal

VI. Removal of implantable cardiac loop recorders may be considered **medically necessary** if it has been thoroughly evaluated and found to be no longer functional and was appropriately placed for medical necessity.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Outpatient Surgical Site of Service, MP420

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Cardiac Arrhythmias

A cardiac arrhythmia is an irregular heartbeat. Although arrhythmias are common, especially with increased age, some arrhythmias can be dangerous and require prompt diagnosis and management. Diagnosing arrhythmias can be difficult because some are asymptomatic or occur infrequently and unpredictably.[1] When a cardiac arrhythmia does cause symptoms, they typically include pre-syncope (feeling faint), syncope (fainting), palpitations, or dizziness. Due to these variations in the clinical presentation of cardiac arrhythmias, long-term ambulatory monitoring is sometimes necessary to obtain an accurate diagnosis.

Recurrent Unexplained Syncope (RUS)

Syncope is a short-lasting (usually 8 to 10 seconds) loss of consciousness caused by a temporary decrease in blood flow to the brain (cerebral hypoperfusion).[2] Recurrent, unexplained syncope (RUS) is a loss of consciousness occurring often or repeatedly for no explainable reason. The primary causes of syncope are cardiac arrhythmias or vasovagal syndromes (loss of consciousness when the body overreacts to certain triggers). This loss of consciousness is inevitably associated with collapse which can lead to a high-risk syncopal episode (e.g. syncope while driving); therefore, the prompt identification and treatment of the cause of syncope is of utmost importance. According to Hongo et al., "after an initial history, physical exam, and electrocardiogram, the cause of syncope can remain unexplained in up to 47% of patients."[3] Although patients with vasovagal syncope have a relatively nonthreatening condition, patients with cardiac arrhythmic cause of syncope, "have a strikingly higher incidence of sudden death than patients with non-cardiovascular syncope."[4]

Cryptogenic Stroke

A stroke is a "brain attack" and occurs when blood flow to the brain is cut off. Cryptogenic stroke is a stroke of unknown origin. Every year in the United States, about one third of all strokes are classified as cryptogenic.[5] Atrial fibrillation (a type of cardiac arrhythmia that causes poor blood flow) is the leading preventable cause of recurrent stroke; therefore, early detection and treatment of atrial fibrillation is critical.[6]

Holter Monitor

Ambulatory Holter electrocardiography is commonly used to diagnose a suspected cardiac arrhythmia in patients who exhibit frequent symptoms.[7] The battery powered device is the size of a small camera and monitors heart rhythms through small electrodes attached to the chest. This noninvasive test provides continuous ECG data over a 24 to 48 hour time period. After the monitoring period, the device is returned to the physician's office where the ECG data is downloaded and reviewed. Due to the short monitoring period, Holter ECGs can be ineffective for detecting infrequent or unpredictable arrhythmias.

External Ambulatory Electrocardiography (ECG)

External ambulatory ECGs are small, portable devices that provide up to 30 days of cardiac rhythm data. There are different types of external ambulatory ECGs, including but not limited to:

1. External Loop Recorders (ELR) are the size of a pager and monitor heart rhythms through two electrodes attached to the chest. These devices use a memory loop recording process where several minutes of ECG activity is recorded and then starts, or "loops", over. ELRs s can be patient activated when symptoms begin or auto-activated when the monitor detects an arrhythmia. Data from the device is usually transmitted to a remote monitoring center for physician review.
2. External patch recorders (e.g., Zio Patch®) are small, water-resistant, adhesive one lead ECGs that attach to the chest and provide ECG monitoring for up to 2 weeks.[8] The device continuously records and stores rhythm data, but the wearer can also press a button when symptoms are detected to allow for symptom-rhythm correlation. At the end of the 2 week monitoring period the patch must be sent in for analysis. A diagnostic report is then given to the patient and physician.
3. MCOT (e.g., CardioNet® Mobile Cardiac Outpatient Telemetry) provides real-time, continuous heart rhythm monitoring through cardiac arrhythmia detection capabilities and cellular technology.[9] The small sensor can be worn as a pendent or on a belt clip and has 3 electrodes that attach to the chest. The sensor continuously monitors ECG data and when an arrhythmia is detected the data is automatically transferred to the monitoring center via wireless cellular technology. The remote monitoring center is staffed 24/7/365 by medical technicians who can contact the patient and physician immediately after detection of a cardiac arrhythmia.

Due to the increased monitoring period of external cardiac event monitors, these devices are useful for diagnosing irregular or infrequent arrhythmias which would not be diagnosed by a standard 12-lead ECG or Holter Monitor.[6]

Implantable Cardiac Loop Recorders (ICLRs)

The implantable cardiac loop recorder is a very small ECG monitoring device that is inserted under the skin, in the chest. ICLRs are commonly the size of a computer USB but newer models are much smaller, only around a few millimeters long. Placement of the device does require an outpatient surgical procedure, but once implanted the ICLR can provide ECG data for up to 3 years. These devices use a memory loop recording process where several minutes of ECG activity is recorded and then starts, or "loops," over. ICLRs can be patient activated through an external remote at symptom initiation or auto-activated when the monitor detects an arrhythmia. Data from the device is usually transmitted to a remote monitoring center for physician review. These monitors are particularly useful in patients who experience cardiac arrhythmia symptoms so infrequently that noninvasive ambulatory monitoring (e.g. Holter monitors or external cardiac rhythm monitors) is unlikely to capture a diagnostic ECG abnormality.[2]

Catheter Ablation

Catheter ablation (also known as Cardiac Ablation) is a procedure wherein long, flexible tubes (catheters) are inserted through a vein or artery, and threaded to the heart. Energy, in the form of heat or extreme cold, is then delivered from the catheter to scar the tissues that are triggering or sustaining abnormal heart rhythms, thereby stopping the arrhythmia.[10]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Device Name	FDA Indications for Use
c devices by Biotronik[11,12] (Biomonitor III, Biomonitor IIIm, Biomonitor 2-Af, Biomonitor)	BioMonitor devices are indicated to detect the following cardiac arrhythmias: • Atrial fibrillation • Bradycardia • Sudden rate drop • High ventricular rate (HVR) • Asystole The BioMonitor is indicated for: • Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias • Patients who experience transient symptoms that may suggest a cardiac arrhythmia • The device has not been tested for and it is not intended for pediatric use
Confirm Insertable Cardiac Monitors by Abbott/St. Jude[13,14] (Confirm Rx Insertable Cardiac Monitor, SJM Confirm Implantable Cardiac Monitor)	The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.
Reveal LINQ Insertable Cardiac Monitoring System (Medtronic)[15]	The Reveal LINQ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

	• Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias • Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia The device has not been tested specifically for pediatric use.
Reveal XT Insertable Cardiac Monitor (Medtronic)[16]	The Reveal XT and DX Insertable Cardiac Monitors are implantable patient-activated and automatically-activated monitoring systems that record subcutaneous ECG and are indicated in the following cases: • Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias • Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain that may suggest a cardiac arrhythmia. The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates, one or more of the data management features in the Reveal Insertable Cardiac Monitor: • To verify whether the implanted device has detected a suspected arrhythmia or device related event.* • To initiate recording of cardiac event data in the implanted device memory. *only applicable to the Reveal XT Patient Assistant Model 9539

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

ICLRs to Diagnose Cardiac Arrhythmias

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of implantable cardiac loop recorders for diagnosing cardiac arrhythmias. Below is a summary of the available evidence identified through July 2024.

Systematic Reviews

- In 2019, Hayes conducted a review of abstracts to evaluate the comparative efficacy of 4 cardiac loop recorders monitor for cardiac arrhythmia (i.e. BioMonitor 2, Confirm Rx, Reveal LINQ, Reveal XT).[17] Having searched the literature through February 2019, Hayes identified 4 abstracts (1 systematic review/meta-analysis, 1 review article, 2 prospective comparative studies). Hayes concluded that conclusions about safety, efficacy and superiority of individual devices could not be established due to a lack of comparative evidence. A review of adverse events found that the Reveal products had significantly higher adverse events reported through the FDA MAUDE database, although these devices have been commercially available longer. This Hayes review was archived on April 4, 2020.

- In 2022 and 2023, ECRI evaluated the safety and efficacy of 2 implantable monitors , the Confirm Rx and the Reveal LINQ, intended for cardiac surveillance for patients at risk of arrhythmia.[18,19] For Confirm Rx, ECRI identified 1 RCT, 1 retrospective comparison study, 5 case series and 1 diagnostic cohort study, totaling 7,599 patients, that indicate that Confirm Rx ICM is safe and provide reliable diagnostic information and clinical utility in patients with AF. ECRI concluded that "these findings need independent validation in larger studies that compare it with standard Holter monitors and report patient-oriented outcomes resulting from Confirm Rx ICM-guided management changes." For Reveal LINQ, ECRI identified 3 systematic reviews, one single-blind, single center RCT (n=142), 2 prospective observational studies and 2 retrospective observational studies. ECRI concluded that " Reveal LINQ II improves arrhythmia detection compared with conventional monitoring but involves some risk of surgical complications; however, the evidence does not clearly demonstrate whether LINQ II reduces long-term cardiovascular events or improves arrhythmia treatment to justify these risks. Available evidence is also too limited to determine how well Reveal LINQ II works compared with MCOT, but data suggest MCOT is safer and as effective or more effective than LINQ devices."

- In 2017, Solbiati and colleagues conducted a systematic review and meta-analysis evaluating the diagnostic yield of ILRs in unexplained syncope.[20] Investigators searched the literature through November 2015, identified eligible studies, assessed study quality, extracted data and pooled results. The primary outcome was the overall diagnostic yield, defined as the proportion of patients with syncope recurrence and an available ILR recording or an automatic detection of a significant arrhythmia. Secondary outcomes were the proportions of patients with the specific etiologic diagnoses on the total of subjects and the proportion of an analyzable ECG recording during symptoms. A random effects model was used for the meta-analyses. In total, 49 studies were included for review (n=4381). The overall diagnostic yield was 43.9% (95% CI = 40.2%, 4.6%; I^2= 79.8%). The proportions of subjects finally diagnosed with arrhythmic syncope, ventricular arrhythmias, supraventricular arrhythmias and bradyarrhythmias were 26.5%, 2.7%, 4.9% and 18.2%, respectively. The proportion of an analyzable ECG recording during symptoms was 89.5% (95% CI = 86.1%, 92.1%; 1236 subjects; 36 studies; I 2 = 44.9%). Half of unexplained syncope subjects implanted with an ILR were diagnosed, and around half had an arrhythmia. Study limitations included heterogeneity in study patient populations and outcome measures. Investigators called for additional studies that adopt homogeneous inclusion criteria and consistent reference standards for the diagnosis of different syncope etiologies.

- A 2016 Hayes systematic review (updated 2019) evaluated 14 studies (7 randomized controlled trials [RCTs] and 7 observational cohort studies) comparing the use of implantable cardiac loop recorders to standard diagnostic tests for the diagnosis and management of recurrent, unexplained syncope (RUS).[2] Some of the standard diagnostic tests that were compared to ICLR included 12-lead ECG, 24-hour Holter monitoring, tilt-table testing, and external loop recorders. The selected studies had sample sizes ranging from n=6 to n=939. The average follow-up time was 9 months to 2 years. The primary outcome evaluated in all studies was the diagnostic yield of ICLR compared to the standard tests. Some studies also evaluated syncope recurrence, ICLR impact on treatment initiation, outcomes of ICLR-directed treatment, quality of life, and adverse events.

  All studies included in the systematic review showed a significantly higher diagnostic yield for ICLRs compared to the standard diagnostic tests. All observational cohort studies reported that diagnostic yield increased with increased monitoring time, which is to be expected since longer monitoring time is more likely to capture infrequent arrhythmias. There were no significant differences for the outcome of syncope incidence during ICLR monitoring. Several of the included studies did not report a significant difference between groups regarding ICLR impact on treatment initiation. Only 1 study reported that the ICLR group had a significantly higher rate of pacemaker implantation and radiofrequency ablation after the ICLR diagnoses. Also of note, no studies reported any adverse events or safety issues related to the ICLR.

  Strengths of the Hayes review included good quality RCTs with large sample sizes and long-term follow-up, which compared the use of ICLRs with standard diagnostic tests. Limitations included the poor quality of 6 of the 7 observational cohort due to a lack of randomization, lack of blinding, loss to follow-up, and lack of reporting statistical significance with some study results. Overall, Hayes reported a B rating, "for use of an implantable loop recorder for evaluation of adult patients with recurrent, unexplained syncope in whom the history, clinical examination, or standard electrocardiogram findings raise the suspicion of an underlying potentially treatable arrhythmia but who have negative or inconclusive results of standard, shorter-term tests, or mixed result(s) on a standard test(s) that require confirmation or elucidation."[2]

- In 2016, Cochrane conducted a systematic review evaluating the efficacy of implantable loop recorders (ILRs) versus diagnostic workup for unexplained recurrent syncope.[21] Investigators searched the literature through April 2015, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 4 trials were included for review (n=579). On the basis of very low quality evidence, investigators reported no significant difference in the risk of long-term morality between ILR patients and patients receiving standard assessments (RR 0.97, 95% CI 0.41 to 2.30). Data on comparative quality of life was inconclusive. Moderate-quality evidence suggested that patients receiving ILR experienced higher rates of diagnosis compared to patients undergoing standard assessment. Study limitations include small sample sizes, inadequate follow-up, lack of blinding and the lack of mortality data from 2 of the 4 studies. Investigators concluded that no evidence demonstrated that ILR reduced patients' long-term mortality as compared to a standard diagnostic assessment. Additional research, measuring clinically relevant outcomes besides

diagnostic rate, were judged necessary to establish the superiority of an ILR-based diagnostic strategy compared to standard assessment.

Randomized Controlled Trials (RCTs)

Three RCTs comparing the diagnostic yield of ICLRs for unexplained cardiac arrhythmias to the standard diagnostic tests were identified.[22-24] All RCTs showed a significant increase in diagnostic yield between ICLRs and standard diagnostic testing for recurrent, unexplained syncope. The RCT by Podoleanu et al. found that patients in the ICLR group were hospitalized for a shorter amount of time and had significantly fewer diagnostic tests than the control group.[22] This same RCT also analyzed the quality of life of patients receiving an ICLR versus standard diagnostic testing, and found no significant differences between groups. Another RCT by Farwell et al. reviewed additional costs incurred by further hospital admissions and diagnostic tests for unexplained syncope. This study indicated that ECG-directed therapy was significantly quicker for ICLR patients and patients had fewer diagnostic tests and hospital stays, resulting in a cost savings. Lastly, none of the RCTs reported severe adverse events related to ICLR.

Strengths of these RCTs included computer generated randomization in all studies, a large sample size (Farwell et al. n=201), and recruitment from 13 different hospital systems (Podoleanu et al.). Limitations included small sample size of less than 100 in two studies (Podoleanu et al. and Krahn et al.), lack of blinding, the selective recruitment of participants from a single hospital (Krahn et al. and Farwell et al.), and a short follow-up period (Farwell et al. only followed participants for 6 months after ICLR implantation). Despite these limitations, the RCTs all showed significantly higher diagnostic yield for the ICLR compared to standard diagnostic tests for patients with recurrent, unexplained syncope.

Nonrandomized Studies

Edvardsson et al. conducted a prospective, multicenter, observational study regarding the use of the Reveal® ICLR to diagnose unexplained recurrent syncope and pre-syncope.[25] The study enrolled 650 subjects, and follow-up data on 570 subjects was used for analysis. At study conclusion, patients had seen an average of 3 different medical specialists for their recurrent, unexplained syncope, had an average of 13 diagnostic tests performed, 70% had been hospitalized at least once for syncope, and 36% had significant trauma associated with syncope. A total of 218 patients experienced syncope during the study, and an ICLR-guided diagnosis was obtained in 78% (170) of cases. Based on the large number of inconclusive diagnostic tests that patients underwent before an ICLR implant and the high diagnostic yield resulting from the use of an ICLR, the authors concluded that if an ICLR is implanted early in patients with recurrent, unexplained syncope a reduced number of tests might be needed. The limitations of this study include the observational design, which did not allow for the evaluation of ICLR compared to other standard diagnostic tests. This study also had significant loss to follow-up, with 12% of implanted patients lacking a follow-up visit. A significant strength of this study is the inclusion of 71 different clinical sites; therefore, creating a large sample size and baseline characteristics generalizable to a broader population.

ICLRs to Diagnose Atrial Fibrillation in Patients with Cryptogenic Stroke

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of implantable cardiac loop recorders for diagnosing atrial fibrillation (AF) in patients with cryptogenic stroke (stroke of unknown cause). Below is a summary of the available evidence identified through July 2024.

Systematic Reviews

- In 2019, Hayes evaluated 9 studies (1 RCT, 1 prospective cohort study, and 7 retrospective studies) comparing the use of implantable loop recorders (ILRs) to standard diagnostic tests for the diagnosis of atrial fibrillation (AF) as the cause of cryptogenic stroke.[26] Hayes determined the included RCT to be of good-quality, while the nonrandomized cohort studies were of poor-quality. The good-quality RCT found that ILR diagnosed significantly more atrial fibrillation than standard monitoring methods. Although the other studies were of poor quality, they had similar results suggesting ILRs are diagnostically useful for identifying AF in patients with cryptogenic stroke. Based on the moderate quality evidence, Hayes gave a C rating for the use of ILR to diagnose AF following cryptogenic stroke. Hayes also indicated "additional good-quality RCTs are needed to assess whether the information yield by ILR monitoring improves clinical management and influences the rate of secondary stroke and overall morbidity and mortality in patients who have experienced a cryptogenic stroke and to define the patient population most likely to benefit from monitoring."[26]

- A systematic review and meta-analysis by Sposato et al. (2015) evaluated the diagnostic utility of sequential phases of cardiac monitoring for identifying atrial fibrillation in patients after cryptogenic stroke or transient ischemic attack.[27] The authors systematically reviewed peer-reviewed literature related to eight AF diagnostic methods: admission ECG, serial ECG, continuous inpatient ECG, continuous inpatient telemetry, Holter monitoring, mobile cardiac outpatient telemetry (MCOT), external loop recorders (ELR), and implantable loop recorders (ILR). Based on the cardiac monitoring method used and time to monitoring, the cardiac monitoring methods were divided into 4 screening phases. Phase 1 (acute assessment in emergency room) was an admission ECG. Phase 2 (in-hospital stay) involved a serial ECG, continuous inpatient ECG, continuous inpatient cardiac telemetry, and in-hospital Holter monitoring. Phase 3 (the first ambulatory period) was the 24-48 hour ambulatory Holter monitor. Phase 4 (second ambulatory period involving the use of long-term sophisticated monitoring methods, usually after previous diagnostic attempts with similar methods) included MCOT, ELR, and ILR.

  The authors included 50 studies giving a sample size of n=11,658. The percentage of patients diagnosed with post-stroke AF through the different cardiac monitoring phases was 7.7% in phase 1, 5.1% in phase 2, 10.7% in phase 3, and 16.9% in phase 4. There was no significant difference between the proportion of patients diagnosed with post-stroke AF using the phase 4 cardiac monitoring methods (MCOT 15.6%, ELR 16.2%, and ILR 16.9%). Overall, the proportion of patients diagnosed with post-stroke atrial fibrillation after the four sequential screening phases was 23.7%.

Strengths of this study include the author's use of PRISMA and Cochrane methodology for systematically reviewing literature and evaluating study quality. Another methodological strength is the large sample size and the author's assessment of heterogeneity and publication bias before conducting the meta-analysis. Limitations include 46% of included studies having potential selection bias and 22% having potential funding bias. Also, the division of the cardiac monitoring methods into different phases also introduces the possibility of misclassification bias. Ultimately, the authors concluded that "by sequentially combining cardiac monitoring methods, atrial fibrillation might be newly detected in nearly a quarter of patients with stroke or transient ischemic attack."[27]

Randomized Controlled Trials (RCTs)

The good-quality CRYSTAL AF (Cryptogenic Stroke and Underlying Atrial Fibrillation) RCT conducted by Sanna et al. (2014) assessed whether the efficacy of long-term monitoring with an insertable cardiac monitor (ICM) is more effective than conventional monitoring for detection of atrial fibrillation (AF) in patients cryptogenic stroke.[28] The RCT enrolled 441 patients who were 40 years of age or older with no diagnosis of AF after 24 hours of standard ECG monitoring. Patients were randomized 1:1 to ICM or standard stroke evaluation (control) and evaluated for 12 months (n=221 ICM; n=220 controls). The control group underwent evaluation and ECG monitoring at scheduled and unscheduled visits with the site investigator. The primary outcome was time to first AF detection of greater than 30 seconds within 6 months. The secondary outcome was time to first AF detection of greater than 30 seconds within 12 months.

By the 6-month follow-up, AF was detected at a significantly higher rate in the ICLR group compared to the control group (8.9% ICM vs. 1.4% control). The average time to detection of AF was 41 days in the ICM group and 32 days in the control group. Also of note, AF episodes were asymptomatic in 74% of the ICM patients. After 12 months, the ICM group still had a significantly higher detection of AF compared to the control group (12.4% vs. 2.0%). The average time to detection of AF was 84 days in the ICM group and 53 days in the control group. AF episodes were again asymptomatic in 79% of the ICM patients.

Strengths of this RCT include the randomized, controlled design, large sample size, control group comparison, low attrition rates, and the use of intention-to-treat analysis. Limitations include the lack of blinding and short follow-up period. The authors indicated another limitation is the inability to identify a causal pathway between the newly discovered atrial fibrillation and the initial stroke, because not all strokes are due to a cardiac arrhythmia. Also, the clinical significance of AF episode of brief duration is unknown. Ultimately, the authors concluded "ECG monitoring with an ICM was superior to conventional follow-up for detecting atrial fibrillation after cryptogenic stroke."[28]

Nonrandomized Studies

Ziegler and colleagues (2015) conducted a retrospective database review of 1,247 patients who received an implantable cardiac monitor (ICM) after cryptogenic stroke to evaluate the incidence and duration of atrial fibrillation (AF) episodes in a large, real-world population of patients.[29] All AF episodes collected within the first 6 months after implantation were independently reviewed by a blinded reviewer. AF

episode duration thresholds were assigned for 2 minutes, 6 minutes, 30 minutes, and 60 minutes. The average follow-up time was 6 months.

The ICM detected 1,521 AF episodes in 147 during the follow-up period. Single AF episodes were detected in 29% of patients, while multiple AF episodes were detected in 71% of patients. At 1 month follow-up, AF had been detected in 4.6%, 4.1%, 3.8%, and 3.5% of patients with AF episodes of 2, 6, 30, and 60 minute duration, respectively. At 6 month follow-up, AF had been detected in 12.2%, 10.4%, 9.1%, and 8.6% of patients with AF episodes of 2, 6, 30, and 60 minute duration, respectively. The average time to AF detection was 58 days.

Strengths of this study include the large sample size, data review by a blinded independent reviewer, and division of the duration of AF episodes. Significant limitations are seen in the retrospective design, short follow-up period, and lack of a comparison group. The authors concluded "the real-world incidence of AF among patients being monitored with an ICM after a cryptogenic stroke validates the findings of the CRYSTAL AF trial and suggests that continuous cardiac rhythm monitoring for periods longer than 30 days may be warranted in the evaluation of patients with cryptogenic stroke."[29]

Five additional nonrandomized studies (4 prospective and 1 retrospective cohort designs) were also identified that evaluated ICLRs for diagnosing atrial fibrillation after cryptogenic stroke.[30-34] All studies suggest that ICLRs are diagnostically efficacious for the identification of AF not diagnosed with standard cardiac monitoring after cryptogenic stroke.

ICLRs to Monitor Post-Catheter Ablation Patients

Systematic Reviews

No systematic reviews evaluating the efficacy of ICLRs to monitor post-catheter ablation patients were identified.

Nonrandomized studies

Several recent cohort studies (n=285) have evaluated the efficacy of continuous ILR monitor after surgical AF ablation.[35-38] Investigators reported equivalent or superior rates of detecting AF when compared with Holter monitoring or electrocardiography at up to 12-months follow-up. Study limitations included retrospective study designs, the high rate of false-positive readings and a limited number of AF events for review.

CLINICAL PRACTICE GUIDELINES

ICLRs to Diagnose Cardiac Arrhythmic Cause of Syncope

European Society of Cardiology (ESC)

In 2018, the ESC conducted an evidence review in support of its guidelines for the diagnosis and management of syncope. The ESC recommended that implantable loop recorders be considered in patients with recurrent episodes of unexplained syncope who are at low-risk of sudden cardiac death.[39]

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

The 2017 evidence-based ACC/AHA/HRS guidelines for managing patients with syncope recommended the use of implantable cardiac monitors for "recurrent, infrequent, unexplained syncope of suspected arrhythmic cause after a nondiagnostic initial workup."[40]

National Institute for Health and Care Excellence (NICE)

The 2014 evidence-based NICE clinical practice guideline recommended the following for people with a suspected cardiac arrhythmic cause of syncope:[41]

- "Offer an ambulatory ECG and do not offer a tilt test as a first-line investigation
    - The type of ambulatory ECG offered should be chosen on the basis of the person's history and frequency of syncope
        - For patients with syncope several times a week:
            - Offer Holter monitoring (up to 48 hours if necessary)
            - If no further syncope occurs during the Holter monitoring period, offer an external event recorder that provides continuous recording with the facility for the patient to indicate when a symptomatic event has occurred
        - For patients with syncope every 1-2 weeks:
            - Offer an external event recorder
            - If the patient experiences further syncope outside the period of external event recording, offer an implantable event recorder
        - For patients with syncope infrequently (less than once every 2 weeks):
            - Offer an implantable event recorder"[3]

American Heart Association/American College of Cardiology Foundation (AHA/ACCF)

The 2014 AHA/ACCF evidence-based statement regarding the evaluation of syncope recommended ICLR use for patients with infrequent syncope (less than once a month) to diagnose an ECG disturbance at the time of symptoms. The AHA/ACCF concluded that, "the use of ICLR over the course of a year in patients with unexplained syncope is more likely to identify the mechanism of syncope compared to a conventional approach that uses Holter or event monitors and electrophysiological testing and is cost effective."[42]

American College of Cardiology Foundation/American Heart Association/European Society of Cardiology (ACC/AHA/ESC)

The 2006 ACCF/AHA/ESC clinical practice guidelines regarding the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death, "recommended the use of ILR in patients with sporadic syncope symptoms of suspected arrhythmic origin that cannot be definitively established by conventional diagnostic techniques such as Holter recording and event monitors."[22]

ICLRs to Diagnose Atrial Fibrillation in Patients with Cryptogenic Stroke

National Institute for Health and Care Excellence (NICE)

The 2020 evidence-based NICE guidelines for Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke recommended Reveal LINQ as an option to help detect atrial fibrillation after cryptogenic stroke, including transient ischemic attacks if ECG monitoring has been done and cardiac arrhythmic case of stroke is suspected. They also state that there is not enough evidence to recommend routine adoption of BioMonitor 2-AF or Confirm Rx.[43]

American Academy of Neurology (AAN)

The 2014 evidence-based AAN guidelines for atrial fibrillation recommended "cardiac rhythm studies for prolonged periods (e.g., for 1 or more weeks) instead of shorter periods (e.g., 24 hours) in patients with cryptogenic stroke without known atrial fibrillation, to increase the yield of identification of patients with occult atrial fibrillation."[44]

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

The 2019 focused update of the 2014 evidence-based ACC/AHA/HRS guidelines for managing patients with atrial fibrillation gave a moderate recommendation that, "In patients with cryptogenic stroke (i.e., stroke of unknown cause) in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF." This recommendation was based on moderate evidence from a randomized trial.[45]

The 2013 evidence-based ACC/AHA/HRS guidelines for early management of patients with acute ischemic stroke stated "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."[46]

ICLRs to Monitor Post-Catheter Ablation Patients

Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), European Cardiac Arrhythmia Society (ECAS), Asia Pacific Heart Rhythm Society (APHRS) and Latin American Society of Cardiac Stimulation and Electrophysiology (SOLAECE)

In 2017, HRS/EHRA/ECAS/APHRS/SOLACE jointly conducted a systematic review in support of its guidance on catheter and surgical ablation of atrial fibrillation.[47] The joint guidance stated that implantable continuous monitors "hold promise for determination of [atrial fibrillation] long-term" but

noted “important limitations” in the devices such as “less than 100% specificity due to myopotentials, atrial and ventricular premature beats, as well as limited memory resulting in electrograms not being retrievable to verify the correct rhythm diagnosis.” [47] The body’s final recommendation “f[ell] short of continuous monitoring” but encouraged trials to “exceed this [minimal] standard where possible” (i.e. provide continuous monitoring). [47]

EVIDENCE SUMMARY

Implantable loop recorders have an established efficacy for diagnosing recurrent, unexplained syncope of suspected cardiac arrhythmic origin. The use of implantable loop recorders for the evaluation of suspected atrial fibrillation after cryptogenic stroke is increasing. The evidence suggests implantable loop recorders are efficacious for diagnosing atrial fibrillation in cryptogenic stroke patients and may be efficacious in monitoring atrial fibrillation in post-catheter ablation patients. However, further randomized controlled trials are needed to establish the superiority, clinical significance, and diagnostic accuracy of ICLRs compared to other cardiac event monitors.

BILLING GUIDELINES AND CODING

GENERAL

CPT codes 33285 and 33286 are for **implantation or removal** of the implantable loop recorder system.

CPT codes 93285 and 93291 are for **in person** device evaluation.

CPT codes 0650T and 93298 are for **remote** device evaluation.

HCPCS code C1764 is for the reporting of the **device** and should be used only by facilities (it should **not** be used on professional claims). HCPCS code E0616 may be used for the reporting of the device for in-office procedures.

CODES*		
CPT	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
	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
HCPCS	C1764	Event recorder, cardiac (implantable)
	E0616	Implantable cardiac event recorder with memory, activator and programmer
	~~G2066~~	**TERMED 12/31/2023** ~~Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results~~

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Agency for Healthcare Research and Quality (AHRQ). Remote Cardiac Monitoring: A Systematic Review. 2007(7/14/2023).https://www.ncbi.nlm.nih.gov/books/NBK299129/.
2. Hayes Inc. Implantable Cardiac Loop Recorders for Diagnosis and Management of Syncope in Adults. https://evidence.hayesinc.com/report/dir.implantable3263. Published 2020. Accessed 7/16/2024.
3. Hongo R, Goldschlager N. Evaluating patients with unexplained syncope. *Cardiovascular reviews & reports.* 2004;25(5):214-220
4. Kapoor WN, Karpf M, Wieand S, Peterson JR, Levey GS. A prospective evaluation and follow-up of patients with syncope. *N Engl J Med.* 1983;309(4):197-204
5. National Stroke Association. What is stroke? https://www.stroke.org/understand-stroke/what-is-stroke/. Accessed 7/16/2024.
6. Gladstone DJ, Spring M, Dorian P, et al. Atrial Fibrillation in Patients with Cryptogenic Stroke. *New England Journal of Medicine.* 2014;370(26):2467-2477.https://www.nejm.org/doi/full/10.1056/NEJMoa1311376.

7. American Heart Association Holter Monitor. https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/holter-monitor. Published 2015. Accessed 7/16/2024.
8. U.S. Food and Drug Administration. 510(k) premarket notification for Telemetry Patch System. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153473. Published 2016. Accessed 7/16/2024.
9. Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: A prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. *Journal of cardiovascular electrophysiology.* 2007;18(3):241-247.https://onlinelibrary.wiley.com/doi/full/10.1111/j.1540-8167.2006.00729.x.
10. National Heart Lung and Blood Institute. Catheter Ablation. https://www.nhlbi.nih.gov/health-topics/catheter-ablation. Accessed 7/16/2024.
11. U.S. Food and Drug Administration. BioMonitor2 (Biotronik). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K152995. Published 2017. Accessed 7/16/2024.
12. U.S. Food and Drug Administration. 510 (k) Premarket Notification. Biomonitor III, Biomonitor IIIm. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K201865. Accessed 7/16/2024.
13. U.S. Food and Drug Administration. Confirm Rx™ Insertable Cardiac Monitor (Abbott/St. Jude). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192593. Published 2017. Accessed 7/16/2024.
14. U.S. Food and Drug Administration. 510 (K) Premarket Notification. Confirm. Product code: MXC. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed 7/16/2024.
15. U.S. Food and Drug Administration. Reveal LINQ Insertable Cardiac Monitoring System (Medtronic). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162855. Published 2017. Accessed 7/16/2024.
16. U.S. Food and Drug Administration. Reveal XT Insertable Cardiac Monitor (Medtronic). https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103764.pdf. Published 2011. Accessed 7/16/2024.
17. Hayes Inc. Product Comparison: Implantable Cardiac Loop Recorders. https://evidence.hayesinc.com/report/crr.cardiacloop4645. Published 2019. Accessed 7/15/2021.
18. ECRI Institute. Confirm Rx Insertable Cardiac Monitor (Abbott Laboratories) for Diagnosing and Monitoring Cardiac Arrhythmia. https://www.ecri.org/components/ProductBriefs/Pages/25642.aspx. Published 2022. Accessed 7/16/2024.
19. ECRI Institute. Reveal LINQ II Insertable Cardiac Monitor (Medtronic plc.) for Patients at Risk of Cardiac Arrhythmia. https://www.ecri.org/components/ProductBriefs/Pages/26379.aspx. Published 2023. Accessed 7/16/2024.
20. Solbiati M, Casazza G, Dipaola F, et al. The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis. *Int J Cardiol.* 2017;231:170-176
21. Solbiati M, Costantino G, Casazza G, et al. Implantable loop recorder versus conventional diagnostic workup for unexplained recurrent syncope. *Cochrane Database Syst Rev.* 2016;4:Cd011637
22. Podoleanu C, DaCosta A, Defaye P, et al. Early use of an implantable loop recorder in syncope evaluation: a randomized study in the context of the French healthcare system (FRESH study). *Archives of cardiovascular diseases.* 2014;107(10):546-552

23. Krahn AD, Klein GJ, Yee R, Skanes AC. Randomized assessment of syncope trial: conventional diagnostic testing versus a prolonged monitoring strategy. *Circulation.* 2001;104(1):46-51
24. Farwell D, Freemantle N, Sulke A. Use of implantable loop recorders in the diagnosis and management of syncope. *European heart journal.* 2004;25(14):1257-1263
25. Edvardsson N, Frykman V, van Mechelen R, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry. *Europace.* 2010;13(2):262-269
26. Hayes Inc. Implantable Cardiac Loop Recorders for Detection of Atrial Fibrillation Following Cryptogenic Stroke. https://evidence.hayesinc.com/report/htb.implantable3080. Published 2019. Accessed 7/16/2024.
27. Sposato LA, Cipriano LE, Saposnik G, Vargas ER, Riccio PM, Hachinski V. Diagnosis of atrial fibrillation after stroke and transient ischaemic attack: a systematic review and meta-analysis. *The Lancet Neurology.* 2015;14(4):377-387.https://www.ncbi.nlm.nih.gov/pubmed/25748102.
28. Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med.* 2014;370(26):2478-2486
29. Ziegler PD, Rogers JD, Ferreira SW, et al. Real-World Experience with Insertable Cardiac Monitors to Find Atrial Fibrillation in Cryptogenic Stroke. *Cerebrovasc Dis.* 2015;40(3-4):175-181
30. Cotter PE, Martin PJ, Ring L, Warburton EA, Belham M, Pugh PJ. Incidence of atrial fibrillation detected by implantable loop recorders in unexplained stroke. *Neurology.* 2013;80(17):1546-1550
31. Christensen L, Krieger D, Højberg S, et al. Paroxysmal atrial fibrillation occurs often in cryptogenic ischaemic stroke. Final results from the SURPRISE study. *European journal of neurology.* 2014;21(6):884-889
32. Ritter MA, Kochhäuser S, Duning T, et al. Occult atrial fibrillation in cryptogenic stroke: detection by 7-day electrocardiogram versus implantable cardiac monitors. *Stroke.* 2013;44(5):1449-1452
33. Jorfida M, Antolini M, Cerrato E, et al. Cryptogenic ischemic stroke and prevalence of asymptomatic atrial fibrillation: a prospective study. *Journal of Cardiovascular Medicine.* 2016;17(12):863-869
34. Etgen T, Hochreiter M, Mundel M, Freudenberger T. Insertable cardiac event recorder in detection of atrial fibrillation after cryptogenic stroke: an audit report. *Stroke.* 2013;44(7):2007-2009
35. Pecha S, Aydin MA, Ahmadzade T, et al. Implantable loop recorder monitoring after concomitant surgical ablation for atrial fibrillation (AF): insights from more than 200 continuously monitored patients. *Heart Vessels.* 2016;31(8):1347-1353
36. Yang P, Pu L, Yang L, et al. Value of Implantable Loop Recorders in Monitoring Efficacy of Radiofrequency Catheter Ablation in Atrial Fibrillation. *Med Sci Monit.* 2016;22:2846-2851
37. Damiano RJ, Jr., Lawrance CP, Saint LL, et al. Detection of Atrial Fibrillation After Surgical Ablation: Conventional Versus Continuous Monitoring. *Ann Thorac Surg.* 2016;101(1):42-47; discussion 47-48
38. Cho HJ, Lee CH, Hwang J, et al. Accuracy of implantable loop recorders for detecting atrial tachyarrhythmias after atrial fibrillation catheter ablation. *International Journal of Arrhythmia.* 2020;21:1-7
39. Brignole M, Moya A, de Lange FJ, et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J.* 2018;39(21):1883-1948
40. Thungavelu Y, Wang W, Lin P, Chen T, Xu K. The clinical utility of vestibular autorotation test in patients with vestibular migraine. *Acta oto-laryngologica.* 2017;137(10):1046-1050

41. National Institute for Health and Care Excellence (NICE). Transient loss of consciousness ('blackouts') in over 16s. https://www.nice.org.uk/guidance/cg109. Published 2014. Accessed 7/16/2024.
42. Strickberger SA, Benson DW, Biaggioni I, et al. AHA/ACCF scientific statement on the evaluation of syncope: from the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation In Collaboration With the Heart Rhythm Society. *J Am Coll Cardiol.* 2006;47(2):473-484
43. National Institute for Health and Care Excellence (NICE). Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke. Diagnostic Guidance. Published 9/2/2020. . https://www.nice.org.uk/guidance/dg41/resources/implantable-cardiac-monitors-to-detect-atrial-fibrillation-after-cryptogenic-stroke-pdf-1053806149573. Accessed 7/16/2024.
44. American Academy of Neurology (AAN). Practice parameter: Stroke prevention in patients with nonvalvular atrial fibrillation. Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology.* 1998;51(3):671-673
45. January C, Wann, SL, Calkins, H, Chen, LY, Cigarroa, JE. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation. American College of Cardiology/American Heart Association. https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000665. Published 2019. Accessed 7/16/2024.
46. Jauch EC, Saver JL, Adams Jr HP, et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2013;44(3):870-947.https://www.ahajournals.org/doi/full/10.1161/STR.0b013e318284056a.
47. Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm.* 2017;14(10):e275-e444

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
7/2023	Changed denial for placement of implantable loop recorder from “investigational” to “not medically necessary.’
9/2023	Annual update. No changes to criteria.
9/2024	Annual update. No changes to criteria. Coding updates.
5/6/2025	Interim update. Policy to only applies to self-funded groups.