Cohere Medical Policy - Internal Loop Recorders

Clinical Guidelines for Medical Necessity Review

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Medical Necessity Criteria

Service: Internal Loop Recorders

Recommended Clinical Approach

Noninvasive ambulatory ECG monitoring is recommended first in patients with clinical scenarios such as symptoms suggestive of an arrhythmia, unexplained syncope, and/or cryptogenic stroke (i.e., stroke of unknown cause) with a concern for atrial fibrillation (AF). Poor diagnostic yield of noninvasive monitoring in the setting of continued symptoms may lead a physician to recommend an internal loop recorder (ILR) for their patient.[1-4] This procedure is performed by a cardiac electrophysiologist (specialized cardiologist) or trained cardiologist, and referral to a center that supports this service is required.

A single outpatient procedure is typical, and the implant's specific battery life determines the length of effectiveness. Periodic recordings are actively or passively transmitted for interpretation by a physician. Subsequent requests may be considered with documentation of device malfunction, an infection requiring removal of the initial device, or incorrect placement resulting in poor sensing, all with a documented continued need for monitoring.

Medical Necessity Criteria

Indications

- ➔ **Internal loop recorders (ILRs)** are considered appropriate if **ANY** of the following are **TRUE**:
  - ◆ **ALL** of the following:
    - No diagnostic conclusions were achieved with non-invasive monitoring methods, including **ANY** of the following[5-6]:
      - Holter monitor; **OR**
      - Extended-wear patch monitor (e.g., long-term continuous cardiac rhythm monitor); **OR**
      - External event monitor/loop recorder; **OR**
      - Mobile cardiac outpatient telemetry (MCOT); **AND**

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- The patient has no other implantable cardiac devices that can detect, record, and transmit data to a physician/cardiologist; **AND**
- The patient has **ANY** positive findings from the following list:
    - Acute (within the past six months), cryptogenic, ischemic stroke or transient ischemic attack (TIA)[7]; **OR**
    - Recurrent or unexplained infrequent syncope without documented orthostasis or autonomic dysfunction[8-9]; **OR**
    - Sporadic symptoms (for greater than or equal to 30 days) suspected to be related to ventricular arrhythmias[9]; **OR**
    - High-risk for arrhythmias due to structural or infiltrative heart disease (e.g., valvular aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease, dilated ischemic or nonischemic cardiomyopathy)[10-11]; **OR**
    - Palpitations that are persistent with symptoms that have not been captured by previous 14-30 day monitoring[6,12]; **OR**
    - A systemic thromboembolic event without a known history of AF and for which maximum sensitivity to detect AF is sought[13]; **OR**

◆ ILR replacement may be appropriate for **ANY** of the following (based upon the continued medical necessity for the device):

- End of battery life; **OR**
- Device malfunction.

Non-Indications

➔ **Internal loop recorders (ILRs)** may not be considered appropriate if **ANY** of the following is **TRUE**:

◆ Anticoagulation decisions based on atrial fibrillation/atrial flutter burden, including post-ablation, are not presently part of the ACC/HRS guidelines. ILR placement for this purpose is not an indication of its use[14]; **OR**

◆ The patient has an existing implanted cardiac device that can provide similar clinical information; **OR**

◆ In the course of the workup, including wearable telemetry, a diagnosis was achieved; **OR**

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- The patient has an active infection or an irreversible bleeding disorder; **OR**
- The patient has no positive clinical risk factors, presentation or history findings, or physical exam findings pertinent to remote ECG monitoring.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal of subcutaneous cardiac rhythm monitor

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Medical Evidence

According to Al-Khatib et al. (2017), in patients with sporadic symptoms, including syncope, implantable recorders are helpful in diagnosing serious tachyarrhythmias (including ventricular arrhythmia) and bradyarrhythmias. They are generally reserved for patients in whom other ambulatory monitoring is nonrevealing due to the infrequency of events. A 25% added yield in diagnosis has been described after an unrevealing external ambulatory monitor.[1]

The International Society for Holter and Noninvasive Electrocardiology (ISHNE) and Heart Rhythm Society (HRS) published a consensus statement on Ambulatory ECG (AECG) and External Cardiac Monitoring/Telemetry, which states the frequency of symptoms should dictate the type of recording: longer-term ECG monitoring is required for more infrequent events. Correlation (or lack of) of symptoms and arrhythmias is key. The most appropriate clinical workflow may include continuous (up to 7 days) AECG monitoring, which, if unsuccessful, is followed by intermittent external loop recording (long-term from weeks to months). Implantable loop recorders (ILR) may be necessary for patients remaining undiagnosed after prolonged noninvasive monitoring. The selection of appropriate technology has to take into account diagnostic power, monitoring, and risk stratification accuracy with consideration of cost-effectiveness, patient acceptance, degree of automaticity, and local availability and experience, as well as symptom frequency, the overall patient clinical condition, and the probability of life-threatening arrhythmia.[6]

Zangiabadian and colleagues (2024) published a systematic review of the predictors of pacemaker requirement in patients with an implantable loop recorder and unexplained syncope. The group concluded that heart conduction disorders, atrial arrhythmias, and underlying medical conditions were the main predictors of the need for pacemaker implantation following loop recorder installation in patients with unexplained syncope.[8]

Giancaterino et al. (2018) published a focused review that includes published reviews of major cardiovascular societies, including the AHA, ACC, and European Society of Cardiology (ESC). Guidelines emphasize the need for a

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comprehensive evaluation, including prolonged cardiac monitoring, to identify underlying AF that may have gone undetected.[12]

Passman (2021) examined literature and indications for incident-based use of direct oral anticoagulation based on the use of implantable devices such as internal loop recorders and consumer-grade devices. Such devices are stated to be used to identify prolonged AF episodes that contribute to stroke risk. Two single-arm trials are described that relate to this approach, including the REACT.COM (Rhythm Evaluation for Anticoagulation with Continuous Monitoring) and TACTIC-AF (Tailored Anticoagulation for Non-Continuous Atrial Fibrillation), both studies using continuous remote monitoring from internal loop recorders. REACT.COM revealed a 94% reduction in anticoagulation use with a one-hour AF duration threshold for the administration of oral anticoagulation, and TACTIC-AF revealed a 75% reduction over a 6-minute threshold. 96 patients with 112 patient-years of follow-up were included in the study with no strokes reported. The invasive nature and expense of cardiac monitoring using insertable monitoring technology were deemed a barrier to this approach.[13]

Diederichsen et al. (2022) conducted a post hoc analysis of the LOOP randomized clinical trial (RCT) for atrial fibrillation (AF). A total of 6004 individuals were included (4503 in the control group and 1501 in the internal loop recorders [ILR]) group. Overall, screening for ILRs did not show a significant decrease in ischemic or severe strokes compared to usual care. However, there may be a potential reduction in these outcomes among participants without a prior history of stroke.[15]

Sagris et al. (2022) published a review on embolic stroke of undetermined source (ESUS), a subtype of ischemic stroke. Long-term continuous monitoring with cardiac implantable electronic devices, especially in selected patients with ESUS, has shown promise in improving the detection of atrial fibrillation. An extended monitoring period increases the chances of capturing infrequent or asymptomatic atrial fibrillation episodes. Unlike traditional intermittent monitoring methods, such as Holter monitoring, long-term continuous monitoring allows for a more prolonged and comprehensive assessment of the patient's cardiac rhythm. Several studies report that long-term cardiac monitoring, facilitated by implantable devices, significantly enhances the likelihood of detecting atrial fibrillation in patients with ESUS.[16]

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Clinical Guideline Revision History/Information

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Version 2	12/29/2023	
Version 3	5/9/2024	
Version 4	7/19/2024	
Version 5	1/16/2025	• Annual review. • Added 2 indications on p. 5 for ILR replacement (end of battery life or device malfunction). • Literature review - Updated references- added reference for first non-indication bullet on p. 5

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