Internal Loop Recorders - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 3.0
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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Internal Loop Recorders (Single Service)

Literature review current through: 5/10/2025
Document last updated: 5/10/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Internal Loop Recorders

General Guidelines

- **Units, Frequency, & Duration:** When medical necessity criteria is met without exclusionary criteria, referral to a cardiac electrophysiologist (a specialized cardiologist) or trained cardiologist to consider the implantation of an internal loop recorder (ILR). A single outpatient procedure is anticipated. The implant duration can be up to four years, depending on the device's battery life. Periodic recordings are actively or passively transmitted for interpretation by a physician.
- **Criteria for Subsequent Requests:** Subsequent requests are only accepted with documentation of device malfunction, an infection that required removal of the initial device, or incorrect placement resulting in poor sensing, all with a documented continued need for monitoring.
- **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 cryogenic stroke (i.e., stroke of unknown cause) with a concern for atrial fibrillation. Poor diagnostic yield of noninvasive monitoring in the setting of continued symptoms may lead a physician to recommend an 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.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Internal loop recorders (ILRs)** are considered appropriate if **ALL** of the following are **TRUE**:

- ◆ No diagnostic conclusions were achieved with non-invasive monitoring methods, including **ANY** of the following[5]:
  - Holter monitor; **OR**
  - Extended-wear patch monitor (e.g., long-term continuous cardiac rhythm monitor); **OR**
  - External event monitor/loop recorder; **OR**
  - Mobile cardiac telemetry; **AND**

- 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 TIA[6]; **OR**
  - Recurrent or unexplained infrequent syncope without documented orthostasis or autonomic dysfunction [7]; **OR**
  - Sporadic symptoms (greater than or equal to 30 days) suspected to be related to ventricular arrhythmias; **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)[8-9]; **OR**
  - Palpitations that are persistent with symptoms that have not been captured by previous 14-30 day external monitors.[10-11]

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; **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**
- The patient has an active infection or an irreversible bleeding disorder; **OR**
- The patient does not have any 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 and programming of subcutaneous cardiac

	rhythm monitor
33286	Removal of subcutaneous cardiac rhythm monitor

Medical Evidence

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.[12]

Sagris et al. (2022) published a review on embolic stroke of undetermined source (ESUS), a subtype of ischemic stroke. Long-term continuous monitoring with CIEDs, 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.[13]

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 comprehensive evaluation, including prolonged cardiac monitoring, to identify underlying AF that may have gone undetected.[10]

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.[7]

National and Professional Organizations

The American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) published the following guidelines:

- *2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation* (2024)[6]

- *Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death* (2020)[1]
- *Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation* (2019)[4]
- *Evaluation and Management of Patients with Syncope* (2017)[2]

The American College of Cardiology (ACC) and American Heart Association (AHA) published the following guidelines:

- *Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy* (2020)[5]
- *Management of Adults with Congenital Heart Disease* (2018)[9]

The International Society for Holter and Noninvasive Electrocardiology (ISHNE) and Heart Rhythm Society (HRS) published a consensus statement on *Ambulatory ECG and External Cardiac Monitoring/Telemetry.*[11]

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Clinical Guideline Revision History/Information

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