Cohere Medicare Advantage Policy - Internal Loop Recorders

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: March 20, 2025

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy - Internal Loop Recorders

Date of last literature review: 03/17/2025
Document last updated: 03/18/2025
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Internal Loop Recorders

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for internal loop recorders.

Recommended Clinical Approach

Noninvasive ambulatory ECG monitoring is recommended first in patients with 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, also known as an insertable cardiac monitor) for their patient.[1–6] This procedure is performed by a cardiac electrophysiologist (a 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.[5,7] Periodic recordings are actively or passively transmitted for interpretation by a physician.[7] 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.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of internal loop recorders. This process helps to prevent both incorrect denials and inappropriate approvals of

medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Though this device requires a minimally invasive procedure, the risks may include pain, swelling, or bruising at the internal loop recorder (ILR) insertion site.[8]
- As with any implanted device, there is the potential for infection or an immune response to implantation, which may require device removal or antibiotic treatment.
- Shifts in ILR placement may lead to data collection failures, which may require the device to be repositioned or replaced and may warrant further evaluation in a hospital setting.[5]
- Additional implantation procedures may be required as the battery depletes, which may occur as early as 2-3 years.[5,7]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- ILRs provide continuous heart rhythm monitoring, improving diagnostic accuracy and increasing the likelihood of detecting arrhythmias before they lead to severe complications, such as stroke or cardiac arrest.[1–6]
- Wireless data transmission can guide faster treatment decisions and allow for early intervention.[5]
- The continuous functioning of ILRs provides long-term insight into cardiac health.[5]
- Accurately diagnosing or ruling out arrhythmias can reduce complications and adverse effects from unnecessary procedures, minimizing healthcare costs and patient burden.[9]
- Eliminating the need for external monitors can improve patient comfort and reduce lifestyle disruptions.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Internal loop recorders (ILRs)** are considered appropriate if **ANY** of the following are **TRUE**[1–6]:
  - ◆ **ALL** of the following:
    - No diagnostic conclusions were achieved after 30 days of non-invasive monitoring methods, including **ANY** of the following[10,11]:
      - Holter monitor; **OR**
      - Extended-wear patch monitor (e.g., long-term continuous cardiac rhythm monitor); **OR**
      - External event monitor / external loop recorder; **OR**
      - Mobile cardiac outpatient telemetry (MCOT); **AND**
    - The patient has no other implantable cardiac devices that can detect, record, and transmit data to a physician/cardiologist[8]; **AND**
    - The patient has **ANY** positive findings from the following list:
      - **ANY** of the following[12]:
        - Cryptogenic stroke; **OR**
        - A systemic thromboembolic event; **OR**
      - Recurrent and unexplained infrequent syncope without documented orthostatic hypotension or autonomic dysfunction[13,14]; **OR**
      - Sporadic symptoms (for greater than or equal to 30 days) reasonably suspected to be related to ventricular arrhythmias[14]; **OR**
      - High risk for arrhythmias due to documented structural or infiltrative heart disease (e.g., valvular aortic stenosis, hypertrophic cardiomyopathy,

cardiac sarcoidosis, complex congenital heart disease, dilated ischemic or nonischemic cardiomyopathy)[15]; **OR**

- ILR replacement may be appropriate for **ALL** of the following:
  - Ongoing or unresolved medical primary indication (as listed above); **AND**
  - **ANY** of the following:
    - End of battery life; **OR**
    - Device malfunction; **OR**
    - Incorrect placement of prior device leading to documented poor sensing.

Non-Indications

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

- ILR placement for the purpose of anticoagulation decisioning based on atrial fibrillation/atrial flutter burden, including post-ablation[15]; **OR**
- The patient has an untreated active infection[8]; **OR**
- The patient has an untreated, irreversible bleeding disorder.[8]

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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

According to an American College of Cardiology guideline by Al-Khatib et al (2017), in patients with sporadic symptoms, including syncope, implantable loop recorders (ILRs) can evaluate whether symptoms are related to or caused by ventricular arrhythmias. They are generally reserved for patients in whom other ambulatory monitoring is nonrevealing due to the infrequency of events.[4]

Giancaterino et al (2018) published a focused review that includes published reviews of major cardiovascular societies, including the American Heart Association (AHA), American College of Cardiology (ACC), and the European Society of Cardiology (ESC). Guidelines emphasize the need for a comprehensive evaluation of patients suspected to have an arrhythmia, including prolonged cardiac monitoring when appropriate, to identify underlying atrial fibrillation (AF) that may have gone undetected.[9]

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. ILRs 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.[11]

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.[13]

Diederichsen et al (2022) conducted a post hoc analysis of the LOOP randomized clinical trial (RCT) for atrial fibrillation (AF). Patients aged 70 years

or older with hypertension, diabetes, heart failure, or previous stroke but no history of AF were assigned to ILR or usual care to assess stroke characteristics. A total of 6004 individuals were included (4503 in the control group and 1501 in the ILR) group. Overall, screening for AF using ILRs did not show a significant decrease in ischemic or severe strokes compared with usual care; however, there may be a potential reduction in these outcomes among participants with no prior history of stroke.[16]

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.[17]

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Clinical Guideline Revision History/Information

Original Date: March 20, 2025		
Review History		