Clinical Policy: Implantable Loop Recorder

Reference Number: CP.MP.243 Coding Implications
Date of Last Revision: 04/22 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
An implantable loop recorder (ILR), also referred to as an insertable or implantable cardiac monitor (ICM), is a subcutaneous monitoring device for the detection of cardiac arrhythmias. It is implanted in the left pectoral region and is MRI-conditional. The device stores events when activated automatically according to programmed criteria or triggered by the patient. Depending on the manufacturer and the specific device, the battery longevity of ILR can range between two to four years.[7] Several ILRs have received FDA approval (e.g., Reveal LINQ, Reveal XT, Conrfirm Rx™ and BioMonitor).[2] This policy addresses the medical necessity criteria for an ILR/ICM.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that an implantable loop recorder/implantable cardiac monitor is considered **medically necessary** for any of the following indications:
- A. Suspected silent atrial fibrillation (AF) in the setting of cryptogenic stroke, when 30-day external ambulatory monitoring is inconclusive or contraindicated;
- B. Suspected or known ventricular arrhythmia when 30-day external ambulatory monitoring is inconclusive or contraindicated;
- C. History of structural or infiltrative heart disease (e.g., valvular aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease) and both of the following:
  1. High risk for arrhythmias (e.g., family history, symptoms, anatomy of structural heart disease);
  2. 30-day external ambulatory monitoring (e.g., external loop recorder) is inconclusive or contraindicated;
- D. Recurrent, unexplained syncope or presyncope and both of the following:
  1. Cardiac arrhythmia is suspected and external ambulatory monitoring (e.g., 30-day external loop recorder) is inconclusive or contraindicated;
  2. Symptoms are infrequent (e.g., less than once per month).

II. It is the policy of health plans affiliated with Centene Corporation that an implantable loop recorder/implantable cardiac monitor may be considered medically necessary following mandatory secondary medical director review when meeting all of the following:
- A. Presenting condition meets one of the following:
  1. Single, abrupt episode of unexplained syncope without prodrome (e.g., sense of warmth, dizziness, pallor, diaphoresis, abdominal pain, changes in vision, or nausea) resulting in injury/trauma and
  2. Significant, recurrent and unexplained palpitations;
- B. Serious cardiac arrhythmia is suspected;

C. 30-day external ambulatory monitoring (e.g., external loop recorder) is inconclusive or contraindicated;
D. Symptoms are infrequent (e.g., less than once per month).

Background

Ambulatory electrocardiography (ECG) is the most frequently employed technology in the evaluation of symptoms suggestive of a cardiac arrhythmia or conduction abnormality.[7] Accurate and timely characterization of arrhythmias is crucial to direct therapies that can have an important impact on diagnosis, prognosis or patient symptom status. The cardiac rhythm information derived from the large variety of ambulatory ECG recording systems often leads to patient-specific medical and interventional management.[5]

Frequency of symptoms should dictate the type of recording; longer term ECG monitoring is required for more infrequent events. Correlation (or lack) of symptoms and arrhythmias is key. The most appropriate clinical workflow may include continuous (short-term- 24 hours to up to 7 days) ambulatory ECG monitoring, which if unsuccessful is followed by intermittent external loop recording (long-term-from weeks to months). For those patients remaining undiagnosed after prolonged, noninvasive monitoring, ILR may be necessary.[5]

Syncope is a symptom that can be due to various causes, ranging from benign to life-threatening conditions- cardiovascular causes are common. The presence of significant cardiovascular diseases, often associated with the cardiovascular causes of syncope, portends a poor prognosis. As such, cardiovascular testing can be a critical element in the evaluation and management of selected patients with syncope.[1] Those at high risk for concerning arrhythmias, known to be associated with the development of ventricular tachycardia, include:

- Palpitations that are sustained, poorly tolerated, or associated with syncope or presyncope;
- Organic heart disease (e.g., scar formation from myocardial infarction, dilated cardiomyopathy of any cause, clinically significant valvular heart disease, hypertrophic cardiomyopathy);
- A personal or family history of arrhythmia, syncope, sudden death, cardiomyopathy, or long QT syndrome.[11]

An implantable loop recorder (ILR) or insertable or implantable cardiac monitor (ICM) is commonly utilized in the evaluation of palpitations or syncope of undetermined etiology, particularly when symptoms are infrequent (e.g., less than once per month) and/or other ambulatory monitoring (e.g., Holter and event monitoring) has been unrevealing or inconclusive.[8, 9]

Several randomized controlled trials (RCTs) and observational studies have demonstrated a benefit of the ILR/ICM in establishing a diagnosis in syncope of unclear etiology. In a prospective study of 60 patients with syncope of unknown origin, the diagnosis (primarily bradyarrhythmia) was made in 55% with ICM, compared with a 19% diagnostic yield with conventional testing (external loop recorder, followed by tilt table testing and electrophysiological study [EPS]).[13] These findings are consistent with other studies, which

generally have shown that patients who underwent the ILR/ICM approach experienced higher rates of diagnosis than those of patients who underwent the conventional approach.[14-16]

The cause of ischemic stroke remains unknown in 20 to 40% of patients, leading to a diagnosis of cryptogenic stroke. Prolonged ECG monitoring with an ICM in these patients (age >40 years) has the advantage of increasing the likelihood of detecting silent atrial fibrillation (AF) that would escape detection with short-term monitoring.[2] A recent RCT established the superiority of an implantable cardiac monitor over conventional monitoring for detecting silent AF, a finding with major clinical ramifications for these patients.[17]

Palpitations are very common, and although usually benign, occasionally are a manifestation of a concerning or potentially life-threatening arrhythmia. The cause of palpitations can be determined in the majority of patients. Common causes include cardiac disorders, medical conditions including endocrine and metabolic abnormalities, psychiatric disorders, medication effects, and drug or other substance use effects.[12] ICMs may have a role for palpitations that are sustained, poorly tolerated, or associated with syncope or presyncope, when other methods have failed to document the cause of palpitations and a concerning or potentially life-threatening arrhythmia is suspected.

American College of Cardiology/American Heart Association Task Force/ Heart Rhythm Society
Syncope

- The choice of a specific cardiac monitor should be determined on the basis of the frequency and nature of syncope events. (Class I)[1]
- To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful.(Class IIa)[1]

Atrial Fibrillation

- 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. (Class IIa recommendation)[2]

Ventricular Arrhythmias and Prevention of Sudden Cardiac Death

- Electrocardiographic monitoring is useful to evaluate whether symptoms, including palpitations, presyncope, or syncope, are caused by ventricular arrhythmias. (Class I recommendation)[6]
- In patients with sporadic symptoms (including syncope) suspected to be related to ventricular arrhythmia, an ICM can be useful. (Class II a recommendation)[6]

American Heart Association/American Stroke Association
In patients with cryptogenic stroke who do not have a contraindication to anticoagulation, long-term rhythm monitoring with mobile cardiac outpatient telemetry, ILR or other approach is reasonable to detect intermittent AF. (Class 2a recommendation)[19]

European Society of Cardiology
Syncope

- ILR is indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria, and a high likelihood of recurrence within the battery life of the device. (Class I recommendation)[7]
- ILR is indicated in patients with high-risk criteria, in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment, and who do not have conventional indications for primary prevention ICD or pacemaker indication. (Class I recommendation)[7]
- ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes. (Class IIa recommendation)[7]

Atrial Fibrillation

In selected stroke patients without previously known AF, additional ECG monitoring using long-term non-invasive ECG monitors or ICMs should be considered to detect AF. (Class IIa recommendation)[20]

Coding Implications

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CPT® Codes	Description
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 Codes	Description
C1764	Event recorder, cardiac (implantable)

HCPCS Codes	Description
E0616	Implantable cardiac event recorder with memory, activator, and programmer
G2066	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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
I47.2	Ventricular tachycardia
I49.9	Cardiac arrhythmia, unspecified
I63.9	Cerebral infarction, unspecified
R00.2	Palpitations
R06.02	Shortness of breath
R07.9	Chest pain, unspecified
R42	Dizziness and giddiness
R55	Syncope and collapse
R94.31	Abnormal electrocardiogram [ECG] [EKG]
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.