

Clinical Policy: Implantable Loop Recorder

Reference Number: CP.MP.243

Date of Last Revision: 11/24

[Coding Implications](#)

[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 ILRs can range between two to four years.⁷ Several ILRs have received approval from the United States Food and Drug Administration (FDA) (e.g., Reveal LINQ, Reveal XT, Confirm 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 (ILR)/implantable cardiac monitor (ICM) 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;
 2. Significant, recurrent and unexplained palpitations;
 - B. Serious cardiac arrhythmia is suspected;

CLINICAL POLICY

Implantable Loop Recorder

- 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).

III. It is the policy of health plans affiliated with Centene Corporation that the replacement of an implantable loop recorder/implantable cardiac monitor may be considered medically necessary when meeting all of the above criteria and the existing monitor is no longer functioning and is outside its warranty (e.g., device is nearing the end of its battery life).

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, and 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 seven 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, an implantable loop recorder (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 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

CLINICAL POLICY

Implantable Loop Recorder

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 based on 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 |

CLINICAL POLICY
Implantable Loop Recorder

| HCPCS Codes | Description |
|-------------|---|
| C1764 | Event recorder, cardiac (implantable) |
| 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 |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---------------|---------------|
| Policy developed and reviewed by specialist. | 04/22 | 04/22 |
| Annual review. Minor rewording in Description and Criteria sections with no impact on criteria. Background updated with no impact on criteria. ICD-10 codes removed. References reviewed and updated. | 04/23 | 04/23 |
| Annual review. Added criteria III. to include requests for replacement implantable loop recorders. Background updated with no impact to criteria. References reviewed and updated. Reviewed by external specialist. | 01/24 | 01/24 |
| Annual review. Background updated with no impact to criteria. References reviewed and updated. | 11/24 | 11/24 |

References

1. Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients with Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society [published correction appears in *Circulation*. 2017 Oct 17;136(16):e271 to e272]. *Circulation*. 2017;136(5):e60 to e122. doi:10.1161/CIR.0000000000000499
2. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons [published correction appears in *Circulation*. 2019 Aug 6;140(6):e285]. *Circulation*. 2019;140(2):e125 to e151. doi:10.1161/CIR.0000000000000665
3. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2020;142(25):e533 to e557. doi:10.1161/CIR.0000000000000938
4. Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society [published correction appears in

- Circulation. 2019 Aug 20;140(8):e506-e508]. *Circulation*. 2019;140(8):e382 to e482. doi:10.1161/CIR.0000000000000628
5. Steinberg JS, Varma N, Cygankiewicz I, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry [published correction appears in *Heart Rhythm*. 2018 Mar 28;:] [published correction appears in *Heart Rhythm*. 2018 Aug;15(8):1276]. *Heart Rhythm*. 2017;14(7):e55 to e96. doi:10.1016/j.hrthm.2017.03.038
 6. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society [published correction appears in *J Am Coll Cardiol*. 2018 Oct 2;72(14):1760]. *J Am Coll Cardiol*. 2018;72(14):e91 to e220. doi:10.1016/j.jacc.2017.10.054
 7. Brignole M, Moya A, de Lange FJ, et al. 2018 ESC Guidelines for the diagnosis and management of syncope [2018 ESC Guidelines for the diagnosis and management of syncope]. *Kardiol Pol*. 2018;76(8):1119 to 1198. doi:10.5603/KP.2018.0161
 8. Madias C. Ambulatory ECG monitoring. UpToDate. www.uptodate.com. Published November 29, 2022. Accessed November 1, 2024.
 9. Benditt D. Reflex syncope in adults and adolescents: Clinical presentation and diagnostic evaluation. UpToDate. www.uptodate.com. Published April 18, 2022. Accessed November 1, 2024.
 10. Benditt D. Syncope in adults: Epidemiology, pathogenesis, and etiologies. UpToDate. www.uptodate.com. Published August 25, 2022. Accessed November 1, 2024.
 11. Kumar K. Atrial fibrillation: Overview and management of new-onset atrial fibrillation. UpToDate. www.uptodate.com. Published March 22, 2023. Accessed November 1, 2024.
 12. Zimetbaum PJ. Evaluation of palpitations in adults. UpToDate. www.uptodate.com. Published September 23, 2021. Accessed November 1, 2024.
 13. 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 to 51. doi:10.1161/01.cir.104.1.46
 14. Farwell DJ, Freemantle N, Sulke N. The clinical impact of implantable loop recorders in patients with syncope. *Eur Heart J*. 2006;27(3):351 to 356. doi:10.1093/eurheartj/ehi602
 15. 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). *Arch Cardiovasc Dis*. 2014;107(10):546 to 552. doi:10.1016/j.acvd.2014.05.009
 16. Sulke N, Sugihara C, Hong P, Patel N, Freemantle N. The benefit of a remotely monitored implantable loop recorder as a first line investigation in unexplained syncope: the EaSyAS II trial. *Europace*. 2016;18(6):912 to 918. doi:10.1093/europace/euv228
 17. Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. 2014;370(26):2478 to 2486. doi:10.1056/NEJMoa1313600
 18. Buck BH, Hill MD, Quinn FR, et al. Effect of Implantable vs Prolonged External Electrocardiographic Monitoring on Atrial Fibrillation Detection in Patients with Ischemic Stroke: The PER DIEM Randomized Clinical Trial. *JAMA*. 2021;325(21):2160 to 2168. doi:10.1001/jama.2021.6128
 19. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack: A Guideline from the

CLINICAL POLICY**Implantable Loop Recorder**

- American Heart Association/American Stroke Association [published correction appears in *Stroke*. 2021 Jul;52(7):e483-e484]. *Stroke*. 2021;52(7):e364 to e467. doi:10.1161/STR.0000000000000375
20. Hindricks G, Potpara T, Dagres N, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC [published correction appears in *Eur Heart J*. 2021 Feb 1;42(5):507] [published correction appears in *Eur Heart J*. 2021 Feb 1;42(5):546 to 547] [published correction appears in *Eur Heart J*. 2021 Oct 21;42(40):4194]. *Eur Heart J*. 2021;42(5):373 to 498. doi:10.1093/eurheartj/ehaa612
 21. Bisignani A, De Bonis S, Mancuso L, Ceravolo G, Bisignani G. Implantable loop recorder in clinical practice. *J Arrhythm*. 2018;35(1):25 to 32. Published 2018 Nov 20. doi:10.1002/joa3.12142
 22. Vilcant V, Kousa O, Hai O. Implantable Loop Recorder. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing LLC; 2022. <https://www.ncbi.nlm.nih.gov/books/NBK470398/>. Accessed November 1, 2024.
 23. Assaf A, Sakhi R, Michels M, et al. Implantable loop recorders in patients with heart disease: comparison between patients with and without syncope. *Open Heart*. 2021;8(2):e001748. doi:10.1136/openhrt-2021-001748
 24. Radovanović NN, Pavlović SU, Kirčanski B, et al. Diagnostic value of implantable loop recorders in patients with unexplained syncope or palpitations. *Ann Noninvasive Electrocardiol*. 2021;26(5):e12864. doi:10.1111/anec.12864

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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CLINICAL POLICY

Implantable Loop Recorder

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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.

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