HEALTHHELP®
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2025 Implantable Loop Recorder

Cardiology

CARD-CILR-BCBSSC

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BlueCross and BlueShield of South Carolina

IMPORTANT
To locate the appropriate updated Clinical Policies for BlueCross and BlueShield of South Carolina, please go to: https://www.southcarolinablues.com/web/public/brands/sc/providers/policies-and-authorizations/medical-policies/

TIP
A National Coverage Determination (NCD) or Local Coverage Determination (LCD) may be necessary to review for Medicare participants. Please go to: https://www.cms.gov/medicare-coverage-database/search.aspx for the latest coverage determination information.

Internal Use Only

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Implantable Loop Recorder (ILR)

NCD 20.15
See also, **NCD 20.15**: Electrocardiographic Services at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.

Preamble: Pediatric Cardiology Preamble

HealthHelp's clinical guidelines for the Cardiology program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

Implantable Loop Recorder (ILR) Contraindications and Exclusions

An (ILR) is contraindicated or excluded when the documentation demonstrates **ANY** of the following: [2]

1. Bleeding disorder that is uncontrolled.
2. Infection that is active (local or systemic).
3. Remote monitoring is inaccessible.

Implantable Loop Recorder (ILR) Guideline

An implantable loop recorder is considered medically appropriate when there is **NO** other concurrent cardiac monitoring and the documentation demonstrates **ANY** of the following:

1. Atrial fibrillation (A-fib) and **ALL** of the following:
    a. Ablation, post-procedure to monitor for dysrhythmia. [6] [4]
    b. Arrhythmia is **NOT** detected on inpatient telemetry or long-term continuous ambulatory electrocardiogram (ECG) monitor, and further evaluation is warranted for treatment planning. [7]
2. Palpitations evaluation, when arrhythmia is suspected and **ALL** of the following: [11]
    a. Evaluation (eg, ambulatory external monitoring, ECG, exercise stress testing, history and physical exam) is non-diagnostic or indeterminate. [1]
    b. Long-term continuous ambulatory ECG monitor (up to 60 days) is non-diagnostic or indeterminate.
    c. Symptoms are infrequent (less than several episodes per month).
3. Stroke, cryptogenic or transient ischemic attack (TIA) is recent (within 90 days), with suspected paroxysmal atrial fibrillation and **ALL** of the following:
    a. Arrhythmia is **NOT** detected on inpatient telemetry or long-term continuous ambulatory ECG monitor, and further evaluation is warranted for formal diagnosis and treatment. [12]
    b. Atrial fibrillation (subclinical) is suspected. [6] [8]
    c. CHA_2DS_2-Vasc score is 2 or higher [6]
    d. Stroke etiology is indeterminate on initial evaluation (eg, ambulatory external monitoring, carotid artery imaging, computed tomography [CT] or magnetic resonance imaging [MRI] brain, ECG, echocardiography [transesophageal, transthoracic]). [12]

e. **NO** contraindication exists to oral anticoagulation (OAC). [6]

4. Syncope is unexplained, when **ANY** of the following:
   a. Arrhythmic etiology is suspected and **ALL** of the following:
      i. Cardiac arrhythmia is **NOT** detected on trial of external ambulatory cardiac event monitoring for at least 30 days. [1]
      ii. Syncope etiology is unknown after evaluation (eg, ambulatory external monitoring, echocardiogram [Echo], electrophysiological study [EPS], history and physical exam, tilt-table test), evaluation is nondiagnostic or indeterminate. [8] [5]
      iii. Syncope evaluation (eg, ambulatory external monitoring, echocardiogram [Echo], electrophysiological study [EPS], history and physical exam, tilt-table test) did **NOT** lead to specific treatment indications for primary prevention implantable cardioverter-defibrillator (ICD) or a pacemaker. [8] [5]
      iv. Syncope is infrequent (less than several episodes per month) and recurrent. [8] [10]
   b. Syncope is high-risk (eg, in sitting position, while driving) and long-term continuous ambulatory ECG monitor (for a minimum of 30 days) was non-diagnostic[1]. [11] [8]

Implantable Loop Recorder (ILR) Removal

Removal of an implantable loop recorder (ILR) is considered medically appropriate when the documentation demonstrates **ANY** of the following: [3]

1. Device failure
2. Infection at the implant site [9] [2]
3. Internal battery is at the end of life. [9]
4. Monitoring is completed.

[1]High-risk syncope occurs with new onset chest discomfort, abdominal pain or headache; during exertion or when supine; sudden onset of palpitations immediately followed by syncope; or the presence of structural heart disease (especially left ventricular [LV] dysfunction and/or history of myocardial infarction [MI]) or abnormal ECG with no warning symptoms or short prodrome (less than 10 seconds); family history of sudden cardiac death or syncope while in a sitting position. [8]

Implantable Loop Recorder (ILR) Procedure Codes

Table 1. Implantable Loop Recorder (ILR) Associated Procedure Codes

CODE	DESCRIPTION
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal, subcutaneous cardiac rhythm monitor
C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator, and programmer

Implantable Loop Recorder (ILR) Summary of Changes

Implantable Loop Recorder clinical guidelines from 2024 to 2025 had the following version changes:

- Citations updated per the evidence.
- Evidence reviewed and indications remained the same.
- Pediatric preamble added

Implantable Loop Recorder (ILR) Definitions

Ablation is a procedure performed in a cardiac catheterization laboratory during an electrophysiology study (EPS) for the purpose of destroying myocardial tissue by delivery of radio-frequency energy, electrical or cryo-energy. The procedure is used to correct heart arrhythmias.
Anticoagulation is a substance that is used to prevent and treat blood clots in blood vessels and the heart.
Arrhythmia is an irregular or abnormal heart rhythm. Arrhythmia refers to any change from the normal sequence of electrical impulses of the heart, causing abnormal heart rhythms. The electrical impulses may happen too fast, too slowly or erratically – causing the heart to beat too fast, too slowly or erratically.
Atrial fibrillation (AF) is a cardiac rhythm disorder characterized by uncontrolled atrial activation without effective atrial contraction. On the electrocardiogram (ECG), P waves are absent. AF is characterized by rapid oscillations or fibrillatory waves that vary in amplitude, shape and timing associated with an irregular ventricular response.

- **Paroxysmal AF** terminates spontaneously or with intervention within 7 days of onset. Episodes typically convert back to sinus rhythm within 48 hours.
- **Persistent AF** is continuous AF sustained beyond 7 days.

Bleeding disorder is a condition in which there is a problem with the body's blood clotting process.

Brugada syndrome is a rare inherited cardiovascular disorder characterized by disturbances affecting the electrical system of the heart. The main symptom is irregular heartbeat and, without treatment, may result in sudden death.

Cardiac event monitor is a device used to record heart rate and rhythm for long-term monitoring of symptoms that occur less than daily. The time frame for use can be up to 30 days.

Carotid artery imaging is a non-invasive diagnostic procedure that uses sound waves to create images of the carotid arteries in the neck. The medical term for this procedure is a carotid artery duplex scan.

CHA_2DS_2-VASc Score is the expansion of CHADS2 (**C**ongestive heart failure, **H**ypertension, **A**ge ≥75, **D**iabetes, **S**troke) to include three additional independent risk factors: **V**ascular disease, age between 65-74, and female sex. This score provides a better discriminated stroke risk in nonvalvular atrial fibrillation (AF) subjects with a baseline CHADS2 score of 0 to 1.

Computed tomography (CT) is an imaging test that uses X-rays to computer analysis to generate cross sectional images of the internal structures of the body that can be displayed in multiple planes.

Cryptogenic stroke is a brain infarction not clearly attributable to a definite cardioembolism, large artery atherosclerosis or small artery disease despite extensive investigation.

Electrocardiogram (ECG or EKG) is a test that measures and records the electrical activity of the heart. The ECG electrical activity is divided into the P wave, PR interval, QRS complex, QT interval, ST segment, T wave and U wave. An ECG is useful in establishing many cardiac diagnoses.

Electrophysiology study (EPS) is a minimally invasive procedure that evaluates the electrical conduction system of the heart to assess the electrical activity, conduction pathways and abnormal heart beats. During an EPS, the sinus rhythm, and supraventricular and ventricular arrhythmias of baseline cardiac intervals, are recorded. The study is indicated to investigate the cause, location of origin and best treatment (drug therapy, catheter ablation or implantable cardioverter-defibrillator), for various abnormal heart rhythms.

Exercise electrocardiogram (ECG) test is a test to check how well the heart handles work, and checks for reduced blood flow in the arteries that supply the heart.

Implantable loop recorder (ILR) is a subcutaneous, single-lead electrocardiographic (ECG) monitoring device used for future treatment planning.

Indeterminate findings are inconclusive or insufficient for treatment planning.

Left ventricular dysfunction is the inability of the ventricle to fill to a normal end-diastolic volume, both during exercise as well as at rest, while left atrial pressure does not exceed 12 mm Hg.

Long-term continuous ambulatory electrocardiogram (ECG) monitor are non-invasive diagnostic tools used to evaluate frequent, unexplained symptoms suggestive of cardiac arrhythmias, and are able to record for more than 48 hours.

Magnetic resonance imaging (MRI) is a non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves.
Palpitations are rapid or irregular heartbeats that a person can feel.
Paroxysmal is a sudden attack or increase of symptoms of a disease (such as pain, coughing, shaking, etc.) that often occurs again and again.
Prodrome describes early signs or symptoms of an illness or health problem that appear before the major signs or symptoms start.
Subclinical is a condition, disease or injury without signs and symptoms that are detectable by physical examination or other medical testing and are usually incidentally found.
Sudden cardiac death (SCD) occurs when the heart malfunctions and unexpectedly and suddenly stops beating due to electrical impulse problems. Myocardial infarction increases the risk of SCD. Conditions associated with SCD include arrhythmogenic right ventricular dysplasia (ARVD), long QT syndrome, hypertrophic obstructive cardiomyopathy (HOCM) or Brugada syndrome.
Syncope is a transient loss of consciousness and postural tone (ability to maintain or change position intentionally) due to insufficient cerebral perfusion. The loss of consciousness is associated with prompt recovery, not needing resuscitation.
Telemetry is a portable device that continuously monitors patient electrocardiogram (ECG), respiratory rate and/or oxygen saturations while automatically transmitting information to a central monitor.
Tilt-table test is a non-invasive diagnostic test that attempts to determine the cause of syncope by creating changes in posture from lying to standing.
Transesophageal echocardiogram (TEE) is a test done by inserting a probe with a transducer down the esophagus, which provides a clearer image of the heart because the sound waves do not have to pass through skin, muscle or bone tissue.
Transient ischemic attack (TIA) is a brief interruption of the blood supply to the brain that causes a temporary impairment of vision, speech or movement. The episode usually lasts for just a few moments but may be a warning sign of a full scale stroke.
Transthoracic echocardiogram (TTE) involves placing a device called a transducer on the chest. The device sends ultrasound waves through the chest wall to the heart. As the ultrasound waves bounce off the structures of the heart, a computer converts them into pictures on the computer screen. A TTE uses sound waves to create pictures of the heart chambers, valves, walls and the blood vessels attached to your heart. The test is also called echocardiography or diagnostic cardiac ultrasound.

Implantable Loop Recorder (ILR) References

[1] Al-Khatib, S.M., Stevenson, W.G., . . . Page, R.L. (2018). 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Circulation, 138*(13), e272–e391.

[2] Beinart, S.C. (2020). Implantable Loop Recorder (Insertable Cardiac Monitor). *Medscape*. Retrieved: March 2024. https://emedicine.medscape.com/article/1920236-overview

[3] British Heart Rhythm Society. (2020). Standards for insertion, follow up and explant of implantable loop recorders [ILRs] by non-medical staff. *British Heart Rhythm Society*. Retrieved: March, 2024. https://bhrs.com/wp-content/uploads/2020/10/BHRS-ILR-Standards-for-Insertion-revised.pdf

[4] Calkins, H., Hindricks, G., . . . Yamane, T. (2017). HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm, 14*(10), e275-e444.

[5] Curtis, A.B. & Tomaselli, G.F. (2022). Approach to the Patient with Cardiac Arrhythmias. P. Libby & R.O. Bonow (Eds.). *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine* (12), (pp. 1145-1162). Philadelphia, PA: Elsevier.

[6] Hindricks, G., Potpara, T., . . . Watkins, C.L. (2020). 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). *European Heart Journal, 42*(5), 373-498.

[7] Mittal. S. (2021). Implantable Loop Recorders - Syncope, Cryptogenic Stroke, Atrial Fibrillation. *Cardiac Electrophysiology Clinics, 13*(3), 439-447.

[8] Nielsen, J.C., Lin, Y.J., . . . Leclercq, C. (2020). EHRA/HRS/APHRS/LAHRS Expert Consensus on Risk Assessment in Cardiac Arrhythmias: Use the Right Tool for the Right Outcome, in the Right Population. *Heart Rhythm, 17*(9), e269-e316.

[9] Scrocco, C., Ben-Haim, Y., . . . Behr, E.R. (2021). Role of subcutaneous implantable loop recorder for the diagnosis of arrhythmias in Brugada syndrome: A United Kingdom single-center experience. *Heart Rhythm, 19*(1), 70-78.

[10] Shen, W.K., Sheldon, R.S., . . . Yancy, C.W. (2017). 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope. *Journal of the American College of Cardiology, 70*(5), e39–e110.

[11] Steinberg, J.S., Varma, N., . . . Piotrowicz, R. (2017). ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. *Heart Rhythm, 14*(7), e55-e96.

[12] (2021). Understanding Diagnosis and Treatment of Cryptogenic Stroke. *American Stroke Association A division of the American Heart Association*. Retrieved: March 2024. https://www.stroke.org/en/professionals/stroke-resource-library/post-stroke-care/cryptogenic-stroke-initiative

Disclaimer section

Purpose

The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.

Clinician Review

These clinical guidelines neither preempt clinical judgment of trained professionals nor advise anyone on how to practice medicine. Healthcare professionals using these clinical guidelines are responsible for all clinical decisions based on their assessment. All Clinical Reviewers are instructed to apply clinical indications based on individual patient assessment and documentation, within the scope of their clinical license.

Payment

The use of these clinical guidelines does not provide authorization, certification, explanation of benefits, or guarantee of payment; nor do the guidelines substitute for, or constitute, medical advice. Federal and State law, as well as member benefit contract language (including definitions and specific contract provisions/exclusions) take precedence over clinical guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and payment are the responsibility of the health plan. Nothing contained within this document can be interpreted to mean otherwise.

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National and Local Coverage Determination (NCD and LCD)

NOTICE
To ensure appropriate review occurs to the most current NCD and/or LCD, always defer to https://www.cms.gov/medicare-coverage-database/search.aspx.

Background

National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) are payment policy documents outlined by the Centers for Medicare and Medicaid Services (CMS) and the government's delegated Medicare Audit Contractors (MACs) that operate regionally in jurisdictions.
CMS introduced variation between different jurisdictions/Medicare Audit Contractors (MACs) and their associated covered code lists with the transition to ICD 10. The variation resulted in jurisdictions independently defining how codes are applied for exclusions, limitations, groupings, ranges, etc. for the medical necessity indications outlined in the NCD and LCD. Due to this variation, there is an inconsistent use/application of codes and coverage determinations across the United States between the different MACs.
In addition, **WITHOUT** notice, CMS can change the codes that indicate medical necessity and the format of the coverage determinations/associated documents (eg, Articles). This is an additional challenge for organizations to keep up with ongoing, unplanned changes in covered codes and medical necessity indications.

Medical Necessity Codes

Due to the variation in code application between jurisdictions/MACs and that updates can happen without notification, HealthHelp is not able to guarantee full accuracy of the codes listed for any Coverage Determination, and advises that prior to use, the associated Coverage Determination Articles are reviewed to ensure applicability to HealthHelp's programs and any associated NCDs and LCDs.

For Internal Use Only:

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