Loop Recorder (Cardiac Event Monitor), Implantable

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Link to Codes

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Clinical Indications

- Implantable loop recorder (cardiac event monitor) may be indicated for **1 or more** of the following(1)(2)(3)(4)(5):
  - Atrial fibrillation, known or suspected, as indicated by **ALL** of the following(10)(11)(12)(13)(14)(15)(16):N
    - Cryptogenic stroke, transient ischemic attack, or systemic thromboembolic event(26)(29)
    - Holter monitor or other noninvasive cardiac monitor contraindicated, or results unrevealing or indeterminate
    - Recurrent paroxysmal atrial fibrillation suspected, and test results may impact patient management
  - History of structural or infiltrative heart disease (eg, valvular aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease) and **ALL** of the following(30)(31)(32)(33):N
    - Holter monitor or other noninvasive cardiac monitor contraindicated, or results unrevealing or indeterminate
    - Patient at high risk for arrhythmias (eg, family history, symptoms, anatomy of structural heart disease)(35)
  - Rhythm surveillance in patient with history of atrial fibrillation-induced cardiomyopathy and **ALL** of the following(28):N

- Left ventricular function improved after rhythm control treatment
- Patient treated with ablation or maintained on antiarrhythmic medication

- Syncope, as indicated by **ALL** of the following(6)(23)(36)(37)(38)(39):
  - Cardiac etiology of syncope, suspected, as indicated by **1 or more** of the following(6)(36)(37):
    - ECG results abnormal (eg, cardiac rhythm other than normal sinus, significant conduction abnormalities, Brugada ECG pattern, long QT syndrome)(4)(55)
    - Family history of sudden death
    - History of chronic heart failure
    - History of pulmonary hypertension
    - History of structural heart disease (eg, valvular aortic stenosis, congenital heart disease, hypertrophic cardiomyopathy) or severe coronary heart disease(4)(35)
    - Recent history of palpitations, abnormal heart rate, or symptomatic arrhythmia(4)(23)(56)
    - Use of medication known to cause malignant arrhythmias (eg, antiarrhythmics, antidepressants, antihistamines)(57)
  - Recurrent or unexplained syncope[A]
  - Test results negative or inconclusive, as indicated by **1 or more** of the following(58)(59):
    - Ambulatory cardiovascular telemetry monitor
    - Electrophysiologic study
    - Holter monitor
    - Non-implantable (external) loop recorder
    - Patch-type cardiac monitor
    - Tilt table testing
- Ventricular arrhythmia, known or suspected(55)(57)

Alternatives

- Alternatives include(1)(6)(10)(12)(60):
  - Ambulatory cardiovascular telemetry monitor(62)
  - Holter monitor. See Holter Monitor AC for further information.
  - Loop recorder, non-implantable. See Loop Recorder (Cardiac Event Monitor), Non-Implantable AC for further information.
  - Patch-type cardiac monitor. See Patch-Type Cardiac Monitor AC for further information.

Evidence Summary

Background

Implantable loop recorders are devices that are implanted subcutaneously, usually in the pectoral region under local anesthesia; they continuously monitor the heart's rhythm for prolonged periods of time. Batteries last up to 3 years. In contrast to non-implantable (external) loop recorders, implantable loop recorders do not require the use of surface electrodes, thereby avoiding a potential adherence issue. Implantable loop recorders record arrhythmic events in response to patient activation or automatic detection of arrhythmias based on predesignated criteria. Data may be monitored continuously at a central station, downloaded at the office, or transmitted by telephone.(1)(6)(7) **(EG 2)** Studies are evaluating remote monitoring capabilities of implantable cardiac monitors; thus far, evidence is unclear as to whether the addition of remote monitoring affects clinical outcomes.(8)(9) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 46 published peer reviewed articles, 13 specialty society or other evidence-based guidelines, and 2 book sections.

For atrial fibrillation, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A systematic review and meta-analysis of 50 studies (with a total of 11,658 patients) found that extended ambulatory cardiac monitoring, as with non-implantable and implantable loop recorders, detected poststroke atrial fibrillation in 16.9% of patients.(17) **(EG 1)** An open-label randomized trial of 300 patients with recent ischemic stroke and no known atrial fibrillation compared electrocardiographic monitoring with either an implantable loop recorder or an external loop recorder and found, at 12-month follow-up, that implantable monitoring was associated with a higher rate of newly detected atrial fibrillation compared with external monitoring.(18) **(EG 1)** A randomized controlled trial of 441 patients with cryptogenic stroke found that, at 6 months, atrial fibrillation had been detected in 8.9% of patients with an implantable cardiac event monitor; atrial fibrillation was detected in 1.4% of patients who underwent conventional follow-up with at least 24 hours of noninvasive electrocardiographic monitoring.(19) **(EG 1)** A subanalysis of this trial found that long-term continuous monitoring with implantable cardiac event monitors was superior in detecting atrial fibrillation as compared with all intermittent monitoring strategies that were evaluated, including 24-hour, 48-hour, and 7-day Holter monitors.(20) **(EG 1)** A prospective observational study of 271 patients with a history of cryptogenic stroke monitored patients with an implantable loop recorder and detected atrial fibrillation (at least one episode of 2 minutes or longer) in 18.0% and 28.2% of patients at a follow-up of 18 months and 36 months, respectively; the median time from enrollment to atrial fibrillation detection was 7.9 months.(21) **(EG 2)** A retrospective observational study of 647 patients concluded that detection of recurrent atrial fibrillation was superior with continuous monitoring (such as that provided by implantable loop recorders) as compared with intermittent monitoring.(22) **(EG 2)** Review articles note that implantable cardiac devices, such as implantable loop recorders, are useful for detecting silent paroxysmal atrial fibrillation in patients with cryptogenic stroke and, in addition to improving risk stratification for stroke,(11)(23) may play a role in monitoring therapies for rate and rhythm control.(24) **(EG 2)** A review article notes that implantable loop recorders have higher sensitivity for the accurate detection of atrial fibrillation than do non-implantable loop recorders, with rates of atrial fibrillation detection of 12% to 15% at 1 year and 30% after 3 years of use.(25) **(EG 2)** Specialty society guidelines for the secondary prevention of ischemic stroke recommend long-term rhythm monitoring, such as with an implantable loop recorder, to detect intermittent atrial fibrillation in patients with cryptogenic stroke who do not have a contraindication to anticoagulation.(16)(26)(27) **(EG 2)** A specialty society guideline states that cardiac event recorders, including implantable loop recorders, are indicated as confirmatory testing in the diagnosis of atrial fibrillation. This guideline also states that implantable loop recorders can be useful to assess the adequacy of rate or rhythm control in known atrial fibrillation.(28) **(EG 2)**

For a history of structural or infiltrative heart disease, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Implantable loop recorders can detect arrhythmias in patients at risk, with implications for therapy.(30) **(EG 2)** Specialty society guidelines note the value of cardiac event monitoring for detecting arrhythmias in adult and pediatric patients with congenital heart disease.(31)(32)(34) **(EG 2)**

For rhythm surveillance in patients with a history of atrial fibrillation-induced cardiomyopathy, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline recommends long-term surveillance with intermittent rhythm surveillance, such as can be provided by an implantable cardiac monitor, to detect recurrent atrial fibrillation in patients with atrial fibrillation-induced cardiomyopathy who have improved left ventricular function after rhythm control.(28) **(EG 2)**

For syncope, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** The value of implantable loop recorders in detecting serious tachyarrhythmias and bradyarrhythmias has been clearly demonstrated, and trials in selected populations (in which neurally mediated syncope had already been excluded) have found higher diagnostic yield (up to 64.5%) as compared with conventional testing with an external loop recorder, tilt table testing, or electrophysiologic testing.(40)(41)(42)(43) **(EG 2)** In a study of 50 patients with infrequent (fewer than one episode per month), sustained (greater than 1 minute) palpitations, only 10% of patients obtained a diagnosis with 24-hour Holter monitoring, non-implantable loop recorder, and electrophysiologic study, as compared with 38% who obtained a diagnosis with implantable loop recording.(44) **(EG 1)** Prospective observational studies of patients with unexplained syncope have found implantable loop recorders to have a diagnostic yield of 51% to 78%.(45)(46)(47) **(EG 2)** A randomized multicenter prospective trial of 78 patients with syncope and

bundle branch block found that the use of an implantable loop recorder revealed significantly more relevant arrhythmias, even in those with a negative electrophysiologic study, than did conventional follow-up without an implantable loop recorder.(48) **(EG 1)** Studies in children with syncope or palpitations have confirmed the utility of implantable loop recorders, with documented diagnostic yield up to 64% and demonstrated ability to activate the recorder at the time of a symptomatic event.(49)(50)(51)(52) **(EG 2)** A specialty society guideline notes that implantable loop recorders may be useful in children with syncope when extensive investigation by other noninvasive means has been nondiagnostic, particularly in pediatric patients with established congenital heart disease and new paroxysmal symptoms.(53) **(EG 2)** Implantable loop recorders may help to exclude other diagnoses that are often confused with syncope, such as epilepsy. Reports have described patients with convulsive episodes treated with antiseizure medications who were diagnosed with serious arrhythmias, such as complete heart block and asystole, after placement of implantable loop recorders.(54) **(EG 2)** A specialty society guideline notes that, although the diagnostic yield of a non-implantable (external) loop recorder may be lower than that of the implantable loop recorder, a noninvasive strategy should be considered in the initial evaluation of a patient with syncope suspected to be of arrhythmic etiology.(6) **(EG 2)** A specialty society guideline recommends the use of an implantable loop recorder early in the evaluation of patients with recurrent syncope of uncertain origin who have a high likelihood of recurrent syncope within the battery life of the device.(37) **(EG 2)**

For ventricular arrhythmia, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society guideline states that cardiac monitoring by implantable loop recorder can be useful in patients with sporadic symptoms, including syncope, suspected to be related to ventricular arrhythmia.(60) **(EG 2)** A specialty society guideline recommends that cardiac monitoring by implantable loop recorder be considered in cases of known ventricular arrhythmia when identification of further, potentially longer arrhythmias would change patient management.(57) **(EG 2)** Review articles note that implantable loop recorders can be helpful as an alternative to an implantable cardioverter-defibrillator in the setting of Brugada syndrome to evaluate ventricular arrhythmias as a cause of unexplained syncope in patients at low risk of sudden cardiac death, though long-term follow-up evidence is lacking.(5)(55)(61) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(63); 42 CFR 422.101(64)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(65); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(66); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(67)

Medicare Coverage Determinations: Medicare Coverage Database(68)

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Footnotes

[A] Syncope is defined as a transient loss of consciousness and postural tone due to inadequate cerebral perfusion, with prompt recovery without resuscitative measures.(6) [A in Context Link 1]

Codes

CPT®: 0650T, 33285, 33286, 93268, 93270, 93271, 93272, 93285, 93291, 93298

HCPCS: C1764, C1833, E0616

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