Clinical Policy Title: Implantable cardiac loop recorders

Clinical Policy Number: 04.01.05

Effective Date: April 1, 2015
Initial Review Date: November 19, 2014
Most Recent Review Date: November 16, 2016
Next Review Date: November 2017

Policy contains:
- Implantable cardiac loop recorders.
- Cryptogenic stroke assessment.
- Syncope evaluation.
- Cardiac arrhythmia.

Related policies:

CP# 04.01.01 Real-time outpatient cardiac monitoring
CP# 18.01.02 Telehealth

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of implantable cardiac loop recorders (ILRs) to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Intermittent cardiac arrhythmia is considered a potential cause for syncope, pre-syncope, stroke or cryptogenic stroke, or symptomatic palpitations, and either:
  - The member has had prior evaluation through a 24-hour Holter monitor and/or a 30-day event recorder without a diagnostic etiology determined.
  - Symptoms occur less frequently than 30 days apart or are not likely to be captured on less-invasive monitoring systems.

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of ILRs are not medically necessary, including for a concern about a lethal arrhythmia.

**Alternative covered services:**

- Evaluation by primary care or specialty physician within the Prestige Health Choice network.
- Standard diagnostic studies, such as Holter monitors, event recordings, electrocardiogram (ECG) and imaging studies.

**Background**

Cardiac dysrhythmias have been implicated in symptom complexes including syncope, seizures, stroke, and sudden death. Frequently, identification of episodic rhythm disturbances is problematic (Mofrad, 2012). Clinicians often adopt a stepwise approach to searching for possible disorders of cardiac rhythm by initially obtaining a standard ECG prior to arranging for a 24-hour Holter monitor to analyze cardiac beat patterns over a one-day period (Epstein, 2013). A longer study may be performed over several days to a month using an externally placed event monitor in which the patient initiates recording of a segment of rhythm, when the patient experiences unusual symptoms that may be indicators of arrhythmia. However, patients may not have symptoms with potentially significant arrhythmias.

ILRs have been proposed as a diagnostic option for identifying cardiac dysrhythmias (Mofrad, 2012). The ILR is implanted subcutaneously, requiring the procedure to be performed in an ambulatory surgical site under aseptic conditions. The ILR provides continuous loop storage of cardiac rhythm when the heart rate exceeds the upper or lower parameters set by the physician. As with an event recorder, the patient may be able to initiate recordings based on symptoms. More recent events replace older ones in memory, and printouts from the recorder are displayed in an ECG format. The battery life of two to three years allows for a much longer evaluation period than with a 24-hour or 30-day recording device.

**Searches**

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).
We conducted searches on October 18, 2016. Search terms were: "arrhythmias, cardiac/diagnosis" [Mesh], "electrocardiography, ambulatory" [Mesh], “implantable cardiac loop recorders,” and “implantable event monitors.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

ILRs may aid in the diagnosis of arrhythmic causes of syncope and stroke when less-invasive procedures have been unrevealing. Since existing studies have not demonstrated the superiority of wearable external cardiac monitors to ILRs, the physician and patient frequently determine the appropriate choice. Inability to wear the external device for the majority of the day is frequently the rationale for choice of an ILR. The ILR is generally better tolerated when monitoring is required over a long time frame.

The evaluation of patients with syncope, pre-syncope, seizures, or palpitations may take a number of clinical directions based on history, physical examination, and pretest probabilities. Zimetbaum and Goldman (2010) have laid out a strategy that allows for using short-term or longer-term monitoring of cardiac rhythms. Unfortunately, determination of the arrhythmic cause of stroke through ILR evaluation has a low positive yield.

Guidelines by the American College of Cardiology (ACC), American Heart Association (AHA), and the European Society of Cardiologists (ESC) recommend a stepwise evaluation using standard ECG, and then progressing through 30-day event monitoring and/or echocardiography before consideration of mobile cardiac outpatient telemetry (MCOT) or ILR (Crawford, 1999; ESC, 2009). The decision for the latter is generally based on the anticipated frequency of events. If symptoms felt attributable to a cardiac cause are more likely to occur greater than 30 days apart, the ILR may be preferred. However, if they are more frequent, the use of MCOT would be less invasive and have a higher likelihood of positive identification of the arrhythmia. The ESC further suggested that initiating ILR earlier in the evaluation of unexplained syncope may be more cost-effective, based on pooled data from observational studies showing a correlation between syncope and ECG at the time of the recorded event (ESC, 2009).

**Policy updates:**
We identified two additional systematic reviews for this policy (Glotzer, 2015; Sposato, 2015). The new findings suggest continuous arrhythmia monitoring for extended durations, including ILR, as part of a stepped diagnostic approach is significantly more effective than short-term monitoring for identifying silent atrial fibrillation (AF) in patients who recently suffered a stroke or transient ischemic attack (TIA). These results do not change previous findings; therefore, no change to the policy is warranted.

In 2016, we identified one systematic review (Canadian Agency for Drugs and Technologies in Health [CADTH], 2016); one systematic review with a meta-analysis (Afzal, 2015); one Cochrane review (Solbiati, 2016); and two evidence-based guidelines (Culebras, 2014; January, 2014). Prolonged rhythm monitoring in outpatient populations with recent stroke improved detection of AF, regardless of device; although monitoring with ILRs had the greatest diagnostic yield, there was only modest improvement associated with monitoring that exceeded 30 days (CADTH, 2016; Afzal, 2015). Both guidelines support the use of longer cardiac surveillance (without specifying the device) in the outpatient setting to identify intermittent, occult AF that is undetectable by other means, as part of the comprehensive evaluation of patients at high risk of AF to improve patient outcomes and prevent recurrent strokes (Culebras, 2014; January, 2014).

In persons with unexplained recurrent syncope, a new Cochrane review of randomized controlled trials (RCTs) found that an ILR-based diagnostic strategy increased the rate of etiologic diagnosis, but the evidence supporting improvement in patient-centered outcomes such as mortality, adverse events, quality of life, and syncope relapses was inconclusive (Solbiati, 2016). These new findings conflict with the ESC guideline recommendations, which were based on observational studies, that favored initiating an ILF-based diagnostic strategy earlier in the work-up (ESC, 2009). According to the ACC Foundation/AHA/Heart Rhythm Society (HRS) guideline, electrophysiological studies (without specifying devices) are integral to selecting persons with cardiac arrhythmia, including unexplained syncope, who might benefit from pacemaker therapy (Epstein, 2013).

These results suggest ILRs may be most effective when other electrocardiographic monitoring has failed to record a correlation between symptoms and a documented arrhythmia, or when symptoms are infrequent and unlikely to be captured by less invasive monitoring. Therefore, the policy was changed to reflect these findings.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>CADTH (2016)</td>
<td>Key points:</td>
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<td></td>
<td>• Systematic review of 36 studies, including 10 studies of ILR (one RCT, seven prospective cohorts, and two retrospective cohorts). All but one study of ILR included patients with embolic stroke of undetermined source or TIA.</td>
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<td></td>
<td>• Overall quality: low with a high risk of bias.</td>
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<td>Clinical</td>
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<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<td>----------</td>
<td>----------------------------------</td>
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<tr>
<td>(ambulatory holter monitors, external loop recorders, MCOT, and ILRs).</td>
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  - Stroke recurrence, stroke mortality, or all-cause mortality not reported in studies.  
  - There was a substantial increase in diagnostic yield of AF post-discharge when monitoring for greater than 24 hours, regardless of device.  
  - Patients monitored with ILRs (ranging between 105 days and 569 days) demonstrated greater numerical diagnostic yields than monitoring for shorter durations with other devices.  
  - While monitoring patients > 30 days demonstrated greater diagnostic yield versus < 30 days, improvements were modest and may be achieved by changes in monitoring technologies alone. |
| Solbiati (2016) Cochrane review ILR versus conventional diagnostic workup for unexplained recurrent syncope. | **Key points:**  
  - Systematic review and meta-analysis of four RCTs (579 total participants).  
  - Overall quality: very low to moderate with high risk of bias.  
  - All-cause mortality: relative risk (RR) 0.97, 95% confidence interval [CI] 0.41 to 2.30 (two RCTs, 255 participants).  
  - No data on short-term mortality.  
  - Adverse events (no meta-analysis): no complications observed (two RCTs).  
  - Higher rates of diagnosis favor ILR: RR 0.61, 95% CI 0.54 to 0.68 (four RCTs, 579 participants).  
  - Insufficient data to comment on the quality of life, cost analysis, ability to prevent recurrences, and impact patient care. |
| Afzal (2015) Outpatient cardiac rhythm monitoring in cryptogenic stroke (CS) | **Key points:**  
  - Systematic review and meta-analysis of three RCTs and 13 observational studies: seven studies of ILR (774 patients) with a median duration of 365 days (range 50 to 569 days), 10 studies of wearable recorders (996 patients) for a median duration of 21 days (range four to 30 days), and one study of seven days of wearable recorders followed by implantation of ILR (included in both groups).  
  - Overall detection of AF with outpatient monitoring: 17.6% (range 12.5% to 22.7%).  
  - Increased detection of AF with prolonged monitoring compared to routine outpatient follow-up (pooled odds ratio [OR] 4.54, 95% CI 2.92 to 7.06; P < 0.00001) (three RCTs).  
  - Significantly higher AF detection with ILR compared to wearable devices (OR 23.3%, 95% CI 13.83 to 32.29 versus OR 13.6%, 95% CI 7.91 to 19.32; P < 0.05). |
| Glotzer (2015) Cardiac monitoring in patients with CS. | **Key points:**  
  - Summary of four single-arm studies and two RCTs comparing standard of care monitoring to invasive and noninvasive monitoring strategies.  
  - Overall quality: low to moderate. Variable study populations, designs, and definitions of outcomes.  
  - Detection rates of AF among CS patients are a function of the length of monitoring, the definition of AF, the duration that constitutes an episode, the interval from the index stroke to the start of monitoring, and patient selection. |
<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Results from RCTs suggest long-term continuous monitoring is significantly more effective than standard of care monitoring for identifying AF in patients who recently suffered a CS. Prolonged ambulatory cardiac rhythm monitoring after a CS or TIA in patients who would be candidates for oral anticoagulants should be considered.</td>
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<tr>
<td>Sposato (2015)</td>
<td><strong>Key points:</strong></td>
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<td>Diagnosis of AF after stroke and TIA.</td>
<td>- Systematic review/meta-analysis of 50 studies (11,658 patients) of cardiac monitoring methods.</td>
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<td>- Stratified into four sequential phases of screening: phase 1 (emergency room) admission ECG; phase 2 (in hospital) serial ECG, continuous inpatient ECG monitoring, continuous inpatient cardiac telemetry, and in-hospital Holter monitoring; phase 3 (first ambulatory period) ambulatory Holter; and phase 4 (second ambulatory period) MCOT, external loop recording and ILR.</td>
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<td>- Summary proportion of patients diagnosed with post-stroke AF: phase 1, 7.7% (95% confidence interval [CI] 5.0 – 10.8); phase 2, 5.1% (95% CI 3.8 – 6.5); phase 3, 10.7% (95% CI 5.6 – 17.2); and phase 4, 16.9% (95% CI 13.0 – 21.2).</td>
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<td>- The overall AF detection yield after all phases of sequential cardiac monitoring 23.7% (95% CI 17.2 – 31.0).</td>
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<td>Culebras (2014) for the American Academy of Neurology</td>
<td><strong>Key points:</strong></td>
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<td>Guideline for the prevention of stroke in persons with nonvalvular AF (NVAF).</td>
<td>- Clinicians might obtain outpatient cardiac rhythm studies in patients with cryptogenic stroke to identify patients with occult NVAF (Level C).</td>
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<td>- Clinicians should routinely offer anticoagulation to patients with NVAF and a history of TIA/stroke (Level B).</td>
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<td>January (2014) for the AHA/ACC/HRS Guideline for the management of patients with AF.</td>
<td><strong>Key points:</strong></td>
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<td>- In the initial clinical evaluation of patients with AF, Holter or event monitoring may be indicated if the diagnosis of type of arrhythmia is in question or for evaluating rate control.</td>
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<td>Kishore (2014)</td>
<td><strong>Key points:</strong></td>
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<td>Detection of AF after ischemic stroke or TIA.</td>
<td>- Meta-analysis of 32 studies.</td>
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<td>- Overall detection rate of any AF was 11.5%.</td>
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<td>- Some patient populations selected based on stroke pathogenesis, age, or pre-screening for AF.</td>
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<td>- Detection rates were higher in selected (13.4%; 95% CI 9.0% – 18.4%) than in unselected patients (6.2%; 95% CI 4.4% – 8.3%).</td>
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<td>- There was substantial heterogeneity even within specified subgroups.</td>
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<td>Epstein (2013)</td>
<td><strong>Key points:</strong></td>
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Citation | Content, Methods, Recommendations
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ACCF/AHA/HRS Guideline for device-based therapy of cardiac rhythm abnormalities. | - Permanent pacemaker implantation is reasonable for syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered or provoked in electrophysiological studies.
- Cardiac electrophysiological studies are indicated to identify cardiac arrhythmia and guide treatment planning, including candidacy for pacemaker therapy.
- Guidelines make no specific recommendation for device type.

Bloch (2010) Cardiac Arrhythmias and Risk Stratification After Acute Myocardial Infarction (CARISMA) study. | **Key points:**
- Long-term cardiac arrhythmias recorded by an ILR in patients with left ventricular ejection fraction (LVEF) ≤ 40% after myocardial infarction.
- Clinically significant bradyarrhythmias and tachyarrhythmias were documented in a substantial proportion of patients with depressed LVEF after acute myocardial infarction. Intermittent high-degree atrioventricular block was associated with a very high risk of cardiac death.

Zimetbaum (2010) Ambulatory arrhythmia monitoring. | **Key points:**
- Intermittent AF is a key indication for ILR because of its threefold higher risk of stroke.
- Meta-analysis of other studies shows the diagnostic yield of ILR between 7% and 90%.
- Compared to external monitoring, ILR should be reserved for patients with infrequent symptoms.

ESC (2009) Guidelines for diagnosis and management of syncope. | **Key points:**
- ILR is indicated in:
  - An early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria listed in Table 11 of the original guideline and a high likelihood of recurrence within battery longevity of the device — evidence level I B.
  - High-risk patients in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment — evidence level I B.
- ILR should be considered to assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain reflex syncope presenting with frequent or traumatic syncopal episodes — evidence level IIa B.
- External loop recorders should be considered in patients who have an inter-symptom interval ≤ four weeks — evidence level IIa B.

**Glossary**

**Atrial fibrillation** — The most common cardiac arrhythmia, in which the atria beat rapidly and irregularly, so that the lower chambers of the heart also beat irregularly. This can increase the risk of stroke or heart failure.
**Cardiac arrhythmia** — An irregular heartbeat. This may be the result of structural or physiologic abnormalities and, based on the etiology and/or type of rhythm disturbance, may range from being clinically insignificant to symptomatic or fatal.

**Cryptogenic stroke** — A stroke of unknown origin.

**Holter monitor** — A portable device used for 24- to 48-hour continuous monitoring of heart rhythm.

**Implantable (cardiac) loop recorder (ILR)** — A heart monitoring device implanted for up to three years to accurately monitor the heart rhythm. Information from the device is downloaded through external interrogation or over a landline. The device is the size of a USB thumb drive.

**Seizures** — Any of a group of syndromes characterized by paroxysmal transient disturbances of brain function that may be manifested as episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or perturbation of the autonomic nervous system; symptoms are due to disturbance of the electrical activity of the brain.

**Syncope** — Temporary loss of consciousness and posture.

**Telemetry** — The recording and transmission of data regarding the electrical activity and functioning of the heart; an MCOT transmits this data to a 24-hour, professionally staffed monitoring center.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Parry SW, Matthews IG. Implantable loop recorders in the investigation of unexplained syncope: a state of the art review. *Heart (British Cardiac Society).* 2010; 96(20): 1611 – 1616.


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>33282</td>
<td>Implantation of patient-activated cardiac event recorder</td>
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<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>I48.0</td>
<td>Paroxysmal atrial fibrillation</td>
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<td>I48.1</td>
<td>Persistent atrial fibrillation</td>
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<tr>
<td>I48.2</td>
<td>Chronic atrial fibrillation</td>
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<tr>
<td>I48.3</td>
<td>Typical atrial flutter</td>
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<td>I48.4</td>
<td>Atypical atrial flutter</td>
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<td>I48.91</td>
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<td>I49.9</td>
<td>Cardiac arrhythmia, unspecified</td>
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<td>R00.2</td>
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<td>R55</td>
<td>Syncope and collapse</td>
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