POWERFUL CARDIAC MONITORING

Indications, Guidelines, Clinical Evidence, and Coding Overview for Diagnosing Suspected Arrhythmias and Monitoring Known A-Fib

Reveal LINQ™
Insertable Cardiac Monitoring System
Indications
The Reveal LINQ™ Insertable cardiac monitor (ICM) is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and has been cleared by the FDA for use in two groups of patients:
- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been specifically tested for pediatric use.

Clinical Evidence
Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF) Study
In 441 patients randomized either to Reveal ICM or standard medical care and followed for 36 months:
- Continuous monitoring detected over seven times more patients with AF at the 12-month end point
- When followed for three years, AF was detected at a rate of 30% in the ICM arm vs. 3% in the standard follow-up arm
- Short-term monitoring is not sufficient as the median time to AF detection over 12 months of follow-up was 84 days
- 97% of patients who had AF detected were prescribed OAC
- 88% of patients with AF would have been missed if only monitored for 30 days

Place of Reveal™ ICM in the Care Pathway and Treatment of Patients with Unexplained Recurrent Syncope (PICTURE) Study
In 570 patients implanted with a Reveal ICM and followed for a year:
- Overall, patients had seen an average of three different specialists for management of their syncope
- The median number of tests performed per patient in the total study population was 13 (inter-quartile range 9 – 20)
- Most patients (70%) had been hospitalized at least once for syncope
  – One third (36%) of these patients had experienced significant trauma in association with a syncopal episode

Randomized Assessment of Syncope Trial (RAST)
- 60 unexplained syncope patients randomized to conventional testing or a Reveal ILR
- The diagnostic yield was 43% for ILR vs. 20% for conventional, and the cost/diagnosis of ILR was 26% less than conventional testing

Recurrent Unexplained Palpitations (RUP) Study
- 50 patients with infrequent sustained palpitations were randomized either to a conventional external monitoring strategy or to a Reveal ILR
- Diagnosis was obtained in 21% of the conventional group and 73% of the ILR group, with significantly lower cost per diagnosis in the ILR group ($4,584 vs. $10,152)
Guidelines

ESC Guidelines: Management of Atrial Fibrillation (2016)\(^6\)
Class IIa
In stroke patients, additional ECG monitoring by long-term noninvasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.

AHA/ACC/HRS Guidelines for the Management of Syncope (2017)\(^7\)
Class I, Class IIa
- If the initial evaluation is unclear and a cardiac cause is suspected, cardiac monitoring is a Class I recommendation.
- The IIa recommendation for ICM is supported by clinical evidence and randomized controlled trials.

AHA/ACC Scientific Statement on the Evaluation of Syncope\(^8\)
“This approach (ILRs) is more likely to identify the mechanism of syncope than is a conventional approach that uses Holter or event monitors and EP testing, and is cost-effective.”

HRS Consensus Statement on Catheter and Surgical Ablation of AF (2012)\(^9\)
Patients in whom discontinuation of systemic anticoagulation is being considered should consider undergoing continuous ECG monitoring to screen for asymptomatic AF/AFL/AT.

Coding distinctions
- ICM: Used to monitor physiologic heart data, generally in patient with heart failure.
- ILR (Reveal LINQ): is used to monitor recorded heart rhythm data to help diagnosis and monitor A-Fib.

Reveal-related procedure coding

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This information is intended only for educational use and does not replace seeking coding advice from the payer and/or your coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for their interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.
**Diagnosis Coding for Suspected Arrhythmias**

Diagnosis coding should reflect the highest level of known specificity. The appropriate code(s) must be used to identify diagnoses, symptoms, conditions, problems, complaints, or other reason(s) for the clinical encounter. If an arrhythmia is suspected, but not yet confirmed, the diagnosis code(s) should reflect the symptoms, signs, or risk factors which have led the physician to suspect an arrhythmia. If the patient has several symptoms, signs, and/or risk factors, multiple diagnosis codes may be used to document the patient’s clinical condition.

### Syncope/Pre-Syncope

**Signs and Symptoms**

- **R00.2** Palpitations
- **R42** Dizziness and giddiness [light-headedness]
- **R55** Syncope and collapse [pre-syncope]
- **R56.9** Unspecified convulsions [seizures NOS]
- **R94.31** Abnormal electrocardiogram [ECG] [EKG]

### A-Fib Monitoring

- **I47.0-I49.9** Paroxysmal tachycardia, atrial fibrillation and flutter, and other cardiac arrhythmias *(include secondary diagnosis for long term anticoagulation therapy, Z79.01 if appropriate)*

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**Classifying Cryptogenic Stroke**

Cryptogenic stroke is an ischemic stroke which, despite extensive work-up, cannot be attributed to underlying cardioembolism, large artery atherosclerosis, small artery occlusion, or other known cause.

The immediate culprit in acute ischemic stroke is embolism, thrombosis, or narrowing/stenosis of a precerebral or cerebral vessel. After acute stroke treatment, work-up focuses on determining the underlying disorder that caused the embolism, thrombosis, or narrowing/stenosis. In most cases, this is ultimately identified as embolism thrown off by the heart, atherosclerotic thrombosis, or small vessel occlusion due, for example, to external compression. Less commonly, other identified underlying etiologies include patent foramen ovale, thrombophilia, and non-bacterial endocarditis.

In cryptogenic stroke, the underlying cause is not identified, either because work-up was negative or because work-up cannot be completed, for example because the cause is reversible and there was insufficient time. Alternately, there may be multiple, concomitant risk factors that do not allow the physician to determine a specific underlying cause. As an ischemic stroke of undetermined etiology, cryptogenic stroke places the patient at higher risk for recurrence.

This material is adapted from the AHA guide: https://www.strokeassociation.org/idc/groups/stroke-public/@wcm/@hcm/@sta/documents/downloadable/ucm_477051.pdf.

### Cryptogenic Stroke

**Acute Episode**

- **I63.0-I63.9** Acute ischemic stroke
- **G45.0-G45.3, G45.8-G45.9** Transient cerebral ischemic attacks and related syndromes

**Post-Acute Phase**

- **I69.30-I69.998** Sequelae of cerebral infarction [late effect of ischemic stroke] and other cerebrovascular disease
- **Z86.73** Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
**Brief Statement**

**Indications**

**Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant**

The Reveal LINQ Insertable cardiac monitor is an implantable, patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia.

The device has not been tested specifically for pediatric use.

**Patient Assistant**

The Patient Assistant is intended for unsupervised use away from a hospital or clinic. The Patient Assistant activates the data management feature in the implanted device memory. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

**Contraindications**

There are no known contraindications for the implant of the Reveal LINQ Insertable cardiac monitor. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

**Warnings/Precautions**

**Reveal LINQ LNQ11 Insertable Cardiac Monitor**

Patients with the Reveal LINQ Insertable cardiac monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radio frequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the device manual for detailed information regarding the implant procedure and EM1 precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

**Patient Assistant**

Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

**Potential Complications**

Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/ adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic’s website at medtronic.com.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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**References**

5. Based on an exchange rate of €1.5 to $1.

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**Medtronic**

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