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

Medtronic

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[1]

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[2]

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)[3]

- 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[4]

- 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)[5]

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

Procedure Coding for Physician and Outpatient Hospital Services

CPT®[10]	Description
33282	Implant pat-active ht record (ILR)
33284	Remove pat-active ht record (ILR)
93285	ILR device eval/programming
93291	ILR device interrogation (in person)
93298	ILR device interrogation (remote, prof svc)
93299	ILR device interrogation (remote, tech svc)

C Code Required for Medicare Hospital OP Services

C1764	Event recorder, cardiac (implantable)

ICD-10-PCS Procedure Code and Definition[11]

0JH632Z	Insertion of Monitoring Device into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach (e.g., Reveal LINQ ICM)
0JPT32Z	Removal of Monitoring Device from Trunk Subcutaneous Tissue and Fascia, Percutaneous Approach (e.g., Reveal LINQ ICM)

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)*

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

References

[1] Sanna T, Diener HC, Passman RS, et al. Cryptogenic Stroke and Underlying Atrial Fibrillation (CRYSTAL AF). *N Engl J Med*. June 26, 2014;370(26):2478-2486.

[2] Edvardsson N, Frykman V, van Mechelin R, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry. *Europace*. February 2011;13(2):262-269.

[3] Krahn AD, Klein GJ, Yee R, Hoch JS, Skanes AC. Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial. *J Am Coll Cardiol*. August 6, 2003;42(3):495-501.

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

[6] Kirchhof P, Benussi, S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Eur Heart J*. Published online August 27, 2016. Accessed online August 31, 2016 at: http://eurheartj.oxfordjournals.org/content/early/2016/08/26/eurheartj.ehw210.

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[8] Strickberger SA, Benson DW, Biaggioni I, et al. AHA/ACCF Scientific Statement on the evaluation of syncope from the American Heart Association Councils and the American College of Cardiology Foundation: in collaboration with the Heart Rhythm Society (2006). *Circulation*. January 17, 2006;113(2):316-327.

[9] Calkins, et al. HRS/EHRA/ECAS expert Consensus Statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm*. June 2007;4(6):816-861.

[10] CPT is a registered trademark of the American Medical Association.

[11] Based on guidance from Clarity Coding, Linda Holtzman, MHA, RHIA, CCS, CCS-P, CPC, CPC-H.

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 patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal™ Insertable cardiac monitor to initiate recording of cardiac event data in the implanted device memory.

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 Medical procedure and EMI 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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Printed in USA. 11/2017