PriorityHealth

MEDICAL POLICY
No. 91618-R0

IMPLANTABLE LOOP RECORDER (ILR)

Effective Date: September 12, 2016	**Review Dates: 5/16, 5/17, 5/18**
Date Of Origin: May 11, 2016	**Status: Current**

I. POLICY/CRITERIA

Priority Health considers an implantable loop recorder (e.g., Reveal Insertable Loop Recorder by Medtronic, Inc.) medically necessary for either of the following indications:

A. For evaluation of recurrent unexplained episodes of pre-syncope, syncope, seizures, palpitations, or dizziness when *both* of the following criteria are met:
   1. A cardiac arrhythmia is suspected as the cause of the symptoms*; ***and***
   2. Either of the following criteria is met:
      a. For persons with heart failure, prior myocardial infarction or significant ECG abnormalities, noninvasive ambulatory monitoring, consisting of 30-day presymptom external loop recordings or MCT (Mobile Cardiovascular Telemetry), fails to establish a definitive diagnosis; ***or***
      b. For persons without heart failure, prior myocardial infarction or significant ECG abnormalities, symptoms occur so infrequently and unpredictably (less frequently than once per month) that noninvasive ambulatory monitoring (MCT or external loop recorders) are unlikely to capture a diagnostic ECG.

B. For evaluation of members with suspected atrial fibrillation as a cause of cryptogenic stroke who have had a nondiagnostic Holter monitor.

II. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***

- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. BACKGROUND

An implantable loop recorder device is inserted just under the patient's skin in the chest area during an outpatient surgical procedure. When symptoms are felt, the patient places a hand-held activator over the recorder to activate the storage of cardiac rhythms. This device can be used for up to three years. The Reveal Insertable Loop Recorder is an FDA-approved implantable memory loop device.

Evidence from a moderate-quality body of evidence suggests that ILR is relatively safe, and as part of a stepwise process, is superior to standard test strategies for patients with recurrent, unexplained syncope (RUS) and an inconclusive or negative diagnosis after initial clinical evaluation. Compared with standard diagnostic tests, ILR has a moderate to high diagnostic yield for detection of ECG changes associated with episodes of syncope as well as identification of specific arrhythmias for which there are effective treatments. While the results are mixed, there is some direct evidence from a moderate-quality body of evidence that ILR monitoring assists in clinical decision making, and that treatment of underlying cardiac causes of syncope detected by ILR is effective since it reduces the recurrence of syncope.

*Clinical or ECG features suggesting arrhythmic syncope

- Syncope during exertion or supine
- Palpitations at the time of syncope
- Family history of SCD(sudden cardiac death)
- Non-sustained VT (ventricular tachycardia)

- Bifascicular-block (LBBB or RBBB combined with left anterior or left posterior fascicular block) or other intraventricular conduction abnormalities with QRS duration ≥120 ms
- Inadequate sinus bradycardia (<50 bpm) or sinoartrial block in absence of negative chronotropic medications or physical training
- Pre-excited QRS complex
- Prolonged or short QT interval
- RBBB pattern with ST-elevation in leads V1-V3 (Brugada pattern)
- Negative T waves in right precordial leads, epsilon waves, and ventricular late potentials suggestive of ARVC(arrhythmogenic right ventricular cardiomyopathy)

V. CODING INFORMATION

ICD-10 Codes that may support medical necessity**:**

I25.2 Old myocardial infarction
I48.0 Paroxysmal atrial fibrillation
I48.1 Persistent atrial fibrillation
I48.2 Chronic atrial fibrillation
I48.91 Unspecified atrial fibrillation

R00.0 Tachycardia, unspecified
R00.2 Palpitations
R07.2 Precordial pain
R07.89 Other chest pain
R07.9 Chest pain, unspecified
R42 Dizziness and giddiness
R55 Syncope and collapse
R94.31 Abnormal electrocardiogram [ECG] [EKG]

Z82.41 Family history of sudden cardiac death
Z82.49 Family history of ischemic heart disease and other diseases of the circulatory system
Z87.74 Personal history of (corrected) congenital malformations of heart and circulatory system
Z98.89 Other specified postprocedural states

CPT/HCPCS Codes:

C1764 Event Recorder, cardiac (implantable)

33282 Implant of patient activated cardiac event recorder
33284 Removal of an implantable, patient-activated cardiac event recorder ***(No Auth)***

93285 Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician

or other qualified health care professional; implantable loop recorder system ***(No Auth)***

93291 Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis ***(No Auth)***

93298 Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional ***(No Auth)***

93299 Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results ***(No Auth)***

VI. REFERENCES

Hayes, Inc. Implantable Cardiac Loop Recorders for Diagnosis and Management of Syncope in Adults, March 10, 2016 and annual reviews.

Cardiac Event Monitors, Aetna Clinical Policy Bulletin @ http://www.aetna.com/cpb/medical/data/1_99/0073.html (Retrieved April 14, 2016 , March 23, 2017 & March 28, 2018)

Ambulatory Event Monitors to Detect Cardiac Arrhythmias, Anthem Blue Cross Clinical UM Guideline, @ https://www.anthem.com/ca/medicalpolicies/guidelines/gl_pw_a053673.htm (Retrieved April 14, 2016 & March 23, 2017)

Implantable Ambulatory Event Monitors and Mobile Cardiac Telemetry, Anthem Blue Cross Medical Policy @ https://www11.anthem.com/ca/medicalpolicies/policies/mp_pw_a050501.htm (Retrieved March 28, 2018)