New Century Health

Cardio Policy:

Implantation of Loop Recorder Systems

POLICY NUMBER UM CARDIO_1146	**SUBJECT** Implantation of Loop Recorder Systems		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 05/01/18, 02/13/19, 12/11/19, 05/13/20, 01/13/21, 08/11/21, 01/12/22, 02/09/22, 12/14/22	**APPROVAL DATE** December 14, 2022	**EFFECTIVE DATE** December 30, 2022	**COMMITTEE APPROVAL DATES** 08/03/11, 12/12/12, 08/22/13, 06/28/14, 08/12/15, 11/28/16, 12/21/16, 11/03/17, 05/01/18, 02/13/19, 12/11/19, 05/13/20, 01/13/21, 08/11/21, 01/12/22, 02/09/22, 12/14/22	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Implantation of Loop Recorder System.

II. DEFINITIONS

The implantable loop recorder (ILR) is a patient-activated monitoring system that records ECG tracings and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia. The device is a programmable cardiac event recorder with looping memory and is implanted subcutaneously usually in a left pectoral or mammary location with a battery life of 15-18 months. The electrodes that sense the heart's activity are on the surface of the device, so no trans venous leads are necessary. This device allows continuous rhythm monitoring that is stored either when manually activated by a patient/parent or automatically when high or low rate parameters are met.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cos –effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. For patients with recurrent syncopal episodes (greater than 2 episodes within 3 months) of uncertain etiology with negative initial work up including Holter and Event monitor. **(AUC Score 9)**[1,2,3,4,5,6]

B. Implantable Loop Recorder is appropriate in patients with recent evidence of cryptogenic stroke to rule out arrhythmic etiology for stroke after initial negative arrhythmic work up with Holter/Event monitor. **(AUC Score 8)**[1,2,3,4,5,6]

C. Removal of ILR for end of battery life. **(AUC Score 8)**

D. Removal of ILR due to pain, discomfort, infection at ILR site, or patient desires the device to be removed. **(AUC Score 8)**

Limitations:

A. There is not enough evidence to support Loop implantation in presence of another Cardiac device (AICD/PPM/CRT etc.) and will not be reviewed/approved.

B. Loop Implantation post Afib ablation is not routinely indicated and will be addressed case by case basis.

C. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review

1. Progress note that prompted request
2. Most recent EKG
3. Latest device interrogation report with strips

B. Primary codes appropriate for this service: 33285- Implantation of Loop Recorder, 33286- Removal of Implantable Loop Recorder

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. National Coverage Determination (NCD) for Electrocardiographic Services (20.15), 2004.

2. Sana M. Al-Khatib, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death - A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2018; 138: e272–e391
3. Calkins H, et al. European Heart Rhythm Association (EHRA); European Cardiac Arrhythmia Society (ECAS); American College of Cardiology (ACC); American Heart Association (AHA); Society of Thoracic Surgeons (STS). HRS/EHRA/ECAS expert Consensus Statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2007; 4 (6):816-861.
4. Angel Moya, et al. Task Force for the Diagnosis and Management of Syncope; European Society of Cardiology (ESC); European Heart Rhythm Association (EHRA); Heart Failure Association (HFA); Heart Rhythm Society (HRS). Nov 2009. Volume 30, Issue 21, Pages 2539-2550.
5. Epstein, A.E, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Journal of the American College of Cardiology. Jan 2013. Volume 61, Issue 3, Pages e6-e75.
6. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
7. NCQA UM 2022 Standards and Elements.