Cardio Policy:

Device Interrogation

POLICY NUMBER UM CARDIO_1256	**SUBJECT** Device (PPM/CRT-P, AICD/CRT-D-P/Subcutaneous ICD, ILR, Life Vest/Wearable Defibrillator) Interrogation		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 01/08/14, 08/12/15, 12/21/16, 07/26/17, 10/11/17, 02/14/18, 12/12/18, 03/13/19, 05/08/19, 07/31/19, 12/11/19, 02/12/20, 05/13/20, 02/10/21, 05/12/21, 11/09/21, 07/13/22, 07/18/23, 12/20/23	**APPROVAL DATE** December 20, 2023	**EFFECTIVE DATE** December 22, 2023	**COMMITTEE APPROVAL DATES** 08/03/11, 01/09/13, 01/08/14, 08/12/15, 12/21/16, 07/26/17, 10/11/17, 02/14/18, 12/12/18, 03/13/19, 05/08/19, 07/31/19, 12/11/19, 02/12/20, 05/13/20, 02/10/21, 05/12/21, 11/09/21, 07/13/22, 07/18/23, 12/20/23	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
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 Automatic Implantable Cardioverter Defibrillator (AICD)/Cardiac Resynchronization Therapy-Defibrillator (CRT-D), Permanent Pacemaker (PPM)/Cardiac Resynchronization Therapy-Pacemaker (CRT-P)/Subcutaneous ICD/ Life Vest Defibrillator and Implantable Loop Recorder (ILR) Interrogation.

II. DEFINITIONS

A **pacemaker** is a medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system.

The **automatic implantable cardioverter defibrillator** (AICD) or implantable cardioverter defibrillator (ICD) is an electronic device designed to detect and treat life-threatening tachyarrhythmia or brady-arrhythmias. The device consists of a pulse generator and electrodes for sensing, pacing and defibrillation.

The **implantable cardiac loop recorder** 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 physician utilizes a programmer to retrieve, display and prints to red data.

CRT-D/CRT-P is cardiac device with multiple leads, Defibrillator or Pacemaker with pacing and sensing function in three or more chambers of heart.

Subcutaneous ICD (pulse generator) is implanted under the skin on the side of the chest below the arm pit. The pulse generator is connected to the electrode which is implanted under the skin from the device pocket along the rib margin to the breastbone with the use of the insertion tool. There are no electrodes/leads placed on (epicardially) or in (endocardial) the heart.

Life Vest/Wearable Defibrillator is worn by patients that places them at risk for sudden cardiac death (SCD):

A. Primary prevention (EF ≤ 35%) including:
    1. After recent MI (coverage during the 40 day ICD waiting period)
    2. Before and after CABG or PTCA (coverage during the 90 day ICD waiting period)
    3. Listed for cardiac transplant
    4. Recently diagnosed non-ischemic cardiomyopathy (coverage during the 3 month ICD waiting period)
    5. NYHA Class IV heart failure
    6. Terminal disease with life expectancy of less than 1 year
B. ICD indications when patient condition delays or prohibits ICD implantation
C. ICD explanation

The life vest allows a patient's physician time to assess their long-term arrhythmic risk and make appropriate plans. It continuously monitors the patient's heart and if a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm.

The **AICD/CRT-D, PPM/CRT-P/Subcutaneous ICD interrogation** is defined as measurement of previously programmed parameters including but not limited to, battery voltage, lead capture and sensing function, heart rhythm, absence, or presence of therapy for ventricular tachyarrhythmias. Once the device battery longevity is reaching effective replacement index (ERI) or once it has reached end of life (EOL) the device will create an alert for replacement.

ILR interrogation includes previously programmed parameters and the heart rate and rhythm during recorded episodes from both patient-initiated, and device algorithm detected events, when present.

Life Vest interrogation includes previously programmed parameters, battery status and the heart rate and rhythm during recorded episodes from both patient-initiated, and device algorithm detected events, when present.

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 cost-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. Routine/surveillance pacemaker interrogation (single, dual leads) as in person can be performed every 6 months. Remote interrogation can be performed every 3 months from last remote interrogation. (Interrogation of device is inclusive of programming service, if performed on the same day.) **(AUC Score 8)**[1,3,4]

B. Trans-telephonic interrogation for PPM - every 12 weeks. **(AUC Score 7)**[2,3,4]

C. Routine/surveillance AICD/CRT-D/CRT-P/subcutaneous ICD interrogation can be done every 3 months irrespective of interrogation being done in person or remotely. (Interrogation of device is inclusive of programming service, if performed on the same day). **(AUC Score 8)**[1,34]

D. Routine loop recorder interrogation in person or remotely can be done every 30 days. **(AUC Score 5)**[1,3,4]

E. Routine loop recorder interrogation can be performed in person or remotely every 3 months. **(AUC Score 7)**[1,3,4]

F. Life vest or wearable defibrillator interrogation is reasonable to perform every 30 days up until 3 months in person only. **(AUC Score 6)**[1,3,4]

G. Recent shock therapy through AICD/CRT-D or any symptom or findings since previous device evaluation for which an interrogation earlier than recommended guideline frequency could help yield a diagnosis, or if permanent adjustment(s) were made during the last evaluation. **(AUC Score 7)**[1,3,4]

H. Monthly device interrogation can be performed if there is evidence of battery depletion (battery voltage < 2.7V) or approaching ERI/EOL during the last device evaluation or the last device evaluation demonstrated lead malfunctioning or lead recall(s) and patient is not pacer dependent. (Interrogation of device is inclusive of programming service, if performed on the same day). **(AUC Score 9)**[1,3,4]

I. Device interrogation is indicated up to 72 hours and once 3-12 weeks post device implantation or pulse generator replacement. **(AUC Score 7)**[1,3,4]

Limitations:

A. Devices with Automatic/Adaptive monitoring capabilities includes monitoring of pacing and sensing thresholds at periodic intervals and device determination of a target output based on the programmable safety margin and programmable minimum amplitude. A request for a device with auto capture capability will be considered a Device Interrogation request.

When a patient is monitored both during clinic visits and trans-telephonically or remotely, the combined frequency of monitoring will be considered in evaluating the reasonableness of the frequency of monitoring services received by the patient.

B. Remote and in-person interrogation cannot be reported at the same time.

C. Subcutaneous ICD and life vest/wearable defibrillator cannot be interrogated remotely.

D. 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. Latest device interrogation report with strips

B. Primary codes appropriate for this service: PPM- 93288, 93293, 93294, AICD-93289, 93295, Remote Interrogation-Technical code for Pacemaker/ICD system up to 90days- 93296, ILR- 93291, 93298, Subcutaneous ICD- 93261, Life Vest/Wearable Defibrillator- 93292 Analyze Anti tachycardia pacemaker system-93724, Remote Interrogation Technical Code for Optivol, ILR, subcutaneous ICD- G2066

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) (20.8.1). Cardiac Pacemaker Evaluation Services. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
2. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) (20.8.1.1). Transtelephonic Monitoring of Cardiac Pacemakers. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
3. Wolk MJ, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. Journal of the American College of Cardiology. Dec 2012. Volume 61, Issue 12, Pages 1318-68.
4. 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.
5. NCQA UM 2023 Standards and Elements.