New Century Health

Cardio Policy:
Device Programming

POLICY NUMBER UM CARDIO_1257	SUBJECT Device (PPM/CRT-P, AICD/CRT-D/ Subcutaneous ICD, ILR, Life Vest/Wearable Defibrillator) Programming		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 08/03/11, 01/09/13, 01/08/14, 08/22/15, 03/28/16, 04/06/16, 11/28/16, 07/15/17, 10/11/17, 03/07/19, 09/11/19, 12/11/19, 07/13/20, 07/14/21, 11/09/21, 07/13/22, 07/18/23	**APPROVAL DATE** July 18, 2023	**EFFECTIVE DATE** July 28, 2023	**COMMITTEE APPROVAL DATES** 08/03/11, 01/09/13, 01/08/14, 08/22/15, 03/28/16, 04/06/16, 11/28/16, 07/15/17, 10/11/17, 03/07/19, 09/11/19, 12/11/19, 07/13/20, 07/14/21, 11/09/21, 07/13/22, 07/18/23	
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 and Implantable Loop Recorder (ILR) programming.

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 tachyarrhythmias or bradyarrhythmias. 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 print stored 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) as listed below.

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 explantation

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/programming** includes documented MANUAL iterative temporary or permanent changes of capture and sensing thresholds, changes in the pacing output of a pacing lead, heart rhythm, upper and lower heart rates, sensor rate response, AV intervals, pacing voltage, pulse duration, sensing value and checking battery voltage. In addition to these programming parameters, ventricular tachycardia detection and therapies are programmed based on device interrogation when medically necessary. When device battery longevity has reached effective replacement index (ERI) or once it has reached end of life (EOL) the device will create an alert for replacement.

ILR programming includes tachycardia and bradycardia rate adjustment based on interrogation when medically necessary.

Life Vest/Wearable Defibrillator programming includes sensing thresholds and ventricular tachycardia detection and defibrillation therapies based on device interrogation when medically necessary. There are no pacing capabilities in Life Vest. Programming of Life Vest is usually done during initial setup of system.

Defibrillator Threshold Test - It is an integral part of implantable cardioverter-defibrillator (ICD) implantation. It is usually performed at the time of initial implantation or after generator replacement. It

involves testing of the device and leads by arrhythmia induction and termination by delivering shock therapy through programmed parameters.

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

Limitations

A. 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.

III. POLICY

Indications for approving a request for medical necessity are:

Device (PPM, AICD/CRT-D/CRT-P/Sub-cut ICD/ILR) Programming: Any MANUAL documented iterative temporary or permanent changes made on thresholds (Sensing and Pacing Thresholds) and/or to other device parameters.

A. Device programming is indicated when there is a change in patient's clinical status possibly related to the device function. **(AUC Score 7)**[1,2,3,4]

B. Device programming is indicated when a change in Anti-Arrhythmic Drug(s) therapy has been done which may affect the programmed parameters. **(AUC Score 7)**[1,2,3,4]

C. Device Programming is indicated if the last device evaluation demonstrated lead malfunctioning or lead recall(s) and/or device battery life approaching ERI/EOL. **(AUC Score 9)**[1,2,3,4]

D. Device Programming is indicated when new permanent changes were done during the last device evaluation or deemed necessary after a recent remote interrogation. **(AUC Score 6)**[1,2,3,4]

E. Routine Programming of Pacemaker (Single, Dual leads) can be done once every 12 months **(AUC Score 7)** and for ICD/CRT-D/CRT-P/ILR twice a year at 6-month interval in a stable patient. **(AUC Score 9)**[1,2,3,4]

F. Device Programming is indicated within 72 hours post device implantation or pulse generator change and then at 3-12 weeks, post device implantation or pulse generator change. **(AUC Score 7)**[1,3,5]

G. DFT testing for devices like AICD and Sub cutaneous ICD including leads may be appropriate at the time of device implantation or generator replacement. **(AUC Score 7)**[1,3,5]

H. DFT testing for devices like AICD and Sub cutaneous ICD including leads can be performed later when patient is stable, if not done at the at the time of device implantation or generator replacement. **(AUC Score 6)**[1,3,5]

Limitations:

A. 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. There is no frequency guidelines available for programming of Life Vest after initial set up.

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-93279, 93280, 93281, AICD-93282, 93283, 93284, ILR-93285, Subcutaneous ICD- 93260, Life Vest/Wearable Defibrillator- 93745 *(for initial programming of system, usually done while patient is hospitalized after the cardiac event.)* 93640- EP eval of single/dual ICD leads including DFT at the time of initial implant or replacement. 93641- EP eval of single/dual ICD leads and generator including DFT at the time of initial implant or replacement. 93642- EP eval of single/dual ICD leads including DFT and programming and reprogramming of sensing and therapeutic parameters. 93644- EP eval of Subcutaneous ICD leads including DFT and programming and reprogramming of sensing and therapeutic parameters.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Bruce L. Wilkoff, MD, et al. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. Heart Rhythm. Feb 2016, Volume 13, Issue 2, Pages e50-e86.
2. David Slotwiner, MD, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm Society. July 2015. Volume 12, Issue 7, Pages e69-e100.
3. Piccini JP Sr, et al. Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death: A Science Advisory From the American Heart Association. Circulation. April 2016. Volume 133, Issue 17, Pages 1715-1727
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.