Cardio Policy:

Automatic Implantable Cardioverter Defibrillator

POLICY NUMBER UM CARDIO_1080	**SUBJECT** Automatic Implantable Cardioverter Defibrillator		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 04/01/11, 11/07/12, 03/10/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/23/17, 05/01/18, 02/13/19, 02/21/19, 04/24/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 10/13/21, 10/12/22, 01/11/23, 02/01/23, 03/16/23, 12/20/23	**APPROVAL DATE** December 20, 2023	**EFFECTIVE DATE** December 22, 2023	**COMMITTEE APPROVAL DATES** 04/01/11, 11/07/12, 03/10/14, 05/15/15, 08/12/15, 11/28/16, 12/21/16, 10/23/17, 05/01/18, 02/13/19, 02/21/19, 04/24/19, 05/08/19, 12/11/19, 05/13/20, 05/28/21, 08/11/21, 10/13/21, 10/12/22, 01/11/23, 02/01/23, 03/16/23, 12/22/23	
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 initial implantation of Automatic Implantable Cardioverter Defibrillator.

II. DEFINITIONS

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

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

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I

recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in the major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions.[2,3,4,5,6,7]

III. POLICY

Indications for approving a request for medical necessity are:

A. A documented episode of cardiac arrest due to ventricular fibrillation (VF). **(AUC Score 9)[1,2,3,4]**

B. A documented episode of VF or sustained VT with coronary anatomy not amenable to revascularization. **(AUC Score 9)[1,2,3,4]**

C. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI). **(AUC Score 9)[1,2,3,4]**

D. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy, or Brugada syndrome type I with history of cardiac arrest, sustained ventricular arrhythmia, or syncope presumed due to ventricular arrhythmia. **(AUC Score 9)[1,2,3,4]**

E. Coronary artery disease with complete revascularization or not amenable for revascularization and with documented prior MI and measured left ventricular ejection fraction (LVEF) less than or equal to 35%, with inducible, sustained VT or VF at EP study and/ or stress testing **(AUC Score 8)[1,2,3,4]**

   1. The MI must have occurred more than 40 days prior to defibrillator insertion and/or
   2. The EP test must be performed more than 4 weeks after the qualifying MI

F. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II or III heart failure, and stable on maximally tolerated GDMT for at least 3 months and measured LVEF less than or equal to 35%. **(AUC Score 9)[1,2,3,4]**

G. Asymptomatic Non-Sustained VT(NSVT)in a re-vascularized patient with Ischemic Cardiomyopathy, less than or equal to 40 days post AMI with LVEF less than or equal to 40% and with inducible VT on EP Study. **(AUC Score 7)[1,2,3,4]**

H. Patients with ischemic dilated cardiomyopathy (IDCM) documented at least 40 days' post MI, NYHA Class I heart failure, and stable) on maximally tolerated GDMT for at least 3 months and measured LVEF less than or equal to 30%. **(AUC Score 9)[1,2,3,4]**

I. Stable Patients with non-ischemic dilated cardiomyopathy (NIDCM), NYHA Class II or III heart failure and stable on maximally tolerated GDMT for at least 3 months and measured LVEF less than or equal to 35%. **(AUC Score 9)[1,2,3,4]** If functional class I with LVEF less than or equal to 35% **(AUC Score 7)[3,4]**

J. Patients with cardiomyopathy, class IV heart failure with LVEF less than or equal to 30%, stable on maximally tolerated GDMT for at least 3 months and are on waiting list for heart transplant. **(AUC Score 8)[1,2,3,4]**

K. Patients must not have-

1. New York Heart Association Classification: IV (bed ridden and with a likelihood of survival less than 1 year.
2. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm
3. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months
4. Had an enzyme-positive MI within past 40 days
5. Clinical symptoms or findings that would make them a candidate for coronary revascularization
6. Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure) and/or associated with a likelihood of survival less than 1 year.
7. Irreversible brain damage from preexisting cerebral disease.

L. Evidence of Lead malfunctioning/recall on recent interrogation in previously implanted device requiring repositioning/replacement/removal. **(AUC Score 7)**[1,2,3]

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.

B. Before implantation of AICD for heart failure and/or ventricular arrhythmias the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[2,3,4,5,6,7]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist or Electro physiologist note that prompted request
   2. Other previous monitoring tests pertinent to referral such as: holster, event monitoring device analysis, EP study report.
   3. Cardiac catheterization, MUGA, ECHO

B. Primary codes appropriate for this service: Primary codes appropriate for this service: 33249 - AICD Implantation, 33223 - Pocket relocation, 33215 - Repositioning of PM or ICD lead, 33216 - Insertion of single lead, 33217 - Insertion of 2 leads PM or ICD, 33218 - Repair single lead PM or ICD, 33220 - Repair 2 leads for PM or ICD, 33230 - Insertion of ICD pulse generator only with existing dual leads, 33240 - Insertion of ICD pulse generator only with existing single lead, 33241 + 33249 - Upgrade from Single to dual chamber AICD, 93640 - DFT testing of ICD leads, 93641 - DFT testing of ICD generator. 33244 - Trans venous extraction of defibrillator lead. 33243 - Extraction of defibrillator lead by Thoracotomy, 75820 - Venogram (prior to implantation).

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 Determinations (NCD) (20.4). Implantable Automatic Defibrillators. Retrieved from https://www.cms.gov [Accessed December 19, 2023].
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. Russo AM, 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. March 2013, Volume 61, Issue 12, Pages 1318-1368.
4. Robert C. Hendel MD, FACC, FAHA, FASNC 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. Cronin EM, et al. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias. Europace. 2019 Aug 1;21(8):1143-1144. doi: 10.1093/europace/euz132. Erratum in: Europace. 2019 Aug 1;21(8):1144. Erratum in: J Arrhythm. 2020 Jan 12;36(1):214. Erratum in: Europace. 2020 Mar 1;22(3):505.
6. Al-Khatib SM, 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. J Am Coll Cardiol. 2018 Oct 2;72(14):e91-e220.
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8. NCQA UM 2023 Standards and Elements.