Cardio Policy:

Subcutaneous ICD Device Implantation and Removal

POLICY NUMBER UM CARDIO_1389	**SUBJECT** Subcutaneous ICD Device Implantation and Removal	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 02/12/20, 01/13/21, 07/14/21, 07/13/22, 01/11/23, 02/01/23, 12/20/23	**APPROVAL DATE** December 20, 2023	**EFFECTIVE DATE** December 22, 2023	**COMMITTEE APPROVAL DATES** 02/12/20, 01/13/21, 07/14/21, 07/13/22, 01/11/23, 02/01/23, 12/20/23
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 Subcutaneous ICD (S-ICD) device.

II. DEFINITIONS

The S-ICD System is a Subcutaneous (under the skin) Implantable Cardioverter Defibrillator for people who are at risk of Sudden Cardiac Arrest. Unlike a transvenous ICD, where the leads are fed into the heart through a vein and attached to the heart wall, the leads for S-ICD are placed just under the skin and not in the heart, leaving the heart and veins untouched and intact. The pulse generator is implanted on the left side of the chest next to the rib cage, just under the arm. The lead is vertically positioned in the subcutaneous tissue of the chest, parallel to and 1-2 cm to the left sternal midline followed by a horizontal segment, at the level of the 6th rib, until it reaches the left anterior axillary line. The lead has an 8-cm shock coil, flanked by two sensing electrodes - the distal one positioned adjacent to the manubriosternal junction and the proximal one adjacent to the xiphoid process.

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 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[2,7,8]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving a request for medical necessity are:

A. S-ICD is appropriate in patients with congenital heart diseases or patients with no venous access who are unsuitable for transvenous ICD. **(AUC Score 8)**[2,3,4]

B. S-ICD is appropriate in high-risk cases of previous device infection, hemodialysis, chronic immunosuppression therapy immunodeficiencies, or artificial heart valves. **(AUC Score 8)**[2,3,4]

C. S-ICD is appropriate in patients who are candidates for cardiac transplant. **(AUC Score 7)**[1,2,3]

D. S-ICD is a reasonable choice in patients with Hypertrophic Cardiomyopathy where there is no indication for Anti-Tachycardia Pacing (ATP). **(AUC Score 7)**[1,2,3]

E. S-ICD is a reasonable choice for Primary prevention of Sudden cardiac death in patients with ischemic/non ischemic dilated cardiomyopathy. **(AUC Score 7)**[1,2,3,4]

F. Procedures for lead repositioning or replacement are appropriate in cases of lead complications involving inappropriate shocks, oversensing, or other specified lead failure. **(AUC Score 7)**[1,2,3,4,5]

Limitations:

A. S-ICD is not indicated in patients with symptomatic bradycardia requiring permanent pacing.

B. S-ICD is not indicated in patients with systolic heart failure and left bundle branch block and has indication for CRT.

C. S-ICD is not indicated in patients with recurrent sustained monomorphic VT treatable with ATP.

D. S-ICD is not indicated in thin patients with poor subcutaneous tissue and abnormalities of chest wall like pectus excavatum.

E. Before Subcutaneous ICD Device can be implanted in a patient with heart failure and/or ventricular arrhythmias the following must be considered: Predicted or observed lack of adequate response to maximally tolerated GDMT[2, 7,8]

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review:
   1. Progress note that prompted request
   2. Echo or MUGA or Cardiac CATH for LV function.
   3. Previous Holter/Event/Loop recorder report

B. Primary codes appropriate for this service: 33270 - Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including

defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed, 33271 - Insertion of subcutaneous implantable defibrillator electrode, 33272 - Removal of subcutaneous implantable defibrillator electrode, 33273 - Repositioning of previously implanted subcutaneous implantable defibrillator electrode, 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. Centers for Medicare & Medicaid Services -Proposed Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4). [Accessed December 19, 2023].
2. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, Heart Rhythm (2017) doi: 10.1016/j.hrthm.2017.10.036.
3. Indranill Basu-Ray, et al. "Subcutaneous Versus Transvenous Implantable Defibrillator Therapy." JACC: Clinical Electrophysiology. Sep 2017, 496; DOI: 10.1016/j.jacep.2017.07.017
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. Olde Nordkamp LR, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. J Am Coll Cardiol 2012; 60:1933.
6. Pedersen CT, et al. 2014 EHRA/HRS/APHRS expert consensus on ventricular arrhythmias. Europace. 2014 Sep;16(9):1257-83.
7. Maddox TM, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2021 Feb 16;77(6):772-810.
8. Yancy CW, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017 Aug 8;136(6):e137-e161.
9. NCQA UM 2022 Standards and Elements.