Cardiac Defibrillator Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Cardiac Defibrillator.

II. Scope

All Utilization Management (UM) staff conducting physical and behavioral health UM review.

III. Exceptions

A. Subcutaneous ICD systems without FDA approval or used for anything other than FDA approved indications will not be approved.

IV. Definitions

Transvenous ICD: Electrodes are fed into the heart through a vein and attached to the heart muscles

Subcutaneous ICD: Electrodes are placed in the skin

V. Policy Statements

A. IU Health Plans considers transvenous implantable cardiac defibrillators (ICD) medically necessary for patients on optimal medical therapy and with a reasonable expectation of survival with a good functional status for more than 1 year for one of the following indications:

1. After evaluation to define the cause of the event and to exclude any completely reversible causes in survivors of cardiac arrest due to ventricular fibrillation (VF) of hemodynamically unstable sustained ventricular tachycardia (VT)

2. Those with structural heart disease and spontaneous sustained VT, whether
hemodynamically stable or unstable
3. Those with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT
4. Those with non-ischemic dilated cardiomyopathy (NIDCM) who have an LVEF (left ventricular ejection fraction) of less than or equal to 35% after 3 months of guideline directed medical therapy (GDMT) and who are in New York Heart Association (NYHA) functional Class II or III Heart Failure (HF)
5. Those with ischemic cardiomyopathy due to a prior myocardial infarction (MI) who are at least 40 days or more post-MI, with LVEF less than or equal to 30% and are in NYHA functional Class I HF after 3 months of GDMT or with an LVEF less than or equal to 35% and in NYHA Class II or III HF after 3 months of GDMT
6. Those with non-sustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study
7. Those with long-QT syndrome who are experiencing syncope or VT while receiving beta-blockers
8. Those with confirmed hypertrophic cardiomyopathy (HCM with two (2) or more major risk factors for sudden cardiac death (SCD) which are the following:
   a. Family history of HCM-related SCD in at least one first degree relative
   b. At least one episode of unexplained syncope within the previous 12 months
   c. Non-sustained VT on ECG
   d. Abnormal blood pressure (BP) response during upright exercise testing
   e. Left ventricular (LV) wall thickness greater than or equal to 30 mm
9. For individuals with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiologic evaluation (catheter ablation or surgical repair may offer possible alternatives in carefully selected individuals)
10. For individuals with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study
11. For individuals with cardiac sarcoidosis when one or more of the following criteria are met:
   a. Sustained VT or survivors of sudden cardiac arrest or with an LVEF of 35% or less
   b. LVEF of greater than 35% with syncope or evidence of myocardial scar by cardiac MRI or PET scan
   c. LVEF of greater than 35% with inducible sustained ventricular arrhythmias
B. Implantable transvenous cardioverter-defibrillator (ICD) therapy is considered medically necessary for individuals with a confirmed Brugada syndrome diagnosis when one of the following criteria is met:
   1. History of unexplained syncope, documented spontaneous sustained VT with or without syncope, or survivor of a cardiac arrest
   2. Family history of a first or second-degree relative with sudden cardiac death due to Brugada syndrome or that is unexplained
C. IU Health Plans considers Subcutaneous Implantable Cardiac Defibrillators (S-ICDs) medically necessary for patients on optimal medical therapy with a reasonable expectation of survival with a good functional status for more than 1 year when all of the following criteria are met:
1. Candidate for ICD implantation based on ACC/AHA/HRS and CMS indications
2. No indication of cardiac rhythms requiring pacing
3. Passed the S-ICD Electrogram (EGM) screening
4. Any of the following conditions putting the member at high risk for complications from endovascular ICD implantation:
   a. Prior device infection
   b. Active systemic infection (bacteremia, sepsis, open ulcers, etc.) or prior systemic infection related to and necessitating implantable device removal
   c. Vascular occlusion/ lack of venous access
   d. Member on dialysis
   e. Hypercoagulable state
   f. Prosthetic valves
   g. Immunocompromised

VI. Background
Sudden cardiac death can be defined as a death due to cardiac causes within one hour of the onset of symptoms. Ventricular fibrillation (VF) or ventricular tachycardia (VT) are the leading causes for sudden cardiac death. The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias, VF and VT. The device consists of a pulse generator and electrodes for sensing and defibrillating.

According to the FDA, the S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, continual (incessant) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing. The S-ICD monitors cardiac rhythms and delivers defibrillation when ventricular tachyarrhythmias are detected. After delivery of a shock, the S-ICD provides post-shock bradycardia pacing therapy when needed.

Code:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>33270</td>
<td>Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluations, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed</td>
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<tr>
<td>33271</td>
<td>Insertion of subcutaneous implantable defibrillator electrode</td>
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<tr>
<td>33272</td>
<td>Removal of subcutaneous implantable defibrillator electrode</td>
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<tr>
<td>33273</td>
<td>Repositioning of previously implanted subcutaneous implantable defibrillator electrode</td>
</tr>
<tr>
<td>33299</td>
<td>Unlisted procedure, cardiac surgery *[Considered medically necessary when used to report implantation of subcutaneous implantable cardioverter defibrillator (S-ICD)]</td>
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<tr>
<td>93260</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system</td>
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<tr>
<td>93261</td>
<td>Interrogation device evaluation (in person) with analysis review and report by physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system</td>
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<td>93644</td>
<td>Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)</td>
</tr>
</tbody>
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### VII. Procedures

None

### VIII. References/Citations


10. National Institute for Health and Clinical Excellence (NICE), Interventional Procedure Guidance (IPG). Insertion of a subcutaneous implantable cardioverter defibrillator for...
prevention of sudden cardiac death, IPG454, Published: April 2013.
https://www.nice.org.uk/guidance/IPG454

http://onlinelibrary.wiley.com/doi/10.1111/jce.12343/abstract;jsessionid=3EA0D7F890673C9C9457859D1361A89B.f01t04

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http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm326541.htm

IX. Forms/Appendices
X. Responsibility
XI. Approval Body/Approval Signatures