Subcutaneous Implantable Cardioverter Defibrillator (ICD) System

I. Description

The automatic implantable cardioverter defibrillator (ICD) is a device designed to monitor a patient’s heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electric shock to terminate these arrhythmias to reduce the risk of sudden death.

Indications for implantable cardioverter defibrillator (ICD) can be broadly subdivided into 1) secondary prevention, i.e., their use in patients who have experienced a potentially life-threatening episode of ventricular tachyarrhythmia (VT) (near sudden cardiac death); and 2) primary prevention, i.e., their use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or ventricular fibrillation (VF). The standard ICD involves placement of a generator in the subcutaneous tissue of the chest wall. Transvenous leads are attached to the generator and threaded intravenously into the endocardium. The leads sense and transmit information on cardiac rhythm to the generator, which analyzes the rhythm information and produces an electrical shock when a malignant arrhythmia is recognized. A totally subcutaneous ICD has also been developed. This device does not employ transvenous leads and thus avoids the need for venous access and complications associated with the venous leads. Rather, the subcutaneous ICD uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver counter shocks through the subcutaneous tissue of the chest wall.

II. Criteria/Guidelines

Subcutaneous cardioverter defibrillators are covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met.

A. The patient has at least one of the following:
   1. inadequate vascular access (e.g., patients on hemodialysis)
   2. are at significant risk for infection (e.g., immunocompromised, history of endocarditis, previous device infections or lead failures)
B. Patient has at least one of the following indications of ICD:

1. One or more episodes of spontaneously occurring and inducible ventricular fibrillation (VF), or syncopal or hypotensive ventricular tachycardia (VT) that is not associated with acute myocardial infarction (AMI); and not due to a remediable cause (e.g., drug toxicity, electrolyte abnormalities, ischemia);

2. Spontaneously occurring but non-inducible documented syncopal or hypotensive VT that was not due to AMI;

3. VT/VF cardiac arrest that was not associated with an inducible ventricular arrhythmia, and not due to AMI;

4. Structural heart disease (such as prior myocardial infarction (MI), congenital heart disease, and/or ventricular dysfunction) and spontaneous, sustained VT (greater than 30 seconds), whether hemodynamically stable or unstable. Note: ICD may also be considered for persons with sustained VT and normal ventricular function;

5. Unexplained syncope, which by history and clinical circumstances was probably due to a ventricular tachyarrhythmia, with either of the following: 1) the presence of reproducible inducible syncopal or hypotensive VT or VF that is not associated with AMI and not due to a remediable cause; or 2) significant left ventricular (LV) dysfunction (LV ejection fraction less than 50%), and structural heart disease such as prior myocardial infarction (MI), congenital heart disease, and/or ventricular dysfunction;

6. Ischemic dilated cardiomyopathy with a history of heart attack and one of the following: a) New York Heart Association (NYHA) Class II or III heart failure (see appendix) with a LVEF less than or equal to 35%, who are at least 40 days post MI, and are on optimal medical therapy, defined as 3 months of maximally titrated doses as tolerated of an ACE inhibitor, beta-blocker, and diuretic; or b) NYHA Class I heart failure (see appendix) with a LVEF less than or equal to 30%, who are at least 40 days post MI, and are on optimum medical therapy; or c) non-sustained VT due to prior MI, and LVEF less than or equal to 40%, and inducible VF or sustained VT at EP study performed at least 96 hours after revascularization or MI;

7. Non-ischemic dilated cardiomyopathy, NYHA Class II or III heart failure (see appendix), and a LVEF less than or equal to 35 % who are on optimal medical therapy, defined as 3 months of maximally titrated doses as tolerated of an ACE inhibitor, beta-blocker, and diuretic;

8. Familial or inherited conditions with a high-risk of life-threatening ventricular tachyarrhythmias, including:
a. Long QT syndrome with either of the following:
   i. Syncope and/or VT while receiving beta-blockers;
   ii. Asymptomatic with one or more of the following risk factors for sudden cardiac death:
      (1) QTc greater than 500 msec, or
      (2) LQT@ or LQT3; or
      (3) Family history of sudden death
b. Hypertrophic cardiomyopathy or arrhythmogenic right ventricular cardiomyopathy (ARVC) with one or more of the following risk factors for sudden cardiac death:
   i. Documented VT; or
   ii. Family history of sudden cardiac death in at least one first-degree relative; or
   iii. Left ventricular thickness of 3 cm or greater; or
   iv. Hypotensive response to exercise treadmill testing (ETT); or
   v. At least one episode of unheralded syncope within the previous 12 months.
c. Catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta-blockers.
d. Brugada Syndrome who have had syncope or who have documented or inducible VT.
e. LV non-compaction cardiomyopathy with either of the following:
   i. Positive family history of sudden cardiac death; or
   ii. Impaired left ventricular ejection fraction (less than 50%)
f. Cardiac sarcoidosis, giant cell myocarditis, or Chagas disease, regardless of LV ejection fraction
g. ICD implantation may be considered in affected members with a familial cardiomyopathy associated with sudden death.

III. Limitations
   A. A subcutaneous ICD must be FDA approved
   B. Patient has no indication for a pacemaker.

IV. Administrative Guidelines
   A. Precertification is required for initial insertion for subcutaneous ICD. Requests must include clinical notes supporting the need for subcutaneous ICD over the standard ICD.
   B. To precertify, please complete HMSA's Precertification Request and mail or fax the form as indicated, along with the necessary documentation.
V. Background

Cardiovascular mortality as a consequence of ventricular fibrillation (VF) or ventricular tachycardia (VT) continues to be a major health problem despite advances in the overall management of cardiovascular disease. Sudden cardiac death kills approximately 400,000 people per year. About 10 to 15% of individuals who experience VT or VF recover, usually with an external cardiac defibrillator. These survivors have various therapeutic options such as the implantable cardioverter-defibrillator (ICD). A number of well-designed studies have shown the effectiveness of the ICD in high-risk patients who have already experienced a myocardial infarction (MI). These studies found that the long-term survival of patients with sustained ventricular tachyarrhythmias after MI, with depressed LV function, is significantly better with an ICD than with amiodarone therapy, even when stratified according to the results of the electrophysiologic (EP) study.

The U.S. Food and Drug Administration (FDA) has approved the Subcutaneous Implantable Defibrillator (S-ICD®) System (Cameron Health, San Clemente, CA) "to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with antitachycardia pacing." The Subcutaneous Implantable Defibrillator (S-ICD®) System uses a lead that is implanted just under the skin along the bottom of the rib cage and breast bone. The S-ICD System consists of: a titanium case containing a battery and electronic circuitry that provides defibrillation therapy and pacing at a rate of 50 beats per minute up to 30 seconds after a shock; a subcutaneous electrode which has a proximal and distal ring electrode on each side of a 3 inch (8 cm) defibrillation coil electrode; and accessories include an electrode insertion tool, programmer, telemetry wand, magnet, suture sleeve, torque wrench, and memory card. The FDA approval was based upon the results of a 321-patient study in which 304 patients were successfully implanted with the S-ICD® System. At the time of implantation, the investigator tested the effectiveness of the device by inducing heart arrhythmias. The S-ICD® System was successful at converting all abnormal heart rhythms that it detected back to normal rhythms. Investigators followed these patients for six months following implantation, during which time the device detected and recorded 78 spontaneous arrhythmias in 21 patients; all arrhythmias were either successfully converted back to normal by the defibrillator or resolved on their own. The FDA noted that, because the S-ICD® System memory stores data from only the 22 most recent arrhythmia episodes, there may have been other detected episodes that could not be
analyzed by investigators. The FDA reviewed safety data based on the entire 321-patient study population to identify complications that can occur during and after implantation of the S-ICD System. The most common complications included inappropriate shocks, discomfort, system infection, and electrode movement, which required repositioning. The FDA reported that 8 patients died during the study; however, experts (who were not involved with the study) could not definitively attribute the deaths to the S-ICD® System. Eleven patients required the removal of the device, and 18 had discomfort that was resolved without repositioning the device or surgery. At the end of six months, more than 90 percent of patients had no complications. As part of the approval, FDA is requiring the manufacturing company to conduct a post market study to assess the long-term safety and performance of the device and to assess differences in effectiveness across genders. The study will follow 1,616 patients for five years. There is currently insufficient published evidence of the effectiveness and safety of this device (Bardy, et al., 2010; Gold, et al., 2012; Jarman, et al., 2012; Köbe, et al., 2012). On September 28, 2012, the S-ICD® system by Cameron Health, Inc. was approved by the FDA “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.”

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References


