

## Medical and Behavioral Health Policy

Section: Surgery

Policy Number: IV-84

Effective Date: 02/26/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

### IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

**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 ICD implantation can be broadly subdivided into: 1) secondary prevention (i.e., use in patients who have experienced a potentially life-threatening episode of ventricular tachyarrhythmia [near sudden cardiac death]); and 2) primary prevention (i.e., use in patients who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening ventricular tachyarrhythmia or ventricular fibrillation).

The standard **transvenous 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. Several transvenous ICDs are approved by the U.S. Food and Drug Administration (FDA) through the premarket application (PMA) approval process. The FDA-labeled indications generally include patients who have experienced life-threatening VT associated with cardiac arrest or VT associated with hemodynamic compromise and resistance to pharmacologic treatment.

A totally **subcutaneous ICD** (S-ICD®) has also been developed. This device does not employ transvenous leads and therefore avoids the need for venous access and complications associated with the venous leads. Rather, the S-ICD® uses a subcutaneous electrode that is implanted adjacent to the left sternum. The electrodes sense the cardiac rhythm and deliver countershocks through the subcutaneous

tissue of the chest wall. In 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.”

**Definitions: New York Heart Association (NYHA) Functional Classification**

Class I - No limitation of physical activity.

Class II - Slight limitation of physical activity.

Class III - Marked limitation of physical activity

Class IV - Unable to carry out any physical activity.

**Policy:**

**I. Transvenous Implantable Cardioverter-Defibrillators**

**A. Adults**

1. The use of an implantable cardioverter-defibrillator (ICD) may be considered **MEDICALLY NECESSARY** for the treatment of ventricular tachyarrhythmias and for the prevention of sudden cardiac death in adults (18 years of age or older) when one of the following indications is present:
  - a. History of cardiac arrest due to ventricular fibrillation (VF) or ventricular tachycardia (VT) neither of which is due to reversible or transient causes; OR
  - b. Spontaneous sustained VT, in patients with structural heart disease; OR
  - c. Spontaneous sustained VT, in patients without structural heart disease, that is not amenable to other treatments; OR
  - d. Syncope of undetermined origin with clinically relevant, hemodynamically significant, sustained VT or VF induced at electrophysiological study; OR
  - e. Left ventricular (LV) dysfunction due to prior myocardial infarction (MI) in patients who are at least 40 days post-MI, have a left ventricular ejection fraction (LVEF) less than or equal to 30%, and are in New York Heart Association (NYHA) Class I\*; OR
  - f. Ischemic dilated cardiomyopathy (IDCM) with NYHA Class II\* or III\* heart failure, documented prior myocardial infarction (MI), at least 40 days post MI, and measured left ventricular ejection fraction (LVEF) less than or equal to 35%; OR
  - g. Non-ischemic dilated cardiomyopathy (NIDCM) with NYHA Class II or III heart failure, and measured LVEF less than or equal to 35%; OR
  - h. Nonsustained VT due to prior MI, LVEF less than or equal to 40%, and inducible VF or sustained VT at electrophysiological study; OR
  - i. Long QT syndrome with syncope and/or VT while receiving beta blockers; OR

- j. Hypertrophic cardiomyopathy (HCM) with one or more of the following risk factors:
  - Prior cardiac arrest;
  - Family history of HCM-related sudden cardiac death (SCD) in at least one first-degree relative;
  - Unexplained syncope within the previous 12 months;
  - Spontaneous nonsustained VT;
  - Spontaneous sustained VT;
  - Abnormal blood pressure response to exercise;
  - LV wall thickness greater than or equal to 30 mm.
2. The use of an implantable cardioverter-defibrillator is considered **INVESTIGATIVE** for all other indications in adults.

#### **B. Pediatrics**

1. The use of an implantable cardioverter-defibrillator may be considered **MEDICALLY NECESSARY** in children and adolescents (< 18 years of age) who meet any of the following criteria:
  - a. Survivors of cardiac arrest, after reversible causes have been excluded; OR
  - b. Symptomatic, sustained ventricular tachycardia in association with congenital heart disease in patients who have undergone hemodynamic and electrophysiologic evaluation; OR
  - c. Congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias.
2. The use of an implantable cardioverter-defibrillator (ICD) is considered **INVESTIGATIVE** for all other indications in children and adolescents.

## **II. Subcutaneous Implantable Cardioverter-Defibrillators**

- A. The use of a subcutaneous implantable cardioverter-defibrillator is considered **INVESTIGATIVE** for **ALL** indications in adult and pediatric patients, due to a lack of evidence demonstrating an impact on improved health outcomes.

### **Coverage:**

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its

medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:**

*The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

**CPT:**

33230 Insertion of pacing cardioverter-defibrillator pulse generator only; with existing dual leads

33231 Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads

33240 Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single lead

33243 Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy

33244 Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by transvenous extraction

33249 Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber

93640 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;

93641 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator

93642 Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

0319T Insertion or replacement of subcutaneous implantable

defibrillator system with subcutaneous electrode  
0320T Insertion of subcutaneous defibrillator electrode  
0321T Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode  
0325T Repositioning of subcutaneous implantable defibrillator electrode and/or pulse generator  
0326T 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)  
0327T Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system  
0328T 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; implantable subcutaneous lead defibrillator system

**HCPCS:**

C1721 Cardioverter-defibrillator, dual chamber (implantable)  
C1722 Cardioverter-defibrillator, single chamber (implantable)  
C1777 Lead, cardioverter-defibrillator, endocardial single coil (implantable)  
C1895 Lead, cardioverter-defibrillator, endocardial dual coil (implantable)  
C1896 Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)  
G0448 Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

**Policy  
History:**

**Developed December 10, 2008**

**Most recent history:**

Revised September 14, 2011  
Reviewed September 12, 2012  
Revised February 13, 2013  
Reviewed February 12, 2014

**Cross  
Reference:**

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