MEDICAL POLICY

Excellus

SUBJECT: IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	EFFECTIVE DATE: 09/16/99 REVISED DATE: 05/17/01, 06/20/02, 04/24/03, 10/15/03, 02/19/04, 03/17/05, 12/15/05, 09/21/06, 07/19/07, 08/21/08, 07/16/09, 07/15/10, 08/18/11, 08/16/12, 08/15/13, 08/21/14, 07/16/15, 03/17/16, 1/19/17, 02/15/18
POLICY NUMBER: 7.01.06 CATEGORY: Technology Assessment	PAGE: 1 OF: 12

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based on our criteria and review of the peer-reviewed literature, use of an implantable cardioverter defibrillator (ICD) has been medically proven to be effective and therefore, **medically appropriate** as *secondary prevention* for patients who meet the following criteria:
   A. A documented episode of sustained ventricular tachyarrhythmia (VT) (greater than 30 seconds) or cardiac arrest, either spontaneous or induced by a electrophysiology (EP) study, not associated with myocardial infarction; or
   B. A documented episode of cardiac arrest due to ventricular fibrillation (VF) and not due to reversible causes; or
   C. Documented cardiac sarcoid, giant cell myocarditis, Chagas disease or LV non-compaction.

II. Based upon our criteria and review of the peer-reviewed literature, use of an implantable cardioverter defibrillator (ICD) has been medically proven to be effective and therefore may be considered **medically appropriate** for *primary prevention* of sudden cardiac death in patients with:
   A. Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class II or class III symptoms with a history of myocardial infarction at least 40 days prior to implantation and left ventricular ejection fraction of 35% or less 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. Ischemic cardiomyopathy with New York Heart Association (NYHA) functional class I symptoms with a history of myocardial infarction at least 40 days prior to implantation and left ventricular ejection fraction of 30% or less 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
   C. Nonischemic dilated cardiomyopathy, New York Heart Association (NYHA) functional Class II or Class III CHF, and left ventricular ejection fraction of 35 % or less, after reversible causes have been excluded and the response to optimal medical therapy has been adequately determined; or
   D. Hypertrophic cardiomyopathy (HCM) with 1 or more of the following major risk factors for sudden cardiac death:
      1. Undiagnosed syncope; or
      2. Family history of sudden death; or
      3. Septal wall thickness of greater than or equal to 30 mm; or
      4. Abnormal blood pressure response to exercise; or
      5. Nonsustained VT (less than 30 seconds); or
   E. Documented familial or inherited conditions, including but not limited to, long QT syndrome, arrhythmogenic right ventricular cardiomyopathy, familial cardiomyopathy, or Brugada syndrome with a high risk of life-threatening ventricular tachyarrhythmias ; or
   F. Nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT observed and/or at electrophysiological study performed at least 96 hours after revascularization or MI; or
   G. Structural heart disease (e.g., prior myocardial infarction, congenital heart disease, and/or ventricular dysfunction) with sustained VT (greater than 30 seconds); or
   H. Structural heart disease (e.g., prior myocardial infarction, congenital heart disease, and/or ventricular dysfunction) with unexplained syncope and left ventricular dysfunction (left ventricular ejection fraction less than 50%); or

I. Syncope of undetermined origin who have clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiology (EP) study; or
J. Catecholamine induced ventricular tachycardia with syncope while on beta-blocker therapy.

III. Based upon our criteria and review of the peer-reviewed literature, use of an ICD is considered **investigational** in primary prevention for patients who:
A. have had an acute myocardial infarction (e.g., less than 40 days before ICD treatment;) or
B. have had a cardiac revascularization procedure in past 3 months (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) or are candidates for a cardiac revascularization procedure; or
C. have NYHA Class IV congestive heart failure unless:
1. Patient is eligible to receive a combination cardiac resynchronization therapy ICD device; or
2. Patient is awaiting heart transplantation; or
3. A left ventricular assist device (LVAD) is being used as destination therapy; or
D. have noncardiac disease that would be associated with life expectancy less than 1 year; or
E. with incessant VT or VF (e.g., hemodynamically stable VT or VF continuing for hours); or
F. have significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.

IV. Based upon our criteria and review of the peer-reviewed literature, the use of a subcutaneous ICD is considered **medically appropriate** when criteria for ICD implantation for primary or secondary prevention is met (*refer to Policy Statement I and II*) AND:
A. Have a contraindication to a transvenous ICD due to one or more of the following:
1. lack of adequate vascular access; or
2. compelling reason to preserve existing vascular; or
3. history of need for explantation of a transvenous ICD due to a complication, with ongoing need for ICD therapy; AND
B. Have no indication for antibradycardia pacing; AND
C. Do not have ventricular arrhythmias that are known or anticipated to respond to antitachycardia pacing.

Refer to Corporate Medical Policy #1.01.01 regarding Electrical Stimulation-Transcutaneous Electrical Nerve (TENS), H-Wave and Interferential Stimulators.

Refer to Corporate Medical Policy #1.01.42 regarding Home Automatic External Defibrillators (AEDs) and Wearable Cardioverter Defibrillators (WCDs).

Refer to Corporate Medical Policy #7.01.58 regarding Cardiac Resynchronization Therapy for the Treatment of Congestive Heart Failure.

POLICY GUIDELINES:

I. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

II. When an ICD is to be implanted there should first be a consultation with an electrophysiologist.

III. Case reports have indicated that transcutaneous electrical nerve stimulators (TENS) have been known to interfere with implantable cardioverter defibrillators (ICD) and pacemakers.

DESCRIPTION:

The implantable cardioverter-defibrillator (ICD) is an electronic device designed to monitor a patient's heart rate, recognize ventricular fibrillation (VF) or ventricular tachycardia (VT), and deliver an electronic shock to terminate these life-threatening arrhythmias. Indications for ICD implantation can be broadly subdivided into:

I. Secondary prevention; e.g., their use in patients who have survived a prior sudden cardiac arrest or sustained VT; or

II. Primary prevention / prophylactic; e.g., their use in patients with ischemic or nonischemic dilated cardiomyopathy or documented familial or inherited conditions, who are considered at high risk for sudden cardiac death but who have not yet experienced life-threatening VT or VF.

While traditional ICDs have been used in the management of symptomatic and/or inducible ventricular tachyarrhythmias, specifically VF and VT, technology has led to the development of a dual chamber ICD that utilizes a sophisticated algorithm to detect and treat episodes of VT, VF, and additionally atrial fibrillation (AF). The prevention and treatment of atrial fibrillation (AF) focuses first on maintaining or restoring sinus rhythm (SR), and then on controlling rate and preventing thromboembolic events.

ICDs may be combined with biventricular pacing that can be used to treat symptoms of advanced heart failure in certain people who already need an ICD. These devices combine an implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT). The defibrillator component detects and treats life-threatening heart rhythms. The CRT component coordinates the beating of the left and right ventricles of the heart so that they work together more effectively to pump blood throughout the body.

There are two different techniques for ICD electrode insertion: epicardial insertion, requiring a thoracotomy; or transvenous insertion, requiring a cutdown for direct vein insertion.

The subcutaneous ICD (subq ICD) was developed to avoid some of the complications arising from using a traditional ICD. The subq-ICD consists of a dedicated external programmer, a subcutaneous pulse generator enclosed in a titanium case, and a single subcutaneous electrode containing both sensing and defibrillating components. The device uses proprietary algorithms to detect ventricular arrhythmias and is capable of delivering a pulse of 80 J. The S-ICD® system (Cameron Health, Inc). received FDA approval on September 28, 2012. The device was approved as defibrillation therapy for patients with life-threatening ventricular tachyarrhythmias and who did not have symptomatic bradycardia, continual ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that can be terminated with anti-tachycardia pacing.

RATIONALE:

Prior to 2003, clinical evidence did not substantiate that implantation of a traditional ICD or a dual chamber ICD improved net health outcomes in patients with non-CAD congestive heart failure, cardiomyopathy, or acute myocardial infarction. Results of recent clinical trials of prophylactic defibrillator implantation have been presented, with varied results; the emerging evidence indicates that the prophylactic implantation of defibrillators reduces mortality among patients with a left ventricular dysfunction and that both ischemic and nonischemic patients achieved similar degrees of benefit from ICD therapy. Evidence published evaluating ICDs in patients with recent acute MI does not establish the safety and efficacy of ICD therapy or demonstrate a reduction in mortality when ICD therapy is used in this population.

A 2002 BCBS Association TEC Assessment focused on two successive randomized clinical trials, known as MADIT I and MADIT II (Multicenter Automatic Defibrillator Implantation Trial) that compared the use of an AICD with conventional therapy among patients with coronary artery disease with a prior history of myocardial infarction and a current history of a reduced ejection fraction. The TEC Assessment offered the following observations and conclusions: For patients who have coronary artery disease with prior myocardial infarction and reduced left ventricular ejection fraction and who are similar to those selected in MADIT I and MADIT II, the available evidence demonstrates a statistically significant improvement in overall mortality associated with AICD treatment compared with conventional therapy.

In October 2004, TEC reassessed AICDs. The Assessment focused on the results of the 5 randomized clinical trials included in the 2002 Assessment and 5 additional RCTs. The 2004 TEC Assessment made the following conclusions: The use of ICD devices meets the TEC criteria in the prevention of sudden death from ventricular tachyarrhythmia in patients who have:

I. Symptomatic* ischemic dilated cardiomyopathy with a history of myocardial infarction at least 40 days before ICD treatment and left ventricular ejection fraction of 35% or less; or

II. Symptomatic* nonischemic dilated cardiomyopathy for more than 9 months' duration and left ventricular ejection fraction of 35% or less.

The use of ICD devices does not meet the TEC criteria in the prevention of sudden death from ventricular tachyarrhythmia in patients who have:

I. had an acute myocardial infarction (i.e., less than 40 days before ICD treatment);
II. New York Heart Association (NYHA) Class IV congestive heart failure (unless patient is eligible to receive a combination cardiac resynchronization therapy ICD device);
III. had cardiac revascularization procedure in past 3 months (CABG or PTCA) or are candidates for a cardiac revascularization procedure; or
IV. noncardiac disease that would be associated with life expectancy less than 1 year.

*Symptomatic heart failure is defined as the presence of dyspnea on exertion, angina, palpitations, or fatigue.

Further analysis of existing trial data using patient-level meta-analysis may further delineate which subgroups of patients are likely to benefit from ICD placement and those unlikely to benefit who can be spared the morbidity of ICD placement.

The ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death recommend a range of ejection fractions below which an ICD might be indicated. The Class I recommendations for primary-prevention ICDs in heart failure support their use for mortality reduction in patients on optimal medical therapy with:

I. LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than or equal to 30% to 40%, and are NYHA functional class II or III.
II. Nonischemic heart disease who have an LVEF less than or equal to 30% to 35% and are NYHA functional class II or III.

The ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death make the following recommendations related to familial or inherited conditions with a high risk of life-threatening ventricular arrhythmia:

Hypertrophic Cardiomyopathy (HCM) patients who are receiving chronic optimal medical therapy and who have reasonable expectation of survival with a good functional status for more than 1 year.
Class I- ICD therapy should be used for treatment in patients with HCM who have sustained VT and/or VF.
Class IIa - ICD implantation can be effective for primary prophylaxis against sudden cardiac death (SCD) in patients with HCM who have one or more major risk factors (Cardiac arrest (VF), Spontaneous sustained VT, Family history of premature sudden death, Unexplained syncope, LV thickness greater than or equal to 30 mm, Abnormal exercise BP, Nonsustained spontaneous VT) for SCD.

Arrhythmogenic Right Ventricular Cardiomyopathy patients who are receiving chronic optimal medical therapy and who have reasonable expectation of survival with a good functional status for more than 1 year.
Class I - ICD implantation is recommended for prevention of SCD in patients with arrhythmogenic RV cardiomyopathy with documented sustained VT or VF.
Class IIa - ICD implantation can be effective for prevention of SCD in patients with arrhythmogenic RV cardiomyopathy with extensive disease, including those with LV involvement, one or more affected family members with SCD, or undiagnosed syncope when VT or VF has not been excluded as the cause of syncope.

Long QT Syndrome (LQTS) patients receiving beta blocker therapy who have reasonable expectation of survival with a good functional status for more than 1 year.
Class I - Implantation of an ICD is recommended for LQTS patients with previous cardiac arrest.
Class IIa - Implantation of an ICD can be effective to reduce SCD in LQTS patients experiencing syncope and/or VT.
Class IIb - Implantation of an ICD may be considered for prophylaxis of SCD for patients in categories possibly associated with higher risk of cardiac arrest such as LQT2 and LQT.

Brugada Syndrome patients receiving chronic optimal medical therapy who have reasonable expectation of survival with a good functional status for more than 1 year.
Class I - An ICD is indicated for Brugada syndrome patients with previous cardiac arrest.
Class IIa - An ICD is reasonable for Brugada syndrome patients with spontaneous ST-segment elevation in V1, V2, or V3 who have had syncope with or without mutations demonstrated in the SCN5A gene.
Class IIa - An ICD is reasonable for Brugada syndrome patients with documented VT that has not resulted in cardiac arrest.

In August 2012, the American College of Cardiology, American Heart Association and the Heart Rhythm Society released updated Cardiac Device-Based Therapy Guidelines. Additional information was added to the indications for the use of pacemakers, ICDs and cardiac resynchronization therapy (CRT) devices. The updated guidelines are a product of expert analysis of recent studies and incorporate data from recent clinical trials. The revised guidelines continue to emphasize optimal medical therapy - which the guidelines frame as, essentially, a prerequisite for ICD implantation or cardiac resynchronization therapy (CRT), is a recurring recommendation throughout the document. Others include the affirmation of LVEF less than or equal to 35% as the threshold for considering a primary-prevention ICD in patients with ischemic or nonischemic heart failure in New York Heart Association (NYHA) functional class II-III, an indication based on the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) trial. Also included as a Class I recommendation is the use of ICDs in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30% and are in NYHA functional Class I. Recommendations continue to indicate that ICD implantation is reasonable for patients with hypertrophic cardiomyopathy who have one or more major risk factors for sudden cardiac death.

A subcutaneous ICD (S-ICD) has been developed as an alternative to venous pacing for patients with obstructed venous access and in patients where continued venous access is difficult to maintain. The S-ICD is indicated for the treatment of life-threatening ventricular arrhythmias and contraindicated for patients with symptomatic bradycardia, incessant VT and in patients with documented spontaneous, frequently recurring VT that is reliably terminated with anti-tachycardia pacing. The subcutaneous defibrillator may be more appropriate in younger children with limited venous access, congenital anomalies and who are more active. A small amount of literature has been published on the subcutaneous ICD, with results so far indicating that the subcutaneous ICD may approximate the performance of a transvenous ICD. The evidence for S-ICD placement in individuals who have indications for a TV-ICD but without indications for antibradycardia pacing and without arrhythmias responsive to antitachycardia pacing includes nonrandomized studies and case series. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. Nonrandomized controlled studies report success rates in terminating laboratory-induced VFs that are similar to TV-ICD. However, there is scant evidence on comparative clinical outcomes of both types of ICD over longer periods. Case series report high rates of detection and successful conversion of ventricular tachycardia, and inappropriate shock rates in the range reported for TV-ICD. This evidence is not sufficient to determine whether there are small differences in efficacy between the 2 types of devices, which may be clinically important due to the nature to the disorder being treated. Also, the adverse event rate is uncertain, with variable rates reported. At least 1 RCT is currently underway to compare the S-ICD with the transvenous ICD. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	33215	Repositioning of previously implanted transvenous pacemaker or pacing cardioverter-defibrillator (right atrial or right ventricular) electrode
	33216	Insertion of a single transvenous electrode, permanent pacemaker or single chamber pacing cardioverter-defibrillator
	33217	Insertion of 2 transvenous electrodes, permanent pacemaker or cardioverter-defibrillator
	33218	Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter defibrillator
	33220	Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber pacing cardioverter-defibrillator
	33222	Revision or relocation of skin pocket for pacemaker
	33223	Revision of skin pocket for cardioverter-defibrillator
	33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion and/or replacement of generator)
	33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (including upgrade to dual chamber system)
	33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
	33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
	33241	Removal of implantable defibrillator pulse generator only
	33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy
	33244	by transvenous extraction
	33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
	33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold 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
	93260	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
	93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system
	93282	Programming device evaluation with iterative adjustment of implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; single lead implantable cardioverter-defibrillator system
	93283	dual lead implantable cardioverter-defibrillator system
	93289	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; single dual, or multiple lead implantable cardioverter-defibrillator system, including analysis of heart rhythm derived data elements
	93295	Interrogation device evaluation (remote), up to 90 days; single, dual or multiple lead implantable cardioverter-defibrillator system with interim physician analysis, review(s) and report(s)
	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	with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator
	93642	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
	93644	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)

HCPCS:	C1721	Cardioverter-defibrillator, dual chamber (implantable)
	C1722	Cardioverter-defibrillator, single chamber (implantable)
	C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
	C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
	C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
	C1899	Lead, pacemaker / cardioverter-defibrillator, combination (implantable)
ICD10:	I2510-I25119	Atherosclerotic heart disease of native coronary artery (code range)

I25.3-I25.42	Aneurysm of heart (code range)
I25.5-I25.6	Myocardial ischemia (code range)
I25.700-I25.759	Atherosclerosis of native coronary artery of transplanted heart (code range)
I25.760-I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart (code range)
I25.790-I25.799	Atherosclerosis of other coronary artery bypass graft(s) (code range)
I25.810-I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris (code range)
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.83-I25.84	Coronary atherosclerosis due to lipid rich plaque or calcified coronary lesion (code range)
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I42.0-I42.9	Cardiomyopathy (code range)
I46.2-I46.9	Cardiac arrest (code range)
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I48.0-I48.91	Atrial fibrillation (code range)
I49.01-I49.02	Ventricular fibrillation or ventricular flutter (code range)
I49.9	Cardiac arrhythmia, unspecified
I50.1	Left ventricular failure
I50.20-I50.23	Systolic (congestive) heart failure (code range)
I50.30-I50.33	Diastolic (congestive) heart failure (code range)
I50.40-I50.43	Combined systolic (congestive) and diastolic (congestive) heart failure (code range)
I50.9	Heart failure, unspecified

REFERENCES:

*ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult summary article. A report of the American College of Cardiology/American Heart Association task force on practice guidelines [http://content.onlinejacc.org/article.aspx?articleid=1136916] accessed 1/2/18.

*Al-Khatib SM, et al. Implantable cardioverter defibrillators and cardiac resynchronization therapy in patients with left ventricular dysfunction: randomized trial evidence through 2004. Am Heart J 2005 Jun;149(6):1020-34

*Almendral J and Josephson ME. All patients with hemodynamically tolerated postinfarction ventricular tachycardia do not require an implantable cardioverter-defibrillator. Circulation 2007 Sep 4;116(10):1204-12.

Aziz S, et al. The subcutaneous defibrillator: a review of the literature. J Am Coll Cardiol 2014 Apr 22;63(15):1473-9.

*Barsheshet A, et al. Applicability of a risk score for prediction of the long-term (8 year) benefit of the implantable cardioverter-defibrillator. J Am Coll Cardiol 2012 Jun 5;59(23):2075-9.

*Begley DA, et al Efficacy of implantable cardioverter defibrillator therapy for primary and secondary prevention of sudden cardiac death in hypertrophic cardiomyopathy. Pacing Clin Electrophysiol 2003 Sep;26(9):1887-96.

*Berul CI, et al. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. J Am Coll Cardiol 2008 Apr 29;51(17):1685-91.

Blue Cross Blue Shield Association. Automatic Implantable Cardioverter Defibrillator (AICD). Medical Policy Reference Manual Policy #7.01.44. 2017 May 08.

*Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Implantable cardioverter-defibrillators for primary prevention of ventricular tachyarrhythmia. 2002 Aug;19.

*Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Use of Implantable Cardioverter-Defibrillators for prevention of sudden death in patients at high risk for ventricular arrhythmia. 2005 Mar;19 (No. 19)

*Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Special report: cost-effectiveness of the Implantable Cardioverter- Defibrillator in primary prevention populations. 2005 Mar;19(No. 20).

Boersma L, et al. Implant and midterm outcomes of the subcutaneous implantable cardioverter-defibrillator registry. The EFFORTLESS study. J Am Coll Cardiol 2017 Aug 15;70(7):830-841.

Boersma L, et al. Infection and mortality after implantation of a subcutaneous ICD after transvenous ICD extraction. Heart Rhythm 2015 Sep 1. pii: S1547-5271(15)01129-7.

Bogush N, et al. Selecting the right defibrillator in the younger patient: transvenous, epicardial or subcutaneous? Int J Cardiol 2018 Jan1;250:133-138.

Bordachar P et, al. Subcutaneous implantable cardioverter defibrillators in children, young adults, and patients with congenital heart disease. Int J Cardiol 2016;203(1):251-8.

*Bunch TJ, et al. Mechanisms of sudden cardiac death in myocardial infarction survivors: insights from the randomized trials of implantable cardioverter-defibrillators. Circulation 2007 May 8;115(18):2451-7.

Burke MC, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator. J Am Coll Cardiol 2015 Apr 28;65(16):1605-15.

*Buxton AE, et al. Limitations of ejection fraction for prediction of sudden death risk in patients with coronary artery disease: lessons from the MUSTT study. J Am Coll Cardiol 2007 Sep 18;50(12):1150-7.

*Chan PS, et al. Effectiveness of implantable cardioverter-defibrillators in patients with ischemic heart disease and left ventricular dysfunction. Arch Intern Med 2006 Nov 13;166(20):2228-33.

Chue CD, et al. Efficacy and safety of the subcutaneous implantable cardioverter defibrillator: a systematic review. Heart 2017 Sep;103(17):1315-1322.

*Desai AD, et al. Predictors of appropriate defibrillator therapy among patients with an implantable defibrillator that delivers cardiac resynchronization therapy. J Cardiovasc Electrophysiol 2006 May;17(5):486-90.

*Epstein AE, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices). Circulation 2008 May 27;117(21):e350-408.

Friedman DJ, et al. Trends in in-hospital outcomes associated with adoption of the subcutaneous implantable cardioverter defibrillator in the United States. JAMA Cardiol 2016 Nov 1;1(8):900-11.

*Fuster V, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: full text: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 guidelines for the management of patients with atrial fibrillation) developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society [http://circ.ahajournals.org/content/114/7/e257.full.pdf+html] accessed 1/2/18.

*Gregoratos G, et al. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices; a report of the American College of Cardiology/American Heart Association task Force on Practice Guidelines.[http://content.onlinejacc.org/cgi/content/short/40/9/1703] accessed 1/2/18.

Groh CA, et al. Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm 2014;11(8):1361-6.

*Jessup M, et al. 2009 focused update: ACCF/AHA guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines developed in collaboration with the International Society for Heart and Lung Transplantation. JACC 2009;53(15):1343-82.

Knops RE, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace 2016 Jul; 18(7): 1010–1015.

Kooiman KM et al. Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: implications for management. Heart Rhythm 2014 Mar;11(3):426-34.

Lelakowski J, et al. Factors predisposing to ventricular tachyarrhythmia leading to appropriate ICD intervention in patients with coronary artery disease or non-ischaemic dilated cardiomyopathy. Kardiol Pol 2012;70(12):1264-75.

Lambiase PD, et al. Evaluation of subcutaneous ICD early performance in hypertrophic cardiomyopathy from the pooled EFFORTLESS and IDE cohorts. Heart Rhythm 2016;13(5)1066-1074.

Lupo PP, et al. Development of an entirely subcutaneous implantable cardioverter-defibrillator. Prog Cardiovasc Dis 2012 May;54(6):493-7.

Mant J, et al. Management of chronic heart failure in adults: synopsis of the National Institute for Health and clinical excellence guideline. Ann Intern Med 2011 Aug 16;155(4):252-9.

*Maron BJ, et al. American College of Cardiology/European Society of Cardiology clinical expert consensus document on hypertrophic cardiomyopathy. A report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents and the European Society of Cardiology Committee for Practice Guidelines. J Am Coll Cardiol 2003 Nov 5;42(9):1687-713.

*Maron BJ, et al Primary prevention of sudden death as a novel treatment strategy in hypertrophic cardiomyopathy. Circ 2003 Jun 17;107(23):2872-5.

*Maisel WH. Pacemaker and ICD generator reliability: meta-analysis of device registries. JAMA 2006 Apr 26;295(16):1929-34.

Maurizi N, et al. Effectiveness of subcutaneous implantable cardioverter-defibrillator testing in patients with hypertrophic cardiomyopathy. Int J Cardiol 2017 Mar 15;231:115-119.

Maurizi N, et al. Prevalence of subcutaneous implantable cardioverter-defibrillator candidacy based on template ECG screening in patients with hypertrophic cardiomyopathy. Heart Rhythm 2016 Feb;13(2):457-63.

McLeod CJ, et al. The subcutaneous implantable cardioverter defibrillator: state-of-the-art review. Eur Heart J 2017 Jan 21;38(4):247-257.

*Moss AJ. What we have learned from the family of multicenter automatic defibrillator implantation trials. Circ J 2010 Jun;74:1038-41.

*Moss AJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. NEJM 2002 Mar 21;346(12):877-83.

Naksuk N, et al. Incidence of appropriate shock in implantable cardioverter-defibrillator patients with improved ejection fraction. J Card Fail 2013 Jun;19(6):426-30.

Pedersen SS, et al. A comparison of the quality of life of patients with an entirely subcutaneous implantable defibrillator system versus a transvenous system (from the EFFORTLESS S-ICD quality of life substudy). Am J Cardiol 2016;118(4)520-526.

*Reichlin Y, et al. Characterization and financial impact of implantable cardioverter-defibrillator patients without interventions 5 years after implantation. QJM 2011 Oct;104(10):849-57.

*Sacher F, et al. Outcome after implantation of a cardioverter-defibrillator in patients with Brugada syndrome: a multicenter study. Circ 2006 Nov 28;114(22):2317-24.

*Saxon LA, et al. Predictors of sudden cardiac death and appropriate shock in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial. Circ 2006 Dec 19;114(25):2766-72.

*Saxon LA, et al. Results of the multicenter RENEWAL 3 AVT clinical study of cardiac resynchronization defibrillator therapy in patients with paroxysmal atrial fibrillation. J Cardiovasc Electrophysiol 2006 May;17(5):520-5.

*Tracy CM, et al. 2012 ACCF/AHA/HRS Focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg 2012 Dec;144(6):e127-45.

Wilcox ME, et al. Recent developments in the subcutaneous ICD. Trends in Cardiovascular Medicine 2016; 26(6):526–535.

Yung D, et al. Survival after implantable cardioverter-defibrillator implantation in the elderly. Circulation 2013 Jun 18;127(24):2383-92.

*Zareba W, et al. Implantable cardioverter defibrillator in high-risk long QT syndrome patients. J Cardiovasc Electrophysiol 2003 Apr;14(4):337-41.

*Zipes DP, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death--executive summary: A report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death) Developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Eur Heart J 2006 Sep;27(17):2099-140.

* key article

KEY WORDS: AICD, Automatic implantable cardioverter defibrillator, Cardiac resynchronization, ICD.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Implantable Automatic Defibrillators. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=3&bc=AgAAgAAAAAAA&.

There is currently a National Coverage Determination (NCD) for Cardiac Pacemakers: Single-Chamber and Dual-Chamber Permanent Cardiac Pacemakers. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=357&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&