MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	Implantable Cardioverter Defibrillator
Policy Number	7.01.06
Category	Technology Assessment
Original Effective Date	10/18/01
Committee Approval	10/18/01, 06/20/02, 04/24/03, 10/15/03, 02/19/04, 03/17/05, 12/15/05, 09/21/06, 07/19/07,
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Current Effective Date	08/17/23
Deleted Date	N/A
Archived Date	N/A
Archive Review Date	N/A
Product Disclaimer	• 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 or Child Health Plus product), medical policy criteria apply to the benefit.
	• If a Medicaid product covers a specific service, and there are no New York State
	Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
	• If a Medicare product (including Medicare HMO-Dual Special Needs Program
	(DSNP) 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.
	• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

PRIMARY PREVENTION:

- I. Based upon our criteria and assessment of the peer-reviewed literature, use of an Implantable Cardiac 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 who have **ANY** of the following:
 - A. Ischemic cardiomyopathy in individuals who have a New York Heart Association (NYHA) Functional Class II or Class III symptoms and ALL of the following:
 - 1. LV dysfunction due to prior MI and ALL of the following:
 - a. LVEF 35% or less and either:
 - i. 40 days or greater since the most recent MI; **OR**
 - ii. LVEF was 35% or less prior to the most recent MI; **OR**
 - B. Ischemic cardiomyopathy who has a New York Heart Association (NYHA) Functional Class I symptoms and ALL of the following;
 - 1. LV dysfunction with prior history of MI, and ALL of the following:
 - a. LVEF was 30% or less and either:
 - i. 40 days or greater since most recent MI; **OR**
 - ii. LVEF was 30% or less prior to most recent MI; **OR**
 - C. Ischemic cardiomyopathy who has non-sustained VT due to prior MI and **ALL** of the following:
 - 1. LVEF of 40% or less: **AND**
 - 2. Have inducible VF or sustained VT at EP study performed at least 96 hours after revascularization or MI; OR
 - D. Nonischemic dilated cardiomyopathy, who have **ALL** of the following:
 - 1. LVEF 35% or less; AND
 - 2. Who have NYHA Functional Class II or Class III CHF; AND
 - 3. Are on optimal medical therapy (OMT) (defined as 3 months of maximally titrated doses as tolerated of an ACE inhibitor/angiotensin II receptor blocker, beta-blocker, and, if needed, a diuretic); **OR**

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- E. Hypertrophic cardiomyopathy (HCM), who have **ONE 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 (systolic blood pressure (SBP) increase of less than 20mm/Hg with exercise or a drop in BP); **OR**
 - 5. Ventricular tachycardia sustained or nonsustained; OR
 - 6. LV apical aneurysm, independent of size; **OR**
 - 7. LV ejection fraction less than 50%; **OR**
- F. Arrhythmogenic right ventricular cardiomyopathy (ARVC), with one or more risk factors for sudden cardiac death (unpredicted syncope, family history of sudden death, VT sustained or non-sustained, clinical signs of RV failure); **OR**
- G. In individuals with normal LV function (LVEF greater than 50%) with positive family history of sudden death; **OR**
- H. Long QT syndrome in the following settings:
 - 1. Syncope and/or VT while receiving beta-blockers or if beta-blockers are contraindicated; **OR**
 - 2. Asymptomatic with other risk factors for sudden cardiac death which include the following; QTc greater than 500msec or LQT 2 or 3, or family history of sudden death; **OR**
- I. Brugada syndrome with syncope or documented or inducible VT or VF; **OR**
- J. Familial cardiomyopathy individuals associated with sudden death; **OR**
- K. Nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT observed and/or at electrophysiological study (EP) performed at least 96 hours after revascularization or MI; **OR**
- L. Sustained VT and normal or near normal ventricular function; **OR**
- M. Structural heart disease (e.g., prior MI, congenital heart disease, and/or ventricular dysfunction) with sustained VT (greater than 30 seconds); **OR**
- N. Structural heart disease (e.g., prior MI, congenital heart disease, and/or ventricular dysfunction and spontaneous, sustained VT (greater than 30 seconds) whether hemodynamically stable or non-stable; **OR**
- O. Syncope of undetermined origin and clinically relevant, hemodynamically significant, sustained VT or VF induced at EP study; **OR**
- P. Unexplained syncope, significant LV function (LVEF less than 50%) and structural heart disease, such as prior MI, congenital heart disease and/or ventricular dysfunction; **OR**
- Q. Catecholaminergic Polymorphic Ventricular Tachycardia who have syncope and/or documented sustained VT, while on beta-blocker therapy; **OR**
- R. Muscular dystrophy diagnosis, regardless of LVEF for **ANY** of the following:
 - 1. Emery-Dreifuss muscular dystrophy (EDMD); **OR**
 - 2. Limb-Girdle Type 1B muscular dystrophy (LGMD1B); OR
 - 3. Myotonic Dystrophy Type 1 with an indication for a permanent pacemaker; **OR**
 - 4. Lamin A/C (LMNA) mutation (for patients who don't meet the above criteria of EDMD or LGMD1B) when there is documentation of **TWO OR MORE** of the following risk factors for sudden cardiac death:
 - a. Non-sustained ventricular tachycardia; OR
 - b. LVEF less than 45%; **OR**
 - c. Non-missense mutation (ins-del/truncating or mutations affecting splicing); **OR**
 - d. Male sex at birth; OR
- II. Based upon our criteria and assessment of the peer-reviewed literature, use of an ICD has not been medically proven to be effective and, therefore, is considered investigational in *primary prevention* for patients who have:
 - A. had an acute MI (e.g., less than 40 days before ICD treatment); **OR**
 - B. had a cardiac revascularization procedure in the past three(3) months (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) unless a separate indication for permanent pacemaker implantation exists; **OR**
 - C. NYHA Class IV heart failure, unless:

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- 1. Patient is eligible to receive a combination cardiac resynchronization therapy (CRT) 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. an expected life expectancy of less than one year, even if meet ICD implantation criteria; OR
- E. incessant VT or VF (e.g., hemodynamically stable VT or VF continuing for hours); **OR**
- F. significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up; **OR**
- G. VF or VT is due to a reversible cause (i.e., severe electrolyte disturbance, drug induced torsades de pointes, acute re-perfused MI with preserved ejection fraction); **OR**
- H. No structural heart disease and is a candidate for ablation.

SECONDARY PREVENTION:

- III. Based upon our criteria and assessment of the peer-reviewed literature, use of an implantable cardioverter defibrillator (ICD) has been medically proven to be effective and, therefore, is considered medically appropriate as *secondary prevention* for patients who have had **ANY** of the following:
 - A. A documented episode of sustained ventricular tachyarrhythmia (either ventricular tachycardia (VT) or ventricular fibrillation (VF) lasting longer than 30 seconds), or cardiac arrest (either spontaneous or induced by an electrophysiology (EP) study) not associated with myocardial infarction (MI) whether hemodynamically stable or nonstable: **OR**
 - B. Survivor of cardiac arrest due to VT or VF after evaluation has excluded any completely reversible causes; OR
 - C. A documented cardiac sarcoid or giant cell myocarditis regardless of left ventricular ejection fraction (LVEF); **OR**
 - D. Documented Chagas disease, regardless of LVEF; OR
 - E. Left ventricular (LV) non-compaction cardiomyopathy (left ventricular ejection fraction (LVEF) less than 50%); **OR**
 - F. LV non-compaction:
 - 1. In individuals with normal LV function (LVEF greater than 50%) with positive family history of sudden death; **OR**
 - 2. In individuals with impaired LV function (LVEF less than 50%) for primary prevention of sudden cardiac death due to malignant ventricular arrythmias.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, the use of a subcutaneous ICD has been medically proven to be effective and, therefore, is considered medically appropriate for patients who have met the criteria for ICD implantation for *primary or secondary prevention* and who meet **ALL** of the following criteria:
 - 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 explanation of a transvenous ICD due to a complication, with ongoing need for ICD therapy; **AND**
 - B. have no indication for anti-bradycardia pacing; AND
 - C. do not have ventricular arrhythmias that are known or anticipated to respond to anti-tachycardia pacing.
- V. Based upon our criteria and the lack of peer-reviewed literature, the use of a substernal implantable cardioverter-defibrillator systems have not been medically proven to be effective and, therefore, is considered investigational.

Refer to Corporate Medical Policy #1.01.01 Transcutaneous and Percutaneous Nerve Stimulation as a Treatment for Pain and Other Conditions

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

Refer to Corporate Medical Policy #7.01.58 Cardiac Resynchronization Therapy (Biventricular Pacemakers) for the Treatment of Congestive Heart Failure

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

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POLICY GUIDELINES

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

II. Case reports have indicated that transcutaneous electrical nerve stimulators (TENS) have been known to interfere with ICDs and pacemakers.

DESCRIPTION

An ICD is an electronic device designed to monitor a patient's heart rate, recognize VF or 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., for use in patients who have survived a prior sudden cardiac arrest or sustained VT; or
- II. Primary prevention or as a prophylactic, e.g., for 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 VT and VF, 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 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, to treat symptoms of advanced heart failure in certain patients who already need an ICD. These devices combine an ICD with 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 U.S. Food and Drug Administration (FDA) approval on September 28, 2012. The device was approved as defibrillation therapy for patients with life-threatening ventricular tachyarrhythmias who have not had symptomatic bradycardia, continual ventricular tachycardia, or spontaneous, frequently recurring VT that can be terminated with anti-tachycardia pacing.

Subq-ICDs are limited by the large size, inability to provide anti-tachycardia pacing, limited bradycardia pacing support, and a higher shock that must be delivered, compared to transvenous ICDs. The substernal or extravascular ICD has been proposed as an alternative to the subq-ICD. The lead is placed under the sternum in the substernal space (anterior mediastinum) for pacing and defibrillation. The placement allows for a lower energy to capture and defibrillate the heart, compared to a subcutaneous lead. There are clinical trials and studies underway to determine the usefulness of this approach for lead placement.

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-coronary artery disease, congestive heart failure, cardiomyopathy, or acute MI. Recent clinical trials of prophylactic defibrillator implantation have presented varied results; the emerging evidence indicates that the prophylactic implantation of defibrillators reduces mortality among patients with an LV dysfunction, and that both ischemic and nonischemic patients achieved similar degrees of benefit from ICD therapy. Published evidence 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.

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The American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death recommended 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 who have:

- LV dysfunction due to MI occurring at least 40 days prior, have an LVEF less than or equal to 30% to 40%, and are NYHA Functional Class II or III; or
- nonischemic heart disease, have an LVEF less than or equal to 30% to 35%, and are NYHA Functional Class II or III.

The ACC/AHA/ESC 2017 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death made the following recommendations related to familial or inherited conditions with a high risk of life-threatening ventricular arrhythmia:

- I. For patients with hypertrophic cardiomyopathy (HCM) who are receiving chronic optimal medical therapy and who have reasonable expectation of survival with a good functional status for more than one 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 due to VF; spontaneous, sustained VT; family history of premature sudden death; unexplained syncope; LV thickness equal to or greater than 30 mm; abnormal exercise BP; spontaneous nonsustained VT) for SCD.
- II. For patients with arrhythmogenic right ventricular (RV) cardiomyopathy who are receiving chronic optimal medical therapy and who have reasonable expectation of survival with a good functional status for more than one 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.
- III. For patients with long QT syndrome (LQTS) who are receiving beta blocker therapy and who have reasonable expectation of survival with a good functional status for more than one year:
 - Class I ICD implantation is recommended for LQTS patients with previous cardiac arrest.
 - Class IIa ICD implantation can be effective to reduce SCD in LQTS patients experiencing syncope and/or VT.
 - Class IIb ICD implantation may be considered for prophylaxis of SCD for patients in categories possibly associated with higher risk of cardiac arrest, such as LQT1 or LQT2.
- IV. Patients with Brugada syndrome who are receiving chronic optimal medical therapy and who have reasonable expectation of survival with a good functional status for more than one year:
 - Class I ICD implantation is indicated for Brugada syndrome patients with previous cardiac arrest.
 - Class IIa ICD implantation 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 ICD implantation is reasonable for Brugada syndrome patients with documented VT that has not resulted in cardiac arrest.

In August 2012, the ACC, the AHA, and the Heart Rhythm Society (HRS) released updated Cardiac Device-Based Therapy Guidelines. Additional information was added to the indications for the use of pacemakers, ICDs, and CRT devices. The updated guidelines are a product of expert analysis of recent studies and incorporate data from recent clinical trials. A recurring recommendation in the revised guidelines is the use of optimal medical therapy as, essentially, a prerequisite for ICD implantation or CRT. Other recommendations 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 NYHA functional class II-III, an indication based on the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Also

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included as a Class I recommendation is the use of ICDs in patients with LV dysfunction due to MI occurring at least 40 days prior, who 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 HCM who have one or more major risk factors for SCD.

A subcutaneous ICD (S-ICD) has been developed as an alternative to venous pacing for patients with obstructed venous access and in whom continued venous access is difficult to maintain. The S-ICD is indicated for the treatment of lifethreatening ventricular arrhythmias and contraindicated for patients with symptomatic bradycardia, incessant VT, and documented spontaneous, frequently recurring VT that is reliably terminated with anti-tachycardia pacing. The subcutaneous defibrillator may also be more appropriate in younger, more active children with limited venous access and congenital anomalies. A small amount of literature, which includes nonrandomized studies and case series, has been published on the S-ICD, with results so far indicating that the S-ICD may approximate the performance of a transvenous ICD (TV-ICD). The evidence for S-ICD placement in individuals who have indications for a TV-ICD, but without indications for anti-bradycardia pacing and without arrhythmias responsive to anti-tachycardia pacing. Relevant outcomes are overall survival, morbid events, quality of life, and treatment-related morbidity and mortality. Non-randomized, 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 VT, 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 two 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 one RCT is currently underway to compare the S-ICD with the TV-ICD. The evidence is insufficient to determine the effects of the technology on health outcomes.

Medtronic PLC is currently testing an extravascular implantable cardioverter defibrillator (EV ICD) system, which consists of an ICD system with a substernal implantable defibrillator electrode to deliver defibrillation and antitachycardia pacing therapy. The Medtronic research teams have completed multiple early research studies, including the Acute Sensing and Defibrillation (ASD), Substernal Pacing Acute Clinical Evaluation (SPACE), and ASD2 studies. There are currently two U.S. clinical trials in progress to investigate and demonstrate the safety and efficacy of the new EV ICD system in humans. The EV ICD system has not received FDA approval.

CODES

- 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 Codes

Code	Description
33212	Insertion of pacemaker pulse generator only; with existing single lead
33213	Insertion of pacemaker pulse generator only; with existing dual leads
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator

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Code	Description
33220	Repair of two transvenous electrodes for permanent pacemaker or implantable defibrillator
33221	Insertion of pacemaker pulse generator only; with existing multiple leads
33222	Relocation of skin pocket for pacemaker
33223	Relocation of skin pocket for implantable defibrillator
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
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	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
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
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

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Code	Description
93282	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; single lead transvenous implantable defibrillator system
93283	dual lead transvenous implantable defibrillator system
93295	Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
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 transvenous 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)
0571T (E/I)	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T (E/I)	Insertion of substernal implantable defibrillator electrode
0573T (E/I)	Removal of substernal implantable defibrillator electrode
0574T (E/I)	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0575T (E/I)	Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, 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
0576T (E/I)	Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter

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Code	Description
0577T (E/I)	Electrophysiological evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
0578T (E/I)	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
	(Report 0578T only once per 90 days)
0579T (E/I)	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
	(Report 0579T only once per 90 days)
0580T (E/I)	Removal of substernal implantable defibrillator pulse generator only
	(Use 0580T in conjunction with 0571T, 0573T for removal and replacement of an implantable cardioverter-defibrillator and substernal electrode[s]
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

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HCPCS Codes

Code	Description
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 Codes

Code	Description
I25.10-I25.119	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)
125.700-125.739	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris (code range)
I25.750-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	Atherosclerosis of other coronary vessels without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris

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Code	Description
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 and flutter (code range)
I49.01-I49.02	Ventricular fibrillation or ventricular flutter (code range)
I49.9	Cardiac arrhythmia, unspecified
I50.1	Left ventricular failure, unspecified
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 [https://www.jacc.org/doi/10.1016/j.jacc.2005.08.023] accessed 07/24/23.
- *Al-Khatib SM, et al. 2017 AHA/ACC/HRS Guideline 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 on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm 2018 Oct;15(10):e190-e252.
- *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.

Ambrosy AP, et al. Is time from last hospitalization for heart failure to placement of a primary prevention implantable cardioverter-defibrillator associated with patient outcomes? Circulation 2018 Dec 11:138(24):2787-2797.

- *Barsheshet A, et al. Applicability of a risk score for prediction of the long-term (8 year) benefit of the implantable cardioverter-defibrillator. <u>J Am Coll Cardiol</u> 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. <u>Pacing Clin Electrophysiol</u> 2003 Sep;26(9):1887-96.

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

Boersma LV, et al. Therapy from a Substernal Lead: The ASD2 Study. J Am Coll Cardiol: Clin EP 2019;5:186-96.

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

Broers ER, et al. Personality traits, ventricular tachyarrhythmias, and mortality in patients with an implantable cardioverter defibrillator: 6 years follow-up of the WEBCARE cohort. General Hospital Psychiatry 2020 Jan; 62:56-62.

*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.

*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. <u>J Am Coll Cardiol</u> 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. <u>Arch Intern Med</u> 2006 Nov 13;166(20):2228-33.

*Desai AD, et al. Predictors of appropriate defibrillator therapy among patients with an implantable defibrillator that delivers cardiac resynchronization therapy. <u>J Cardiovasc Electrophysiol</u> 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.

Fong KY, et al. Subcutaneous versus transvenous implantable defibrillator therapy: a systematic review and meta-analysis of randomized trials and propensity score-matched studies. <u>Journal of the American Heart Association</u> 2022 Jun;11(11):1-18.

Friedman P, et al. Extravascular ICD Pivotal Study Investigators. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med 2022 Oct 6;387(14):1292-1302.

*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 [https://www.ahajournals.org/doi/full/10.1161/circulationaha.106.177292] accessed 07/24/23.

*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.[https://sciencedirect.com/science/article/pii/S0735109702025287?via%3Dihub] accessed 07/24/23.

Hernandez-Ojeda J, et al. The role of clinical assessment and electrophysiology study in Brugada syndrome patients with syncope. JAHJ 2019;10.016.

Hess PL,et al. Decision-making regarding primary prevention implantable cardioverter-defibrillators among older adults. Clinical Cardiology 2019 Nov;1-9.

Ip, James E. Managing elevated subcutaneous implantable cardioverter-Defibrillator defibrillation thresholds: The importance of implantation technique. Journal of Cardiovascular Electrophysiology 2021 Jan.

*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. <u>JACC</u> 2009;53(15):1343-82.

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Kawamura I, et al. Patient characteristics and in-hospital complications of subcutaneous implantable cardioverter-defibrillator for Brugada syndrome in Japan. <u>Journal of Arrhythmia</u> 2019 Aug;35:842–847.

Kleeman T, et al. Long-term performance and lead failure analysis of the Durata defibrillation lead compared to its previous model, the recalled Riata defibrillation lead. <u>Journal of Cardiovasc Electrophysiol</u> 2019 Jul;30:2012-2019.

*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. <u>J Am Coll Cardiol</u> 2003 Nov 5;42(9):1687-713.

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

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

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

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

*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.

Ricciardi D, et al. Clinical impact of defibrillation testing in a real-world S-ICD population: Data from the ELISIR registry. <u>J Cardiovasc Electrophysiol</u> 2020;1-9.

Rordorf R, et al. Subcutaneous versus transvenous implantable defibrillator: an updated meta-analysis. <u>Heart Rhythm</u> Society 2021 Mar;18(3):382-391.

*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. <u>J Cardiovasc Electrophysiol</u> 2006 May;17(5):520-5.

Sholevar DP, et al. Feasibility of extravascular pacing with a novel substernal electrode configuration: the substernal pacing acute clinical evaluation (SPACE) study. <u>Heart Rhythm</u> 2018;15:536–542.

Sirico G, et al. Myotonic dystrophy type 1 and high ventricular vulnerability at the electrophysiological evaluation: ICD yes or not? Acta Myol 2020 Mar 1;39(1):32-35.

*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.

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

Zeitler EP, et al. Complications involving the subcutaneous implantable cardioverter-defibrillator: Lessons learned from MAUDE. Heart Rhythm 2020 Mar;17(3):447-454.

*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

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Death) Developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. <u>Eur Heart J</u> 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: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=4&bc=AAAAgAAAAAA& accessed 07/24/23.