



2015 Subcutaneous Implantable Defibrillator (the S-ICD[™] System) Coding Guide – Rhythm Management

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Beginning January 1, 2015 physicians and hospital outpatient facilities are to use new CPT Category I codes to report S-ICD™ System procedures.

Providers should ensure that their coding and claims processing systems are updated to reflect the new CPT Category I codes for implementation beginning January 1, 2015.

Physician Coding

Category I CPT Code ¹	Description	Work Relative Value Unit (RVU)*
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	9.10
33271	Insertion of subcutaneous implantable defibrillator electrode	7.50
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead	6.05
33241	Removal of implantable defibrillator pulse generator only	3.29
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator, single lead system	6.06
33272	Removal of subcutaneous implantable defibrillator electrode	5.42
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode	6.50
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)	3.29
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	.74
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	.85

^{*} Centers for Medicare and Medicaid Services. Medicare Program: CY2015 Physician Fee Schedule Final Rule, CMS-1612-FC

Hospital Outpatient Coding and Payment

Category I CPT Code ¹	Description	APC	2015 Medicare National Avg. Payment*
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	0108	\$30,806
33271	Insertion of subcutaneous implantable defibrillator electrode	0090	\$6,543
33240	Insertion of implantable defibrillator pulse generator only with existing single lead	0107	\$22,908
33241	Removal of implantable defibrillator pulse generator only	0105	\$2,346
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system	0107	\$22,908
33272	Removal of subcutaneous implantable defibrillator electrode	0105	\$2,346
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode	0105	\$2,346
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)	NA	NA
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	0690	\$35
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	0690	\$35

^{*} Centers for Medicare and Medicaid Services. Medicare Program: CY2015 Hospital Outpatient Prospective Payment System and ASC Final Rule, CMS-1613-FC

C-Codes

CMS requires hospitals to report device-related Category Codes (C-Codes) on Medicare claims when medical devices are used in procedures performed in the outpatient setting. Listed below are C-codes for reporting the S-ICDTM System implant procedures. For a complete list of C-Codes go to CMS' 2014 Alpha-Numeric HCPCS File found at http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html

C-Code	Description	
C1722	Cardioverter-defibrillator, single chamber (implantable)	
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)	

For Non-Medicare patients, hospitals should check with payers for specific coding requirements.

Ambulatory Surgery Center (ASC) Coding and Payment

Medicare allows most S-ICDTM System procedures to be performed in the ASC setting.

Category I CPT Code ¹	Description	2015 Medicare National Avg. Payment*
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	\$27,204
33271	Insertion of subcutaneous implantable defibrillator electrode	\$5,650
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead	\$20,286
33241	Removal of implantable defibrillator pulse generator only	\$1,287
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system	\$20,286
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode and/or pulse generator	\$1,287

^{*} Centers for Medicare and Medicaid Services. Medicare Program: CY2015 Hospital Outpatient Prospective Payment System and ASC Final Rule, CMS-1613-FC

Hospital Inpatient Coding

ICD-9 Procedure Code	Procedure Description	
37.20	Non-invasive programmed electrical stimulation [NIPS]	
37.70	Initial insertion of lead (electrode), not otherwise specified	
37.75	Revision of lead (electrode)	
37.77	Removal of lead(s) (electrodes) without replacement	
37.79	Revision or relocation of cardiac device pocket	
37.94	Implantation or replacement of automatic cardioverter/defibrillator, total system	
37.95	Implantation of automatic cardioverter/defibrillator leads(s) only	
37.96	Implantation of automatic cardioverter/defibrillator pulse generator only	
37.97	37.97 Replacement of automatic cardioverter/defibrillator leads(s) only	
37.98	Replacement of automatic cardioverter/defibrillator pulse generator only	
89.49	Automatic implantable cardioverter/defibrillator (AICD) check	

There is associated hospital inpatient MS-DRG payment based on documentation of appropriate ICD-9 Diagnosis Coding and ICD-9 Procedure coding combinations. The American Hospital Association (AHA) has confirmed that the S-ICD System procedures will be reported using the above listed procedure codes. This confirmation is referenced in the Fourth Quarter 2012 issue of American Hospital Association (AHA) Coding Clinic (pages 88 and 104). The AHA Central Office serves as the official U.S. Clearinghouse on medical coding for the proper use of the ICD-9-CM systems.

Hospital Inpatient Payment

MS-DRG	MS-DRG Description	FY2015 National Average Base Payment*
MS-DRG 222	Cardiac defib implant w cardiac cath w AMI/HF/shock w MCC	\$50,777
MS-DRG 223	Cardiac defib implant w cardiac cath w AMI/HF/shock w/o MCC	\$36,908
MS-DRG 224	Cardiac defib implant w cardiac cath w/o AMI/HF/shock w MCC	\$45,008
MS-DRG 225	Cardiac defib implant w cardiac cath w/o AMI/HF/shock w/o MCC	\$34,378
MS-DRG 226	Cardiac defibrillator implant w/o cardiac cath w MCC	\$40,808
MS-DRG 227	Cardiac defibrillator implant w/o cardiac cath w/o MCC	\$31,963
MS-DRG 245	AICD generator procedures	\$26,266
MS-DRG 265	AICD lead procedures	\$16,799

^{*} Centers for Medicare and Medicaid Services. Medicare Program: <u>FY2015 Hospital Inpatient Prospective Payment System, Final Rule;</u> August 19, 2014.

Medical Necessity and Site of Service

Determination of inpatient or outpatient status is a decision made by the physician based on the patient's clinical condition.

Coverage

<u>Medicare</u>: The S-ICD[™] System is covered under the National Coverage Determination (NCD) for ICDs as the S-ICD System is classified as a defibrillator that treats life-threatening arrhythmias. Patients indicated for the S-ICD System must also meet the requirements of the NCD for ICDs. CMS has communicated this coverage guidance to the local Medicare contractors.

As part of the NCD (20.4) for Implantable Automatic Defibrillators, please note the following reporting requirements for primary prevention:

- Hospitals must enter all patients receiving an ICD (subcutaneous or transvenous) for primary prevention into the ICD Registry.
- Claims submitted for Medicare patients implanted with an ICD system (subcutaneous or transvenous) for primary prevention require the Q0 (zero) modifier to be appended to the implant procedure code.
 The Q0 modifier indicates the patient has been enrolled in the ICD Registry.
- Claims submitted for services provided in a clinical trial or registry require the reporting of the corresponding Clinical Trial Number*. The Clinical Trial Number for the ICD Registry is NCT01999140**

<u>Medicaid</u>: Many state Medicaid programs have begun to cover S-ICD procedures; including the following plans as of March 1, 2015. Check your local Medicaid program fee schedule for updates regarding S-ICD coverage.

Arizona Minnesota

Colorado North Carolina

Connecticut New Mexico

Florida Ohio

Idaho Utah

Iowa Vermont Kansas Virginia

Michigan Washington

Wyoming

^{*}http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8401.pdf

^{**}http://clinicaltrials.gov/

<u>Private payers</u>: There is a growing list of private payers that explicitly cover the S-ICD system under current coverage policies for ICDs; including the following plans as of March 1, 2015.

Aetna (National) Cigna (National) Kaiser (CA)

BCBS MI Coventry Healthcare (National) PreferredOne (MN)
BCBS ND HCSC BCBS (TX, OK, IL, NM, MT) Priority Health (MI)

CareFirst BCBS (VA, DC, MD) HealthNet (AZ, CA, CT, NJ, NY) Select Health / Intermountain

Healthcare IDN (Utah)

TriCare (National)

Boston Scientific is working with commercial payers to raise clinical awareness of the S-ICD System and encourage positive coverage of the S-ICD procedures. Your support is welcome in this process.

Private payers may cover therapies they feel are clinically beneficial even in the face of non-coverage coverage policies. It is recommended that providers seek pre-authorization or pre-determination prior to performing the S-ICD System implant to confirm medical necessity, align with payer coverage policies, and when non-covered, pursue patient case-by-case coverage. (See prior-authorization section of this coding guide for more information.)

Commonly Billed S-ICD[™] System Scenarios

Kev:

Moderate sedation (For these procedures, moderate [conscious] sedation is included and cannot be billed separately when provided by the same physician. See AMA's 2012 Current Procedural Terminology for specific guidelines.)

+ Add-on code

Physician Category I Codes¹

Hospital Outpatient and ACS Category I Codes¹

Hospital Inpatient ICD-9-CM Codes²

1. Initial S-ICD System implant, with defibrillator threshold testing at time of implant

Scenario 1: Physician Category I Codes¹

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

Scenario 1: Hospital Outpatient and ASC Category I Codes¹

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

Scenario 1: Hospital Inpatient ICD-9-CM Codes²

37.94 Implantation or replacement of automatic cardioverter-defibrillator, total system [AICD]

Note: Device testing during procedure – omit code

Implantation of defibrillator with leads (epicardial patches), formation of pocket (abdominal fascia) (subcutaneous), any transvenous leads, intraoperative procedures for evaluation of lead signals, and obtaining defibrillator threshold measurements

Techniques: lateral thoracotomy, medial sternotomy, subxiphoid procedure Code also extracorporeal circulation, if performed (39.61)

Code also any concomitant procedure [e.g., coronary bypass (36.10 - 36.19) or CCM, total system (17.51)]

Excludes:

Implantation of cardiac resynchronization defibrillator, total system [CRT-D] (00.51)

2. Replacement of S-ICD Pulse Generator with defibrillator threshold testing at time of implant

Scenari	io 2:	Physician Category I Codes ¹
)	33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
93644-	-26/51 ³	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)
Scenari	io 2:	Hospital Outpatient and ASC Category I Codes ¹
)	33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system
)	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)
Scenari	io 2:	Hospital Inpatient ICD-9-CM Codes ²
	37.98	Replacement of automatic cardioverter-defibrillator pulse generator only
		Note: Device testing during procedure – omit code
		Excludes: Replacement of cardiac resynchronization defibrillator, pulse generator device only [CRT-D] (00.54)
	93644 Scenar	93644-26/51 ³ Scenario 2: 93644 Scenario 2:

3. S-ICD System Follow-up (in person)

Scenario 3: Physician Category I Codes¹

61 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.

or

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.

Scenario 3: Hospital Outpatient Category I Codes¹

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.

or

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 by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system

3. S-ICD System Follow-up (in person) continued

Scenario 3: Hospital Inpatient ICD-9-CM Code²

89.49 Automatic implantable cardioverter-defibrillator (AICD) check

Bedside check of an AICD or cardiac resynchronization defibrillator [CRT-D] Checking pacing thresholds of device Interrogation only without arrhythmia induction

Excludes:

Catheter based invasive electrophysiologic testing (37.26) Non-invasive programmed electrical stimulation [NIPS] (arrhythmia induction) (37.20)

Please note that the S-ICD System does not have the capability for remote monitoring at this time.

Prior-Authorization

Medicare does not perform or require prior-authorization for S-ICD[™] System procedures.

Commercial insurance plans

Prior-authorization is a process established by commercial insurance plans that allows a physician to submit a treatment plan prior to surgery. The insurer reviews the treatment plan as well as the patient's insurance benefits and medical policy to determine if the treatment is covered. When a service is not covered, the prior-authorization is a process for providers to request an exception to a non-coverage policy for a patient. As prior-authorization processes vary by insurer, it is important to contact the insurer and follow their specific requirements.

Prior-authorization requests typically include the following elements:

- Patient information name, date of birth, policy number
- Details of the patient's medical history
- Description of the patient's current condition and treatment plan
- Letter of medical necessity (LOMN) documenting the patient's medical need
- Proposed procedure(s), medical device implanted and rationale for treatment
- Proposed location of service and dates planned
- Summary of the clinical evidence supporting the treatment plan including comorbidities and copies of published literature supporting the safety and effectiveness. Recent peer review literature regarding the S-ICD System includes:
 - S-ICD Pivotal IDE Trial; demonstrated the safety and efficacy to support FDA approval and comparability to TV-ICDs. Weiss, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. *Circulation*. 2013; 128: 944-953. http://circ.ahajournals.org/content/128/9/944.abstract?sid=30ebcc07-3390-418a-b603-a0c955feb915
 - Dong-term S-ICD Registry; the largest cohort of real-world S-ICD System data, demonstrated comparable performance to TV-ICDs. The interim analysis confirms the clinical benefits of the S-ICD System in a broad range of patients at risk of sudden cardiac arrest. P.D. Lambiase, C. Barr, D.A. Theuns, R. Knops, P. Neuzil, J.B. Johansen, S. Pedersen, S. Kääb, F. Murgatroyd, H.L. Reeve, N. Carter, L. Boersma and o. b. o. t. E. Investigators., "Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry.," European Heart Journal, no. March 2014. http://eurheartj.oxfordjournals.org/content/early/2014/03/25/eurheartj.ehu112.full.pdf+html?sid=53 41a925-21e3-4d32-9502-d2673262d126
 - S-ICD Patient Selection; clinical review on appropriate patient selection for the S-ICDTM System. J.E. Poole and M.R. Gold, "Who Should Receive the Subcutaneous Implanted Defibrillator?: The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing.," *Circ Arrhythm Electrophysiol.*, vol. 6, pp. 1236-1245, 2013. http://circep.ahajournals.org/content/6/6/1236
- Description of the technology and rationale for its use in the patient's surgery
- Copy of the FDA approval letter (available through your Boston Scientific Sales Representative or by calling 1-800-CARDIAC, and ask for the reimbursement support line)

How to Handle Denials - Commercial Insurance Plans

Despite utilization of a robust prior authorization program, providers may occasionally experience denials. Most commercial insurance plans have a documented appeals process. Refer to the plan's provider manual or contact the insurer to obtain the appeals policy.

- 1. Speak with the plan's Medical Director. During that conversation, focus on the benefits of the medical technology and the medical necessity based on the patient's individual symptoms, diagnosis and comorbidities
- 2. Submit an appeal
- 3. Request a third party peer-to-peer review conducted by a board-certified Electrophysiology physician

Denial appeal letters typically include the following elements:

- Provide the rationale for filing an appeal (denial of coverage, medical necessity, etc.)
- Date of denial/denial letter
- Reference the denial reason and associated denial code, if applicable
- Detail the patient's diagnosis and course of treatment including adverse outcomes or lack of improvement from prior therapies.
- Describe the surgery in detail
- Describe any medical device and its benefits as they relate to the patient's condition.
 Emphasize the advantages of the medical device as compared to another medical device or approach
- State the rationale and benefits of the technology and how its use can be expected to produce a superior clinical outcome for the patient
- Discuss personal experiences and outcomes of surgical cases using the medical device
- Reference peer review literature to support the clinical determination regarding medical necessity. Recent peer review literature regarding the S-ICD System include:
 - S-ICD Pivotal IDE Trial; demonstrated the safety and efficacy to support FDA approval and comparability to TV-ICDs. Weiss, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. Circulation. 2013; 128: 944-953. http://circ.ahajournals.org/content/128/9/944.abstract?sid=30ebcc07-3390-418a-b603-a0c955feb915
 - Long-term S-ICD Registry; the largest cohort of real-world S-ICD System data, demonstrated comparable performance to TV-ICDs. The interim analysis confirms the clinical benefits of the S-ICD System in a broad range of patients at risk of sudden cardiac arrest. P.D. Lambiase, C. Barr, D.A. Theuns, R. Knops, P. Neuzil, J.B. Johansen, S. Pedersen, S. Kääb, F. Murgatroyd, H.L. Reeve, N. Carter, L. Boersma and o. b. o. t. E. Investigators., "Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry.," European Heart Journal, no. March 2014. http://eurheartj.oxfordjournals.org/content/early/2014/03/25/eurheartj.ehu112.full.pdf+html?sid=5341a925-21e3-4d32-9502-d2673262d126
 - S-ICD Patient Selection: clinical review on appropriate patient selection for the S-ICDTM System. J.E. Poole and M.R. Gold, "Who Should Receive the Subcutaneous Implanted Defibrillator?: The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing.," *Circ Arrhythm Electrophysiol.*, vol. 6, pp. 1236-1245, 2013. http://circep.ahajournals.org/content/6/6/1236
- Provide a contact name and phone number as well as the willingness to answer questions or provide additional information
- Request a specific timeframe for a response

Coding & Reimbursement Support

Boston Scientific is dedicated to providing physicians, allied health professionals and hospitals with world-class programs and services to help advance the standard of patient care and appropriate access to life-enhancing technologies.

Call 1.800.CARDIAC (227.3422) and ask for the Reimbursement Customer Support Line.

References and Disclaimers

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

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² American Medical Association: 2014 ICD-9-CM for Hospitals, Volumes 1, 2 and 3, Professional Edition, Chicago, IL.

³ Modifiers 26 (professional component) and 51 (multiple procedures) are for physician billing only. See the AMA's 2015 Current Procedural Terminology for complete descriptions. Always verify appropriate usage with payers. American Medical Association: 2015 Current Procedural Terminology (CPT), Professional Edition, Chicago, IL. Current Procedural Terminology (CPT) is copyright 2014 by the American Medical Association (AMA). All Rights Reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use. CPT is a registered trademark of the American Medical Association