2014 Subcutaneous Implantable Defibrillator (the S-ICD® System) Coding Guide

Boston Scientific

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Cardiology, Rhythm and Vascular

Contents

Coding Highlights –

Beginning January 1, 2013, physicians and hospital outpatient facilities are to use new CPT Category III **codes 0319T-0328T** to report S-ICD® System procedures. Providers should reference full details, descriptions and notes for CPT Category III codes 0319T-0328T on the AMA Web site at **www.ama-assn.org/go/cpt**.

CPT Category III codes are temporary codes that allow data collection for emerging technology, services, and procedures. These codes are intended to be used to substantiate widespread usage. CPT Category III codes are not referred to the AMA-Specialty RVS Update Committee (RUC) for valuation because no relative value units (RVUs) are assigned to Category III codes. Physician and hospital outpatient payment is based on the policies of payers and not on a yearly fee schedule.

See page 14 for important information about the uses and limitations of this document. CRM-125401-AC JAN2014

Physician Coding

For Subcutaneous Implantable Defibrillator (the S-ICD® System) procedures, providers will use the Category III CPT codes (0319T-0328T) for reporting insertion, removal, replacement, and device analysis. These Category III CPT codes will be specific for S-ICD System reporting to allow Medicare and private payers to more appropriately determine utilization and capture resource use associated with these procedures.

Unlike CPT codes that currently have established work units and resources, Category III CPT codes will not have Relative Value Units (RVUs) associated with their reporting; therefore, physicians will need to select an existing procedure (i.e., transvenous ICD implant) with similar resource use as the S-ICD System implant to serve as a reference for mapping appropriate professional payment when communicating with payers. Payment will be at the discretion of payers.

Boston Scientific strongly recommends that providers pre-authorize the S-ICD System implant with their private payers to alleviate any challenges with coverage. Medicare does not provide pre-authorization for services; therefore, providers should document defibrillator candidacy under the NCD for ICDs and also supply a copy of the FDA approval letter for the S-ICD System. Listed below are the Category III CPT codes for reporting S-ICD System procedures performed by physicians.

Category III CPT Code[1]	Description
0319T	Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode
0320T	Insertion of subcutaneous defibrillator electrode
0321T	Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode
0322T	Removal of subcutaneous implantable defibrillator pulse generator only
0323T	Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only
0324T	Removal of subcutaneous defibrillator electrode
0325T	Repositioning of subcutaneous implantable defibrillator electrode and/or pulse generator
0326T	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
0327T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system
0328T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis; implantable subcutaneous lead defibrillator system

Hospital Outpatient Coding and Payment

For Subcutaneous Implantable Defibrillator (the S-ICD® System) procedures, hospital outpatient providers will use the Category III CPT codes (0319T-0328T) for reporting insertion, removal, replacement, and device analysis.

Listed below are the Category III CPT codes for reporting S-ICD System procedures performed by outpatient hospitals.

Category III CPT Code[1]	Description	APC	2014 Medicare National Avg. Payment*
0319T	Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode	0107	$25,018.18
0320T	Insertion of subcutaneous defibrillator electrode	0106	$4,601.98
0321T	Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode	0107	$25,018.18
0322T	Removal of subcutaneous implantable defibrillator pulse generator only	0105	$2,317.70
0323T	Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only	0107	$25,018.18
0324T	Removal of subcutaneous defibrillator electrode	0105	$2,317.70
0325T	Repositioning of subcutaneous implantable defibrillator electrode and/or pulse generator	0105	$2,317.70
0326T	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	NA	Packaged service/item; no separate payment made
0327T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system	0690	$36.15
0328T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis; implantable subcutaneous lead defibrillator system	0690	$36.15

* Centers for Medicare and Medicaid Services. Medicare Program: CY2014 Hospital Outpatient Prospective Payment System and ASC Final Rule

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-ICD® System implant procedures. For a complete list of C-Codes go to CMS' 2013 Alpha-Numeric HCPCS File found at http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html

CMS has established outpatient coding edits which map the specific C-Codes reported to their respective CPT procedure code. The list of coding edits is not all-inclusive and Medicare will add edits to the list on a quarterly basis in conjunction with the quarterly Outpatient Coding Editor (OCE) release. For more information on the C-Code edits, go to: http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/NCCI-Coding-Edits.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 who have commercial insurance, hospitals should check with payers to determine if additional coding requirements are applicable. Generally, commercial payers do not require the use of C-Codes and, therefore, may only require the use of CPT codes.

Ambulatory Surgery Center (ASC) Coding and Payment

In the 2014 Final Rule for Outpatient Hospitals and Ambulatory Surgery Centers, CMS has included the S-ICD® System procedures as appropriate for being performed in the ASC site of service. The only exclusions specific to S-ICD System procedures from the approved ASC list are procedures 0324T, 0327T and 0328T.

Refer to the table below for payment specific rates for S-ICD System procedures in the ASC.

Category III CPT Code[1]	Description	2014 Medicare National Avg. Payment*
0319T	Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode	$22,882
0320T	Insertion of subcutaneous defibrillator electrode	$2,542
0321T	Insertion of subcutaneous implantable defibrillator pulse generator only with existing subcutaneous electrode	$22,882
0322T	Removal of subcutaneous implantable defibrillator pulse generator only	$1,280
0323T	Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only	$22,882
0325T	Repositioning of subcutaneous implantable defibrillator electrode and/or pulse generator	$1280
0326T	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	Packaged service/item; no separate payment made

* Centers for Medicare and Medicaid Services. Medicare Program: CY2014 Hospital Outpatient Prospective Payment System and ASC Final Rule

Hospital Inpatient Coding and Payment

Listed below are ICD-9CM procedure codes that are used when reporting S-ICD® System procedures performed in the hospital inpatient setting.

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 (AICD) Includes 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 (electrophysiologic studies [EPS])
37.95	Implantation of automatic cardioverter/defibrillator leads(s) only
37.96	Implantation of automatic cardioverter/defibrillator pulse generator only
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—includes bedside check of an AICD or cardiac resynchronization defibrillator (CRT-D); checking pacing thresholds of device; interrogation only without arrhythmia induction

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. Coding Clinic updates can be found at: http://www.ahacentraloffice.com/

Hospital Inpatient Payment

MS-DRG	MS-DRG Description	FY2014 National Average Base Payment*
MS-DRG 222	Cardiac defib implant w cardiac cath w AMI/HF/shock w MCC	$51.133
MS-DRG 223	Cardiac defib implant w cardiac cath w AMI/HF/shock w/o MCC	$37,266
MS-DRG 224	Cardiac defib implant w cardiac cath w/o AMI/HF/shock w MCC	$44,787
MS-DRG 225	Cardiac defib implant w cardiac cath w/o AMI/HF/shock w/o MCC	$34,337
MS-DRG 226	Cardiac defibrillator implant w/o cardiac cath w MCC	$40,655
MS-DRG 227	Cardiac defibrillator implant w/o cardiac cath w/o MCC	$32,128
MS-DRG 245	ICD generator procedures	$27,271
MS-DRG 265	ICD lead procedures	$15,595

* Centers for Medicare and Medicaid Services. Medicare Program: FY2014 Hospital Inpatient Prospective Payment System, Final Rule; August 19, 2014

Medical Necessity and Site of Service

Determination as to the appropriate classification of patient status as inpatient or outpatient is a clinical decision best made by the patient's physician after a careful consideration of multiple clinical factors including, but not limited to, the specific procedure planned, the urgency of the procedure, the hemodynamic stability of the patient, patient comorbidities and the likelihood and consequences of complications arising from the procedure.

Coverage

Medicare: 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 the same coverage guidance to the local Medicare contractors. Boston Scientific will work with CMS and local Medicare contractors to address any inconsistencies should they arise between local versus national coverage.

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.
- All Medicare patients implanted with an ICD system (subcutaneous or transvenous) would need to append the Q0 modifier with the ICD implant CPT code for patients indicated for primary prevention, including the Category III CPT code 0319T. The Q0 modifier indicates the patient has been enrolled in the ICD Registry.

Private payers: As most private payer use Medicare's NCD as a basis for their own coverage policies, we expect private payers will cover the S-ICD System under their current coverage policies for ICDs. Note that with the use of Category III CPT codes, some private pay plans may initially treat coverage for the S-ICD System as being experimental and investigational. Therefore, it is important that providers seek pre-authorization or pre-determination prior to performing the S-ICD System implant to confirm medical necessity and alignment with payer coverage policies (see prior-authorization section of this coding guide for more information). Boston Scientific recommends this practice in order to explain the benefits for the S-ICD System with private payers. These requests should include a letter of medical necessity documenting the patient's medical need, a copy of the FDA approval letter, as well as published literature supporting the safety and effectiveness of the S-ICD System. The Reimbursement Support line is available to assist you with these materials by calling 1-800-CARDIAC and this information is also available through your sales representative.

Sometimes, private payers will cover therapies they feel are clinically beneficial even with the lack of specific coding and in the face of investigational coverage policies. Boston Scientific is working with the major commercial payers to raise clinical awareness of the S-ICD System so that they are prepared to address your inquiries. Your support is welcome in this process.

Commonly Billed S-ICD® System Scenarios

Key:

⊙ **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 III Codes[1] | **Hospital Outpatient** Category III Codes[1] | **Hospital Inpatient** ICD-9-CM Codes[2]

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

Scenario 1: Physician Category III Codes[1]

⊙ **0319T** Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode

⊙ **0326T–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)

Scenario 1: Hospital Outpatient and ASC Category III Codes[1]

⊙ **0319T** Insertion or replacement of subcutaneous implantable defibrillator system with subcutaneous electrode

⊙ **0326T** Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

Scenario 1: Hospital Inpatient ICD-9-CM Codes[2]

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*

Scenario 2:	***Physician Category III Codes[1]***
⊙ **0323T**	Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only
⊙ **0326T-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)

Scenario 2:	***Hospital Outpatient and ASC Category III Codes[1]***
⊙ **0323T**	Removal of subcutaneous implantable defibrillator pulse generator with replacement of subcutaneous implantable defibrillator pulse generator only
⊙ **0326T**	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

Scenario 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)

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

Scenario 3:	***Physician Category III Codes[1]***
0327T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system.
or	
0328T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis; implantable subcutaneous lead defibrillator system.

Scenario 3:	***Hospital Outpatient Category III Codes[1]***
0327T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system.
or	
0328T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis; implantable subcutaneous lead defibrillator system

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

Scenario 3: Hospital Inpatient ICD-9-CM Code[2]

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 so it would be inappropriate for providers to utilize these codes.

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 and the applicable patient responsibility (e.g., coinsurance and/or copay, deductibles, and out-of-pocket amounts). As prior-authorization processes vary by insurer, it is important to contact insurance plans 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 include:
    - Rowley, C. P., Gold, M.R., (2012). "Subcutaneous Implantable Cardioverter Defibrillator." Circ Arrhythm Electrophysiol. 2012;5:3 587-593, doi:10.1161/CIRCEP.111.964676
    - Bardy, G. H., W. M. Smith, et al. (2010). "An entirely subcutaneous implantable cardioverter-defibrillator." N Engl J Med 363(1): 36-44
- 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 with tiered levels established for adjudication. It is best to refer to the plan's provider manual and contact the insurer to obtain the appeals policy in a timely manner as most appeals have a designated timeframe.

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:
    - Rowley, C. P., Gold, M.R., (2012). "Subcutaneous Implantable Cardioverter Defibrillator." Circ Arrhythm Electrophysiol. 2012;5:3 587-593, doi:10.1161/CIRCEP.111.964676
    - Bardy, G. H., W. M. Smith, et al. (2010). "An entirely subcutaneous implantable cardioverter-defibrillator." N Engl J Med 363(1): 36-44
- 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: 2013 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 2013 Current Procedural Terminology for complete descriptions. Always verify appropriate usage with payers. American Medical Association: 2013 Current Procedural Terminology (CPT), Professional Edition, Chicago, IL. Current Procedural Terminology (CPT) is copyright 2012 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

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