SAMPLE PRIOR AUTHORIZATION LETTER FOR THE S-ICD™ SYSTEM

NOTE TO PHYSICIAN: This sample letter is not meant to be used as a form letter. You should customize the letter to reflect the particular background, medical history and diagnosis of the specific patient, as well as any special requirements of the payer involved. You are responsible for providing true, accurate and complete information concerning the applicable diagnosis and procedure codes and the patient's medical record, and ensuring the medical necessity of the procedure.

This letter is intended as an example for your consideration and may not include all the information necessary to support your prior authorization request. The requesting facility is entirely responsible for ensuring the accuracy, adequacy, and supportability of all information provided. As a reminder, Medicare does not preauthorize medical procedures. It is recommended that you contact your patient's insurance company to obtain specific inclusion/exclusion criteria.

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA-approved label.

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. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions.

Instructions for completing the prior authorization letter:

1. Please customize this letter for each patient. Fields required for customization are **highlighted in yellow**.
2. It is important to provide the most complete information to assist with the prior authorization process.
3. Review the health plan S-ICD Medical Policy and include rationale and supporting documentation for all medical necessity requirements. Be aware that health plans medical necessity requirements may vary for patients with similar indications.
4. Upon review of the policy, determine if patient meets the criteria for implantation of an S-ICD.
    a. If so, use Template A.
    b. If the patient does not meet requirements, or if it is unclear if the patient meets requirements, but you believe the S-ICD is the most appropriate therapy, utilize Template B. In the event the prior authorization request is rejected, utilize the denial appeal template provided separately.
5. If you have questions, please contact CRM.Reimbursement@bsci.com or 1.800.CARDIAC and ask for S-ICD Reimbursement. Ext 24114

TEMPLATE A – DELETE THIS LINE UPON FINALIZATION OF LETTER

[Date]

Attention: Surgery Preauthorization Department
[Insurance Company Name]

RE: Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim # _____

Dear Madam/Sir:

This letter is to request approval for the surgery, hospital, and post-surgical care associated with the planned implantation of the Subcutaneous Implantable Defibrillator (the S-ICD™ System) for [patient name]. This patient is scheduled for surgery on [insert date]. I have attached clinical documentation to support a determination of medical necessity for S-ICD implantation.

The S-ICD System is clinically appropriate for my patient as they do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing. In addition, your health plan's coverage policy [insert policy name and number] states that the S-ICD [may be/ is] considered medically necessary for patients requiring an implantable defibrillator that have the following risk factors associated with implantation of a traditional ICD: [insert list of risk factors from the policy that apply to the patient – or replace with a single risk factor as appropriate]. The enclosed information supports the presence of these/this risk factors in my patient. Therefore, I have determined that S-ICD implantation is justified.

Based upon the above criteria and the information enclosed, I request that approval be granted for surgery for [Patient name]and all related services as soon as possible. Please fax your approval to my office at the following number [fax number] or contact me with additional questions. I can be reached conveniently at [telephone number].

Sincerely,

[Physician Name]
[Practice Name]

Enclosures

- History and physical
- MD order and progress notes
- Pertinent test reports with written interpretation

TEMPLATE B
[Date]

Attention: Surgery Preauthorization Department
[Insurance Company Name]

RE: Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim # _____

Dear Madam/Sir:

This letter is to request approval for the surgery, hospital, and post-surgical care associated with the planned implantation of the Subcutaneous Implantable Cardioverter Defibrillator (the S-ICD™ System) for [**patient name**]. This patient is scheduled for surgery on [**insert date**]. I have attached clinical documentation to support a determination of medical necessity for the S-ICD System.

The S-ICD is an FDA-approved defibrillator that provides reliable defibrillation therapy for the treatment of ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing. It functions very similarly to commercially available transvenous ICDs with the exception that the S-ICD electrode (lead) is placed subcutaneously and does not touch the heart or vascular system.

[insert name of insurer]'s policy concerning coverage conditions for the S-ICD System [insert policy name and number] states that this therapy [may be/ is] considered medically necessary for patients requiring an implantable defibrillator with the following conditions: [insert conditions as appropriate]. Although my patient does not strictly fit the above criteria, I believe the S-ICD is the most appropriate therapeutic choice for them due to the following: [list specific conditions as appropriate]. The clinical appropriateness of S-ICD in my patient is further justified considering recent coverage decisions, society recommendations, and published clinical evidence as follows:

- CMS' Coverage Analysis Group has determined that the S-ICD System is covered under the National Coverage Determination (NCD) for ICDs which was updated in February 2018 and includes no further restrictions on coverage beyond the FDA indication.
- The 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death provides a Class IIa (moderate strength) recommendation for the S-ICD System in patients indicated for an ICD in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated. The committee also provided a Class I recommendation for S-ICD use in the subset of the above patients who have either inadequate vascular access or are at high-risk for infection.
- The Heart Rhythm Society has provided a coverage recommendation on their website including the following statement: "HRS recommends that private health insurance companies provide coverage for subcutaneous implantable cardiac defibrillator therapy, consistent with FDA labeling."

- The AMA established CPT 1 codes for reporting S-ICD System procedures (i.e., 33270) on January 1, 2015.
- The published clinical evidence associated with the S-ICD continues to show that the S-ICD can be utilized in accordance with its FDA-approved indication. Recent articles are summarized in the attachment.

Based upon the above criteria and the information enclosed, I have determined that this procedure is medically appropriate for [Patient name] and request that approval be granted for surgery and all related services as soon as possible. Please fax your approval to my office at the following number [fax number] or contact me with additional questions. I can be reached conveniently at [telephone number].

Sincerely,

[Physician Name]
[Practice Name]

Enclosures

- History and physical
- MD order and progress notes
- Pertinent test reports with written interpretation
  Heart Rhythm Society (HRS) S-ICD Coverage Recommendation
- Summary of Published Clinical Evidence

Clinical Literature supporting safety and efficacy of the S-ICD System

Boston Scientific's S-ICD System™ is FDA approved and is proven safe and effective for treating patients that are candidates for ICDs. The implant/replacement procedure is consistent with the current Medicare National Coverage Determination (NCD) for ICDs, and the literature also supports the clinical evidence for these systems for patients that are candidates for ICDs. Published clinical data on the S-ICD System therapy includes:

- **S-ICD Pivotal IDE Trial**
  The IDE study was designed to demonstrate statistical superiority in the primary safety and efficacy of the S-ICD System relative to pre-specified performance goals defined in conjunction with the FDA. Both endpoints were met with a high degree of confidence. Based on the efficacy and safety results of the IDE Trial detailed below, the FDA Advisory Panel voted 7-1 that the S-ICD was effective and 8-0 that it was safe. Weiss, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. *Circulation*. 2013; 128: 944-953

- **Long-term S-ICD Registry Midterm Follow-up**
  This publication provides the first analysis from the fully enrolled EFFORTLESS registry with an average follow-up of 3.1 years (985 patients across 42 sites in 10 European countries). At one year, S-ICD-related and overall complications occurred in 2% and 8.4% of patients, respectively. Inappropriate shocks occurred in 8.1% of patients at one year and 11.7% after 3.1 years. There have continued to be no reports of lead failure or endocarditis.

  At the time of implant, over 99% of patients had a successful conversion of induced VT/VF. Conversion success for discrete spontaneous episodes was 97.4%. The authors conclude: "This analysis of the full EFFORTLESS cohort over the first-year post-implantation demonstrates that the S-ICD remains safe and effectives in the treatment of lethal ventricular arrhythmias, with a low incidence of device upgrade for bradycardia, cardiac resynchronization therapy pacing, or ATP, and a low rate of implant complications." (Boersma L, Barr C, Knops R, Theuns D, Eckardt L, Neuzil P, Scholten M, Hood M, Kuschyk J, Jones P, Duffy E, Husby M, Stein K, Lambiase PD; EFFORTLESS Investigator Group. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol. 2017 Aug 15;70(7):830-841.)

- **Pooled analysis of IDE Study and EFFORTLESS Registry**
  The IDE study data was combined with the European EFFORTLESS Registry data to publish long term follow up on the safety and efficacy of the S-ICD System. The study designs and endpoints were similar, enabling this Pooled Analysis. Key highlights include: No electrode failures, No endovascular or systemic infections, and acute major complication rate of 2%. (Burke, M.C., et al., Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator. Journal of the American College of Cardiology, 2015. 65(16): p. 1605-1615.

- **Meta-analysis of Case-Controlled Studies**
  This review of published evidence from case-controlled studies including the SICD compared rates of lead and non-lead complications, infection, and inappropriate shocks. Lead- related complications were found to be statistically significantly higher in the TV-ICD patients relative to the S-ICD patients with an eight-fold higher rate of lead complications for the TV-ICD patients(p=.0001) and an odds

ratio of 0.13 (95% CI: 0.05-0.038) in favor of S-ICD patients. In addition to the significantly higher complication rate for TV-ICD devices, there was no difference in other complications including infections and inappropriate shocks between patients receiving the S-ICD or TV-ICD. (Basu-Ray I, Liu J, Jia X, Gold M, Ellenbogen K, DiNicolantonio J, et al. Subcutaneous Versus Transvenous Implantable Defibrillator Therapy: A Meta-Analysis of Case-Control Studies. JACC: Clinical Electrophysiology. 2017;3(13):1475-83. http://www.sciencedirect.com/science/article/pii/S2405500X17306151

- **Early Results from the US Post-Approval Study**
  This registry study was mandated by the U.S. Food and Drug Administration following approval of the S-ICD System and was designed to assess long-term, "real-world" outcomes. This first publication contains 30-day safety and effectiveness results on 1,637 study patients enrolled across 86 centers. The authors note the contemporary S-ICD patients enrolled in this trial are more conventional ICD patients then enrolled in prior studies and the substantial number of study centers provides a wider range of physician experience.

  Two-thirds of study subjects had both a primary prevention indication and an EF<35%. Additional frequent co-morbidities included hypertension (61.6%), diabetes (33.6%), and kidney disease (25.6%). In over 90% of cases, patients were considered a candidate for either ICD and 52.4% of these subjects preferred to be implanted with the S-ICD. Successful conversion of induced ventricular tachycardia/ventricular tachycardia occurred in 98.7% of patients. The 30-day freedom from complications was 96.7%. The authors concluded that the 30-day outcomes were appropriate and consistent with prior S-ICD research. (Gold MR, Aasbo JD, El-Chami MF, Niebauer M, Herre J, Prutkin JM, Knight BP, Kutalek S, Hsu K, Weiss R, Bass E, Husby M, Stivland TM, Burke MC. Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm. 2017 May 11. [Epub ahead of print])