SAMPLE APPEAL LETTER FOR THE S-ICD™ SYSTEM PROCEDURE IMPLANT

PLEASE NOTE: This letter is intended as an example for your consideration and may not include all the information necessary to support your appeal request. The requesting facility is entirely responsible for ensuring the accuracy, adequacy, and supportability of the information provided. 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.

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

Instructions for completing the sample appeal letter:

1. Please customize the appeals template based on the medical appropriateness of the S-ICD System for your patient. Fields required for customization are **highlighted in yellow**.
2. Review and understand the health plan's reason for the denial; your appeal letter needs to clearly address the points raised in the health plan's denial letter.
3. For the S-ICD clinical scenarios, please choose the scenarios most appropriate for your patient, or create your own and then delete the scenarios not relevant.

[Date]

Attention: Appeals Department
Reference number:
[Insurance Company name]
[Insurance Company address]
[Fax:]

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

RE: Request for Reconsideration of Coverage for Subcutaneous Implantable Defibrillator (the S-ICD™ System) Implant

To Whom It May Concern:

I am contacting you on behalf of my patient, [**name**] to rescind a prior denial received on [**date**] for the implant of the subcutaneous implantable defibrillator (the S-ICD™ System) for the treatment of life-threatening ventricular tachyarrhythmias. This letter documents the medical necessity for this therapy and provides information about the patient's medical history and treatment, as well as a description of the procedure.

The S-ICD System Therapy
Boston Scientific's S-ICD System is classified as a defibrillator that senses, detects, and treats malignant ventricular tachyarrhythmias. The S-ICD received PMA approval from the FDA in 2012 for use in the same patients who are indicated for a transvenous-ICD. The small percentage of patients who experience symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing are not indicated for an S-ICD The major difference between transvenous ICDs (TV-ICD) and the S-ICD is that the S-ICD has no leads touching the heart, thereby eliminating intravascular lead complications, like cardiac perforation, venous thrombosis, tamponade, valvular obstruction or pneumothorax.

CMS' Coverage Analysis Group has directed its Medicare Administrative Contractors (MAC) that the S-ICD System is covered under the National Coverage Determination (NCD) for ICDs which was updated in February 2018. The NCD has no further restrictions on coverage beyond criteria specified in the FDA indications. The American Medical Association approved CPT 1 codes for reporting S-ICD System procedures (i.e., 33270) on January 1, 2015.

Medical Rationale for the S-ICD System

My patient is at risk for sudden cardiac death (SCD) and qualifies for implantation of a defibrillator in accordance with established clinical guidelines and national coverage guidance.

- 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 its website including the following statement: "HRS recommends that private health insurance companies provide

coverage for subcutaneous implantable cardiac defibrillator therapy, consistent with FDA labeling."

Since the FDA approval of the S-ICD System, patients have access to this defibrillation therapy where the leads do not touch the heart. The S-ICD System is not a "new" therapy as the benefits of defibrillators has been clearly established in many clinical studies, but it is an evolution and refinement of the transvenous ICD technology to meet a clinical need. In this particular case, my patient would derive more benefit from the S-ICD System because of the following:

[The following are common clinical scenarios in which the S-ICD System may be appropriate for medical necessity. If appropriate for specific patient circumstances, physicians may choose to include one or more of these scenarios to be included with the appeal. Feel free to create your own if the scenarios not presented here may also be applicable. ***After you check the appropriate scenario(s), please delete those scenarios that are not relevant.****]*

☐ My patient is not indicated for bradycardia or VT termination pacing and neither is anticipated.

- Background: Data shows that 70% of patients under age 75 who received a VR or DR ICD did not have an indication for brady pacing at implant (Data on DR devices from Gasparini et at JACC EP 2017; Data on VR devices from LATTITUDE BSci data on file).
- Significance: The Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death support as reasonable the implantation of an S-ICD in patients who meet indications for an ICD if pacing for brady cardia or VT termination or as part of the CRT is neither needed nor anticipated. (Al-Khatib, et al Heart Rhythm 2017).
- Reason why S-ICE is medically appropriate for my patient: [Physician provides medical rationale. This may include but not limited to the following: patient has no symptoms indicating atrial and/or right ventricular pacing.

☐ My patient is relatively young and subject to the probability of outliving the lifespan of the transvenous lead or needing ICD system replacements over the course of his/her lifetime.

- Background: Transvenous ICD leads are at significant risk for failure over time. The transvenous lead failure rate over time is reported in ≥ 20% of leads after 10 years of indwelling time.[1] Transvenous leads may be subject to more mechanical stress over time because they are exposed to > 30 million cardiac contractions per year.
- Significance: My patient would benefit from the S-ICD System because a transvenous ICD lead subjects the patient to the future risk of needing an ICD lead extraction, which carries mortality risk as there is intravascular tissue ingrowth around the lead over time. In situations where the entire system is replaced, unlike a transvenous ICD system, the S-ICD System does not require extracting the subcutaneous lead from the heart.
- Reason why S-ICD is medically appropriate for my patient: [Physician provides medical rationale. This may include but is not limited to the following: There is no significant flexion of the S-ICD system or S-ICD lead as it is not placed in the heart and therefore is not subject to cardiac motion. The possibility of needing a transvenous laser or mechanical lead extraction from the heart and vascular tissue in the future is eliminated.]

[1] Kleeman et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period >10 years. *Circulation*. 2007;115:2474-2480.

☐ My patient is an appropriate candidate for ICD therapy but he/she has limited or no venous access (occluded veins or congenital anomalies) which prohibit implantation of a transvenous ICD system.

- Background: Implantation of a new transvenous ICD system has been reported in the literature to be associated with a 30-50% risk of ipsilateral venous occlusion.[2] With a prior history of venous access problems, the risk of symptomatic venous occlusion is likely to be higher with the introduction of a transvenous system.
- Significance: Traditionally, transvenous ICDs are implanted on the left side for the most optimal defibrillation vector to facilitate programming. Venous access issues on the left side may make same sided implantation difficult or challenging; therefore, a separate incision to facilitate a right-sided approach may need to be utilized. This could result in symptomatic venous occlusion, discomfort associated with swelling, and the need for anticoagulants to mitigate the risk of complications from bleeding.
- Reason why S-ICD is medically appropriate for my patient: [Physician provides medical rationale. This may include but is not limited to the following: The S-ICD System is not intravascular and problems associated with venous access or venous occlusions do not apply.]

☐ My patient has significant renal dysfunction which may require the need for future transvenous access for hemodialysis.

- Background: Patients with significant renal dysfunction may need permacaths/vascaths and/or AV fistulas in the future as renal dysfunction progresses.
- Significance: AV fistulas on the same side of a transvenous ICD system put the shunt at significant risk for occlusion. Additionally, placement of the transvenous ICD system on the contralateral side may put the patient at risk for venous occlusion on this side and possibly preclude future shunt placement on this side should the current shunt fail.
- Reason why S-ICD is medically appropriate for my patient: [Physician provides medical rationale. This may include but is not limited to the following: The S-ICD™ System does not touch the vascular system; therefore, it will not interfere with vascular access issues.]

☐ My patient is at high risk for complication with a transvenous ICD system because [Physician document patient's clinical circumstances; this may include but is not limited to the following: immunocompromised, bacteremia, channelopathies (e.g., long-QT syndrome, Brugada, hypertrophic cardiomyopathy), history of endocarditis, or previous device infections or lead failures].

- Background: The following are risk factors for infection in a transvenous system: Diabetes, Renal Insufficiency, Systemic Anticoagulation, Chronic Steroid Use, Prior device infection, Prosthetic valve.[3]
- Reason why S-ICD is medically appropriate for my patient: [Physician provides medical rationale. This may include but is not limited to the following: The S-ICD system significantly reduces the added risk for endocarditis for an ICD system because it is not intravascular. In the IDE study,

[2] Haghjoo M et al. Predictors of venous obstruction following pacemaker or implantable Cardioverter-defibrillator implantation: a contrast venographic study on 100 patients admitted for generator change, lead revision, or device upgrade. Europace. 2007;9: 328-332.

[3] Klug D et al. Risk factors related to infections of implanted pacemakers and Cardioverter-defibrillators: Results of a large prospective study. Circulation 2007;116:1349-1355.

there were no reports of S-ICD–related endocarditis[4], a complication reported in 22% to 54% of cardiac device infections and associated with a 2-fold increase in mortality.[5,6]]

The S-ICD System Safety and Effectiveness
Published clinical data on the safety and effectiveness of the S-ICD System therapy include:

- **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.

[4] Weiss, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. Circulation. 2013; 128: 944-953.
[5] LE KY, Sohail MR, et al. Clinical predictors of cardiovascular implantable electronic device-related infective endocarditis. Pacing Clin Electrophysiol. 2011; 34:450–459.
[6] Athan E, Chu VH, et al. ICE-PCS Investigators. Clinical characteristics and outcome of infective endocarditis involving implantable cardiac devices. JAMA. 2012;307:1727–1735.

- **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])

The available evidence is sufficient to determine clinical outcomes for the long term.

Potential Benefits of the S-ICD System
The S-ICD System provides an option for my patient because no leads touch the heart or the vasculature system and the patient is still able to receive life-saving therapy from an implantable defibrillator.

[**Physician to provide any additional comments supporting their choice (both physician and patient) of the S-ICD System implant as an alternative to transvenous ICDs.**]

I feel that [**patient name**] will benefit greatly from the S-ICD System implant. [**His/Her**] qualify of life and well-being is greatly impacted by ventricular fibrillation. In addition to ventricular fibrillation, [**patient**] also suffers from [**list all other health-related conditions that patient suffers from and include diagnoses that apply. Provide a brief description of patient's therapies, including medical management, to date**].

The S-ICD System provides a significant clinical benefit for my patient, [**patient name**] while at the same time addressing ICD candidacy based on established guidelines for heart failure from the American

Heart Association (AHA)/Heart Rhythm Society (HRS)/American College of Cardiology (ACC), European Society of Cardiology (ESC), and the Medicare NCD for ICDs. The S-ICD System™ should be treated in the same category for coverage as defibrillators.

I ask that you reconsider coverage of the S-ICD™ System implant for my patient based on the above arguments and the medical necessity for this procedure. This procedure is supported by both my patient and my medical judgment. [**Patient name**] is medically appropriate for this procedure, and we request that reconsideration be granted for surgery and all related services as soon as possible. Please feel free to call me at [**physician's phone number**]. Thank you in advance for your immediate attention to this request.

Sincerely,

[**Physician Name**]
[**Practice Name**]
[**Phone Number**]

Enclosures

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