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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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.

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.

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 evidence, guidelines and national coverage guidance.

- On August 6, 2020 the *New England Journal of Medicine* published the results of the **PRAETORIAN** Randomized Control Trial, the first to compare the safety and efficacy of the S-ICD to the transvenous ICD. In the PRAETORIAN trial, a total of 849 patients with a class I or IIa indication for ICD therapy and without the need for pacing were enrolled and followed for a median of 4 years. Of the patients, 426 were assigned to receive an S-ICD and 423 were assigned to a TV-ICD, with similar baseline characteristics in the two groups. These baseline characteristics are comparable to those of other major ICD trials, thereby showing that the trial reflects a general ICD population.

  The primary end point of the trial was a composite of device-related complications and inappropriate shocks during a median follow-up of 4 years, and an upper 95 percent confidence limit of 1.45 for the hazard ratio of the primary end point was used to test for noninferiority. At a median follow-up of 49.1 months, the primary end point occurred in 68 patients in the 14 subcutaneous ICD group and in 68 patients in the transvenous ICD group (Kaplan-Meier event-

rate 15 estimates at 48 months, 15.1% and 15.7%, respectively; HR, 0.99; 95% CI, 0.71 to 1.39; P=0.01 for 16 noninferiority, P=0.95 for superiority). Device-related complications occurred in 31 and 44 patients 17 respectively (HR, 0.69; 95% CI, 0.44 to 1.09). Inappropriate shocks occurred in 41 and 29 patients, 18 respectively (HR, 1.43; 95% CI, 0.89 to 2.30). Mortality occurred in 83 and 68 patients, respectively 19 (HR, 1.23; 95% CI, 0.89 to 1.70). Appropriate shocks occurred in 83 and 57 patients, respectively (HR, 20 1.52; 95% CI, 1.08 to 2.12). These findings indicate that S-ICDs should be considered in all patients in need of an ICD without pacing indication.[1]

- Presented as a Late Breaking Clinical Trial at Heart Rhythm Society 2020, the global, prospective, non-randomized UNTOUCHED study evaluated the safety and efficacy of the EMBLEM S-ICD System for primary prevention of sudden cardiac death specifically in patients with a left ventricular ejection fraction (LVEF) ≤35%, the most common population to be indicated for ICD therapy. Data demonstrated S-ICD therapy had an inappropriate shock-free rate of 95.9% at 18-months post-procedure, meeting the primary endpoint with a rate comparable to or lower than those seen in previous S-ICD and transvenous implantable cardioverter-defibrillator (TV-ICD) studies. Data also demonstrated a 97.6% inappropriate shock-free rate at one year for patients who had the SMART Pass sensing filter, enabled on the newest generation EMBLEM MRI™ S-ICD System devices.[2]

- 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."

- 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.

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[1] Knops R. et al., A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial N Engl J Med 2020; 383:526-536 DOI: 10.1056/NEJMoa1915932

[2] Gold, M, et al. Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED) Trial PrimaryResults. LBCT HRS 2020.

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).
- Additionally, the findings of the PRAETORIAN randomized control trial indicate the S-ICDs should be considered in all patients in need of an ICD without pacing complications.
- Reason why S-ICD 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.[3] 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.]

[3] 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. And/OR

☐ My patient has significant renal dysfunction which may require the need for future transvenous access for hemodialysis.(Both of these are frequent S-ICD medical necessity requirements).

- 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.[4]
- 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, there were no reports of S-ICD–related endocarditis[5], a complication reported in 22% to 54% of cardiac device infections and associated with a 2-fold increase in mortality.[6,7]]

The S-ICD System Safety and Effectiveness

Additional published clinical data on the safety and effectiveness of the S-ICD System are listed in the attached bibliography. The available evidence is sufficient to determine clinical outcomes for the long term.

Potential Benefits of the S-ICD System

[**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**].

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[4] 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.

[5] Weiss, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. Circulation. 2013; 128: 944-953.

[6] LE KY, Sohail MR, et al. Clinical predictors of cardiovascular implantable electronic device-related infective endocarditis. Pacing Clin Electrophysiol. 2011; 34:450–459.

[7] 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.

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

Additional Clinical Bibliography for the Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)

1. Knops R. et al., A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial N Engl J Med 2020; 383:526-536 DOI: 10.1056/NEJMoa1915932
2. Bardy, G. H., W. M. Smith, et al., An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010; 363:36-44.

3. Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. CIRCULATION. Vol. 128, no. 9. (August 2013.): 944-953.

4. Lambiase, et al. A worldwide experience with a totally subcutaneous ICD; Preliminary results of the EFFORTLESS S-ICD Registry. European Heart Journal Mar 2014. 2014;35(25):1657-65.

5. Olde Nordkamp, L.R. *et al.* Rationale and design of the PRAETORIAN trial: a Prospective, randomized comparison of subcutaneous and transvenous implantable cardioverter-defibrillator therapy. *Am. Heart.J.* 2012 May;163(5):753-760.e2. doi: 10.1016/j.ahj.2012.02.012

6. M.C. Burke et al. Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-year Results from a Pooled Analysis of the IDE Study and EFFORTLESS Registry. *JACC* 2015 April;65(16): 1605-15.

7. Priori, SG. et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *Eur Heart J.* 2015 Nov 1;36(41):2793-2867.

8. Gold, MR, Aasbo, JD, El-Chami, MF, et al., Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm, 2017. 14(10): p. 1456-1463.

9. Gold, MR, Knops, R, Burke, MC, et al, The Design of the Understanding Outcomes With the EMBLEM™ S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED): *PACE.* 2017 Jan;40(1):1-8.

10. Al-Khatib, SM, Stevenson, WG, Ackerman, MJ, et al., 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Circulation,* 2017;138(13);, 2017.

11. Basu-Ray, I, Liu, J, Jia, X, et al., Subcutaneous Versus Transvenous Implantable Defibrillator Therapy. J Am Coll Cardiol EP. 2017 Dec, 3 (13) 1475-1483.

12. Al-Khatib, SM, Stevenson, WG, Ackerman, MJ, et al., 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. Circulation, 2017;138(13);

13. Healey, J, et al. Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). The Lancet. 385(9970): p. 785-791.

14. Blatt, JA, Poole, JE, Johnson, GW, et al., No benefit from defibrillation threshold testing in the SCD-HeFT. J Am Coll Cardiol, 2008. 52(7): p. 551-6.

15. Kutyifa V, et al. Clinical Impact, Safety, and Efficacy of Single- versus Dual-Coil ICD Leads in MADIT-CRT J Cardiovasc Electrophysiol 2013;24:1246-52

16. Gold MR et al. Efficacy and Temporal Stability of Reduced Safety Margins for Ventricular Defibrillation: Primary Results From the Low Energy Safety Study (LESS). Circulation 2002;105:2043-2048.

17. Boersma, L, Barr, C, Knops, R, et al., Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol, 2017. 70(7): p. 830-841.

18. Burke, MC, Gold, MR, Knight, BP, et al., Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator. Journal of the American College of Cardiology, 2015. 65(16): p. 1605-1615.

19. Blatt JA et al. No Benefit From Defibrillation Threshold Testing in the SCD-HeFT . J Am Coll Cardiol 2008;52:551–6

20. Brignole, M, Occhetta, E, Bongiorni, MG, et al., Clinical evaluation of defibrillation testing in an unselected population of 2,120 consecutive patients undergoing first implantable cardioverter-defibrillator implant. J Am Coll Cardiol, 2012. 60(11): p. 981-7.

21. Gold, MR, Aasbo, JD, El-Chami, MF, et al., Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm, 2017. 14(10): p. 1456-1463.

22. Boersma LV, El-Chami MF, Bongiorni MG, et al., Understanding Outcomes with the EMBLEM S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED): Clinical characteristics and perioperative results. Heart Rhythm, 2019 16 (11): 1636-44.

23. Knops RE, Brouwer TF, Barr CS, Theuns DA, Boersma L, Weiss R, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace. 2016;18(7):1010-5.

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