SAMPLE APPEAL TEMPLATE

LUX-Dx™ IMPLANT FOR EVALUATION OF ATRIAL FIBRILLATION POST-ABLATION

1. Please customize the appeals template based on the medical appropriateness of the LUX-Dx™ subcutaneous cardiac rhythm monitor for your patient. **Highlighted** fields require customization. Make sure to delete highlighted fields to avoid confusion or misinterpretation.

2. Review and understand the health plan's rationale for the denial and address the points raised in the health plan's denial letter directly.

3. **Do not** include this instruction page in your submission.

Disclaimer

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 clinician 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.

[Physician Letterhead]

[Date]

Attention: Appeals Department
Reference Number:
[Insurance Company Name]
[Insurance Company Address]
[Fax:]

RE: Request for Reconsideration of Coverage for Subcutaneous Cardiac Rhythm Monitor (LUX-DX™) Implant

Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group or Claims #: _____

Diagnosis: [list ICD-10 Dx code and Diagnosis Code Descriptor]

Services:

Professional Services

Code	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming

Facility Services

Code	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
C1764	Event Recorder, Cardiac (Implantable)

Please note, this is for illustrative purposes only and should be customized based on medical necessity and applicability to each case.

Dear **[Payer contact name]**:

I am contacting you on behalf of my patient, **[name]** to rescind prior denial received on **[date]** for the implant of the subcutaneous cardiac rhythm monitor (the LUX-Dx™). This letter documents the medical necessity for this service and provides information about the patient's medical history including need for monitoring atrial fibrillation following ablation procedure and evidence supporting the use of long-term monitoring via SCRM in the post ablation patient population.

The LUX-DX™ System Therapy

The LUX-Dx™ subcutaneous cardiac rhythm monitor is intended to monitor and record subcutaneous ECG (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath.

Medical Rationale for the LUX-Dx™ System

My patient is at risk for _____ and qualifies for implantation of a subcutaneous cardiac rhythm monitor in accordance with established clinical evidence, guidelines and national coverage guidance.

> Under FDA labeling[1], subcutaneous cardiac rhythm monitors (also known as implantable loop recorders [ILRs] or insertable cardiac monitors [ICMs]) are indicated for adults at risk of developing an abnormal heart rhythm or have symptoms that may suggest a cardiac arrythmia such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. Subcutaneous cardiac rhythm monitors address an otherwise unmet clinical need through uninterrupted, long-term cardiac monitoring for patients with symptoms which recur too infrequently to be detected by shorter-term external monitoring modalities. Subcutaneous cardiac rhythm monitors have been covered by Medicare since 2004 under the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for Electrocardiographic Services (20.15).

A growing body of evidence, referenced below, supports long-term monitoring for atrial fibrillation in patients following ablation procedure.

Clinical Evidence

- Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation: Executive summary. J Arrhythm. Oct 2017; 33(5): 369-409. Section 8: Follow-up Considerations ..... e342 Monitoring for Complications in the First Months After AF Ablation; ECG Monitoring Pre- and Postablation. https://www.hrsonline.org/guidance/clinical-resources/2017-hrsehraecasaphrssolaece-expert-consensus-statement-catheter-and-surgical-ablation-atrial

[1] U.S. Food and Drug Administration. LUX-Dx™ Insertable Cardiac Monitor K193473 approval letter, June 26, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193473.pdf.

- Jonathan S. Steinberg, MD, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry https://www.hrsonline.org/guidance/clinical-resources/2017-ishne-hrs-expert-consensus-statement

  > *7.1.3. Efficacy of ablation procedure; In order to detect asymptomatic recurrence of arrhythmias after ablation, the following optional screening modalities at 6-month intervals were recommended: (1) AECG monitoring for 4 weeks around the follow-up interval, including symptom-triggered recordings and weekly transmissions for asymptomatic episodes; (2) 24- to 72-hr Holter monitoring; or (3) 30-day autotriggered event monitoring or AECG. According to EHRA/ HRS consensus, a minimum follow-up of 6–12 months with regular monitoring of arrhythmia is required to assess the efficacy of ablation.*

- Craig T. January, MD, PhD, FACC, L. Samuel Wann, MD, MACC, FAHA, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation. https://www.hrsonline.org/guidance/clinical-resources/2020-update-2016-accaha-clinical-performance-and-quality-measures-adults-atrial-fibrillation-or

- A recent RCT established the superiority of an implantable cardiac monitor over conventional monitoring for detecting silent AF, a finding with major clinical ramifications for these patients. (https://www.nejm.org/doi/full/10.1056/NEJMoa1313600)

- Pokushalov E, Romanov A, Corbucci G, et al. Ablation of paroxysmal and persistent atrial fibrillation: 1-year follow-up through continuous subcutaneous monitoring. J Cardiovasc Electrophysiol. Apr 2011; 22(4): 369-75. https://www.ahajournals.org/doi/10.1161/CIRCEP.113.000495

  > *Conclusions: Our study demonstrated the superiority of a second ablation procedure compared with AAD once the first ablation fails; the use of long-term continuous ECG monitoring facilitated the objective quantification of AF burden progression and to assess AF freedom at the end of a long follow-up.*

- Kapa S, Epstein AE, Callans DJ, et al. Assessing arrhythmia burden after catheter ablation of atrial fibrillation using an implantable loop recorder: the ABACUS study. J Cardiovasc Electrophysiol. Aug 2013; 24(8): 875-81. https://www.ahajournals.org/doi/10.1161/circ.124.suppl_21.A12521

- Shah S, Barakat A, Saliba W, et al. Recurrent atrial fibrillation after initial long-term ablation success: Electrophysiological findings and outcomes of repeat ablation procedures. Circ Arrhythm Electrophysiol. Apr 2018; 11(4). https://www.ahajournals.org/doi/abs/10.1161/CIRCEP.117.005785

  > *Study demonstrated frequency of longer-term recurrence of atrial fibrillation. Median arrhythmia-free time was 52 months followed by re-ablation procedure*

- Hussein A, Saliba W, Martin D, et. al. Natural history and long-term outcomes of ablated atrial fibrillation. Circ Arrhythm Electrophysiol. Apr 2011; 4: 241-278. https://www.ahajournals.org/doi/10.1161/circep.111.962100

  Study demonstrated 23.8% of patients had recurrence of atrial fibrillation within the first year; and 8.9% had late recurrence within the first 55 months.

- BCBS Evidence Street on Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry findings: Individuals with atrial fibrillation following ablation who receive long-term ambulatory cardiac monitoring = the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

In closing, I ask that you reconsider coverage of the LUX -DX™ implant for my patient based on the above arguments, literature support 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 implant 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