SAMPLE APPEAL TEMPLATE

LUX-Dx™ IMPLANT FOR MONITORING AND MANAGEMENT OF ATRIAL FIBRILLATION, INCLUDING 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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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements.

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[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

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

Facility Services

CPT 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 the need for monitoring and management of atrial fibrillation. It also includes evidence supporting the use of long-term monitoring via SCRM within but not limited to the post ablation patient population.

The LUX-Dx™ System Therapy
The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (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. The LUX-Dx ICM is indicated for atrial fibrillation monitoring in patients that have been previously diagnosed with or treated for atrial fibrillation.

The LUX-Dx has not been tested specifically for pediatric use.

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 who 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 that recur too infrequently to be detected by shorter-term external monitoring modalities. Additionally, the subcutaneous cardiac rhythm monitors are indicated for atrial fibrillation monitoring in patients that have been previously diagnosed or treated for atrial fibrillation. 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). Additionally, several local Medicare contractors (MACs) have specific policies providing explicit coverage for monitoring and management of anti-arrhythmic drug dosage and to assess the effectiveness of arrhythmia therapy (e.g., post ablation) such as the following Novitas Solutions policy: LCD - Ambulatory Electrocardiograph (AECG) Monitoring (L39490).

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

Clinical Evidence

Guidelines and Expert Consensus

- Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation: A report of the American College of

[1] U.S. Food and Drug Administration. LUX-Dx™ Insertable Cardiac Monitor K252593 clearance letter, September 12, 2025. 510(k) Premarket Notification.

Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2024;149(1):e1-e156. doi:10.1161/CIR.0000000000001193

"Cardiac monitoring may be advised to AF patients for various reasons, such as for detecting recurrences, screening, or response to therapy." (pe24)

- Tzeis S, Gerstenfeld EP, Kalman J, et al. 2024 European Heart Rhythm Association/Heart Rhythm Society/Asia Pacific Heart Rhythm Society/Latin American Heart Rhythm Society expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Europace*. 2024;26(4):euae043. doi:10.1093/europace/euae043

Clinical Studies

- Aguilar M, Macle L, Deyell MW, et al. Influence of monitoring strategy on assessment of ablation success and postablation atrial fibrillation burden assessment: Implications for practice and clinical trial design. *Circulation*. 2022;145(1):21-30. doi:10.1161/CIRCULATIONAHA.121.056109

- Aguilar M, Macle L, Ditac G, et al. Atrial fibrillation burden is underestimated by non-invasive monitoring: The CIRCA-DOSE trial. *European Heart Journal.* Published online 2025: 1-3. https://doi.org/10.1093/eurheartj/ehaf647

These two analyses (Aguilar et al., 2022 and Aguilar et al., 2025) from the CIRCA-DOSE study demonstrated that ICM detected more atrial tachyarrhythmia recurrences post-ablation than simulated short-term and intermittent monitoring strategies and further highlighted the limitations of intermittent monitoring for accurately assessing AF burden in this population.

- Balabanski T, Brugada J, Arbelo E, et al. Impact of monitoring on detection of arrhythmia recurrences in the ESC-EHRA EORP atrial fibrillation ablation long-term registry. *Europace*. 2019;21(12):1802-1808. doi:10.1093/europace/euz216

This study demonstrated higher post-ablation detection rates of AF with an ICM compared to shorter term/non-continous methods (12-lead ECG, Holter, trans-telephonic ECG monitor).

- Bjorkenheim A, Brandes A, Chemnitz A, Magnuson A, Edvardsson N, Poci D. Rhythm control and its relation to symptoms during the first two years after radiofrequency ablation for atrial fibrillation. *Pacing Clin Electrophysiol*. 2016;39(9):914-25. doi:10.1111/pace.12916

Compared to intermittent monitoring post-ablation, an ICM detected AF recurrence earlier and in a greater number of patients. The study concludes, "Continuous monitoring was superior to intermittent follow-up in detecting AF episodes and assessing the AF burden."(p914)

- Davtyan K, Shatakhtsyan V, Poghosyan H, et al. Radiofrequency versus cryoballoon ablation of atrial fibrillation: An evaluation using ECG, holter monitoring, and implantable loop recorders to monitor absolute and clinical effectiveness. *Biomed Res Int*. 2018;2018:3629384. Published 2018 Mar 12. doi:10.1155/2018/3629384

In patients undergoing radiofrequency ablation, an ICM detected significantly more atrial arrhythmia recurrences compared to conventional (ECG and Holter) monitoring in the same patients. In patients who received cryoablation, there was not a difference in recurrence detection between ICM and conventional monitoring; however, the cryoablation patients had fewer asymptomatic episodes. These results highlight the value of long-term continuous monitoring especially for detecting asymptomatic recurrences.

- Eitel C, Husser D, Hindricks G, et al. Performance of an implantable automatic atrial fibrillation detection device: impact of software adjustments and relevance of manual episode analysis. Europace. 2011;13(4):480-485. doi:10.1093/europace/euq511

  In this study a subset of AF patients underwent pulmonary vein isolation and were monitored via ICM and serial 7-day Holter recordings. The ICM detected AF in 4 patients that were missed by serial Holter monitoring.

- 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. *Journal of Cardiovascular Electrophysiology*. 2013;24(8):875-881. doi:10.1111/jce.12141

  This study demonstrated that an ICM detected significantly more arrhythmia recurrence post-ablation than conventional monitoring via transtelephonic monitor in the same patient group. While the study calls out the need to address potential for false detection, it concludes that "ILRS may be useful in monitoring these patients after ablation." (p875)

- Katapadi A, Chelikam N, Garg J, et al. Dynamic data-driven management of atrial fibrillation with implantable cardiac monitors: The MONITOR AF Study. *Heart Rhythm.* Published online 2025:1-7. doi:10.1016/j.hrthm.2025.01.011

  The MONITOR AF study evaluated the impact of ICM monitoring for clinical management of AF by comparing AF patients with vs. without ICM. Patients who received an ICM had lower rates of stroke and AF-related hospitalization. The study concludes, "The real-world management of AF with ICMs is associated with early access to EP care and appropriate therapeutic interventions, leading to improved rhythm control and AF-related clinical outcomes." (p6)

- Mansour MC, Gillen EM, Garman A, et al. Healthcare utilization and clinical outcomes after ablation of atrial fibrillation in patients with and without insertable cardiac monitoring. *Heart Rhythm O2*. 2022;3(1):79-90. doi:10.1016/j.hroo.2021.12.005

  This analysis of US administrative claims found that patients who underwent an AF ablation and had an ICM experienced fewer severe cardiovascular events and associated costs compared to ablation patients without an ICM.

- Unni RR, Prager RT, Odabashian R, et al. Rhythm monitoring strategy and arrythmia recurrence in atrial fibrillation ablation trials: A systematic review. *CJC Open.* 2022;4(5):488-496. doi:10.1016/j.cjco.2022.02.001

  This meta-analysis of randomized controlled trials (RCTs) of AF ablation found that for patients with paroxysmal AF undergoing pulmonary vein isolation, "continuous rhythm monitoring detected higher rates of atrial arrhythmia recurrence compared to RCTs utilizing an intermittent rhythm-monitoring strategy." (p495)

- Yang P, Pu L, Yang L, et al. Value of implantable loop recorders in monitoring efficacy of radiofrequency catheter ablation in atrial fibrillation. *Medical Science Monitor.* 2016;22:2846-2851. doi:10.12659/MSM.897333

  This study of AF patients undergoing radiofrequency catheter ablation (RFCA) found that more AF recurrences were identified by ICM compared to traditional follow-up in the same group of patients. The study concludes, "The use of ILR in monitoring the efficacy

of AF RFCA was better than with traditional examinations. ILR can promptly detect asymptomatic AF and record the onset characteristics of ECG events after AF RFCA, thus providing a basis for objectively determining efficacy and recurrence rates, defining characteristics of other cardiac events, and contributing to development of reasonably effective clinical treatment programs." (p2850)

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