SAMPLE APPEAL TEMPLATE FOR THE LUX-Dx™ 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 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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Instructions for completing the sample appeal template:

1. Please customize the appeals template based on the medical appropriateness of the LUX 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.

[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 Cardiac Rhythm Monitor (LUX-Dx™) 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 cardiac rhythm monitor (the LUX-Dx™) 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 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).

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

Potential Benefits of the SCRM

[Physician to provide any additional comments supporting their choice (both physician and patient) for implant of the SCRM.]

I feel that [patient name] will benefit greatly from a subcutaneous cardiac rhythm monitor implant. [Patient name's] quality of life and well-being is greatly impacted. In addition to _____, [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].

I ask that you approve coverage of the LUX-Dx 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 approval 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]
[Phone Number]

Enclosures

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

See important notes on the uses and limitations of this information on page 1.

Highlighted Clinical Evidence

We have included the following LUX-Dx-specific clinical evidence for your review:

- LUX-Dx Clinical Compendium
- Timeline of LUX-Dx Clinical Trials and Publications

Additionally, the following clinical compendium includes published research related to subcutaneous cardiac rhythm monitors (SCRMs) more broadly. Resources have been organized by three primary clinical indications: stroke, syncope, and atrial fibrillation. The following list is comprehensive and organized by relevance, but not all inclusive.

Stroke

- Guidelines and expert consensus:
  - Spooner MT, Messé SR, Chaturvedi S, et al. 2024 ACC expert consensus decision pathway on practical approaches for arrhythmia monitoring after stroke. *Journal of the American College of Cardiology*. 2025;85(6):657-681. doi:10.1016/j.jacc.2024.10.100
  - 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 Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024;149(1):e1-e156. doi:10.1161/CIR.0000000000001193
  - Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 guideline for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline from the American Heart Association/American Stroke Association. *Stroke*. 2021;52(7):e364-e467. doi:10.1161/STR.0000000000000375
- Highlighted clinical studies
  - Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. 2014;370(26):2478-2486. doi:10.1056/NEJMoa1313600
  - Saha SA, Rosemas S, Sarkar S, et al. A large, real-world cohort analysis of arrhythmia detection and therapeutic interventions in patients with insertable cardiac monitors and long-term monitoring. *J Cardiovasc Electrophysiol*. Published online December 17, 2025. doi:10.1111/jce.70214
  - Quartieri F, Harish M, Calò L, et al. New insertable cardiac monitors show high diagnostic yield and good safety profile in real-world clinical practice: results from the international prospective observational SMART Registry. *Europace (London, England)*. 2023;25(5). doi:10.1093/europace/euad068
  - Yaghi S, Ryan MP, Gunnarsson CL, et al. Longitudinal outcomes in cryptogenic stroke patients with and without long-term cardiac monitoring for atrial fibrillation. *Heart Rhythm O2*. 2022;3(3):223-230. doi:10.1016/j.hroo.2022.02.006
  - Chalfoun N, Pierobon J, Rosemas SC, et al. A cost comparison of atrial fibrillation monitoring strategies after embolic stroke of undetermined source. *Am Heart J Plus*. 2022;21:100195. doi:10.1016/j.ahjo.2022.100195
  - Edwards SJ, Wakefield V, Jhita T, Kew K, Cain P, Marceniuk G. Implantable cardiac monitors to detect atrial fibrillation after cryptogenic stroke: A systematic review and economic evaluation. *Health Technol Assess*. 2020;24(5):1-184. doi:10.3310/hta24050
  - Ziegler PD, Rogers JD, Ferreira SW, et al. Long-term detection of atrial fibrillation with insertable cardiac monitors in a real-world cryptogenic stroke population. *Int J Cardiol*. 2017;244:175-179. doi:10.1016/j.ijcard.2017.06.039
  - Buck BH, Hill MD, Quinn FR, et al. Effect of implantable vs prolonged external electrocardiographic monitoring on atrial fibrillation detection in patients with ischemic stroke: The PER DIEM randomized clinical trial. *JAMA*. 2021;325(21):2160-2168. doi:10.1001/jama.2021.6128

See important notes on the uses and limitations of this information on page 1.

- Milstein NS, Musat DL, Allred J, et al. Detection of atrial fibrillation using an implantable loop recorder following cryptogenic stroke: Implications for post-stroke electrocardiographic monitoring. *J Interv Card Electrophysiol*. 2020;57(1):141-147. doi:10.1007/s10840-019-00628-6
- Chew DS, Rennert-May E, Quinn FR, et al. Economic evaluation of extended electrocardiogram monitoring for atrial fibrillation in patients with cryptogenic stroke. *Int J Stroke*. 2021;16(7):809-817. doi:10.1177/1747493020974561

Syncope

- Guidelines and expert consensus:

  - Brignole M, Moya A, de Lange FJ, et al. 2018 ESC guidelines for the diagnosis and management of syncope. *Eur Heart J*. 2018;39(21):1883-1948. doi:10.1093/eurheartj/ehy037
  - Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation (New York, NY)*. 2019;140(8):e382-e482. doi:10.1161/CIR.0000000000000628
  - Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2017;136(5):e60-e122. doi:10.1161/CIR.0000000000000499

- Highlighted clinical studies:

  - Solbiati M, Casazza G, Dipaola F, et al. The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis. *Int J Cardiol*. 2017;231:170-176. doi:10.1016/j.ijcard.2016.12.128
  - Saha SA, Rosemas S, Sarkar S, et al. A large, real-world cohort analysis of arrhythmia detection and therapeutic interventions in patients with insertable cardiac monitors and long-term monitoring. *J Cardiovasc Electrophysiol*. Published online December 17, 2025. doi:10.1111/jce.70214
  - Quartieri F, Harish M, Calò L, et al. New insertable cardiac monitors show high diagnostic yield and good safety profile in real-world clinical practice: results from the international prospective observational SMART Registry. *Europace (London, England)*. 2023;25(5). doi:10.1093/europace/euad068
  - Sutton BS, Bermingham SL, Diamantopoulos A, et al. Economic value of insertable cardiac monitors in unexplained syncope in the United States. *Open heart*. 2021;8(1):e001263. doi:10.1136/openhrt-2020-001263
  - Frazier-Mills CG, Johnson LC, Xia Y, Rosemas SC, Franco NC, Pokorney SD. Syncope recurrence and downstream diagnostic testing after insertable cardiac monitor placement for syncope. *Diagnostics (Basel)*. 2022;12(8):1977. doi:10.3390/diagnostics12081977

Atrial Fibrillation

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

- Highlighted clinical studies:

See important notes on the uses and limitations of this information on page 1.

- 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
- 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
- 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
- Saha SA, Rosemas S, Sarkar S, et al. A large, real-world cohort analysis of arrhythmia detection and therapeutic interventions in patients with insertable cardiac monitors and long-term monitoring. *J Cardiovasc Electrophysiol*. Published online December 17, 2025. doi:10.1111/jce.70214
- Quartieri F, Harish M, Calò L, et al. New insertable cardiac monitors show high diagnostic yield and good safety profile in real-world clinical practice: results from the international prospective observational SMART Registry. *Europace (London, England)*. 2023;25(5). doi:10.1093/europace/euad068
- 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
- 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
- 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. doi:10.1155/2018/3629384
- 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
- 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
- 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

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