SAMPLE REQUEST FOR COVERAGE 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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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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Instructions for completing the sample request for coverage template:

1. Please customize the request for coverage 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 coverage guidelines; your letter needs to clearly indicate the patient's conditions applicable to the health plan's coverage guidelines.

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[Date]

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

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

RE: Request for 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 request approval for coverage on [date] for the implant of the implantable 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).

Potential Benefits of the SCRM

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

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[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. [His/Her] qualify 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 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 Cardiac Rhythm Monitor

1. Bisignani A. et al, Implantable loop recorder in clinical practice J Arrhythm. 2019 Feb; 35(1): 25–32.

2. 2021 ISHNE/HRS/EHRA/APHRS Collaborative Statement on mHealth in Arrhythmia Management: Digital Medical Tools for Heart Rhythm Professionals | Heart Rhythm Society (hrsonline.org)

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