**WATCHMAN FLX™ LEFT ATRIAL APPENDAGE CLOSURE DEVICE**

**Sample Letter of Medical Necessity**

**This following sample letter must be customized** to reflect the background, medical history and diagnosis of the specific patient, and to address any special requirements of the payer.

* This letter is an example for your consideration and may not include all the information necessary to support your prior authorization request.
* The clinician has responsibility for providing accurate and complete information concerning the applicable diagnosis and procedure codes, and for supporting medical necessity.
* The requesting facility is responsible for ensuring the accuracy and adequacy of all information provided.
* It is recommended that the patient’s insurance company be contacted for specific information regarding coverage criteria.
* Medicare does not preauthorize medical procedures.

**Instructions:**

1. Sections which require customization are **highlighted in yellow**. Edit these sections to reflect medical appropriateness of the WATCHMAN FLX LAAC Device for the individual patient.
2. It is important to provide the most complete information to assist with the prior authorization process.
3. Delete the highlighted instructions for completion, so the health plan does not misinterpret the resulting submission as a form letter.
4. Questions may be directed to WATCHMAN.reimbursement@bsci.com or your local Boston Scientific Health Economics and Market Access Manager.­

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[Date]

Attention: Surgery Preauthorization Department

[Insurance Company address]

RE: Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Policy Holder Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Patient ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Policy, Group, or Claim: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Scheduled surgery date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RE: Prior Authorization Requested for Procedure: CPT code: 33340 and ICD-10 PCS procedure code: 02L73DK**

To Whom it May Concern:

On behalf of my patient, I am requesting approval for the surgery, hospital stay, and post-surgical care associated with the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device implant procedure.

The WATCHMAN FLX LAAC Device is an FDA approved device indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

* Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc (1) scores and are recommended for anticoagulation therapy;
* Are deemed by their physicians to be suitable for warfarin; and
* Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

Prior Authorization is requested for the following codes:

* **CPT code 33340**: Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

[Include CPT codes (93312-93320, or 93325 or 93355) for performing transesophageal echocardiography (TEE) as applicable.]

* **ICD10-PCS code 02L73DK**: Occlusion of left atrial appendage with intraluminal device, percutaneous approach. NOTE: CMS has restricted this procedure to the inpatient hospital site of service.

To support this appeal, I am providing the following:

* Patient history & physical and operative reports, supporting medical necessity of the LAAC implant procedure
* CMS National Coverage Determination:

<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281>

* Link to FDA Approval. The FDA approved WATCHMAN FLX™ LAAC Device on July 21, 2020. To access the WATCHMAN FLX™ LAAC Device approval document, visit the FDA website at: <https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013S035A.pdf>
* A summary of clinical evidence, with associated references

<https://www.watchman.com/content/dam/watchman/downloads/download-center/reimbursement/WATCHMAN_Coverage_Clinical_Evidence_Summary.pdf>

Current Coverage Status:

My patient meets the coverage criteria for the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device implant procedure as defined by the insurance policy:

[Include policy language. Specify how the patient’s clinical status aligns with the criteria]

**OR**

My patient does not have explicit coverage for the WATCHMAN FLX™ LAAC Device implant procedure under their current insurance policy. Prior authorization is therefore being requested based the coverage criteria as defined within the CMS National Coverage Determination for LAAC (20.34), described below:

[Specify how the patient’s clinical status aligns with the criteria]

* A CHADS2 score ≥ 2 or CHA2DS2-VASc score ≥ 3
* A formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC.
* A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation

To access the NCD for percutaneous LAAC therapy in its entirety, please [click here](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281).

Based upon the medical necessity for my patient, I am requesting that approval be granted for WATCHMAN FLX™ LAAC Device implant procedure and all related services as soon as possible.

* Please fax prior-authorization approval to my office at [fax number]
* Please contact me with any questions at [telephone number]

Physician may choose to insert additional comments regarding why this procedure is viewed as a preferable alternative to long-term anticoagulation therapy for this particular patient.

Sincerely,

**[Physician Name]**

**[Practice Name]**

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1. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC, Jr., et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2019;16(8):e66-e93.