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Advancing science for life™

WATCHMAN™
INTEGRATED LAAC SOLUTIONS

WATCHMAN FLX Pro Left Atrial Appendage Closure Device Physician Peer-to-Peer Appeal Guide

For questions regarding WATCHMAN LAAC Device reimbursement, please contact:

Email: WATCHMAN.Reimbursement@bsci.com

Please go to www.watchmandownloadcenter.com to access a sample prior authorization template and additional resources.

The FDA Approved the WATCHMAN FLX™ Pro LAAC Device on September 5, 2023.

To access the WATCHMAN FLX Pro LAAC Device approval document, visit the FDA website

See page 2 for important information about the uses and limitations of this document.

Important Information

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies.

This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice.

Boston Scientific encourages providers to submit accurate and appropriate claims for services. **It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered.**

It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

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. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.

Physician Peer-to-Peer Appeal Guide:

WATCHMAN FLX Pro LAAC Device

This guide is intended to support peer-to-peer appeal conversations between the implanting physician and health plan Medical Directors following a pre-procedural denial of coverage for the WATCHMAN FLX LAAC Device procedure.

STEP 1 Understand the Denial

- Anticipate denials from insurers that have not yet established positive coverage policies for WATCHMAN LAAC Device.
- Review the reason for denial, as well as the payer-specific process for appealing pre-procedural denials.

STEP 2 Qualify the Reviewer

- If the plan does not have a positive coverage policy in place, start by confirming that the payer representative to whom you are speaking has the authority to overturn the denial by making a patient-specific exception to the current policy. If not, your time spent advocating will not be productive. Request a peer-to-peer review by an individual who has this authority.
- Verify the reviewer's medical specialty and understanding of stroke management and atrial fibrillation treatment options. If the reviewer is not familiar with this specialty area, consider requesting a "like-specialty peer-to-peer review", which indicates that you wish to speak with a physician of similar training, such as a Cardiologist, Interventional Cardiologist or Electrophysiologist.

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STEP 3

Review Status of FDA Approval, CMS and Commercial Coverage

FDA Approval

The FDA Approved the WATCHMAN FLX Pro LAAC Device on September 5th, 2023.

To access the WATCHMAN FLX Pro LAAC Device approval document, visit the FDA website

According to FDA Labeling: WATCHMAN FLX Pro LAAC Device is indicated to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc 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.

CMS National Coverage Determination

Effective February 8th, 2016, Centers for Medicare and Medicaid Services (CMS) established a National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34). Details regarding requirements for coverage are provided on the CMS website at National Coverage Determination for Left Atrial Appendage Closure (20.34). This policy provides patient access to WATCHMAN LAAC Device for all Medicare beneficiaries, including those covered by Medicare Advantage plans.

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Under the CMS NCD, primary medical criteria for coverage are as follows:

- A $CHADS_2$ score ≥2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA_2DS_2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)
- 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. Additionally, the shared decision-making interaction must be documented in the medical record.
- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.

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STEP 4 Focus on Securing Coverage for an Individual Patient

- The goal is to obtain one-time access to the WATCHMAN FLX Pro LAAC Device by requesting a patient-specific exception to current policy. This is not the appropriate forum to advocate for a change in policy.
- Present evidence to demonstrate that your patient is a candidate for the WATCHMAN FLX Pro LAAC Device.
  - Reference the specific indication from the payer's policy.
  - If no written policy exists, reference indications within the Medicare National Coverage Determination (NCD) for LAAC .
  - Refer to established clinical guidelines from the key physician societies American College of Cardiology, Heart Rhythm Society, and The Society for Cardiovascular Angiography and Interventions. The three national societies jointly advocated in support of coverage with Centers for Medicare and Medicaid Coverage for the Left Atrial Appendage Closure Therapy in patients with non-valvular atrial fibrillation and as an alternative to warfarin for stroke prevention.
- Focus discussion on the specific patient's need for a WATCHMAN FLX Pro LAAC Device. Demonstrate that the patient meets FDA labeling requirements and highlight patient-specific reasons for seeking a non-pharmacologic alternative to warfarin, such as:
  - Patient has non-valvular atrial fibrillation and has a history of major bleeding while taking therapeutic anticoagulation therapy.
  - Patient is unable to maintain a stable INR or comply with regular INR monitoring over the long term, placing him/her at heightened risk of a thrombotic or bleeding event.

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- Patient's occupation or lifestyle places him/her at high risk of major bleeding secondary due to trauma, and therefore has a reason to seek a non-pharmacologic alternative to long-term anticoagulation.

STEP 5 Support with Clinical Evidence

A complete clinical evidence summary is available at watchmandownloadcenter.com by clicking on the "Reimbursement" tab, and selecting WATCHMAN Approval/Coverage Status and Clinical Evidence.

Please reach out to the Boston Scientific Health Economics and Market Access team with questions related to specific payer denials.

Watchman.Reimbursement@bsci.com

STEP 6 Determine Next Steps

If the reviewer denies the appeal by deferring to a non-coverage policy, request information regarding next steps for a for an expedited internal appeal.

WATCHMAN FLX Pro Brief Summary
watchman.com/en-us-implanter/watchman-flx-pro-brief-summary.html

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