



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](#)



WATCHMAN FLX Pro Device | Brief Summary

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

Intended Use/Indications for Use

WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage.

Indications for Use

The WATCHMAN FLX Pro Device is 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 CHA₂DS₂-VASc scores and are recommended for anticoagulation therapy.
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

Contraindications

Do not use the WATCHMAN FLX Pro Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Step 7).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN FLX Pro Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of anticoagulation therapy, aspirin, or P2Y12 inhibitor.

Warnings

Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient.
- This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/ or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria (Step 15) are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised

Precautions

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.
- Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Pro Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure should not exceed 690 kPa (100 psi).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

MRI Safety Information

A person with the Boston Scientific WATCHMAN FLX Pro Closure Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WATCHMAN FLX Pro Closure Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of up to 8 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Potential Adverse Events

Air embolism, Airway trauma, Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medication, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, Bruising, hematoma, or seroma near the catheter insertion site, Cardiac perforation, Chest pain/discomfort, Confusion post-procedure, Congestive heart failure, Contrast-related nephropathy, Cranial bleed, Death, Decreased hemoglobin, Deep vein thrombosis, Device embolism, Device fracture, Device thrombosis, Edema, Embolism, Excessive bleeding, Fever, Fistula, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardial erosion, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, Renal failure, Respiratory insufficiency/failure, Stroke - Hemorrhagic, Stroke - Ischemic, Surgical removal of the device, TEE complications (e.g., throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular or vascular damage, Vasovagal reactions

There may be other potential adverse events that are unforeseen at this time.

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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 CHADS₂ or CHA₂DS₂-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 CHADS₂ score ≥ 2 (Congestive heart failure, Hypertension, Age > 75 , Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA₂DS₂-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.