


Boston Scientific
Advancing science for life™

WATCHMAN™
INTEGRATED LAAC SOLUTIONS

WATCHMAN FLX Pro Left Atrial Appendage Closure Device Supporting Patient Access

The following information is provided to assist providers in addressing patient-specific insurance requirements for the WATCHMAN LAAC Device procedure and associated services.

For questions regarding WATCHMAN FLX Pro LAAC Device reimbursement, please contact:

Email: WATCHMAN.Reimbursement@bsci.com

Please go to www.watchmandownloadcenter.com for additional resources.

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

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

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 CHA_2DS_2-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.

97097061 Rev. B. 7

Supporting Patient Access

STEP 1

Determine Insurance Coverage

Coverage is dependent of the individual's health plan coverage and benefits.

Original Medicare

Original Medicare beneficiaries have access to the Left Atrial Appendage Closure procedure with the WATCHMAN FLX Pro LAAC Device under a National Coverage Decision: NCD CED 20.34.

Medicare Advantage

Medicare Advantage Health plans are administered by Medicare Advantage Organizations (MAO). MAO plans are required to offer the same coverage as Original Medicare, however MAOs conduct a medical necessity review through Utilization Management (UM). The review for medical necessity may take up to two weeks. The MAO is required to communicate their decision to the provider and patient in writing.

Medicaid

Medicaid plans vary with respect to their coverage of the WATCHMAN FLX Pro LAAC Device. You may contact the Boston Scientific Reimbursement Support Line for information regarding state-specific coverage status.

Commercial Insurance

Patients often obtain health insurance from their employer, or purchase through an exchange. Commercial health insurance contractually requires prior authorization before services are rendered. The Commercial Health Insurance reviews applicable data and reviews for medical necessity. Their determination is communicated to the provider and patient in writing. This process can take up to two weeks.

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STEP 2

Request Prior-Authorization or Pre-Determination

The prior-authorization process involves obtaining advance notification from the health plan that medical necessity and other coverage criteria have been met as set forth by the payer.

- Boston Scientific encourages providers to seek WATCHMAN LAAC Device procedure prior-authorization or pre-determination for patients covered by commercial policies.
- Traditional Medicare does not require or accept prior-authorization requests.

If the plan does not have an established positive coverage policy for LAAC, anticipate a denial and be prepared to appeal (see STEP THREE). Many insurers will grant approvals on a case-by-case basis, following appeal.

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

- The prior-authorization process for elective procedures (including LAAC) typically takes 2+ weeks, not including time for appeals. BSC therefore recommends that providers allow at least three weeks for prior-authorization approvals, or delay scheduling until prior-authorization is confirmed. Urgency with respect to expedited approval may be communicated to the payer as deemed appropriate.

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It is suggested to include the following information within the prior authorization submission:

- Patient insurance information: Name, ID and phone number (provide a front/back copy of patient's insurance card)
- Letter of Medical Necessity, edited and signed, to include:

- Appropriate rational to seek an alternative to long-term anticoagulation therapy for stroke risk reduction.

- Patient history & physical (H&P), Previous cardiac-related procedures, other relevant clinical information.

- Risk of stroke based on CHADS2 score >2 or CHA2DS2-VASc score >3.

- List of current diagnosis codes (ICD-10-CM), which may include:
  - I48.91 – Unspecified atrial fibrillation
  - I48.21 – Permanent atrial fibrillation
  - I48.0 – Paroxysmal atrial fibrillation
  - I48.11 – Longstanding persistent atrial fibrillation
  - I48.19 – Other persistent atrial fibrillation

*The NCD 20.34 does not cover I48.20, Chronic atrial fibrillation, unspecified

- Relevant procedure codes CPT® and/or ICD-10-PCS codes), such as:
  - 33340 – Percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation.
  - 02L73DK – Occulsion of left atrial appendage with intraluminal device, percutaneous approach.

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- Supporting documentation including, office visit notes and/or hospital notes containing:
  - Documentation of past anticoagulation-related complications.
  - Fall risk.
  - Inability to maintain a stable therapeutic International Normalized Ratio (INR).
  - Chronic medical condition, occupation or lifestyle placing the patient at high risk for major bleeding (HAS-BLED).
  - Documentation that the patient can tolerate short-term anticoagulation therapy.
  - Shared decision-making result around the LAAC procedure from an independent, non-interventional physician.
  - Attestation from an interventional cardiologist, electrophysiologist, or cardiac surgeon that meets the training and on-going cardiac procedure performance requirements.
  - Documentation that the patient will reside under the care of a cohesive, multidisciplinary team (MDT) of medical professionals both preoperatively and postoperatively.
  - Documented patient enrollment and facility participation in a, prospective, national, audited, LAAC registry.
  - Documentation that the patient can tolerate OAC/warfarin therapy post-op for up to 6 weeks

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STEP 3

Appeal Prior-Authorization Denial

Commercial Plan

Plans that do not have an established coverage policy may consider LAAC to be experimental and investigational, and deny coverage as a result. Providers/patients have the option to seek case-by-case coverage by requesting an exception to the policy.

Best Practices for Appealing a Commercial Plan Denial:

- Ask for clarification regarding the reason for the denial... is it due to documentation, patient criteria, or coverage? The insurer will communicate their decision for the prior authorization decision.
- Review the denial to prepare an appropriate response to the insurer's request and initiate the appeals process in accordance with the insurer's defined processes.
- Request a peer-to-peer review with a like-specialty physician (i.e. a Cardiologist, Interventional Cardiologist or Electrophysiologist). Plans are obligated to provide participating providers with the opportunity to speak with a qualified physician to request an exception to the coverage policy on a case-by-case basis.
- Provide the patient with options for advocating on their own behalf
  - Patient may submit a personal letter to accompany the doctor's appeal.
  - Patients can engage the plan directly with an appeal.

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Supporting Patient Access

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Medicare Advantage

All Medicare beneficiaries have access to WATCHMAN FLX Pro LAAC Device under the CMS National Coverage Determination (20.34). Denials from Medicare Advantage plans may still occur however, as not all commercial plans maintain current information regarding Medicare coverage status. If coverage is denied for a Medicare beneficiary, provide information regarding CMS coverage policy 20.34 (available at www.cms.gov) to support an appeal.

Medicaid

Medicaid plans vary with respect to their coverage of the WATCHMAN FLX Pro LAAC Device. You may contact the Boston Scientific Reimbursement Support Line for information regarding state-specific requirements and the process for appealing denials.

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STEP 4

Engage in Internal Appeal

To prepare for a successful Internal Appeal, investigate the reason for the denial.

Discuss whether it is due to documentation issues, patient criteria or coverage. Make sure to prepare comments that directly address insurer's reason for denial.

Best Practices for Internal Appeals:

- Include information about FDA approval and CMS National Coverage Determination. A summary of clinical evidence can be found here.
- Reference the indication from the payer's policy. If no written policy exists, reference the coverage criteria according to the CMS NCD link. As appropriate, detail how the patient meets these indications for coverage.
- Provide compelling patient-specific reasons why the individual would benefit from LAAC, including details regarding past anticoagulation-related complications, fall risk, inability to maintain a stable therapeutic International Normalized Ratio (INR), or a medical condition, occupation or lifestyle placing the patient at high risk of major bleeding
- Reference available peer-reviewed publications that demonstrate the benefits of LAAC for indicated patients.
- Reference established coverage status for LAAC under other commercial plans.
- Expedited Internal appeals can be requested with a cardiologist that has experience with the WATCHMAN LAAC Device.

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STEP 5

External Appeal

External Review

A patient has the right to take their appeal to an independent third party for review. This is called an external review. External review means that the insurance company no longer gets the final say over whether to pay a claim.

If the Health Insurance company maintains their denial, the final decision is communicated to the provider and patient in writing. The documentation is required to provide contact data for an external appeal.

Types of denials that can go to external review:

1) Any denial that involves medical judgment where the patient or provider may disagree with the health insurance plan.

2) Any denial that involves a determination that a treatment is experimental or investigational.

3) Cancellation of coverage based on the insurer's claim that a patient gave false or incomplete information when they applied for coverage.

What are a patient's rights in an external review?

Insurance companies in all states must offer an external review process that meets the federal consumer protection standards.

State

A state may have an external review process that meets or goes beyond these standards. If so, insurance companies in the state will follow the state's external review processes. A patient will get all the protections outlined in that process.

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Federal

If a state doesn't have an external review process that meets the minimum consumer protection standards, the federal government's Department of Health and Human Services (HHS) will oversee an external review process for health insurance companies in that state.

Depending on the plan and location, the following may apply to the patient:

- In states where the federal government oversees the process, insurance companies may choose to participate in an HHS-administered process or contract with independent review organizations.
- If the plan doesn't participate in a state or HHS-Administered Federal External Review Process, the health plan must contract with an independent review organization.

How to learn more about a state's external review?

Look at the information on your Explanation of Benefits (EOB) or on the final denial of the internal appeal by the health plan. The EOB will provide contact information for the organization that will handle your external review.

There may be exceptions with regards to Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage Using the HHS Administered Federal External Review Process

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The Center for Consumer Information & Insurance Oversight

Consumers' Rights to Appeal Health Plan Decisions

Under the Affordable Care Act, consumers have the right to appeal decisions made by health plans created after March 23, 2010. The law governs how insurance companies handle initial appeals and how consumers can request a reconsideration of a decision to deny payment. If an insurance company upholds its decision to deny payment, the law provides consumers with the right to appeal the decisions to an outside, independent decision-maker, regardless of the type of insurance or state an individual lives in.

https://www.cms.gov/CCIIO/Programs-and-Initiatives/Consumer-Support-and-Information/External-Appeals

The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that sets minimum standards for most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans.

ERISA requires plans to provide participants with plan information including important information about plan features; requires plans to establish a grievance and appeals process for participants to get benefits from their plans.

https://www.dol.gov/general/topic/retirement/erisa

References and Resources

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2 American Medical Association: 2017 ICD-10-PCS for Hospitals – The Complete Official Draft Code Set, Professional Edition, Chicago, IL.

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