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

**Boston Scientific Prior Authorization Team**
Provides assistance in submitting prior authorization requests and appeals. Release of patient information is required.

**Phone (toll free):** (877) 786-1050
*Press 1 to connect with WATCHMAN Prior Authorization or Appeals support.*

Submit completed Boston Scientific prior authorization forms and associated materials to:

**Email:** PreAuthSupport@bsci.com

**Fax:** 877-835-2520

**Boston Scientific Reimbursement Support Line**
Addresses questions regarding appropriate coding, documentation and payer coverage policies.

**Email:** WATCHMAN.reimbursement@bsci.com

**Voicemail:** (877) 786-1050
*Press 2 to leave a message. Messages are monitored M-F, 8am — 4pm CT and responses are typically on the same or following business day.*
INDICATIONS FOR USE

The WATCHMAN 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 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.

The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

CONTRAINDICATIONS

Do not use the WATCHMAN Device if:
- Intracardiac thrombus is visualized by echocardiographic imaging.
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a device. See Table 46 in the DFU.
- Any of the customulary contraindications for other percutaneous catheterization procedures (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 warfarin, aspirin, or clopidogrel.
- The patient has known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

WARNINGS

- Device selection should be based on accurate LAA measurements obtained using fluoro and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0°, 45°, 90°, 135°).
- Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria.
- If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.
- The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period.
- Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.
- For single use only. Do not reuse, reprocess, oristerilize.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN 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 the device.
- Use caution when introducing the 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 device, do not allow the WATCHMAN 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 100 psi.
- In view of the concerns that were raised by the RE-ALIGN1 study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism, Airway trauma, Allergic reaction to contrast media/medications or device materials, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematoma or seroma, Cardiac perforation, Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Groin pain, Groin puncture bleed, Hematruia, Hemoatypsis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection / pneumonia, Interatrial septum thrombus, Intracranial bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the appendage / movement of device from appendage wall, Myocardia erosion, Nausea, Oral bleeding, Percardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneuuryym, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (thromb pain, bleeding, esophageal trauma), Thrombectomy, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions

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

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.


IMPORTANT INFORMATION – DISCLAIMER

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

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.
STEP 1  DETERMINE INSURANCE COVERAGE

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

Commercial Policy
Boston Scientific encourages providers to seek prior-authorization or pre-determination for patients covered by commercial policies (see STEP TWO below).

Medicare Advantage
All participants in Medicare Advantage plans have access to the WATCHMAN LAAC Therapy under the National Coverage Determination for LAAC (20.34). Medicare Advantage plans are required to offer the same coverage to participants as is available to other Medicare beneficiaries.

Medicare
Medicare beneficiaries have access to the WATCHMAN LAAC Therapy under the National Coverage Determination for LAAC (20.34). The policy defines several criteria which must be met to qualify for coverage. Medicare-eligible patients with supplemental plans will need to review the commercial policy to determine whether their plan will provide coverage as a secondary insurer.

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

**Boston Scientific Prior-Authorization Team**

Boston Scientific’s Prior-Authorization Team is available to assist facility/clinic staff in seeking prior-authorization, pre-determination or pre-certification for the WATCHMAN LAAC procedure. At the request of a Health Care Professional, Boston Scientific’s Prior-Authorization Team can facilitate the necessary preparation, coordination and follow-up support.

Health insurance Portability and Accountability Act (HIPAA) Business Associate Agreement becomes effective upon the submission of protected health information (PHI) to Boston Scientific for prior authorization assistance. The Business Associate Agreement describes Boston Scientific privacy practices and obligations to safeguard patient information, and is available for review online.
• 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.

The Boston Scientific Prior-Authorization Team requires submission of the following items:

• Prior Authorization Request Form (see supporting forms and sample letter templates section for examples of these items)

• Provider Intake Form (see supporting forms and sample letter templates section for examples of these items)

• 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:
  - Medical rationale describing the patient-specific benefits of WATCHMAN LAAC as an alternative to long-term anticoagulation therapy for stroke risk reduction
  - History and Physical (H&P), office/hospital notes, previous cardiac-related procedures, relevant clinical documentation
  - Risk of stroke based on CHADS2 or CHA2DS2-VASc scores
  - List of current diagnoses (ICD-10 diagnosis codes 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
- Relevant procedure codes (CPT code 33340; ICD-10-CM procedure code 02L73DK)

- Documentation of 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.

- Documentation that the patient can tolerate warfarin therapy post-op for up to 6 weeks.

Complete the above items and submit to the Boston Scientific Prior – Authorization Team

Email: PreAuthSupport@bsci.com
Fax: 877-835-2520
STEP 3  APPEAL PRIOR-AUTHORIZATION DENIAL

If the prior-authorization request is denied, seek clarification from the payer regarding the specific reason for the denial prior to appeal. Denials may occur due to reasons other than coverage policy limitations, such as coding or documentation errors. Many insurers will grant approvals on a case-by-case basis, following appeal. The BSC Prior Authorization Team can assist with appeals. The process includes the following:

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...
SUPPORTING PATIENT ACCESS
Continued

Medicare Advantage

All Medicare beneficiaries have access to WATCHMAN LAAC Therapy 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 LAAC Therapy. You may contact the Boston Scientific Reimbursement Support Line for information regarding state-specific requirements and the process for appealing denials.

Contact information on At-A-Glance page
To prepare for a successful Peer-to-Peer Review, investigate the reason for the denial... is it due to documentation, patient criteria, or coverage? Prepare comments that directly address the insurer’s reason for denial.

Best Practices for Peer-to-Peer Reviews:

- Confirm the reviewer’s medical specialty, as well as his/her ability to assess the patient’s suitability for LAAC as an alternative to long-term anticoagulation therapy for stroke risk management. If not, request to speak with someone who is.

- Some plans engage third party reviewers, who are not empowered to make decisions that contradict written coverage policies.
  - Confirm that the reviewer with whom you are speaking has the ability to make an exception to the coverage policy. If not, request to speak with someone that does.

- Confirm that the reviewer is aware of FDA approval status and CMS coverage status for the WATCHMAN LAAC implant procedure, as well as the CPT I code effective date of Jan 1, 2017.

- 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.
SUPPORTING PATIENT ACCESS
Continued

• 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

Contact information on At-A-Glance page
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.

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.

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.
SUPPORTING PATIENT ACCESS
Continued

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.

REFERENCES AND RESOURCES

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