2020 WATCHMAN REIMBURSEMENT

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

REIMBURSEMENT GUIDE

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 customary 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 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 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, or resterilize.

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, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, 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.

1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

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.

REIMBURSEMENT

FOUND IN THIS SECTION

1. WATCHMAN™ Reimbursement Guide
2. Importance of Documentation and the impact on MS-DRG Assignment-WATCHMAN™
3. WATCHMAN™ Importance of Appropriate Charging Guide
4. Sample Claim Forms
5. WATCHMAN™ Payer List
6. Supporting Patient Access (Prior Authorization and Appeals Request) – Associated Forms and Templates
   - Supporting Patient Access for the WATCHMAN™ LAAC Implant Procedure and Associated Services
   - Supporting Forms and Sample Letter Templates
7. LAAO Registry

THIRD PARTY SOURCES

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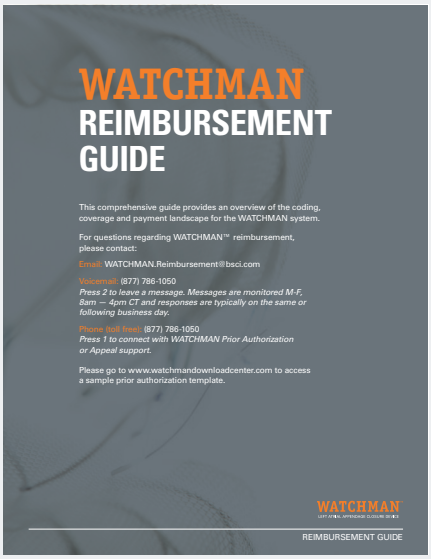
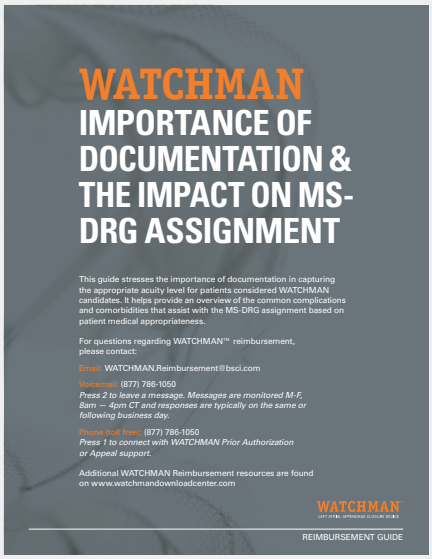
CONTACT INFORMATION – AT-A-GLANCE



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.

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



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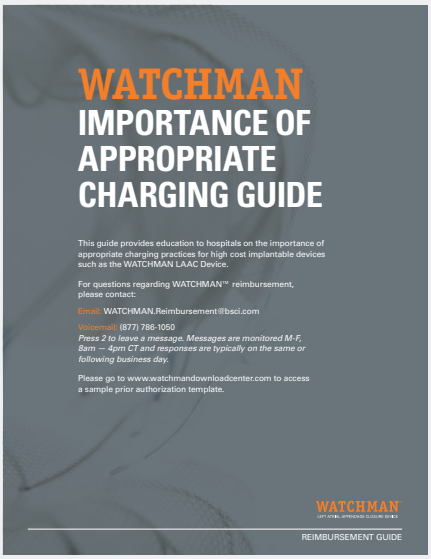

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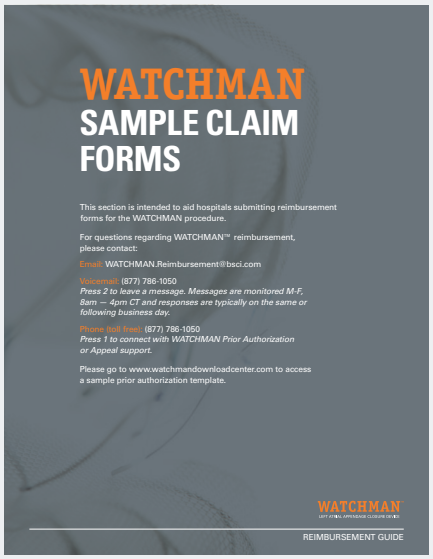

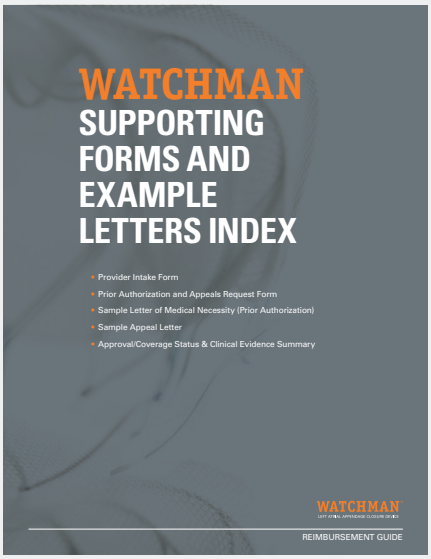

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PRIOR AUTHORIZATION TEAM

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

Email: PreAuthSupport@bsci.com

FAX: 877-835-2520

REIMBURSEMENT SUPPORT LINE

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WATCHMAN.Reimbursement@bsci.com

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WATCHMAN REIMBURSEMENT GUIDE

This comprehensive guide provides an overview of the coding, coverage and payment landscape for the WATCHMAN system.

For questions regarding WATCHMAN™ reimbursement, please contact:

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

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2020 WATCHMAN Left Atrial Appendage Closure Device (The WATCHMAN Device) Coding Guide – Structural Heart

On February 8, 2016 CMS established coverage for WATCHMAN under NCD 20.34 f or percutaneous Left atrial appendage closure (LAAC) therapy.

Boston Scientific is pleased to announce that CMS has finalized the national coverage determination (NCD) for percutaneous LAAC therapy which provides coverage for WATCHMAN when specific conditions are met. The effective date of the NCD is Feb. 8, 2016.

To access the NCD in its entirety, please visit the CMS website or see page 3 of the Guide.

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

REIMBURSEMENT OVERVIEW

The table below provides an overview of coding, coverage and payment for the WATCHMAN Left Atrial Appendage Closure (LAAC) Therapy across sites-of-service and by payer.

	Coding	Medicare		Private Payer	
		Coverage Dependent on payer contract	Payment	Coverage	Payment
Hospital Inpatient	ICD-10 procedure code 02L73DK*	NCD for percutaneous LAAC therapy effective on Feb 8, 2016	Most common mappings are MS-DRG 273 or 274	Varies by Payer policy for LAAC procedures-check with specific payer	Dependent on payer contract
Hospital Outpatient	CPT code 33340	Designated as "Inpatient Only"	NA	Check with Payer specific specific payer	Payer specific
Physician	CPT code 33340	NCD for percutaneous LAAC therapy effective on Feb 8, 2016	Per the Medicare Physician's Fee Schedule	Refer to payer policy for LAAC procedures	Dependent on payer contract

NATIONAL COVERAGE DETERMINATION (NCD 20.34)

On February 8, 2016, CMS issued the final decision memo that supports a national coverage determination (NCD) for Medicare beneficiaries undergoing Percutaneous Left Atrial Appendage (LAAC) Closure Therapy. NCD 20.34 outlines specific criteria for WATCHMAN eligibility.

The criteria focus primarily on eligible patients, formal shared decision making, operator and infrastructure requirements, and submission of certain data to a national registry for LAAC procedures. The criteria are highlighted below (bolded for emphasis) and we encourage providers to read the decision memo in its entirety for additional detail.

Eligible Patients

- Must have a $CHADS_2$ score ≥ 2
- CHA_2DS_2-VASc score ≥ 3
- Show documented evidence of a formal shared decision interaction between the patient and an independent, non-interventional physician using an evidenced-based decision making tool on oral anticoagulants.

1 CMS references the following decision-making tools: http://guidance.nice.org.uk/CG180/PatientDecisionAid/pdf/English http://www.acponline.org/patients_families/products/brochures/afib_booklet.pdf

2 The American College of Cardiology provides tools that may also be useful: http://www.acc.org/tools-and-practice-support/quality-programs/anticoagulation-initiative/anticoagulation-shared-decision-making-tool https://www.acponline.org/practice-resources/patient-education/resources

- Suitable for short-term warfarin, but deemed unable to take long-term oral anticoagulation.

NATIONAL COVERAGE DETERMINATION (NCD 20.34)

Continued

The WATCHMAN Procedure

- The WATCHMAN Procedure must be performed in a hospital with an established structural heart disease or electrophysiology program.
- The procedure must be performed by an interventional cardiologist or electrophysiologist or cardiovascular surgeon meeting the following criteria:
  1. Trained by the manufacturer
  2. ≥ 25 interventional cardiac procedures involving transseptal punctures through an intact septum
  3. Continues to perform ≥ 25 interventional cardiac procedures involving transseptal punctures through an intact septum, with at least 12 being LAAC over a two year period
- Patients must be enrolled in a prospective national registry.

CMS has certified the LAAO Registry™ (NCT02699957) as the national registry for data collection for LAAC procedures. The long-term data collection supports CMS's coverage with evidence development (CED) to ensure better visibility of safety and effectiveness of LAAC procedures. The registry certification announcement is located at: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. Hospitals performing WATCHMAN must contact the National Cardiovascular Data Registry (NCDR®) at ncdr@acc.org or 1-800-257-4737 to enroll in the LAAO Registry™.

PHYSICIAN REIMBURSEMENT

Physician Coding

Effective January 1, 2017, physicians will report the WATCHMAN implant procedure using the **CPT Code 33340**. For CY2020, the work relative value unit (RVU) for this code is 14.00 with a total RVU of 22.93. The global period for this code is 0 days

CPT Code[1]	Description
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement, left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

Based on CMS billing instructions, physician claims will need to have the following items to support the NCD for percutaneous LAAC procedures.[1] For dates of service on or after February 8th (the NCD effective date), physician claims will be processed only when billed with the following codes.

- CPT33340
- Primary ICD-10 diagnosis code (one of the following):
  - 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
- Place of service code: 21 (inpatient hospital)
- Secondary diagnosis code **Z00.6**
- Modifier Q0
- Clinical trial number (NCT02699957} in item 23 of CMS – 1500 form or electronic equivalent

1 MLN Matters® Number MM9638 for Percutaneous Left Atrial Appendage Closure (LAAC) released on May 6, 2016. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9638.pdf.

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PHYSICIAN REIMBURSEMENT

Continued

Co-surgeon Billing

CPT Code + Modifier	Description
33340-62	Left atrial appendage closure can be billed by two surgeons by appending the -62 modifier to 33340 (eg. 33340-62).

This modifier has a two specialty requirement. For example, an EP and IC can perform the procedure together and bill for their part of the implantation. Each surgeon will bill 33340-62 and be paid 62.5% of Medicare's allowable.

Thus, the total physician payment from Medicare would be at 125% of what would normally be paid if one surgeon were performing the procedure. Each operator will be required to submit a post-operative note outlining their involvement in the procedure. Period for this code is 0 days.

Echocardiography

Transesophageal echocardiography (TEE) plays a critical role in visualization and assisting with appropriate candidacy for the WATCHMAN Device. Based on our Directions for Use, the WATCHMAN procedure involves use of TEE imaging as follows:

CPT Code	Directions for Use
93312	**Baseline TEE:** Performed prior to the implant procedure to determine if the patient is a suitable candidate for the WATCHMAN Device.
93355	**Intraoperative TEE:** Performed during the WATCHMAN implant procedure and provides guided imaging to facilitate device placement.
93312	**Follow up TEE:** Performed at 45 days and 12 months after the WATCHMAN implant to ensure appropriate endothelization/ healing of the left atrial appendage (LAA). Based on physician assessment, additional follow up TEE may be recommended.

PHYSICIAN REIMBURSEMENT

Continued

The baseline and follow up TEE to support the WATCHMAN procedure may be reported with the following code as appropriate:

CPT Code	Description
93312	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report.

The **code 93355** applies to intraoperative TEE's done during WATCHMAN and other structural heart interventional procedures. **Code, 93355** includes real-time guidance, image acquisition, documentation and interpretation during transcatheter intracardiac procedures. The work value for this **code is 4.66** with total RVUs of 6.58 for CY2020.

NOTE: Code 93355 is reported once per intervention and only by an individual who is not performing the interventional procedure (i.e., WATCHMAN implant). A corrective coding initiative (CCI) edit exists with the code pairs 33340 and 93355 which indicate that these code pairs should not be reported together.

The complete descriptor for code 93355 is: 93355: Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (e.g.,TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D.

PHYSICIAN REIMBURSEMENT

Continued

Physician Coverage

CMS established a national coverage determination (NCD) for percutaneous LAAC therapy. The NCD defines specific criteria for physicians and hospitals performing LAAC therapy with an effective date of February 8, 2016. As a result, codes used to report the WATCHMAN procedure should no longer be treated as investigational and experimental technology. Medicare administrative contractors (MACs) and Medicare Advantage plans must follow the national coverage policy established by the NCD. We expect WATCHMAN implants performed prior to the NCD effective date would be adjudicated by the local contractors based on their policies in place at the time of the WATCHMAN implant.

Private and commercial payers may choose to follow the NCD guidance or establish their own policies for LAAC therapy. Therefore, it is important to understand payer policies and seek prior authorizations with private payers to establish the medical necessity for WATCHMAN in advance of performing the implant.

Resources to support this process are provided in the Payer Communications and Prior Authorization sections of this document and on the website www.bostonscientific.com.

Physician Payment[2]

The code used by physicians to report left atrial appendage closure with implant procedures is 33340. For CY2020, this code has the below values.

Code	Description	RVU	National Payment
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.	14 work RVU's 22.93 Total RVU's	$828

Commercial payment will vary and will be at discretion of the payer.

Work RVU's account for the physician's time, technical skill and effort, mental effort and judgment, and stress to provide the service

Total RVU's include work RVU's as well as practice expense RVUs (nonphysician clinical and nonclinical labor of the practice, expenses for building space, equipment, and office supplies) and malpractice RVU's (accounts for the cost of malpractice insurance premiums).

2 National Average Medicare physician payment rates calculated using the 2020 conversion factor is 36.0896.

HOSPITAL REIMBURSEMENT

Hospital Coding*

Inpatient hospital procedures will be reported using **ICD10** procedure codes **(ICD-10-PCS)**. The appropriate ICD10 procedure code for reporting the WATCHMAN implant is **02L73DK**:

ICD-10 Procedure Code[1]	Procedure Description
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach

1 MLN Matters® Number MM9638 for Percutaneous Left Atrial Appendage Closure (LAAC) released on May 6, 2016. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9638.pdf

Medicare has determined that the WATCHMAN LAAC procedure must be performed in the inpatient hospital site of service. The WATCHMAN procedure is not an approved procedure in the outpatient hospital setting. The Medicare inpatient-only list of codes is found in Addendum E.

Medicare's "Inpatient-Only" list at 42 C.F.R. § 419.22(n) defines services that support an inpatient admission and Part A payment as appropriate, regardless of the expected length of stay. Therefore, Medicare's two midnight rule does not apply to "In-patient Only" procedures. Additional information can be found by checking this link: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/ReviewingHospitalClaimsforAdmissionFINAL.pdf

Some private payers may allow the WATCHMAN procedure to be performed in the hospital outpatient setting, but coverage and payment will vary so it is important to verify and confirm with your payer.

Based on CMS billing instructions, hospital claims will need to have the following items to support the NCD for percutaneous LAAC procedures.[2] For dates of service on or after February 8th, 2016 (the NCD effective date), hospital claims will be paid only when billed with the following codes:

- ICD-10 procedure code 02L73DK
- Primary ICD-10 diagnosis code (one of the following):
  - I48.91 – Unspecified Atrial Fibrillation
  - I48.21 – Permanent Atrial Fibrillation
  - I48.0 – Paroxysmal Atrial Fibrillation

HOSPITAL REIMBURSEMENT

Continued

  - I48.11 – Longstanding Persistent Atrial Fibrillation
  - I48.19 – Other Persistent Atrial Fibrillation
- Secondary diagnosis code Z00.6
- Condition code 30 (Qualifying clinical trial)
- Value code D4: Clinical trial number (NCT02699957)

C-codes*

The WATCHMAN procedure is designated by Medicare as an inpatient only procedure. Therefore, no C-code is assigned to the WATCHMAN Device. C-codes are reported for device-intensive procedures performed in the outpatient hospital site of service.

Hospital Payment

Inpatient services are assigned to Medicare Severity Diagnosis Related Groups (MS-DRGs) for payment. Based on the inpatient ICD-10-PCS code (02L73DK) and the most typical diagnosis of atrial fibrillation, WATCHMAN procedures will likely map to MS-DRG 273 or 274. This assignment is representative of percutaneous intracardiac procedures such as WATCHMAN LAAC implants, cardiac surgical ablations, and transcatheter mitral valve replacement procedures.

MS-DRG	MS-DRG Description	FY2020 National Average Base Payment*
MS-DRG 273	Percutaneous Intracardiac Procedures with MCC	$23,240
MS-DRG 274	Percutaneous Intracardiac Procedures without MCC	$19,792

*Centers for Medicare and Medicaid Services. Medicare Program: FY2020 Hospital Inpatient Prospective Payment System, Final Rule; August 2, 2019.

HOSPITAL REIMBURSEMENT

Continued

Hospital Coverage

As of effective date February 8, 2016, CMS established coverage for the WATCHMAN LAAC procedure under the NCD for percutaneous LAAC therapy when seven conditions are met. Upon implementation of CMS's program instructions, the NCD creates uniform and consistent coverage for appropriate Medicare beneficiaries... Medicare Advantage Plans must also follow the NCD. (Please refer to the NCD coverage section on page 3.) WATCHMAN implants performed prior to the NCD effective date will be adjudicated by the local contractors based on their policies in place at the time of the procedure.

CMS is covering LAAC under coverage with evidence development (CED) which requires data collection to better monitor the long-term efficacy of this therapy on Medicare beneficiaries. As part of CED, hospitals must participate in the national registry for LAAC. CMS has certified the National Cardiovascular Data Registry (NCDR®) LAAO Registry™ (Left Atrial Appendage Occlusion) as the official registry for the LAAC NCD. Please contact NCDR about enrollment and questions on data collection by going to the NCDR website, contacting them at ncdr@acc.org or by calling 1-800-257-4737.

Private and commercial payers may choose to follow the NCD guidance or establish their own policies for LAAC therapy. Therefore, it is important to seek prior authorizations with private payers to establish the medical necessity for WATCHMAN in advance of performing the implant. Resources to support this process are provided in the Payer Communications and Prior Authorization sections of this document or click on the website: www.bostonscientific.com.

PAYER COMMUNICATIONS

FDA Approval

The WATCHMAN LAAC Device has received FDA approval so it should not be treated as an investigational device. Please go to www.bostonscientific.com to access the FDA approval letter to include in your prior authorization and appeals requests.

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 $CHADS_2$ or CHA_2DS_2- $VASc^3$ 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.

Category III CPT Code for the WATCHMAN LAAC Procedure

Effective February 8, 2016, WATCHMAN procedures should no longer be treated as investigational and experimental by MACs and Medicare Advantage Plans if patients satisfy all conditions for coverage as defined in the NCD. It is important to work with MACs and commercial payers prior to the effective date of the NCD to establish medical necessity for the procedure via the appeals or prior authorization process.

Private payer, coverage will be based on their policies for LAAC procedures. It is important that physicians and hospital providers check existing policies in advance of performing WATCHMAN implants. In addition, physician and hospital providers should always seek prior authorization for individual coverage consideration of WATCHMAN based on the patients' clinical condition. Prior authorization and peer-to-peer reviews are recommended tools for assisting with patient access in light of private payer non-coverage policies that may exist in lieu of the NCD. Please refer to the Prior-Authorization section to assist with best practices in securing approval for WATCHMAN LAAC procedures.

3 January, CT. et al. *2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation*. JACC. 2019; doi: 10.1161/CIR.0000000000000665.

PRIOR AUTHORIZATION RESOURCES

Traditional Medicare

Medicare fee-for-service does not offer prior authorizations for any services including the WATCHMAN LAAC procedure.

Medicare Advantage and Other Private Payers

Prior authorization is a process established by commercial insurance plans that allows a physician to submit a treatment plan prior to surgery. The insurer reviews the treatment plan as well as the patient's insurance benefits and medical policies to determine if the treatment is covered and the applicable patient responsibility (e.g., coinsurance and/or copay, deductibles, and out-of-pocket amounts). As prior authorization processes vary by insurer, it is important to contact insurance plans and follow their specific requirements.

Prior authorization requests typically include the following elements:

- Patient information — name, date of birth, policy number
- Details of the patient's medical history
- Description of the patient's current condition and treatment plan
- Letter of medical necessity (LOMN) documenting the patient's medical need
- Proposed procedure(s), medical device implanted and rationale for treatment
- Proposed location of service and dates planned
- Summary of the clinical evidence supporting the treatment plan including comorbidities and copies of published literature supporting the safety and effectiveness. Please see References and Resources page at the end of the Reimbursement Guide for examples of Peer Review Literature regarding WATCHMAN.
- Description of the technology and rationale for its use
- Copy of the FDA approval letter (available through your Boston Scientific Sales Representative)

Contact information on **At-A-Glance** page

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

APPEALING DENIALS

MACs, commercial and private payers have documented appeals processes for reconsidering denials. Since Medicare does not perform prior authorizations, providers would proceed with performing the procedure (based on the patient meeting the coverage indications as outlined in the NCD), submit the claim to the MAC, and then wait to receive a payment or denial. If the MAC denies the claim, Medicare has a defined appeals process with up to five levels of appeals. Additional information and an overview of this process are found by clicking here. The first level of Medicare appeal is known as "Redetermination" allows providers to appeal the denial within 120 days from the date of the initial claim denial. Medicare provides a specific form (Form CMS-20027) to standardize the information needed to request initial redeterminations. If you should receive a denial from the Medicare contractor, you have the right to appeal the claim by referencing the NCD and indicating how your patient meets the coverage criteria.

In lieu of the NCD for LAAC therapy, many private payers have decided to cover WATCHMAN, but some plans may continue with existing non-coverage policies. Therefore, we encourage providers to continue to seek prior authorizations with private payers to establish medical necessity in advance of performing the procedure. Should you receive denials, appeals information for the private payers is often found in the plan's provider manual and/or website or by contacting the insurer directly. If you need to appeal a prior authorization denial, physician providers should request a peer-to-peer review with a like specialty (i.e. Electrophysiology or Interventional Cardiology) to best communicate the WATCHMAN LAA closure procedure and patient treatment pathway.

During the peer to peer review, focus on the benefits of the WATCHMAN™ LAAC technology and the medical necessity based upon the individual patient's symptoms, diagnosis and comorbidities. Clinicians may also request a third party peer-to-peer review of the claim requesting a board-certified Electrophysiologist or cardiologist who understands the therapy.

Appeal Letters

Appeal letters typically include the following elements for both Medicare and private payers:

Provide the rationale for filing an appeal (denial of coverage, medical necessity, etc.)

- Date of denial/denial letter
- Reference the denial reason and associated denial code, if applicable

APPEALING DENIALS

Continued

- Detail the patient's diagnosis and course of treatment including adverse outcomes or lack of improvement from prior therapies.
- Describe the procedure in detail
- Describe any medical device and its benefits as they relate to the patient's condition. Emphasize the advantages of the medical device as compared to another medical device or approach
- State the rationale and benefits of the technology and how its use can be expected to produce a superior clinical outcome for the patient
- Discuss personal experiences and outcomes of surgical cases using the medical device
- Reference peer review literature to support the clinical determination regarding medical necessity. Please see References and Resources page at the end of the Reimbursement Guide for examples of Peer Review Literature regarding WATCHMAN.
- Provide a contact name and phone number as well as the willingness to answer questions or provide additional information
- Request a specific timeframe for a response

Access customizable **SAMPLE APPEALS TEMPLATES** at watchmandownloadcenter.com

CODING AND REIMBURSEMENT SUPPORT

Boston Scientific is dedicated to providing physicians, allied health professionals and hospitals with world-class programs and services to help advance the standard of patient care and appropriate access to life-enhancing technologies.

REFERENCES AND RESOURCES

Summary of Clinical Evidence

- Reddy VY, Sievert H, Halperin J, et al. Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation: A randomized clinical trial. JAMA. 2014; 312(19): 1988-1998.

- Holmes DR, Jr., Doshi SK, Kar S, et al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient- Level Meta-Analysis. J Am Coll Cardiol. 2015; 65(24):2614-2623.

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- Alli, O., S. Doshi, et al. (2013). "Quality of Life Assessment in the Randomized PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) Trial of Patients at Risk for Stroke With Nonvalvular Atrial Fibrillation." Journal of the American College of Cardiology 61(17): 1790-1798.

- Gangireddy, S. R., J. L. Halperin, et al. (2012). "Percutaneous left atrial appendage closure for stroke prevention in patients with atrial fibrillation: an assessment of net clinical benefit." European Heart Journal 33(21): 2700-2708.

- Holmes, DR, Reddy VY, Doshi, SK et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial (PROTECT AF). Lancet. 2009; 374:534-42.

- Reddy, VY, Doshi, SK, Sievert, H et al. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-year follow-up of the PROTECT AF (WATCHMAN left atrial appendage system for embolic protection in patients with atrial fibrillation) Trial. Circulation. 2013; 127: 720-729.

REFERENCES AND RESOURCES

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- Holmes DR, Kar S, Price M, Whisenant B, Sievert H, Doshi S, Huber K, Reddy V.Prospective randomized evaluation of the WATCHMAN left atrial appendage Device in patients with atrial fibrillation versus long-term warfarin therapy; the PREVAIL trial. Journal of the American College of Cardiology, Vol. 4, No. 1, 2014, 1-11.

- Reddy VY, Sievert H, Halperin J, et al. Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation: A randomized clinical trial. JAMA. 2014; 312(19): 1988-1998.

- Holmes DR, Jr., Doshi SK, Kar S, et al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient- Level Meta-Analysis. J Am Coll Cardiol. 2015; 65(24): 2614-2623.

- Reddy, V. Y., D. N. Gibson, et al. (2017). "Post-Approval U.S. Experience With Left Atrial Appendage Closure for Stroke Prevention in Atrial Fibrillation." Journal of the American College of Cardiology 69(3): 253-261.

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- Gangireddy, S. R., J. L. Halperin, et al. (2012). "Percutaneous left atrial appendage closure for stroke prevention in patients with atrial fibrillation: an assessment of net clinical benefit." European Heart Journal 33(21): 2700-2708.

Reimbursement Guide References

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The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

WATCHMAN

IMPORTANCE OF DOCUMENTATION & THE IMPACT ON MS-DRG ASSIGNMENT

This guide stresses the importance of documentation in capturing the appropriate acuity level for patients considered WATCHMAN candidates. It helps provide an overview of the common complications and comorbidities that assist with the MS-DRG assignment based on patient medical appropriateness.

For questions regarding WATCHMAN™ reimbursement, please contact:

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.

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

Additional WATCHMAN Reimbursement resources are found on www.watchmandownloadcenter.com

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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 customary 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 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 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, or resterilize.

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, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, 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.

1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

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.

THE IMPORTANCE OF MEDICAL DOCUMENTATION

Often times, physicians hear the mantra, "If it isn't documented in the medical record, then it didn't happen." This is important from a compliance and reporting perspective because appropriately capturing a patient's clinical condition impacts how hospitals are reimbursed under the Medicare severity-adjusted DRG system. Under this system, payment is influenced by the patient's age, gender and diagnosis codes. Specificity of both the principal and secondary diagnoses is imperative to reimbursement accuracy. The accurate presentation of patient risks and illness severity helps hospitals receive appropriate reimbursement for the care of these patients.

Major Complications and Comorbidities

The presence of a major complication or comorbidity (MCC) or complication or comorbidity (CC) generally is representative of a patient that requires more resources; therefore, hospitals are paid more to care for these patients. Greater specificity in documenting the patient's diagnosis allows the coder to select the diagnosis code which most accurately reflects the patient's condition resulting in assignment to the appropriate MS-DRG.

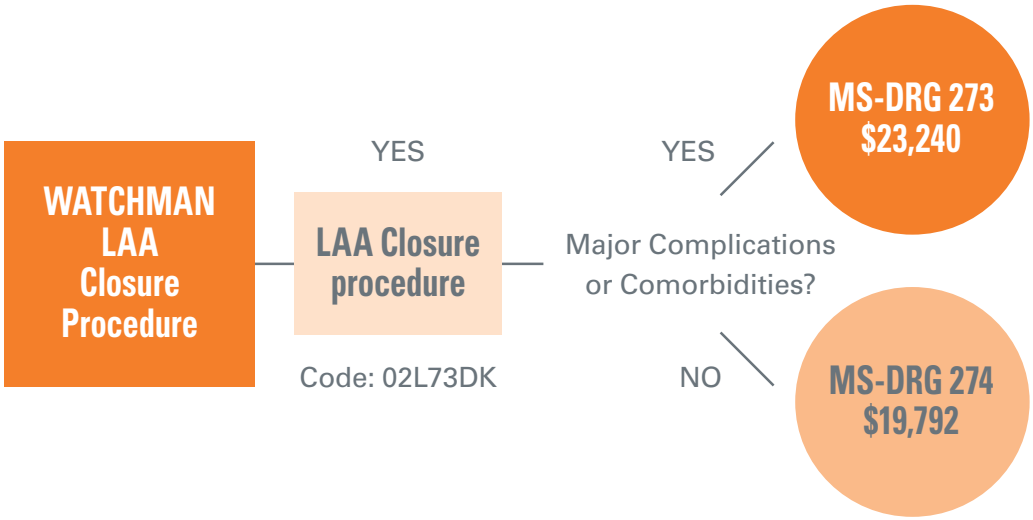
The WATCHMAN Left Atrial Appendage (LAA) closure procedures map most commonly to **MS-DRGs 273** and **274** when reported with inpatient procedure code: 02L73DK (Insertion of a left atrial appendage device, transseptal catheter technique) and the common diagnosis of atrial fibrillation. Below are the aforementioned MS-DRG descriptors:

DRGs	Description
MS-DRG 273	Percutaneous Intracardiac Procedures with MCC
MS-DRG 274	Percutaneous Intracardiac Procedures without MCC

Medicare Program: FY2020 Hospital Inpatient Prospective Payment System, Final Rule; Updated August 2, 2018. Payment based on FY2020 National Base Payment).

THE IMPORTANCE OF MEDICAL DOCUMENTATION

Continued



Example

The examples below represent different levels of acuity for a patient that presents with atrial fibrillation and undergoes the WATCHMAN LAA Closure procedure (inpatient code: 02L73DK). The examples demonstrate how the presence of a major complication or comorbidity (MCC) impacts the MS-DRG assignment.

Example #1

Codes	Description
I48.91 I48.21 I48.0 I48.11 I48.19	**Principal diagnosis:** Atrial Fibrillation
Z00.6	Encounter for examination for normal comparison and control in clinical research program
MS-DRG 274	**MS-DRG assignment:** Percutaneous Intracardiac Procedures without MCC
FY2020 National Base Payment: $19,793	

THE IMPORTANCE OF MEDICAL DOCUMENTATION

Continued

Example #2

Codes	Description
I48.91 I48.21 I48.0 I48.11 I48.19	**Principal diagnosis:** Atrial Fibrillation
Z00.6	Encounter for examination for normal comparison and control in clinical research program
I50.33	**Secondary diagnosis:** Acute on chronic diastolic heart failure. Diagnosis code I50.33 is classified as a major complication and comorbidity.
MS-DRG 273	MS-DRG assignment: Percutaneous Intracardiac Procedures with MCC
FY2020 National Base Payment: $23,240	

Medicare Program: FY2020 Hospital Inpatient Prospective Payment System, Final Rule; Updated August 2, 2018. Payment based on FY 2020 National Base Payment).

Below is an example of some of the MCC, CC, and non-CC conditions that may be relevant to your WATCHMAN™ Implant patients. This is not an all-inclusive list and providers should refer to the CMS website (Tables 6I and 6J) for a comprehensive and current year's listing of those diagnosis codes that are considered MCC's and CC's. Please note that any diagnosis code not on the MCC or CC list is considered a non CC diagnosis code and represents the lowest level of severity of illness and resource use.

THE IMPORTANCE OF MEDICAL DOCUMENTATION

Continued

Major Complications/Comorbid Conditions (Top 9 Reported)	
Codes	**Description**
N18.6	End stage renal disease
I50.33	Acute on chronic diastolic (congestive) heart failure
150.23	Acute on chronic systolic (congestive) heart failure
J96.01	Acute respiratory failure with hypoxia
J95.821	Acute post-procedural respiratory failure
J96.00	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia
I50.31	Acute diastolic (congestive) heart failure
J18.9	Pneumonia, unspecified organism
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure

Since physicians were limited by the inclusion and exclusion criteria of the WATCHMAN clinical trials (PROTECT AF, CAP, PREVAIL, CAP II), most WATCHMAN Implant patients in the trials mapped to MS-DRG 251. The current MS-DRGs for WATCHMAN are 273 and 274. Thus, it is important that physicians appropriately assess their WATCHMAN Implant eligible patients to ensure that documentation supports the appropriate level of patient acuity.

NOTE: Please note that coding is complicated and it is important that healthcare providers work with their coders to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. Complete documentation in the medical record cannot be overemphasized.

WATCHMAN
IMPORTANCE OF APPROPRIATE CHARGING GUIDE

This guide provides education to hospitals on the importance of appropriate charging practices for high cost implantable devices such as the WATCHMAN LAAC Device.

For questions regarding WATCHMAN™ reimbursement, please contact:

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.

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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

INDICATIONS FOR USE

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- Are deemed by their physicians to be suitable for warfarin; and
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- 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 customary 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 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 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, or resterilize.

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.
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- 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, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions

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

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1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

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THE IMPORTANCE OF APPROPRIATE CHARGING GUIDE

Establishing Appropriate Hospital Charges

On October 1, 2015, the ICD 10 reporting mechanism became effective for reporting hospital inpatient procedures. The ICD 10 procedure code for reporting WATCHMAN implants is 02L73DK (occlusion of left atrial appendage with intraluminal device, percutaneous approach). This procedure code maps to MS-DRGs 273 and 274 for hospital inpatient payment.

ICD-10 Code	Description
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach

Hospitals should continue to capture all charges and resources reported with the WATCHMAN implant. This is important because CMS uses hospital charges and cost report data to determine payment rates under the Inpatient prospective payment system. For example, claims data from October 1, 2014 through September 30, 2015 were used to determine payment rates for discharges that took place from October 1, 2015 through September 30, 2016. Therefore, it is important to appropriately capture all charges associated with WATCHMAN implants for CMS to set payment rates that most accurately reflect procedure costs, including the cost of the devices utilized. Since the WATCHMAN LAAC procedure is relatively new, prior claims data for insertion of left atrial appendage device (ICD-9 procedure **code 37.90**) procedures typically reflect costs in a clinical trial setting. The cost parameters and resources reflected may vary based on clinical practice so it is important that your documentation and charges accurately reflect what is occurring in your hospital. (The Medicare claims reflect data that predate the year for which rates are being set usually by two years.)

THE IMPORTANCE OF APPROPRIATE CHARGING GUIDE

Continued

How this applies to WATCHMAN LAAC Device

The WATCHMAN LAAC procedures present a critical opportunity for CMS to collect and track resources associated with the system implant. These procedures are reported with ICD10 procedure code 02L73DK for specifically tracking transcatheter closure of the LAA with an implant. CMS reviews the MS-DRG definitions annually to ensure that each group continues to include cases with clinically similar conditions that require a comparable level of inpatient resources.

ICD-10 Procedure Code[3]	Description
02L73DK	With ICD10, specifically tracking transcatheter closure of the LAA with an implant.

Generally, when the data demonstrates that subsets of clinically similar cases within a MS-DRG consume significantly different amounts of resources, CMS may reassign them to a different MS-DRG with comparable resource use or create a new MS-DRG category.

This means that if the resources (i.e., costs, length of stay, etc.) for the WATCHMAN LAAC procedure fall outside their current DRG classification and the volume is significant enough where it impacts those DRGs, then CMS may reconsider placement into another comparable DRG or create a new category altogether. CMS created new MS-DRGs 273 and 274 effective on October 1, 2015 for WATCHMAN implants because of the reasons described above. Boston Scientific will continue to monitor and analyze this data over the next two years to ensure that these MS-DRGs payment categories are appropriate in best representing the hospital resources associated with these implants. This is the reason why it is important to account for all the resources utilized in performing the WATCHMAN LAAC implants.

Contact information on **At-A-Glance** page

WATCHMAN
SAMPLE CLAIM FORMS

This section is intended to aid hospitals submitting reimbursement forms for the WATCHMAN procedure.

For questions regarding WATCHMAN™ reimbursement, please contact:

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.

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

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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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 customary 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 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 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, or resterilize.

PRECAUTIONS

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CMS 1500 Claim Example for WATCHMAN™ LAAO Device

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

10d. CLAIM CODES (Designated by NUCC)

12. PA ... ETING & SIGNING THIS FORM. ... the release of any medical or other information necessary ... either to ... SI

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services SIGNI

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. O... QUAL

16. DATES ... FROM ... CCUPATION ... D YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. 17b.

18. HOSPIT... FROM ... ERVICES ... D YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD Ind. 0

A. I480 B. Z006 C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER 02699957

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	01	01	17	01	02	17	21		33340	Q0	A,B		1		NPI	
2															NPI	
3																
4																
5																
6															NPI	

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Item 21A designates the primary diagnosis codes as required by Medicare. One of the following diagnosis codes are allowed:
I48.0-Paroxysmal atrial fibrillation
I48.1-Persistent atrial fibrillation
I48.2-Chronic atrial fibrillation I48.91-Unspecified atrial fibrillation

Item 21B designates the secondary ICD-10-CM diagnosis code Z00.6 (Encounter for examination of participant in clinical research program) to indicate the patient is participating in the LAAO registry.

Item 23 designates the National Clinical Trial (NCT) number for the Left Atrial Appendage Occlusion (LAAO) registry.

Item 24B designates place of service (POS) 21 for inpatient hospital as required by Medicare.

Item 24D designates the CPT code 33340 for the WATCHMAN™ device.

Item 24D designates the HCPCS modifier Q0 (Investigational clinical service provided in a clinical research study) to indicate the patient is participating in the LAAO registry.

Sources:

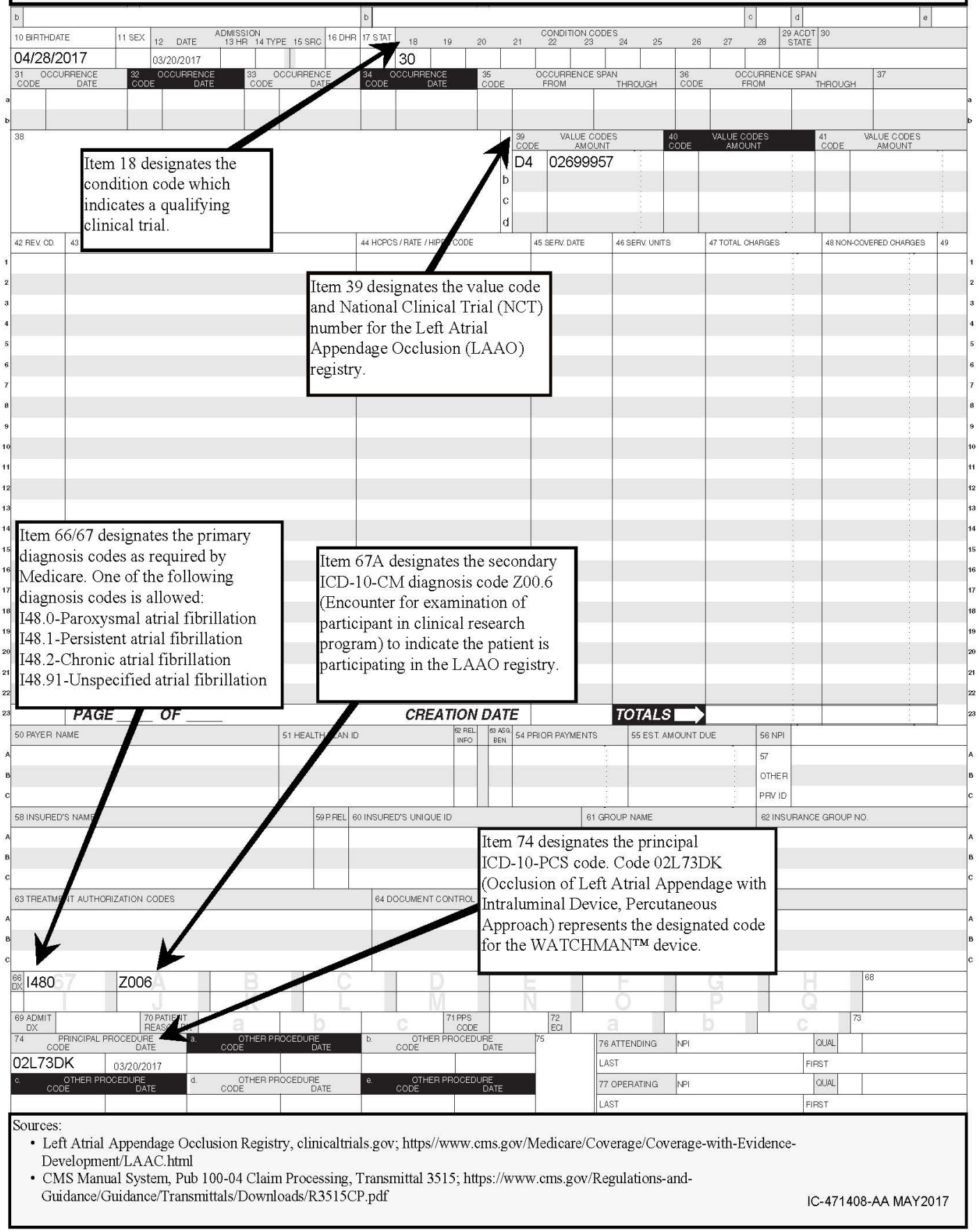
Items 21A-21B & 24B-24D) CMS Medicare Claims Processing Transmittal 3515; Medlearn Matters Number MM9638

Item 23-1) CMS Medicare Medlearn Matters Number MM9638; Claims Processing Transmittal 2955

Item 23-2) Left Atrial Appendage Occlusion Registry, clinicaltrials.gov; https//www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html

Item 24D) Official AMA CPT code description 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.

CMS Inpatient UB-04 Claim Example for WATCHMAN™ LAAO Device



Sources:

- Left Atrial Appendage Occlusion Registry, clinicaltrials.gov; https//www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html
- CMS Manual System, Pub 100-04 Claim Processing, Transmittal 3515; https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3515CP.pdf

IC-471408-AA MAY2017

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CONTRAINDICATIONS

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- 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.
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- There are contraindications to the use of warfarin, aspirin, or clopidogrel.
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WARNINGS

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WATCHMAN Private Payer Coverage (December 2019)

Total Covered Lives: 85 Million

Health Plan	Primary Service Area	Health Plan	Primary Service Area
AmeriHealth	PA, NJ, DC	CareSource	OH
Arkansas Health	AR	Centene	Nationwide
Avera	FL, SD, IA, NB	Health Net Federal Services	National
AvMed	FL	Arizona Complete Health	AZ
BCBS of AL	AL	Bridgeway Health Solutions	AZ
BCBS of AR	AR	Health Net (CA)	CA
BCBS Health Advantage	TX	California Health and Wellness	CA
BCBS of AZ	AZ	Sunshine Health	FL
BCBS of FL	FL	Peach State Health	GA
BCBS of IL	IL	Celtic (IL)	IL
BCBS of Kansas	KS	IlliniCare Health	IL
BCBS of Kansas City	KS	Managed Health Services (IN)	IN
BCBS of Louisiana	LA	Sunflower State Health	KS
BCBS of MA	MA, RI	Louisiana HealthCare Connections	LA
BCBS of MI	MI	CeltiCare Health	MA
BCBS of MS	MS	Michigan Complete Health	MI
BCBS of MT	MT	Home State Health	MO
BCBS of NC	NC	Magnolia Health	MS
BCBS of NM	NM	Nebraska Total Care	NE
BCBS Western NY	NY	New Hampshire Healthy Families	NH
BCBS of OK	OK	SilverSummit	NV
BCBS of RI	RI	Buckeye Health	OH
BCBS of TN	TN	Trillium Community Health	OR
BCBS of TX	TX	Health Net (OR)	OR
BCBS of SC	SC	Pennsylvania Health & Wellness	PA
BCBS of Wyoming	WY	Absolute Total Care	SC
BCBS of Federal Employee Program	Nationwide	Superior HealthPlan	TX
BCBS of Wyoming	WY	Coordinated Care	WA
Blue Cross ID	ID	Managed Health Services (WI)	WI
Blue Shield CA	CA	Coordinated Care Health Plan	WA
Capital Health Plan	FL	Dean Health Plan	WI
Capital Bluecross	PA	Emblem Health	NY, CT, NJ, FI, PA, NC, MA, SC, GA, CA
CareFirst BCBS	DC, MD, VA	Excellus	NY, CT

PAYER LIST

Continued

WATCHMAN Private Payer Coverage (December 2019) continued			
Health Plan	Primary Service Area	Health Plan	Primary Service Area
Fallon	MA, NY, CT, FL, PA, SC	Optima (Sentara)	VA, OH, NC, WV, FI, MD, PA, SC, GA, CA
Group Health	WA	Optum Health	MN
Harvard Pilgrim	MA, NH, ME, CT, RI, NY, VT, FL, CA, TX, NJ, PA, GA, AZ, OH, NC, VA, IL, WA, UT, SC, IN, MD, MI, CO	Paramount Healthcare	OH, MI
Hawaii Medical Services Association (HMSA)	HI	Premera Blue Cross	WA, AK, OR
Health Alliance of MI	MI	Prevera 360	WI
HealthNow (BCBSWNY, BCBSNENY)	NY	Priority Health	MI
Health New England	MA, CT	Regence Health Plan	IA, OH, UT, WA
Highmark BCBS	DE, PA, WV	Scott & White Health Plan	TX
Horizon BCBS	NJ	Select Health	SC
Humana	Nationwide	Summa Health	OH, MD
Independence Blue Cross	PA	TriCare	Nationwide
Kaiser Permanente	Nationwide	Tufts Health Plan	MA, RI, NY
LifeWise	OR, WA	UPMC	PA
Medical Mutual of Ohio	OH	Univera	NY
Nebraska Blue	NE		

NOTE: Covered lives for Commercial and Federal plans is based on estimates available from Policy Reporter, and excludes those covered by Medicare Advantage plans and/or Medicaid.

PAYER LIST

Continued

WATCHMAN Medicare and Medicare Advantage Coverage (December 2019)	
Total Covered Lives: 60 Million	
Health Plan	Primary Service Area
Medicare & Medicare Advantage	The CMS National Coverage Determination guarantees access for Medicare and Medicare Advantage patients.

NOTE: To access the NCD in it's entirety, please visit the final decision memo at https://www.cms.gov and search "Decision memo for percutaneous Left Atrial Appendage Closure."

WATCHMAN Medicaid Payer Coverage (December 2019)	
Total Covered Lives: 38.2 Million	
Health Plan	Primary Service Area
Medicaid	AL, AZ, CA, CT, HI, IN, MN, NJ, NY, PA, UT, VA, WI

NOTE: Covered lives for Medicaid payer plan is based on estimates available from Decision Resource Group.

WATCHMAN
SUPPORTING PATIENT ACCESS

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.

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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 customary 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 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 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, or resterilize.

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, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, 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.

1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

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.

SUPPORTING PATIENT ACCESS

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.

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 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 safe-guard patient information, and is available for review online.

SUPPORTING PATIENT ACCESS

Continued

- 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

SUPPORTING PATIENT ACCESS

Continued

- 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

Contact information on **At-A-Glance** page

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

STEP 4 ENGAGE IN PEER-TO-PEER REVIEW

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

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..

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.

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

Contact information on **At-A-Glance** page

REFERENCES AND RESOURCES

1 CPT ©2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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

WATCHMAN

SUPPORTING FORMS AND EXAMPLE LETTERS INDEX

- Provider Intake Form
- Prior Authorization and Appeals Request Form
- Sample Letter of Medical Necessity (Prior Authorization)
- Sample Appeal Letter
- Approval/Coverage Status & Clinical Evidence Summary

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

REIMBURSEMENT GUIDE

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 customary 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 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 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, or resterilize.

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, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, 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.

1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14.

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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.

GUIDEPOINT Reimbursement Resources

Boston Scientific
Advancing science for life™

WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device Provider Intake Form

I Acknowledge, that I have received a copy of the Privacy Letter along with a copy of the Business Associate Agreement.

Authorized Representative Signature	**Printed Name**	**Date**

Please complete & return via toll free fax at 877-835-2520 or email: PreAuthSupport@bsci.com

Physician Information

Physician:		Practice Name:		
Address:				
City:	State:	Zip:	Phone:	Fax:
Contact(s):			Email:	
TIN:	**Billing NPI:**		**Doctor NPI:**	
BCBS:	**Medicaid:**		**UPIN:**	**Other:**

Please Provide Facility Information below. Medicare restricts WATCHMAN implants to the inpatient hospital site of service.

Facility Information

Facility:				
Address:				
City:	State:	Zip:	Phone:	Fax:
Contact(s):			Email:	
TIN:	Billing NPI:		BCBS:	Other:

Comments

Boston Scientific Internal Use Only - WATCHMAN Sales Representative Information:

Sales Rep Name:	Phone:	CS Name:	Phone:	Territory:

☐ **IMPORTANT:** If you would like an On-Board Call, where your Pre-authorization Support Specialist will give you an overview of BSC's pre-authorization or appeals process, please check the box and a BSC Pre-authorization Support Specialist will contact you. Thank you!

Mann Biomedical Park 25155 Rye Canyon Loop, Valencia, CA 91355

GUIDEPOINT
Reimbursement Resources

Boston Scientific
Advancing science for life™

TO:

DATE:

RE: HIPAA Business Associate Agreement and Protecting Patient Privacy

Dear Valued Boston Scientific Provider:

Boston Scientifics' Prior authorization and appeals support team takes the protection of patient privacy seriously. We understand and are responsive to our obligations under the Health Insurance Portability and Accountability Act (HIPAA) and its amendments under the Health Information Technology for Economic and Clinical Health Act (HITECH Act) in connection with insurance pre-authorization support assistance offered to facilitate patient access to Boston Scientific's WATCHMAN™ Left Atrial Appendage Closure Device (i.e., benefits verification, pre-authorization, and/or predetermination and appeals assistance).

The business associate agreement that describes our privacy practices and your obligations as a provider can be found on the following pages of this document.

By providing us PHI for the pre-surgical authorization and/or appeals process, you give Boston Scientific's Prior Authorization and Appeals Team consent to act on your behalf for the purposes of obtaining, submitting, and receiving all patient information as it relates to the prior authorization and appeals process for the WATCHMAN implant procedure. This consent will remain active until you revoke it.

We look forward to working with you and your patients in our continued partnership to provide you exceptional levels of customer service while improving the quality of patient care. If you have any questions, please feel free to call us at 1-866-287-0778.

Sincerely,

Richard Reynolds

Chief Privacy Officer
Boston Scientific Corporation

BOSTON SCIENTIFIC CORPORATION
BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT ("**BA Agreement**") is entered into by and between Boston Scientific Corporation ("**Boston Scientific**"), with offices at 300 Boston Scientific Way, Marlborough, MA 01752 and the entity or individual (**"Provider"**) to whom Boston Scientific makes available reimbursement assistance to assist patient access to its medical technologies by facilitating the preparation and submission of requests for coverage determinations and prior authorizations, as allowed under the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("Reimbursement Assistance"). These services require the exchange of information about patients that is protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as applicable to Business Associates, as well as any amendments or additions thereto, including amendments made by the HITECH Act and GINA (defined below). The Provider is a "Covered Entity" as that term is defined in HIPAA, and the parties desire to establish the responsibilities of both parties regarding HIPAA-covered information and to meet their obligations under HIPAA.

1. Definitions. Unless otherwise specified in this BA Agreement, all capitalized terms used in this BA Agreement not otherwise defined have the meaning set forth in HIPAA, as amended from time to time.

1.1 "**Breach Notification Rule**" means the breach notification regulations at 45 CFR Part 160 and 45 CFR Part 164, Subpart D, as they exist now or as they may be amended.

1.2. "Compliance Date" or **"Compliance Dates"** shall mean the date established by HHS or the United States Congress for effective date of applicability and enforceability of HIPAA and the HITECH Act

1.3 "**Data Aggregation**" shall have the meaning assigned to such a term in 45 CFR § 164.501, and includes, but is not limited to, combining Phi created or received to permit data analysis services for Provider as specified in a written agreement and consistent with this BAA.

1.4. "Designated Record Set" shall have the meaning assigned to such term in 45 CFR § 164.501, but shall be limited to any item, collection or grouping of PHI maintained, created, or received by or for Provider.

1.5. "Destruction" means the use of a technology or methodology by which the media on which the PHI is stored or recorded has been shredded, destroyed, cleared, or purged, as appropriate, such that the PHI cannot be read, retrieved, or otherwise reconstructed. Redaction is inadequate for the purposes of destruction.

1.6. "**Electronic PHI**" or "**EPHI**" shall mean Electronic Protected Health Information, as defined in 45 CFR § 160.103, limited to the information received from or created or received on behalf of Provider by Boston Scientific solely for the purposes of Boston Scientific's provision of Reimbursement Assistance in its capacity as a Business Associate.

1.7. "Encryption" shall mean a technology or methodology that utilizes an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key, and such confidential process or key that might enable decryption has not been breached, and shall have the meaning given to such term under HIPAA, including 45 CFR § 164.304.

1.8. "HIPAA" shall mean Health Insurance Portability and Accountability Act, as modified and amended, and its implementing regulations, and incorporating any amendments thereto made by the HITECH Act, GINA, and any other applicable laws or regulations.

1.9. "HITECH Act" shall mean the Health Information Technology for Economic and Clinical Health Act, found in Title XIII of the American Recovery and Reinvestment Act of 2009, enacted February 17, 2009, and any implementing regulations or guidance thereunder.

1.10. **"Individual"** shall have the same meaning as the term "individual" in 45 CFR § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

1.11. "**Protected Health Information**" or "**PHI**" shall have the meaning set forth in 45 CFR § 164.103, limited, however, to the information that Boston Scientific creates, accesses, or receives on behalf of Provider for purposes of Boston Scientific's provision of Reimbursement Assistance.

1.12. "**Privacy Rule**" shall mean the privacy regulations at 45 CFR Part 160 and 45 CFR Part 164, Subparts A and E, as they exist now or as they may be amended.

1.13. **"Secretary"** shall mean the Secretary of the Department of Health and Human Services or his designee.

1.14. "**Security Rule**" shall mean the security regulations at 45 CFR Part 160 and 45 CFR Part 164, Subparts A and C, as they exist now or as they may be amended.

1.15. **"Unsecured PHI"** shall have the meaning assigned to such term in 45 CFR § 164.402, limited, however, to the information that Boston Scientific creates, accesses, or receives on behalf of Provider.

2. Use and Disclosure Obligations

2.1. **Use or Disclosure.** Boston Scientific agrees to use and/or disclose PHI only as permitted or required by this BA Agreement or as Required by Law applicable to Boston Scientific;

2.2. **Minimum Necessary.** Boston Scientific will take reasonable efforts to limit requests for, use and disclosure of PHI to the minimum necessary to accomplish the intended request, use or disclosure.

2.3. **Safeguards.** Boston Scientific agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as permitted or required by this BA Agreement and will comply with the Security Rule with respect to Electronic PHI that Boston Scientific creates, receives, maintains, or transmits on behalf of Provider.

2.4. **Reporting.** Boston Scientific agrees to promptly notify Provider if Boston Scientific has knowledge that PHI has been used or disclosed by Boston Scientific in a manner that violates this BA Agreement.

2.4.1. To the extent that Boston Scientific creates, receives, maintains, or transmits Electronic PHI, Boston Scientific agrees to report promptly to Provider any Security Incident of which Boston Scientific becomes aware as determined by Boston Scientific involving PHI in accordance with the Breach Notification Rule. Boston Scientific shall, following the discovery of a Breach of Unsecured PHI, notify Provider of such Breach without unreasonable delay and in no event later than sixty (60) calendar days after the discovery, including the identification of each Individual whose Unsecured PHI has been, or is reasonably believed to have been, accessed, acquired or disclosed during the Breach. A Breach shall be treated as discovered as of the first day on which such Breach is known or reasonably should have been known by Boston Scientific.

2.4.2. Without in any way intending to limit the generality of the obligation in the foregoing paragraph, the parties to this agreement acknowledge and agree that this section constitutes notice by Business Associate to Covered Entity of the ongoing existence and occurrence of attempted but Unsuccessful Security Incidents for which no additional notice to Covered Entity

shall be required. Unsuccessful Security Incidents shall include, but not be limited to, pings and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denials of service and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of Covered Entity's electronic PHI.

2.5. **Subcontractors and Agents.** Boston Scientific agrees to require all its subcontractors and agents that create, receive, maintain, transmit, use, disclose, or have access to PHI to perform Reimbursement Assistance for Provider to agree, in writing, to the same restrictions and conditions on the use and/or disclosure of PHI that apply to Boston Scientific, including that all of its subcontractors and agents to whom Boston Scientific provides Electronic PHI agree to comply with the applicable standards of the Security Rule and implement reasonable and appropriate safeguards to protect such Electronic PHI. If Boston Scientific becomes aware of a pattern of activity or practice of a subcontractor that constitutes a material violation of the subcontractor's obligations under the written agreement described above, Boston Scientific agrees to take reasonable steps to cure or end the violation, and if such steps are unsuccessful, to terminate the agreement if feasible.

2.6. **Accountability.** Boston Scientific agrees to make internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Boston Scientific on behalf of the Provider available to the Secretary upon request in a time and manner directed by the Secretary for purposes of the Secretary determining the Provider's compliance with HIPAA.

2.7. **Access and Correction.** To the extent Boston Scientific maintains the requested PHI as part of a Designated Record Set, access shall be provided to Provider to PHI in a Designated Record Set in order to meet the requirements under 45 CFR § 164.524 within fifteen (15) business days of a request. All requests directly from an Individual shall be directed by Boston Scientific to the Provider. If Provider requests that access be provided to an Individual, Boston Scientific shall provide access to the Individual to PHI in a Designated Record Set within thirty (30) days in order to meet the requirements under 45 CFR § 164.524. Within sixty (60) days of a request by the Provider or subject Individual, to the extent Boston Scientific maintains the requested PHI as part of a Designated Record Set, Boston Scientific agrees to make any appropriate amendment(s) or correction(s) to PHI in a Designated Record Set that Provider directs or agrees to pursuant to 45 CFR § 164.526.

2.8. **Accounting.** To the extent Boston Scientific maintains the requested PHI as part of a Designated Record Set, Boston Scientific agrees to document and make available to Provider, for a reasonable cost-based fee (under conditions permitted by HIPAA if an Individual requests an accounting more than once during a twelve month period), such disclosures of PHI and information related to such disclosures necessary to respond to such request for an accounting of disclosures of PHI, in accordance with 45 CFR § 164.528 within thirty (30) days of a proper request by the Provider. Within sixty (60) days of proper request by subject Individual, to the extent Boston Scientific maintains the requested PHI as part of a Designated Record Set, Boston Scientific agrees to make available to the Individual the information described above. Boston Scientific shall retain copies of any accountings for a period of six (6) years from the date the accounting was created.

2.9. **Mitigation.** Boston Scientific agrees to mitigate, to the extent practicable, any harmful effect that is known to Boston Scientific of a use or disclosure of PHI by Boston Scientific in violation of this BA Agreement.

2.10. **Restrictions on Use or Disclosure.** Within fifteen (15) business days of a request of the Provider, Boston Scientific agrees to implement restrictions on the use or disclosure of PHI agreed to by the Provider at the request of an Individual in accordance with 45 CFR § 164.522.

2.11. **Remuneration in Exchange for PHI**. Except as permitted under 45 CFR § 164.502(a)(5)(ii), Boston Scientific agrees that it shall not directly or indirectly receive remuneration in exchange for PHI from or on behalf of the recipient of such PHI.

3. **Permitted Uses and Disclosures of PHI.** Unless otherwise limited herein, in addition to any other uses and/or disclosures permitted or required by this BA Agreement or required by law, Boston Scientific may:

3.1. make any and all uses and disclosures of PHI necessary to provide Reimbursement Assistance to Provider;

3.2. use the PHI in its possession for its proper management and administration and to fulfill any legal responsibilities of Boston Scientific;

3.3. disclose the PHI in its possession to a third party for the purpose of Boston Scientific's proper management and administration or to fulfill any legal responsibilities of Boston Scientific; provided, however, that the disclosures are Required by Law or Boston Scientific has received from the third party written assurances that (i) the information will be held confidentially and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the third party; and (ii) the third party will notify Boston Scientific of any instances of which it becomes aware in which the confidentiality of the information has been breached;

3.4. perform Data Aggregation for the Health Care Operations of Provider;

3.5. de-identify any and all PHI created or received by Boston Scientific under this BA Agreement; provided, however, that the de-identification conforms to the requirements of the Privacy Rule. Such resulting de-identified information would not be subject to the terms of this BA Agreement; and

3.6. may use the PHI to create Limited Data Sets consistent with the requirements of 45 CFR § 164.514(e)(2) of the Privacy Rule ("**LDS**"). Boston Scientific may use or disclose the LDS only for the limited purposes of Research, Public Health, or Health Care Operations, and the LDS will include only the minimum data fields necessary to accomplish these limited purposes. Boston Scientific will comply with this BA Agreement with respect to the use and disclosure of the LDS.

4. **Responsibilities of Provider.** Provider agrees:

4.1. to obtain any consent, authorization or permission that may be required by the Privacy Rule or any other applicable federal, state or local laws and/or regulations prior to furnishing PHI to Boston Scientific and will notify Boston Scientific of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Boston Scientific's use or disclosure of PHI.

4.2. to inform Boston Scientific of any PHI that is subject to any arrangements permitted or required of Provider under the Privacy Rule that may materially impact in any manner the use and/or disclosure of PHI by Boston Scientific under this BA Agreement, including, but not limited to, restrictions on the use and/or disclosure of PHI as provided for in 45 CFR § 164.522 and agreed to by Provider;

4.3. to notify Boston Scientific of any limitation(s) in the notice of privacy practices of the Provider in accordance with 45 CFR. § 164.520, to the extent that such limitation may affect Boston Scientific's use or disclosure of PHI.

4.4. to not request that Boston Scientific use or disclose PHI in any manner that would exceed that which is minimally necessary under HIPAA or that would not be permitted by a Covered Entity;

4.5. to have entered into "Business Associate Agreements" with any third parties (e.g., case managers, brokers or third party administrators) to which Provider directs and authorizes Boston Scientific to disclose PHI; and

4.6. prior to using the name or any trademark or tradename of Boston Scientific in any written or oral communication to the public, including any notices provided under HIPAA, to first give Boston Scientific the opportunity to review and comment on the proposed communication.

5. Term and Termination. This BA Agreement will be effective as of the Effective Date and will continue in effect until terminated in accordance with the provisions herein.

5.1. Termination by Provider. Upon Provider's determination of a breach of a material term of this BA Agreement by Boston Scientific, Provider will provide Boston Scientific written notice of that breach in sufficient detail to enable Boston Scientific to understand the specific nature of that breach and afford Boston Scientific an opportunity to cure the breach; provided, however, that if Boston Scientific fails to cure the breach within a reasonable time specified by Provider, which shall not be less than thirty (30) days, Provider may terminate this BA Agreement and the Reimbursement Assistance to the extent that the Reimbursement Assistance requires Boston Scientific to create or receive PHI. If Provider terminates this BA Agreement, Boston Scientific will have no continuing obligation to provide any Reimbursement Assistance to the Provider.

5.2. Termination by Boston Scientific. Without limiting any other termination rights of the parties, upon Boston Scientific's knowledge of a material breach by the Provider of this BA Agreement, Boston Scientific shall notify Provider of such breach and the Provider shall have thirty (30) days to cure such breach. In the event the Provider does not cure the breach, or cure is infeasible, Boston Scientific shall have the right to immediately terminate this BA Agreement and the underlying Reimbursement Assistance.

5.3. Return of PHI. Except as provided in the section below, upon termination of this BA Agreement for any reason, Boston Scientific will return or destroy all PHI received from Provider, or created or received by Boston Scientific on behalf of Provider. This provision will apply to PHI that is in the possession of subcontractors or agents of Boston Scientific.

5.4. Protection of PHI. In the event that Boston Scientific determines that returning or destroying the PHI is infeasible, Boston Scientific will notify Provider of the conditions that make return or destruction infeasible. In that event: (i) Boston Scientific will extend the protections of this BA Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Boston Scientific maintains such PHI; and (ii) Provider will comply with its obligations under this BA Agreement with respect to any PHI retained by Boston Scientific after the termination or expiration of this BA Agreement. This section will survive any termination or expiration of this BA Agreement.

6. Indemnification. Each party (the **"Indemnifying Party"**) shall indemnify and hold the other party and its officers, directors, employees and agents (each an **"Indemnified Party"**) harmless from and against any claim, cause of action, liability, damage, cost or expense (**"Liabilities"**) to which the Indemnified

Party becomes subject to as a result of third party claims (including reasonable attorneys' fees and court or proceeding costs) brought against the Indemnified Party, which arise as a result of: (i) the material breach of this BA Agreement by the Indemnifying Party; or (ii) the gross negligence or willful misconduct of the Indemnifying Party, except to the extent such Liabilities were caused by the Indemnified Party. A party entitled to indemnification under this Section 6 shall give prompt written notification to the Indemnifying Party of the commencement of any action, suit or proceeding relating to a third party claim for which indemnification is sought, subject to applicable confidentiality constraints. The Indemnifying Party shall be entitled to assume control of the defense of such action, suit, proceeding or claim with competent counsel of its choosing. Indemnification shall not be required if any claim is settled without the Indemnifying Party's consent, which such consent shall not be unreasonably withheld. NOTWITHSTANDING THE FOREGOING PROVISIONS OF THIS SECTION, IN NO EVENT WILL AN INDEMNIFYING PARTY BE LIABLE TO AN INDEMNIFIED PARTY UNDER CONTRACT, TORT, OR ANY OTHER LEGAL THEORY FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, PUNITIVE, OR SPECIAL LOSSES OR DAMAGES OF ANY KIND.

7. Miscellaneous.

7.1. Amendment. The parties acknowledge that the foregoing provisions are designed to comply with the mandates of HIPAA. Boston Scientific may amend this BA Agreement from time to time to the extent that any changes or amendments to HIPAA require changes to this BA Agreement by providing electronic notice of the amended BA Agreement and by posting an updated version of the BA Agreement on the Boston Scientific website. The BA Agreement shall be automatically amended to incorporate the changes set forth in such amendment provided by Boston Scientific to Provider, unless Provider objects to such amendment in writing within fifteen (15) days of receipt of such written notice. In the event that Provider objects timely to such amendment, the parties shall work in good faith to reach agreement on an amendment to the BA Agreement that complies with the changes to the HIPAA regulations. If the parties are unable to reach agreement regarding an amendment to the BA Agreement within thirty (30) days of the date that Boston Scientific receives any written objection from the Provider, either Boston Scientific or Provider may terminate this BA Agreement upon ninety (90) days written notice to the other party. Any other amendment to this BA Agreement unrelated to compliance with applicable law and regulations shall be effective only upon execution of a written agreement between the parties.

7.2. No Third-Party Beneficiaries. Nothing express or implied in this BA Agreement or any associated agreement between the parties is intended to confer, nor shall anything herein confer, upon any person other than the parties and the respective successors or assigns of the parties, any rights, remedies, obligations or liabilities whatsoever.

7.3. Severability. If any provision of this BA Agreement is found invalid or unenforceable by a court of competent jurisdiction, the remaining portions will remain in full force and effect.

7.4. Waiver. No failure or delay by either party in exercising any right hereunder will operate as a waiver thereof.

7.5. Assignment. If a party wishes to assign or otherwise transfer this BA Agreement, or any of its rights or obligations hereunder, to anyone, such party must obtain the other's prior written consent, which will not be unreasonably withheld provided that it will be reasonable to withhold consent if the assignee is a competitor of the non-assigning party. Boston Scientific may assign this BA Agreement, or any of its rights or obligations hereunder, to any of its affiliates without any notice to or consent of Provider. Any attempted assignment or transfer not expressly

permitted by the foregoing will be void. This BA Agreement will be binding on the parties, their successors and permitted assigns.

7.6. **Interpretation.** Any ambiguity in this BA Agreement shall be resolved in favor of a meaning that permits the Provider and Boston Scientific to comply with HIPAA and be construed in light of any applicable interpretation or guidance on HIPAA, the Privacy Rule, the Security Rule, and/or the Breach Notification Rule issued by HHS or the Office for Civil Rights.

7.7. **Contradictory Terms.** The parties agree that any provision of any other agreement between the parties, including any other business associate agreement, regardless of when executed, which concerns the parties' exchange of PHI and which contradicts one or more terms of this BA Agreement, or which would have the effect of diminishing a right, increasing a duty, or shortening a deadline applicable to Boston Scientific under this BA Agreement (collectively, a **"Contradictory Term"**), shall be superseded by the terms of this BA Agreement unless Boston Scientific expressly waives such superseding effect in a separately written agreement referencing this section.

7.8. **Notices.** All notices pursuant to this BA Agreement must be given in accordance with the following. If to Boston Scientific, by postal mail to 25155 Rye Canyon Loop, Valencia, CA 91355, Attn: Reimbursement Assistance or by facsimile to 1-877-835-2520. If to Provider, by address or facsimile on record with Boston Scientific's Reimbursement Assistance.

7.9. **Effective Date.** This BA Agreement shall be effective as of the provision of Reimbursement Assistance by Boston Scientific to Provider; provided, however, that any term or condition that relates to obligations of either party only will be effective on the later of the effective date of this BA Agreement or the compliance date applicable to such obligations under HIPAA.

7.10. **Acceptance by Provider.** Execution of this BA Agreement by Provider is not required. Provider shall be deemed to have accepted this BA Agreement in all respects by providing PHI to Boston Scientific for performance of Reimbursement Assistance by Boston Scientific as a Business Associate after the Effective Date.

CONFIDENTIAL Fax completed form and supporting clinical documentation to **1-877-835-2520** ***CONFIDENTIAL***

WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device

Section 1	Patient, Physician, and Hospital information		
Patient's Full Name:		Patient's DOB:	
Physician Name:	Name of Surgery Site:		Surgery Date:
State:	NPI#		TIN#
Site of Surgery:	☐ Inpatient Hospital * ☐ Outpatient Hospital	*Medicare restricts code 33340 to inpatient hospital site of service.	
Procedure Type:	☐ WATCHMAN Device Implant (Percutaneous transcatheter left atrial appendage closure procedure with implanted device)		

Section 2 **Diagnosis Code(s):** List all diagnosis codes that support medical necessity for the Watchman Implant

Primary Diagnosis Code: Please complete for primary and/or secondary diagnosis codes and provide other diagnosis codes that might be applicable for documenting patient level of acuity.

Primary diagnosis code: _____

Secondary diagnosis code:_____ Additional diagnosis code/s: _____

Physician's Order: Please indicate services requested for the WATCHMAN Implant

Section 3	CPT/HCPCS codes
CPT Code*	Description
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

Section 4	ICD10 CM Procedure Code
ICD-10 CM Procedure code	ICD-10 Descriptor
02L73DK ☐	Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach

Section 5 **Physician Certification Section**

By signing below, I certify that (**1**) I am the physician identified in the first section of this document, (**2**) I have completed this document in its entirety (or reviewed it carefully after it was completed by an employee under my direction), (**3**) all the information provided by me or my staff, including the patient diagnosis, codes selected and medical documentation supporting the WATCHMAN procedure is true, accurate, and complete to the best of my knowledge. 4) I have included documentation to support medical necessity for LAA closure

Physician Signature_____

Required: Please fax patient clinical documentation (e.g., treatment history, physician notes) and insurance information along with the prior authorization form.

The WATCHMAN LAAC system 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 an increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-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.

1) https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013b.pdf
2) 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.

WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE
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™ 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 voicemail: (877) 786-1050 and press 2 to leave a message. Messages are monitored daily, with responses typically on the same or following business day. Pone (toll free): (877) 786-1050 and press 1 to connect with WATCHMAN Prior Authorization or Appeals support.

[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™ Left Atrial Appendage Closure (LAAC) implant procedure.

The WATCHMAN 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 $CHADS_2$ or CHA_2DS_2-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 request, I am providing the following:

- Patient history & physical and operative reports, supporting medical necessity of the LAAC implant procedure
- FDA approval status and CMS National Coverage Determination for this service
- Summary of clinical evidence, with associated references

Current Coverage Status:

My patient meets the coverage criteria for the WATCHMAN LAAC 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 LAAC 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.

Based upon the medical necessity for my patient, I am requesting that approval be granted for the WATCHMAN LAAC 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]

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.

WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE
Sample Appeal Letter

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 appeal 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™ Device for the individual patient.

2. It is important to provide the most complete information to assist with the appeals 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 voicemail: (877) 786-1050 and press 2 to leave a message. Messages are monitored daily, with responses typically on the same or following business day. Pone (toll free): (877) 786-1050 and press 1 to connect with WATCHMAN Prior Authorization or Appeals support.

[Date]

Attention: Appeals Department
Reference number: [ ]
[Insurance Company name]
[Insurance Company address]
[Fax:]

RE: Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim #: _____
Date of Denial: _____

RE: Request for Coverage Reconsideration for the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Implant

To Whom It May Concern:

On behalf of my patient, I am appealing a denial for the surgery, hospital stay, and post-surgical care associated with the WATCHMAN™ Left Atrial Appendage Closure (LAAC) implant procedure. This letter documents the medical necessity for this therapy and provides information about the patient's medical history and treatment, as well as a description of the procedure.

Principal Diagnosis

- [list ICD10 diagnosis code and diagnosis code descriptor]

Procedure/Service (see attached physician report &/or hospital report)

- [if physician report] **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.]
- [if hospital report] **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
- FDA approval status and CMS National Coverage Determination for this service
- Summary of clinical evidence, with associated references

Current Coverage Status:

My patient meets the coverage criteria for the WATCHMAN LAAC 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 LAAC 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

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

- Please fax 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's name]
[Practice name]

WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE
Approval/Coverage Status & Clinical Evidence Summary

FDA Approved on March 13, 2015

The WATCHMAN Left Atrial Appendage Closure (LAAC) implant procedure received FDA approval on March 13, 2015 and has been established as safe and effective for treating patients within its approved indication. The 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 $CHADS_2$ or CHA_2DS_2-VASc [January CT, et al 2019] 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 established February 8, 2016

CMS finalized a National Coverage Determination for percutaneous LAAC (20.34) on February 8, 2016. The NCD establishes uniform coverage and access to the WATCHMAN Device for Medicare beneficiaries who meet specific patient criteria, including:

- A $CHADS_2$ score ≥ 2 or CHA_2DS_2-VASc score ≥ 3
- A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation
- Documented evidence of a formal shared decision-making interaction between the patient and an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation.

To access the NCD for percutaneous LAAC therapy in its entirety, visit the CMS website at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281

2019 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation

The 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation recommends Percutaneous LAAO therapy as a **Class IIb therapy and LOE B-NR.**

The guidelines state that Percutaneous LAAO may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation. The updated guidelines specifically note that the Watchman device provides an alternative for patients who are poor candidates for long-term oral anticoagulation (because of the propensity for bleeding or poor drug tolerance or adherence). The guidelines are consistent with and reinforce WATCHMAN's labeling and the CMS coverage decision which support the use of WATCHMAN as an option for AF patients at an increased risk of stroke who have relative contraindications to long-term anticoagulation.

Clinical Condition and Treatment Options

Atrial fibrillation (AF) is the most common cardiac arrhythmia, currently affecting more than 5 million Americans [Go AS, et al 2013.] In AF, the left atrium does not beat - instead it fibrillates meaning that it barely moves. Because of this, AF patients have a five-fold increased risk of stroke due to blood pooling in the left atrium and left atrial appendage (LAA). The pooled blood can form blood clots (i.e., thrombus formation), which can break off and go into the systemic circulation and lodge somewhere else in the body. Most commonly, these clots will lodge in the brain causing a stroke. Ninety-one percent of left atrial thrombi in non-valvular atrial fibrillation have been shown

to be isolated to, or originate in, the LAA [Blackshear JL, et al 1996.] The most common treatment for reducing the risk of these strokes from forming is using oral anticoagulants. Warfarin has been used for many years and works by interfering with the body's clot forming mechanisms. Despite its proven efficacy, long-term warfarin therapy is not well-tolerated by some patients, has a very narrow therapeutic range, and carries a high risk for bleeding complications.

WATCHMAN Left Atrial Appendage Closure

The WATCHMAN Left Atrial Appendage Closure Device is a first-of-its-kind, proven alternative to long-term warfarin for stroke risk reduction in patients with non-valvular atrial fibrillation. WATCHMAN is the most studied LAAC device in the world and is the only one with long-term data from randomized trials and prospective, multi-center registries.

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 $CHADS_2$ or CHA_2DS_2-VASc [January CT, et al 2014] 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 Left Atrial Appendage is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for warfarin therapy in those patients with non-valvular AF who are eligible for warfarin. Implant of the WATCHMAN Device is performed under general anesthesia in a cardiac catheterization laboratory. The WATCHMAN Device is implanted percutaneously via a transcatheter approach, using a standard transseptal technique.

Clinical Evidence

The WATCHMAN clinical program consists of eight prospective investigational studies (PILOT, PROTECT AF, CAP, PREVAIL, and CAP2, EWOLUTION, and WASP) which include more than 3,300 patients implanted and >10,000 patient-years of follow-up regarding WATCHMAN™ Device performance. Final, five-year results from the PROTECT AF, CAP and PREVAIL studies have been published and/or presented. These long-term data continue to demonstrate the WATCHMAN Device is a safe alternative to long-term warfarin therapy which offers comparable stroke risk reduction and enables patients to stop taking warfarin.

The PILOT study [Sick PB, et al 2007] enrolled the first clinical study patient in 2002 and proved the safety and feasibility of WATCHMAN™ implant. The prospective randomized study PROTECT AF [Holmes D, et al 2009] enrolled the first clinical study patient in 2005 and was published in the *Lancet* in August 2009 with a mean follow-up of 18 months. The efficacy results were very compelling in that 87% of patients were successfully implanted with the device and able to discontinue warfarin therapy 45 days post-implant. Patients in the device group also had a 38% lower risk of stroke, systemic embolism, and cardiovascular or unexplained death when compared to patients treated with warfarin alone. Several subsequent analyses have been performed over the course of follow-up and continue to demonstrate a durable benefit in primary efficacy event reduction. [Reddy V, et al 2013, Reddy V, et al 2014, Holmes DR, et al 2014]

The prospective, multi-center **C**ontinued **A**ccess to **P**ROTECT AF (CAP) Registry enrolled the first trial patient in 2009 and enrolled a total of 566 patients using the same inclusion and exclusion criterial as the PROTECT AF study. These patients have completed all study follow-up (mean 4.2 years) with final results published in *JACC* [Holmes, DR et al 2019.] Ninety-four percent (94%) of patients in the study were successfully implanted and procedure complications were significant reduced when compared to the PROTECT AF experience [Reddy V, et al 2011]. In addition, 96% of patients discontinued warfarin after 45 days post-implant. While there was not a warfarin control arm as a comparator in

the study, the rate of ischemic strokes in CAP was similar to the rate seen in the PROTECT AF device arm (1.2 vs 1.4 per 100 patient years, respectively).

The cadence and growing body of clinical evidence continues to support the medical value and safety of the WATCHMAN ™ implant therapy. The PREVAIL randomized control study enrolled it's first patient in 2012, all patients have completed the required follow-up (mean 4.0 years). First results were published in 2014 in *JACC* and support that WATCHMAN™ was successfully implanted with low complication rates and no differences in procedure-related events between new and experienced operators [Holmes DR, et al 2014.] Since the device was approved by the FDA in March of 2015, procedural safety data for both new and experience operators continues to show consistent results between 1.5% and 2% for major serious adverse events. [Varosy P, et al 2017 and Reddy, et al 2017] Furthermore, PREVAIL also showed that 92% of patients were able to discontinue warfarin therapy 45 days post implant, and >99% were able to discontinue warfarin therapy after 12 months.

The efficacy endpoint of the trial used a Bayesian statistical model that incorporated a portion of the PROTECT AF results, efficacy results for PREVAIL are presented in conjunction with PROTECT AF in order to fully describe the effect of LAAC therapy compared to warfarin. As a result, a patient-level meta-analysis using the final results of both randomized trials and were published in 2017 in *JACC* [Reddy V, et al 2017.] The 5-Year Patient-Level Meta-Analysis of PROTECT AF and PREVAIL (2:1 Randomization) provided the totality of the evidence from both randomized trials for the WATCHMAN ™ therapy after study required follow-up was completed for both randomized trials. This analysis demonstrated that LAAC with WATCHMAN provided stroke reduction in non-valvular atrial fibrillation patients that was comparable to warfarin with additional, statistically significant reductions in disabling or fatal stroke, hemorrhagic stroke, cardiovascular and all-cause mortality, as well as major non-procedure related bleeding.

The totality of the clinical evidence of WATCHMAN ™ reinforces the following clinical outcomes [Reddy VY, et al 2017]

- A reduction of 18% (p=0.27) in all-cause stroke, systemic embolism and cardiovascular/unexplained mortality
- Comparable to warfarin for stroke, with statistically significant reductions by 55% in disabling/fatal stroke (p=0.03) and an 80% reduction in hemorrhagic strokes (p=0.002)
- Statistically significant reductions in all-cause and CV/unexplained mortality respectively 27% (P=0.04) and 41% (p=0.03)
- 72% reduction in major bleeding >6 months post-procedure vs warfarin [Price MJ, et al 2015]

The WATCHMAN™ Device is the only FDA approved device for percutaneous left atrial appendage closure and is the most studied LAAC device in the world. WATCHMAN is the only LAAC device with long-term clinical data from both randomized clinical trial and prospective, multi-center registries, with five-year follow-up data on the majority of patients. These long-term data demonstrate that the WATCHMAN ™ Device is a safe alternative to long-term warfarin therapy which offers comparable stroke risk reduction and enables patients to stop taking warfarin.

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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.

Brief Summary Statement (BSS)

Overview

Product: Watchman LAA Closure Dev w Del Sys – DFU 90746221

Rx Statement: Include the following with every Brief Summary Statement:

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.

Content

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.

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 customary 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 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 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., 0º, 45º, 90º, 135º).
- 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 or resterilize.

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-ALIGN 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
- Hematuria
- Hemoptysis
- Hypotension
- Hypoxia
- Improper wound healing
- Inability to reposition, recapture, or retrieve the device

(cont'd)

- 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
- Nausea
- Oral bleeding
- Pericardial effusion / tamponade
- Pleural effusion
- Prolonged bleeding from a laceration
- Pseudoaneurysm
- Pulmonary edema
- Renal failure
- Respiratory insufficiency / failure
- Surgical removal of the device
- Stroke – Ischemic
- Stroke – Hemorrhagic
- Systemic embolism
- TEE complications (throat pain, bleeding, esophageal trauma)
- Thrombocytopenia
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular damage
- Vasovagal reactions

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

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WATCHMAN

PHYSICIAN PEER-TO-PEER APPEAL GUIDE:

WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE

For questions regarding WATCHMAN™ reimbursement, please contact:

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.

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

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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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 customary 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.
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- 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 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, or resterilize.

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.
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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, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic , Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, 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.

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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.

PHYSICIAN PEER-TO-PEER APPEAL GUIDE:

WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (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 (LAAC) Device implant procedure.

STEP 1 UNDERSTAND THE DENIAL

- Anticipate denials from insurers that have not yet established positive coverage policies for WATCHMAN LAAC Device implants.
- 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 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.

STEP 3 REVIEW STATUS OF FDA APPROVAL, CMS AND COMMERCIAL COVERAGE

FDA Approval

The FDA approved the PMA application for the WATCHMAN Device on March 13, 2015. The FDA has posted the Integrated Summary of Safety and Effectiveness Data (SSED), the approval, Implant System Directions for Use, and the Patient Guide on its website at FDA Approval Order Statement.

According to FDA Labeling: WATCHMAN LAA Closure Technology 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 for all Medicare beneficiaries, including those covered by Medicare Advantage plans.

PHYSICIAN PEER-TO-PEER APPEAL GUIDE

Continued

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.

Commercial Coverage

Positive coverage policies for WATCHMAN LAAC have been established by over 30 national and regional health plans representing over 80 million covered lives. Examples include: Humana, TRICARE, BCBS FEP, Health Net, AmeriHealth and numerous BCBS Licensees. A complete list of plans that provide coverage for WATCHMAN LAAC is available at www.watchmandownloadcenter.com click on Reimbursement to access “WATCHMAN Private Payer List”.

STEP 4 FOCUS ON SECURING COVERAGE FOR AN INDIVIDUAL PATIENT

- The goal is to obtain one-time access to the WATCHMAN LAAC therapy 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 (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 (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.

- 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

Key Clinical Benefits include:

- A reduction of 18% (p=0.27) in all-cause stroke, systemic embolism and cardiovascular/unexplained mortality
- Comparable to warfarin for stroke, with statistically significant reductions by 55% in disabling/fatal stroke (p=0.03) and an 80% reduction in hemorrhagic strokes (p=0.002)
- Statistically significant reductions in all-cause and CV/unexplained mortality respectively 27% (P=0.04) and 41% (p=0.03)
- 72% reduction in major bleeding >6 months post-procedure vs warfarin

NOTE: A complete evidence summary is available at www.watchmandownloadcenter.com click on Reimbursement to access to "Approval/Coverage Status and Clinical Evidence Summary".

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 second appeal.

WATCHMAN
LAAO REGISTRY™

The Center for Medicare and Medicaid Services (CMS) has identified the LAAO Registry as an approved registry to meet the requirements of the national coverage determination (NCD) for Medicare patients undergoing percutaneous left atrial appendage closure.

For more information about the LAAO Registry, please contact:

Phone (toll free): (800) 257-4737
Press 1 to connect with WATCHMAN Prior Authorization or Appeals support.

Visit: www.acc.org/LAAORegistry

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

LAAO Registry

GETTING STARTED

1. Go to NDCR Website: https://cvquality.acc.org/NDCR-Home.
2. Click on “Join a Registry” and fill out required information and choose LAAO Registry under Hospital Registries.

   NOTE: Your hospital will be responsible for a $15,000 registry fee each year.
3. Download LAAO Registry Packet.
4. Complete enrollment materials.
5. Mail completed materials along with payment to NCDR.