GUIDEPOINT Reimbursement Resources

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# 2016 WATCHMAN Left Atrial Appendage Closure Device (The WATCHMAN™ Device) Coding Guide- Structural Heart

## Contents



***CMS establishes coverage for WATCHMAN under the NCD for 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 go to the CMS website or see page 3 of the Guide.

## 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 | 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 as of October 1, 2015 | Varies by Payer policy for LAAC procedures-check with specific payer | Dependent on payer contract |
| Hospital Outpatient | CPT III code 0281T | Designated as "Inpatient Only" | NA | Check with specific payer | NA |
| Physician | CPT III code 0281T | NCD for percutaneous LAAC therapy effective on Feb 8, 2016 | At local contractor's discretion; Requires add'l documentation | Refer to payer policy on Category III CPT codes & LAAC procedures | At payer's discretion; Requires add'l documentation |

*Report with ICD10 procedure code on and after service dates of October 1, 2015.

# National Coverage Determination (NCD)

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. The decision summary 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 or a $CHA_2DS_2$-VASc score ≥ 3**.
- There must be 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.**
  - 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
  - The American College of Cardiology recently released their CardioSource tool for AF Treatment Options that may also be a useful resource:
    http://www.acc.org/tools-and-practice-support/quality-programs/anticoagulation-initiative/anticoagulation-shared-decision-making-tool
- Patients **must be suitable for short-term warfarin, but deemed unable to take long-term oral anticoagulation**.
- The 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:
  - Trained by the manufacturer
  - **≥ 25 interventional cardiac procedures involving transseptal punctures through an intact septum**
  - 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**.

Generally, there is a delay in the effective date and the implementation date of the NCD because the latter involves CMS issuing program instructions to the local Medicare contractors on how to process and accept claims in compliance with the NCD. The implementation timeframes are very similar to the administrative processes with the transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve replacement (TMVR) NCDs. We anticipate the percutaneous LAAC NCD to follow a similar pathway. Once CMS issues these instructions, local Medicare contractors will make changes to their claims processing systems to ensure that WATCHMAN claims can be processed no later than the implementation date.

Upon certification of the national LAAC registry, CMS will communicate the approved registry on its coverage with evidence development (CED) website:
https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-

Development/index.html. Hospitals are encouraged to contact National Cardiovascular Data Registry (NCDR®) at ncdr@acc.org or 1-800-257-4737 for questions on data collection requirements. We expect the NCDR to submit their Left Atrial Appendage Occlusion (LAAO) Registry™ to CMS for certification as an approved registry under the LAAO NCD.

# Physician Reimbursement

## Physician Coding

### WATCHMAN Procedure

Physicians will report the WATCHMAN implant procedure using the Category III CPT Code 0281T.

| Category III CPT Code[1] | Description |
|---|---|
| 0281T | 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 |

Providers should not use the unlisted codes 93799, unlisted cardiovascular service or procedure, or 33999, unlisted cardiac surgery procedure as the Category III CPT Code 0281T is reserved specifically for reporting the WATCHMAN LAAC procedure.

The Category III CPT Code 0281T is designated with a status indicator of "C" which indicates that this service must be provided in the hospital inpatient site of service. Some private payers may allow this procedure to be performed in the hospital outpatient setting; verify and confirm with your payer in advance.

Based on CMS instructions for TAVR, TMVR we expect the following requirements for LAAC. For dates of service on or after February 8th (the NCD effective date), we anticipate there will be additional reporting requirements for reporting WATCHMAN LAAC procedures furnished to Medicare beneficiaries. It is likely that physicians may need to report Category III CPT Code 0281T with modifier **– Q0** to indicate that the patient is participating in the registry with ICD-10 CM diagnosis code **Z00.6** (examination of participant in clinical research program) as a secondary diagnosis code. In addition, physicians may likely need to reference the NCT (National Clinical Trial- 8 digits) number in field 19 of the CMS1500 claim form for electronic submission when the registry has been finalized. (For paper claim's submission, billers should include "CT" followed by the 8 digit NCT number in field 19.) After CMS issues program instructions to the local Medicare contractors, please anticipate specific provider communications related to claims reporting requirements to support the NCD in a Medicare Learning Network (MLN Matters®) article.

The American Medical Association (AMA) has announced creation of a new CPT1 code for reporting percutaneous LAAC implants that will be effective on January 1, 2017. Boston Scientific will communicate details on this code when available.

### 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:

- *Baseline TEE*: Performed prior to the implant procedure to determine if the patient is a suitable candidate for the WATCHMAN Device. (CPT code: 93312)

- *Intraoperative TEE*: Performed during the WATCHMAN implant procedure and provides guided imaging to facilitate device placement (CPT code: 93355).

- *Follow up TEE*: Typically performed 45 days 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 at 6 months and one year post implant to assess appropriate closure of the LAA (CPT code: 93312).

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

**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 6.43 for CY2016.

**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 0281T and 93355 which indicate that these code pairs should not be reported together. This CCI edit will accept a modifier to provide additional clarification of why these code pairs may 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 Coverage

Category III CPT Codes are often used to track utilization of new and emerging technologies, such as the WATCHMAN Device. CMS finalized the national coverage determination (NCD) for percutaneous LAAC therapy which will provide consistent coverage for the WATCHMAN LAAC Device to Medicare beneficiaries as a stroke risk reduction therapy when seven conditions for candidacy are met. The NCD establishes uniform criteria for physicians and hospitals performing LAAC therapy with an effective date of February 8, 2016. As a result, Category III CPT Code 0281T should no longer be treated as investigational and experimental technology upon the contractors' implementation of CMS's program instructions. Medicare

local contractors (MACs) and Medicare Advantage plans must follow the national coverage policy established by the NCD as per the effective date when CMS's program instructions are implemented. (See discussion of coverage on page 3 of the NCD section.) 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 follow their existing policies established 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 and on the website www.bostonscientific.com.

## Physician Payment

Category III CPT Codes do not have assigned Relative Value Units (RVUs) for calculation of physician payment. When communicating with payers, physicians will need to report 0281T as well as select an existing procedure with similar resources, time, and competencies to serve as a reference for mapping appropriate professional payment. (Refer to the Physician Procedure Crosswalk Analogy.) The CPT reference code should be documented in the medical record to support appropriate payment consideration of the WATCHMAN procedure. Physician payment will be at the discretion of the payer. We anticipate when the CPT1 code for percutaneous LAAC implants is effective on January 1, 2017, assigned RVU's and established payment rates will be in place.

# Physician Crosswalk Table

**Experienced WATCHMAN™ Device implanters and professional societies have identified the following procedures as comparable to a WATCHMAN implant in terms of resource utilization. Clinician opinions may vary. Physicians are encouraged to crosswalk to a procedure that they feel is most comparable. RVUs associated with the comparable procedure are reported on the claim.**

| | WATCHMAN Procedure | Comparable Procedures | |
|---|---|---|---|
| **CPT™ code and description** | **0281T**<br>Percutaneous left atrial appendage closure with implant<br>(LAA**)** | **93580**<br>Percutaneous transcatheter closure of congenital interatrial communication with implant<br>(PFO or ASD)<br>**AND**<br>**+93462**<br>Left heart catheterization by transseptal puncture through intact septum or by transapical puncture | **93581**<br>Percutaneous transcatheter closure of a congenital ventricular septal defect with implant<br>(VSD) |
| **2016 Physician Fee Schedule Value*** | **Total RVU: 0**<br>(Category III CPT codes do not have assigned relative value units.)<br><br>**Paid at individual payer discretion** | **Total 2016 RVU: 34.47**<br>**Total Payment: $1,235**<br><br>**Procedure 93580**<br>Work RVU: 17.97<br>Transitional PE RVU: 6.48<br>Malpractice RVU: 3.95<br>Nat Avg. Payment: $1,017<br>AND<br>**Procedure +93462**<br>Work RVU: 3.73<br>Transitional PE RVU: 1.48<br>Malpractice RVU: 0.86<br>Nat Avg. Payment: $217 | **Total 2016 RVU: 38.75**<br>**Total Payment: $1,387**<br><br>**Procedure 93581**<br>Work RVU: 24.39<br>Transitional PE RVU: 8.51<br>Malpractice RVU: 5.78<br><br>Nat Avg. Payment: $1,387 |
| **Sedation type** | General anesthesia | Conscious sedation | General anesthesia |
| **Imaging Technique** | Use real-time intraoperative transesophageal echocardiography (TEE) and fluoroscopy to facilitate device placement | Use real-time intracardiac echocardiography (ICE) and fluoroscopy to facilitate device placement | Use real-time transesophageal echocardiography (TEE) and fluoroscopy to facilitate device placement |
| **Catheterization approach** | Right heart catheterization | Right heart catheterization | Femoral vein and artery |
| **Access technique** | **Transseptal puncture** | Use congenital defect | Typically, femoral artery retrograde to access left ventricle. May include transseptal puncture. |
| **Procedural steps** | • Access left atrial appendage<br>• Size opening and choose appropriate device size<br>• Position in LAA<br>• Reposition if necessary<br>• Deploy device to close off LAA | • Access defect<br>• Size defect and choose appropriate device size<br>• Position in defect<br>• Reposition if necessary<br>• Deploy device to close defect | • Access defect<br>• Size defect and choose appropriate device size<br>• Position in defect<br>• Reposition if necessary<br>• Deploy device to close defect |

* The CY2016 PFS conversion factor is **$35.8043** which is reflected in the physician payment rates.

# Hospital Reimbursement

## Hospital Coding

Effective **October 1, 2015**, all inpatient hospital procedures will be reported using ICD10 procedure codes (ICD-10-PCS). The appropriate ICD10 procedure code for reporting the WATCHMAN implant is:

| ICD-10 Procedure code[2] | Procedure Description |
|---|---|
| 02L73DK | Occlusion of left atrial appendage with intraluminal device, percutaneous approach |

Medicare has determined that the WATCHMAN LAAC procedure must be performed in the inpatient hospital site of service. The Category III CPT Code 0281T is designated with a status indicator of "C" which limits this procedure to be done in the inpatient hospital setting only. 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 clicking this link.

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 instructions for TAVR, TMVR we expect the following requirements for LAAC As of the NCD effective date, local Medicare contractors may likely require reporting with ICD10-PCS procedure code 02L73DK with secondary diagnosis code **Z00.6** (examination of participant in clinical research program), **condition code 30** (qualifying clinical trial), and the **8- digit NCT number** (for the qualified registry) when CMS certifies the national LAAC registry. After CMS issues program instructions to the local Medicare contractors, please anticipate specific provider communications related to claims reporting requirements to support the NCD in a Medicare Learning Network (MLN Matters®) article.

### 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 medical 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.

In the FY2016 Final Inpatient Hospital Rule, CMS moved WATCHMAN implants into a new MS-DRG specific to "percutaneous intracardiac procedures." This payment category is represented by new MS-DRGs 273 and 274 which result in an average increase of ~19% from former MS-DRG assignments of 250 and 251. All hospitals benefit from the new DRG assignment **effective October 1, 2015**.

| MS-DRG | MS-DRG Description | FY2016 National Average Base Payment** |
|---|---|---|
| MS-DRG 273 | Percutaneous Intracardiac Procedures with MCC | $ 20,961 |
| MS-DRG 274 | Percutaneous Intracardiac Procedures without MCC | $ 14,288 |

** Centers for Medicare and Medicaid Services. Medicare Program: FY2016 Hospital Inpatient Prospective Payment System, Final Rule; July 31, 2015

## 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 that replace local Medicare contractors' policies that may be contradictory of the national guidance. Medicare Advantage Plans must also follow the NCD as of the effective date. (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 additional data collection efforts 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 is in the process of working with the National Cardiovascular Data Registry (NCDR®) in certifying the LAAO Registry™ (Left Atrial Appendage Occlusion) as the official registry for the LAAC NCD. This process can take up to two months and we encourage hospitals to contact NCDR about enrollment and questions on data collection during the certification process by going to the NCDR website or contacting them at ncdr@acc.org or by calling 1-800-257-4737. Coverage could be at risk if the registry is not certified, so we encourage you to contact CMS or your local contractor if you have questions.

Private and commercial payers may choose to follow the NCD guidance or follow their existing policies established 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[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.

### 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 the seven 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. It may take time for the MACs and Medicare Advantage Plans to update their policies so if you inadvertently receive denials, please reference the NCD and how your patients meet the NCD criteria in your appeals or prior authorizations to support coverage of WATCHMAN.

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.

[1] January CT, Wann LS, Alpert JS, et. al., 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 Practice Guidelines and the Heart Rhythm Society, Circulation, 2014; 130: e199-e267.

# 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. Recent peer review literature regarding the WATCMAN include:
    - 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.
    - 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. doi:10.1016/j.jacc.2015.04.025.
- Description of the technology and rationale for its use in the patient's surgery

- Copy of the FDA approval letter (available through your Boston Scientific Sales Representative or by calling 1-800-CARDIAC, and ask for the reimbursement support line)

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

## 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 medical necessity), submit the claim to the MAC, and then wait to receive a payment or denial. For service dates prior to the NCD effective date, the patient discussion may involve completion of the Advanced Beneficiary Notice (ABN) when there is a likelihood that Medicare may not pay for an item or service. For additional information about ABN, please click here. 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" where providers have 120 days from the date of the receipt of the initial claim decision to appeal. 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 on or after the NCD effective date, please appeal the claim by referencing the NCD and 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.

When speaking with the plan's Medical Director, 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 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
- Detail the patient's diagnosis and course of treatment including adverse outcomes or lack of improvement from prior therapies.
- Describe the surgery 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. Recent peer review literature regarding the WATCHMAN device include:

    - 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.
    - 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. doi:10.1016/j.jacc.2015.04.025.

- 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

Please go to the WATCHMAN Device website: www.bostonscientific.com to access a sample appeals template that you can customize specific to the medical appropriateness of WATCHMAN Device for your patients.

## Coding & 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.

Call **1.800.CARDIAC (227.3422)** and ask for “WATCHMAN Reimbursement.”

All WATCHMAN reimbursement resources are easily accessed at www.bostonscientific.com.

## Important Information

Health economics 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 provided 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. Boston Scientific does not promote the use of its products outside their FDA-approved label.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

## References

[1] CPT copyright 2015 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: 2016 ICD-10-PCS for Hospitals-The Complete Official Draft Code Set, Professional Edition, Chicago, IL.