

**2015 WATCHMAN Left Atrial Appendage Closure Device
(The WATCHMAN™ Device) Coding Guide- Structural Heart**

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Reimbursement Overview

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

| | Coding | Medicare | | Private Payer | |
|---------------------|---------------------------------|--|--|--|---|
| | | Coverage | Payment | Coverage | Payment |
| Hospital Inpatient | ICD-9 procedure code 37.90 * | Varies by locality | Most common assignments are DRG 251 or 250 through Sept 30, 2015. Effective Oct 1, 2015, DRG 273 and 274 will be the new payment mappings. | Varies by Payer policy for LAA Closure procedures | Dependent on payer contract |
| | ICD-10 procedure code 02L73DK** | | | | |
| Hospital Outpatient | CPT III code 0281T | Designated as “Inpatient Only” | NA | Likely Not Allowed | NA |
| Physician | CPT III code 0281T | Refer to contractor policy on Category III CPT codes | At local contractor’s discretion; Requires add’l documentation | Refer to payer policy on Category III CPT codes & LAA Closure procedures | At payer’s discretion; Requires add’l documentation |

*Report with ICD9 procedure code through September 30, 2015.

**Report with ICD10 procedure code on October 1, 2015.

Physician Reimbursement

Physician Coding

WATCHMAN Procedure

For the WATCHMAN LAA Closure procedure, physicians will use the Category III CPT Code 0281T to report implantation of the WATCHMAN device. This code became effective on January 1, 2012 and is used specifically to allow Medicare and private payers to more appropriately determine utilization and capture resources associated with the WATCHMAN LAA Closure procedure.

| 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 LAA Closure 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.

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:** This TEE is usually performed prior to the implant procedure to determine if the patient is a suitable candidate for the WATCHMAN Device. (CPT code: 93312)
- **Intraoperative TEE:** This TEE is performed during the WATCHMAN implant procedure and provides guided imaging to facilitate device placement (CPT code: 93355).
- **Follow up TEE:** This TEE is performed usually 45 days after the WATCHMAN implant to ensure appropriate endothelialization/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

For the intraoperative TEE, the American Society of Echocardiography (ASE) has recently received approval for a new interventional transesophageal echocardiography code for use beginning in 2015. This will also apply to WATCHMAN implants utilizing intraoperative TEE. This code, 93355 is intended to be used to report TEE services during an interventional procedure for 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 6.40 for CY2015. 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.

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 are reported together.

Physician Coverage

Category III CPT Codes are often used to track utilization of new and emerging technologies, and are often assigned prior to FDA approval. As a result, most Medicare administrative contractors (MACs) and private payers treat Category III codes as investigational and experimental and default to non-coverage of procedures reported with these codes. It is important that providers reach out to their MACs for case-by-case consideration and have informed discussions with their patients about the procedure and the possibility of non-coverage. 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](#).

Payers may consider coverage on a case-by-case basis. The physician will need to provide justification for medical necessity and appropriateness based upon the patient's particular circumstance and should always seek prior authorizations for WATCHMAN implants. Traditional Medicare does not offer prior authorization and providers would need to work with local contractors in appealing denials. Resources to support this process are provided in the Payer Communications and Prior Authorization sections of this document.

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 select an

existing procedure with similar resource use to serve as a reference for mapping appropriate professional payment. (Refer to the Physician Procedure Crosswalk Analogy.) Payment will be at the discretion of payers and are often “carrier priced.”

Physicians who have RVU-based compensation plans should also talk with their employer or practice manager to establish a value for the WATCHMAN implant procedure, in order to be credited appropriately for their work. Refer to physician crosswalk table.

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.

| | | | |
|---|---|---|---|
| CPT™ code and description | 0281T Percutaneous left atrial appendage closure with implant (LAA) | 93580 Percutaneous transcatheter closure of congenital interatrial communication with implant (PFO or ASD) AND +93462 Left heart catheterization by transseptal puncture through intact septum or by transapical puncture | 93581 Percutaneous transcatheter closure of a congenital ventricular septal defect with implant (VSD) |
| 2015 Physician Fee Schedule Value* | Total RVU: 0 (Category III CPT codes do not have any relative value units.) Paid at individual payer discretion | Total 2015 RVU: 34.33 Total Payment: \$1,227 Procedure 93580 Work RVU: 17.97 Transitional PE RVU: 6.47 Malpractice RVU: 3.86 Nat Avg. Payment: \$1,012 AND Procedure +93462 Work RVU: 3.73 Transitional PE RVU: 1.47 Malpractice RVU: 0.83 Nat Avg. Payment: \$216 | Total 2015 RVU: 38.68 Total Payment: \$1,383 Work RVU: 24.39 Transitional PE RVU: 8.61 Malpractice RVU: 5.68 Nat Avg. Payment: \$1,378 |
| Sedation type | General anesthesia | Conscious sedation | General anesthesia |
| Imaging Technique | Use real-time 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 | <ul style="list-style-type: none"> • Access left atrial appendage • Size opening and choose appropriate device size • Position in LAA • Reposition if necessary • Deploy device to close off LAA | <ul style="list-style-type: none"> • Access defect • Size defect and choose appropriate device size • Position in defect • Reposition if necessary • Deploy device to close defect | <ul style="list-style-type: none"> • Access defect • Size defect and choose appropriate device size • Position in defect • Reposition if necessary • Deploy device to close defect |

*As a result of the recent SGR passed earlier this year, the current conversion factor (CF) of \$35.8228 remains effective until December 31, 2014 with a zero percent update beginning January 1 through March 31, 2015. The CY2015 PFS CF for January 1, 2015 through March 31, 2015 is **\$35.7547** which is reflected in the physician payment rates noted above.

Hospital Reimbursement

Hospital Coding

The ICD-9-CM procedure code used to report a WATCHMAN™ implant in the hospital inpatient setting is provided below. The ICD9 coding methodology remains in effect until September 30, 2015.

| ICD-9 Procedure code ² | Procedure Description |
|-----------------------------------|---|
| 37.90 | Insertion of a left atrial appendage device, transseptal catheter technique |

Effective on **October 1, 2015**, all inpatient hospital procedures will be reported using ICD10 procedure codes. The appropriate ICD10 procedure code for reporting the WATCHMAN implant is as follows:

| ICD-10 Procedure code ³ | Procedure Description |
|------------------------------------|--|
| 02L73DK | Occlusion of left atrial appendage with intraluminal device, percutaneous approach |

Medicare has determined that the WATCHMAN LAA Closure 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 in the inpatient hospital only and it is not an approved procedure in the outpatient hospital. 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. As an inpatient-only procedure, WATCHMAN device implant procedures are not restricted by Medicare’s two midnight rule. Additional information can be found by clicking the [link](#).

Some private payers may allow this 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.

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-9 code (37.90) and a diagnosis of atrial fibrillation, WATCHMAN procedures would typically map to MS-DRG 250 or 251. This mapping is representative for FY2015 (or through September 30, 2015).

| MS-DRG | MS-DRG Description | FY2015 National Average Base Payment* |
|------------|---|---------------------------------------|
| MS-DRG 250 | Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC | \$ 17,529 |
| MS-DRG 251 | Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC | \$ 11,965 |

* Centers for Medicare and Medicaid Services. Medicare Program: [FY2015 Hospital Inpatient Prospective Payment System, Final Rule](#); August 22, 2014

In the FY2016 Final Inpatient Hospital Rule, CMS moved WATCHMAN implants into a new DRG specific for “percutaneous intracardiac procedures.” This new payment category is represented by new MS-DRGs 273 and 274 which result in an average increase of ~19% from the current base national payment rates. All hospitals benefit from the new DRG assignment **effective on 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

Regardless, it is always the responsibility of the provider to adhere to local coverage guidance and private payer policies when applicable. Because Category III code 0281T is explicitly non-covered by most Medicare contractors, hospitals should anticipate denials for left atrial appendage closure procedures. Hospitals should work with local contractors to appeal denials in supporting the medical necessity of the WATCHMAN implant.

It is important that providers reach out to their MACs for case-by-case consideration and have informed discussions with their patients about the procedure and the possibility of non-coverage. 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](#).

Payer Communications

Category III CPT Codes and Implications for WATCHMAN™ LAA Closure Procedures

WATCHMAN implant claims reported with Category III code 0281T will likely be denied by local Medicare contractors in the absence of a local or national coverage decision (LCD or NCD). It is important that providers work with their local Medicare contractors to appeal these denials based on medical necessity. Appeals and support materials are referenced throughout this guide. In the interim, Boston Scientific is working with Medicare to minimize the coverage gap to ensure appropriate access for your patients that qualify for this important therapy.

For private payers, coverage will be based on their policies for Left Atrial Appendage Closure procedures. We highly encourage physicians and hospital providers to check for 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 LAA Closure based on your patients' medical circumstances. Prior authorization and peer-to-peer reviews are recommended tools for assisting with patient access in light of non-coverage policies. Please refer to the Prior-Authorization section to assist with best practices in securing approval for WATCHMAN LAA Closure procedures.

FDA Approval

The WATCHMAN LAA Closure device has received FDA approval so it should not be treated as an investigational device. Please go to <http://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 CHADS₂ or CHA₂DS₂-VASc¹ 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 Resources

Medicare

Medicare does not offer prior authorizations for any services including the WATCHMAN LAA Closure procedure.

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.

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 policy 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 WATCHMAN 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

Medicare contractors and commercial 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. 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.

Appeals information regarding private payer processes are found in the plan’s provider manual and/or website or by contacting the insurer directly. If you need to appeal a prior authorization decision, 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

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² American Medical Association: 2014 ICD-9-CM for Hospitals, Volumes 1, 2 and 3, Professional Edition, Chicago, IL.

³ American Medical Association: 2015 ICD-10-PCS for Hospitals-The Complete Official Draft Code Set, Professional Edition, Chicago, IL.

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