

# 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:

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**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](http://www.watchmandownloadcenter.com) to access a sample prior authorization template.

## 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 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 <sup>3</sup>	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