WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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WHICH OF YOUR NVAF PATIENTS ARE RIGHT FOR WATCHMAN?

Patient has an increased stroke risk and is recommended for oral anticoagulation (OAC). *(CHA_2DS_2-VASc ≥ 2 in men, ≥ 3 in women).*

YES | NO

Patient is suitable for short-term OAC use. *(See 45-day post-procedure regimen).*

YES | NO

Patient has appropriate rationale to seek a non-pharmacologic alternative for stroke risk reduction. *(See patient selection).*

YES | NO

PATIENT MAY BE A CANDIDATE FOR THE

WATCHMAN LAAC Device*

**See full indication on back page.*

PATIENT CONSULT

To better understand your patient's need for an alternative to OAC therapy, you may ask them the below questions during consult:

Do you sometimes miss or forget to take your blood thinner?

- Do you struggle filling or picking up your prescription?
- What other medications are you taking?

Is the cost of your blood thinner a concern for you?

- Do you ever skip or split doses to extend your prescription?

Does being on a blood thinner interfere with your daily tasks or activities?

- Have you had challenges with your diet due to your blood thinner medication?
- Have you had to modify your lifestyle due to being on a blood thinner?

Have you experienced side effects from your blood thinner?

- Have you noticed bruising or bleeding?

Do you have concerns about falling?

- Do you live with someone who is able to help you in case of a fall?

PATIENT SELECTION

The WATCHMAN implant may be an appropriate option for your NVAF patients who identify as one or more of the following:

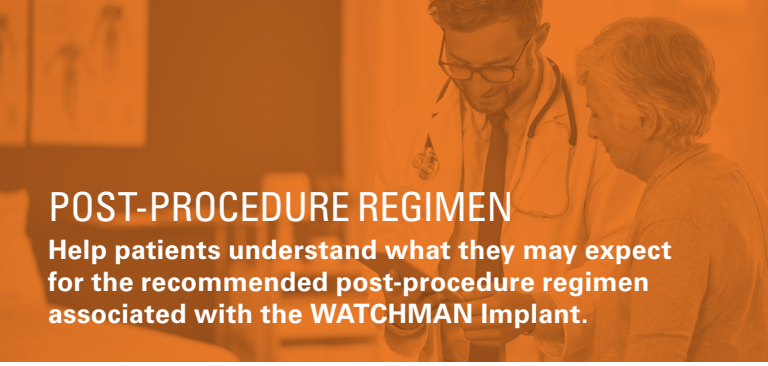
BLEEDER
History of major and/or non-major bleeding.

FUTURE BLEEDER
High propensity for bleeding based on high-risk HAS-BLED> CHA_2DS_2-VASc; includes fall risk.

NON-COMPLIANT
Struggles with maintaining a therapeutic INR, skips doses or discontinues OAC medication.

OCCUPATION AND/OR QUALITY OF LIFE
History of major and/or non-major bleeding.

DRUG INTERACTION
Not suitable for long-term warfarin use due to other medical treatment needs.



POST-PROCEDURE REGIMEN

Help patients understand what they may expect for the recommended post-procedure regimen associated with the WATCHMAN Implant.

Post-Procedure Therapy

IMPLANT

Warfarin + ASA*
(81-100 mg) daily — 45 DAYS

45-DAY TEE**

Clopidogrel (75 mg) + ASA
(300-325 mg) daily — 4.5 MONTHS

6 MONTHS POST-PROCEDURE

ASA (300-325 mg) daily — DESTINATION THERAPY

** ASA = Aspirin*

***If leak >5 mm, patients remain on warfarin + ASA until seal documented, skipping the Clopidogrel +ASA pharmacotherapy.*

PATIENT COST

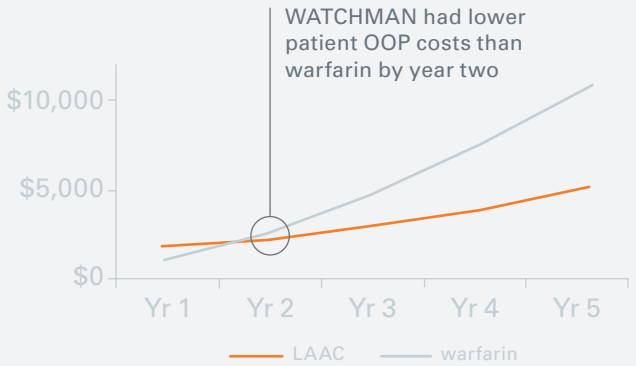
Help your patient understand what they may expect in terms of cost and post-procedure regimen associated with the WATCHMAN Implant.

Patient Costs for WATCHMAN Implant*

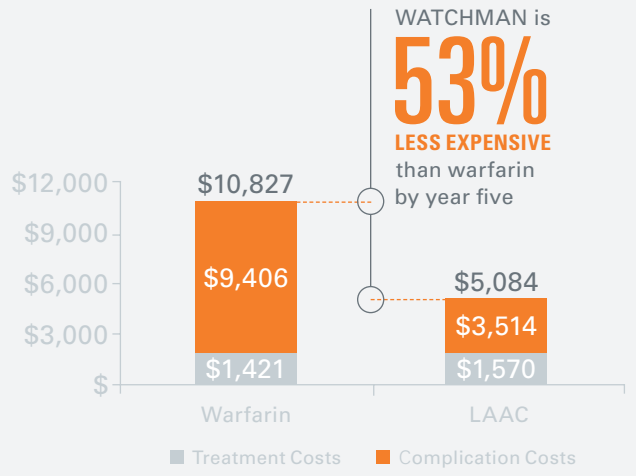
		TOTALS
PREPARING FOR WATCHMAN		
Pre-Screening TEE*	$90	**$96**
WATCHMAN IMPLANT		
Inpatient Deductible (Medicare Part A)	$1,364	
Medical Services Deductible (Medicare Part B)	$185	
PHYSICIAN PROFESSIONAL FEE COPAYS		
Implanter	$166	
Anesthesiologist	$102	
Intraoperative TEE Operator	$47	**$1,865**
POST-WATCHMAN THERAPY		
Warfarin/Clopidogrel/ASA through 1 year	$67	
45-day follow-up TEE	$96	
1-year follow-up TEE	$96	**$259**
Total Estimated Patient OOP Costs: $2,219		

**The patient out-of-pocket cost shown above is an estimated amount calculated based on an average Medicare patient in 2019.*

ANNUAL CUMULATIVE PATIENT OOP COSTS



AVERAGE TOTAL OOP COSTS AT YEAR FIVE



Armstrong S, et al. ISPOR 2015.

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 $CHADS_2$ 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.

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.

*Payer coverage policies may not be consistent with BSC device labeling. In some cases, payer policies may include procedures, indications or criteria (such as a specific definition of $CHADS_2$ or CHA_2DS_2-VASc scores or contraindication to warfarin) which may differ from the FDA label.

For more information, please visit: WATCHMAN.com/HCP

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