WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific

Advancing science for life™

SHARED DECISION MAKING:
AN EVIDENCE-BASED CORNERSTONE OF LAAC THERAPY

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AN EVIDENCE BASED CORNERSTONE OF LAAC THERAPY

Shared decision making is a collaborative process that allows patients and their providers to make health care treatment decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.[1]

HOW SHARED DECISION MAKING WORKS[2]:

- In clinical scenarios characterized by more than one viable treatment or screening option, providers facilitate shared decision making by:
  - Encouraging patients to communicate what they care about
  - Providing decision aids that raise the patient's awareness and understanding of treatment options and possible outcomes

IMPLEMENTING SHARED DECISION MAKING IN CLINICAL PRACTICE

The SHARE Approach[3]

S — **Start** the Conversation with your patient

H — **Help** your patient explore and compare treatment options

A — **Assess** your patient's values and preferences

R — **Reach** a decision with your patient

E — **Evaluate** your patient's decision

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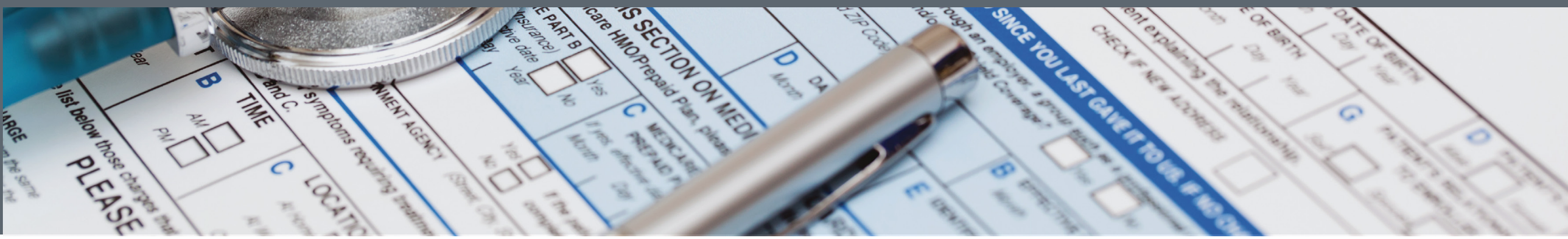
NOW COVERED NATIONALLY BY CMS AND AN EXPANDING NUMBER OF COMMERCIAL INSURERS



National Coverage Determination (NCD) for percutaneous LAAC Therapy*

- The Centers for Medicare and Medicaid Services (CMS) issued a final decision memo supporting the NCD for percutaneous LAAC therapy (NCD 20.34) when specific conditions are met[4]
- This major milestone provides appropriate and uniform coverage for Medicare beneficiaries that is largely consistent with the WATCHMAN FDA label

The conditions of this NCD place the treatment decision in the hands of physicians and patients who have reason to seek an alternative to long-term anticoagulation.

**Effective Feb 8, 2016.*

QUESTIONS? For questions related to WATCHMAN reimbursement, please call 1-800-CARDIAC

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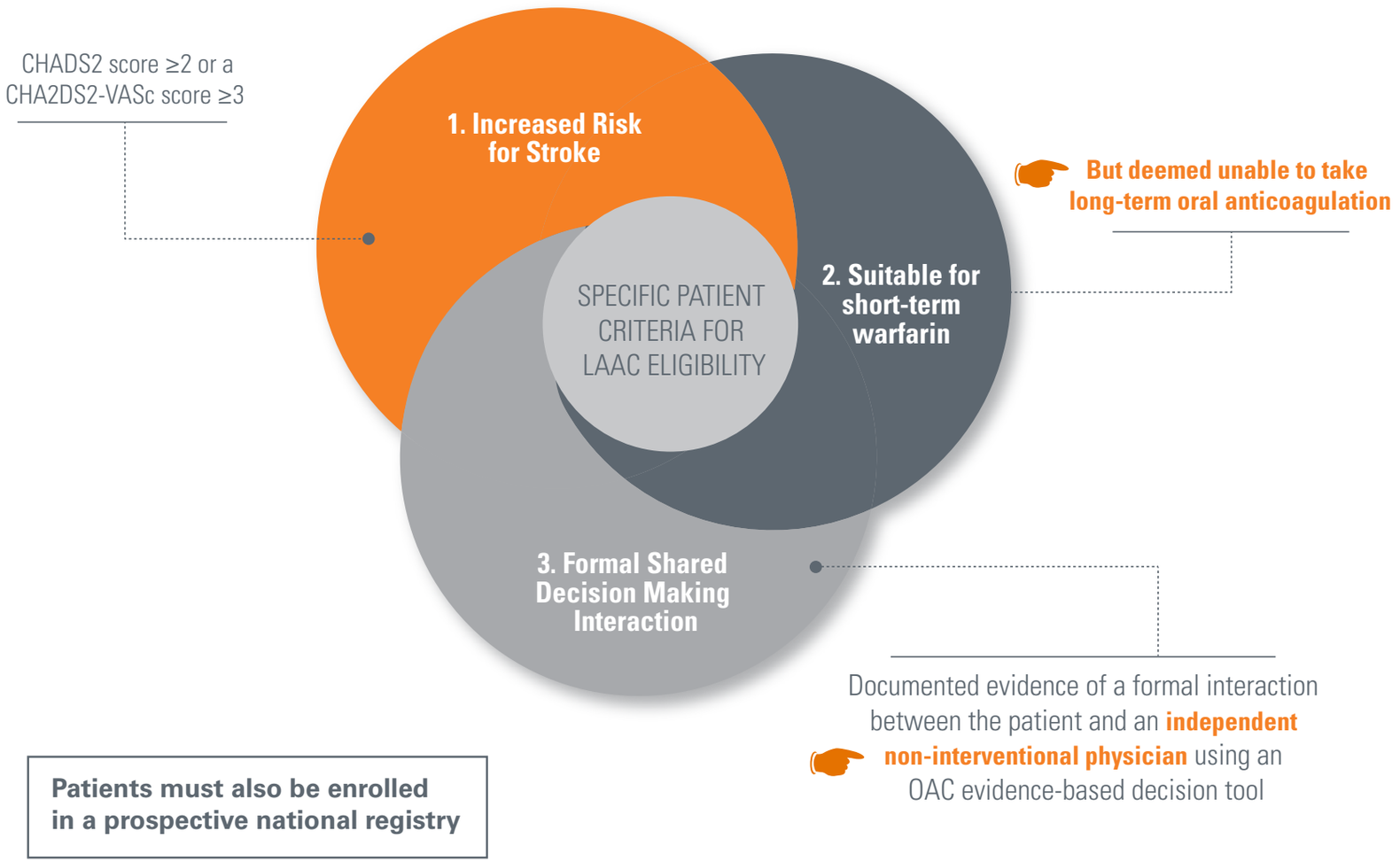
SPECIFIC PATIENT CRITERIA FOR LAAC ELIGIBILITY INCLUDE THE FOLLOWING AND MUST BE DOCUMENTED IN PATIENT'S MEDICAL RECORD:



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SPECIFIC PATIENT CRITERIA FOR LAAC ELIGIBILITY INCLUDE THE FOLLOWING AND MUST BE DOCUMENTED IN PATIENT'S MEDICAL RECORD:

CHADS2 score ≥2 or a CHA2DS2-VASc score ≥3

1. Increased Risk for Stroke

But deemed unable to take long-term oral anticoagulation

What does deemed unable to take long-term oral anticoagulation mean?

X

Specific factors may include (but not limited to) one or more of the following:

- A history of major bleeding while taking oral anticoagulants
- A career or lifestyle that increases the risk of major bleeding (secondary to trauma)
- Prior experience of being inadequately controlled on oral anticoagulants
  - Inability to maintain stable INR
  - Inability to comply with regular INR monitoring and unavailability of an approved alternative OAC

Interaction

Documented evidence of a formal interaction between the patient and an **independent non-interventional physician** using an OAC evidence-based decision tool

Patients must also be enrolled in a prospective national registry

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1. Increased Risk for Stroke

But deemed unable to take long-term oral anticoagulation

Who is an independent non-interventional physician?

A physician other than the implanter who is qualified to have a meaningful discussion with the patient regarding atrial fibrillation and stroke treatment options.

Examples of non-interventional physicians include:

- Primary care provider
- Non-interventional cardiologist
- Neurologist or those who have experience caring for stroke patients

Interaction

Documented evidence of a formal interaction between the patient and an **independent non-interventional physician** using an OAC evidence-based decision tool

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OAC EVIDENCE BASED DECISION TOOLS

CMS encourages the use of an evidence-based tool in any physician and patient discussions to help document the appropriateness of LAAC as a non-pharmacological treatment option in comparing the risk-benefit to oral anticoagulants

- Patient-provider discussions may uncover barriers to change that include physical pain, emotional difficulties, financial concerns, and lack of confidence in one's ability to change
- These and other barriers can then be addressed so that a realistic personal prevention plan is formulated with specific and achievable outcomes

Shared Decision Making Resources

ACP American College of Physicians
Leading Internal Medicine, Improving Lives

https://www.acponline.org/patients_families/products/brochures/afib_booklet.pdf

NICE National Institute for Health and Care Excellence
Patient decision aid

https://www.nice.org.uk/guidance/cg180/resources/patient-decision-aid-243734797

CardioSmart American College of Cardiology

http://www.acc.org/tools-and-practice-support/quality-programs/anticoagulation-initiative/anticoagulation-shared-decision-making-tool

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CALCULATE YOUR NVAF PATIENT'S STROKE AND BLEEDING RISK

CHADS$_2$ SCORE | CHA$_2$DS$_2$VASc SCORE | HAS-BLED SCORE

CHADS$_2$ Score (Stroke Risk)

	Condition	Points
C	Congestive Heart Failure	1
H	Hypertension (SBP > 160)	1
A	Age ≥ 75 Years	1
D	Diabetes mellitus	1
S_2	Prior stroke/TIA	2
TOTAL POINTS		

Score	Yearly Stroke Risk (%)
0	1.9
1	2.8
2	4.0
3	5.9
4	8.5
5	12.5
6	18.2

Use the CHADS$_2$ and CHA$_2$DS$_2$VASc calculator to determine your patients AF stroke risk based on specific criteria

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CALCULATE YOUR NVAF PATIENT'S STROKE AND BLEEDING RISK

CHA$_2$DS$_2$VASc Score (Stroke Risk)

	Condition	Points
C	Congestive Heart Failure	1
H	Hypertension (SBP > 160)	1
A	Age ≥ 75 Years	2
D	Diabetes mellitus	1
S_2	Prior stroke, TIA or thromboembolism	2
V	Vascular disease (PAD,MI)	1
A	Age 65-74 years	1
Sc	**Sex** category (Female)	1
TOTAL POINTS		

Score	Yearly Stroke Risk (%)
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7
6	9.8
7	9.6
8	6.7
9	15.2

Use the CHADS$_2$ and CHA$_2$DS$_2$VASc calculator to determine your patients AF stroke risk based on specific criteria

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CALCULATE YOUR NVAF PATIENT'S STROKE AND BLEEDING RISK

HAS-BLED Score
(Bleeding risk with warfarin)

	Condition	Points
H	Hypertension	1
A	Abnormal renal/liver function (1pt each)	1 or 2
S	Hemorrhagic Stroke	1
B	Bleeding history or disposition	1
L	Labile	1
E	Elderly	1
D	Current drugs (medication) or alcohol use (1pt each)	1 or 2
TOTAL POINTS		

Score	Yearly Major Bleeding Risk (%)
0	1.13
1	1.02
2	1.88
3	3.74
4	8.7
5+	Not well validated

Use the HAS-BLED calculator to determine your patient's bleeding risk based on specific criteria

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., 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-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.

References:
1. Six Steps of Shared Decision Making. © 2012 by Informed Medical Decisions Foundation.
2. Barry MJ, Edgman-Levitan S. Shared decision making—the pinnacle of patient-centered care. N Engl J Med. 2012;366(9):780-781
3. Agency for Healthcare Research and Quality. U.S. Department of Health & Human Services. http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/index.html. Accessed September 23, 2016.
4. Centers for Medicare & Medicaid Services. Decision memo for percutaneous left atrial appendage (LAA) closure therapy (CAG-00445N). https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281&ExpandComments=n&DocID=CAG-00445N&bc=gAAAAAgAAgAAAA%3d%3d&. Published February 8, 2016. Accessed September 23, 2016.

Learn more about the WATCHMAN Device and to find the nearest implanting center www.watchman.com/hcp

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