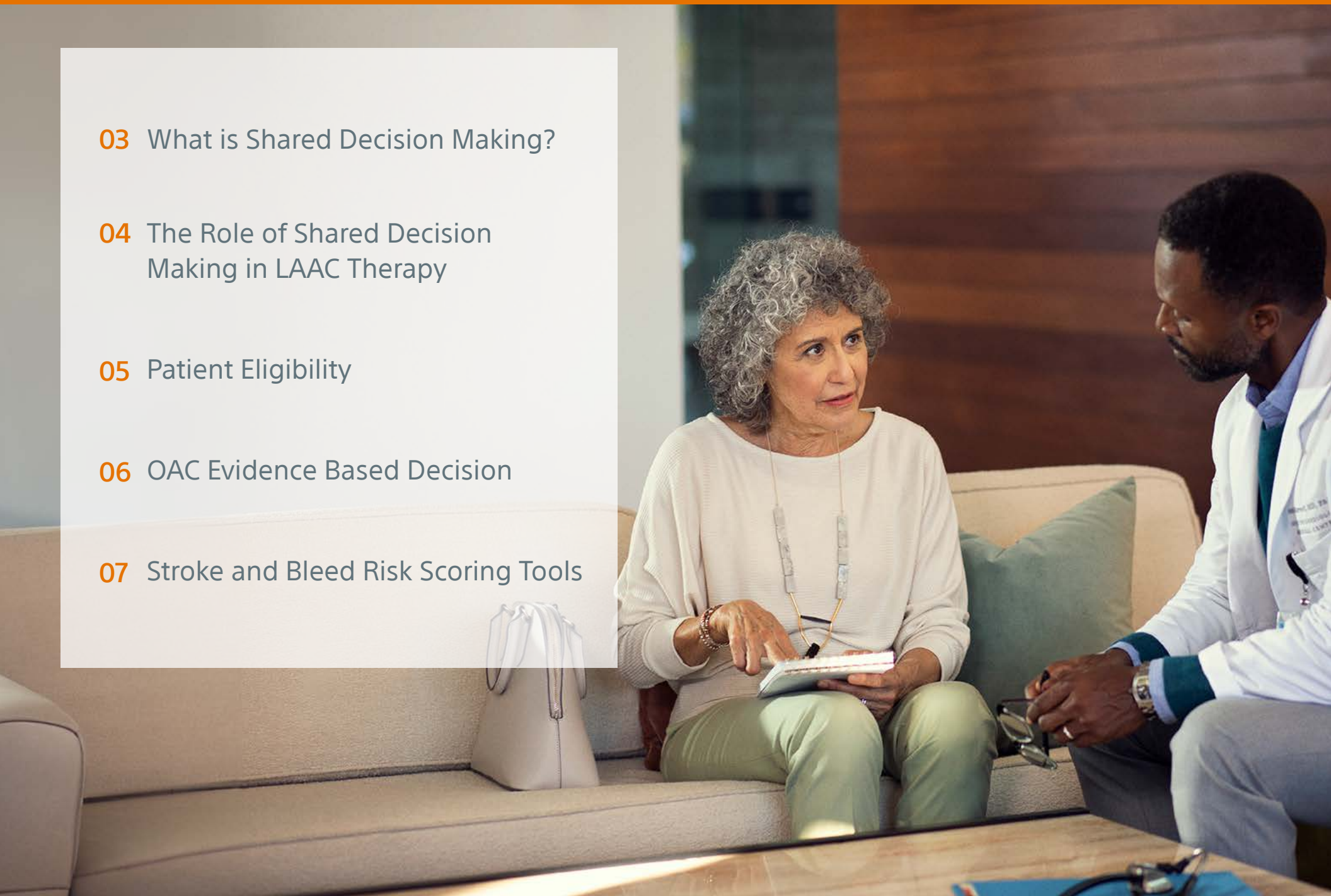

WATCHMAN™

INTEGRATED LAAC SOLUTIONS

# Shared Decision Making: An Evidence-Based Cornerstone of LAAC Therapy

# Table of Contents

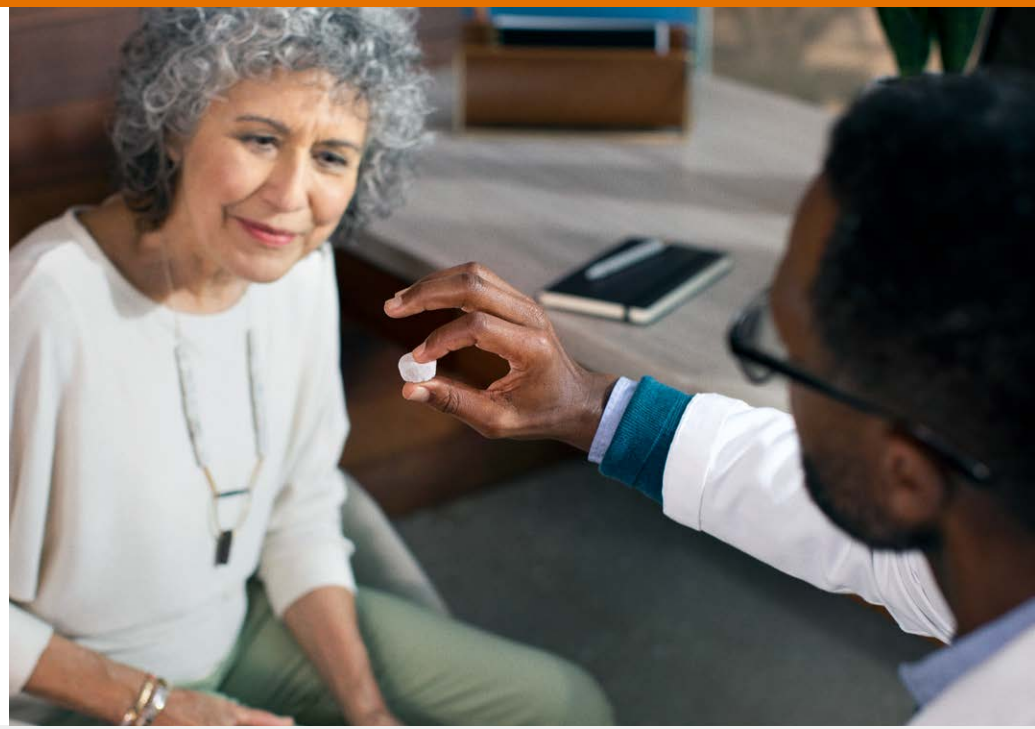




# What is Shared Decision Making?

## Shared Decision Making: 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

| S | H | A | R | E |
|---|---|---|---|---|
| **Start** the Conversation with your patient | **Help** your patient explore and compare treatment options | **Assess** your patient's values and preferences | **Reach** a decision with your patient | **Evaluate** your patient's decision |

# The Role of Shared Decision Making in LAAC Therapy

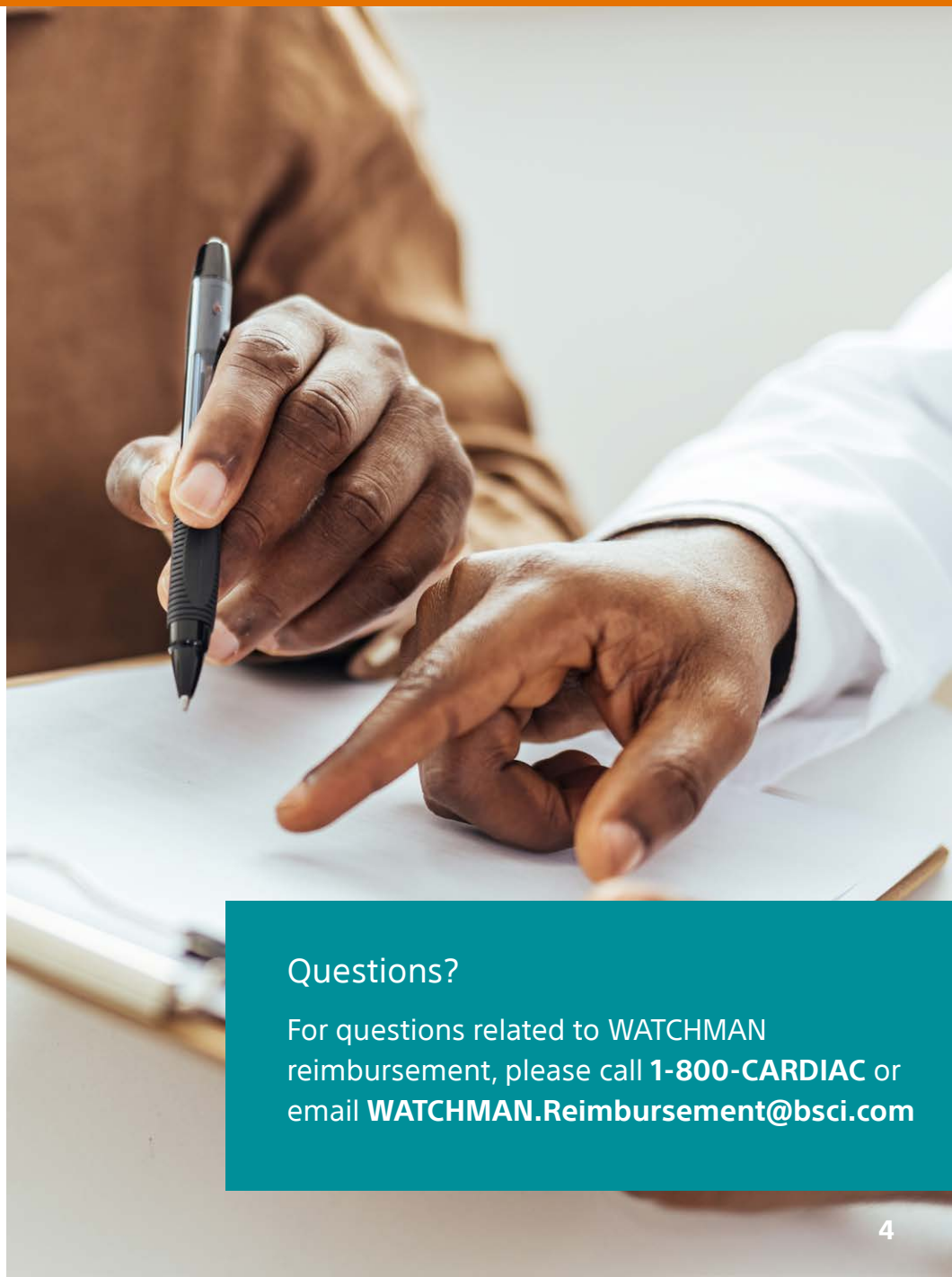
## Now covered nationally by CMS and an expanding number of commercial insurers

### 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.*



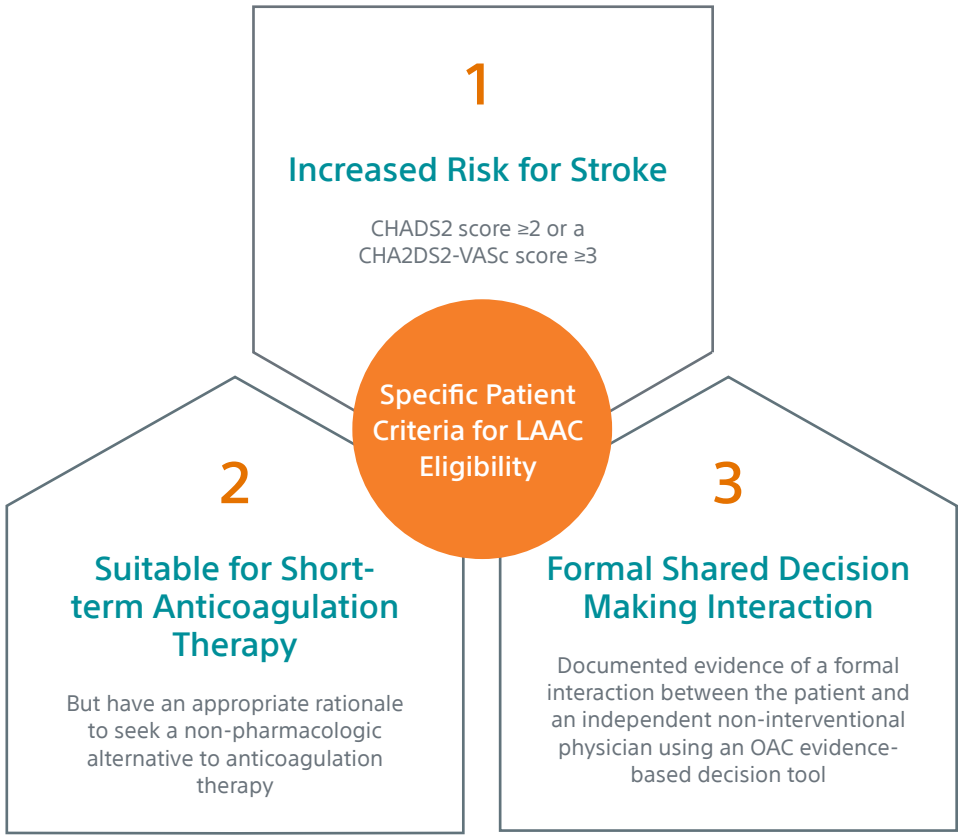
### Questions?

For questions related to WATCHMAN reimbursement, please call **1-800-CARDIAC** or email **WATCHMAN.Reimbursement@bsci.com**

# Patient Eligibility

## Specific patient criteria for LAAC eligibilty include the following and must be documented in patient's medical record:

*Patients must also be enrolled in a prospective national registry*




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

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

- A history of major bleeding while taking anticoagulation therapy
- The patient's prior experience with oral anticoagulation (if applicable)
- A medical condition, occupation, or lifestyle placing the patient at high risk of major bleeding secondary to trauma
- The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis

### 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. Please consult your program's legal counsel to agree on which physicians meet that criteria. Examples of specialists that may be suitable, pending your legal counsel approval are:

- Primary Care Provider
- Non-Interventional Cardiologist
- Neurologists or those who have experience caring for stroke patients

# OAC Evidence Based Decision

## 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 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

NICE
National Institute for Health and Care Excellence

nice.org.uk/guidance/ng196

CardioSmart
American College of Cardiology

cardiosmart.org/topics/atrial-fibrillation/preventing-stroke/choosing-blood-thinners-or-left-atrial-appendage-closure

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

acponline.org/practice-resources/patient-and-interprofessional-education

# Stroke and Bleed Risk Scoring Tools

## Calculate Your NVAF Patient's Stroke and Bleeding Risk

**$CHADS_2$ Score**

Use the $CHADS_2$ and $CHA_2DS_2VASc$ calculator to determine your patients AF stroke risk based on specific criteria

### $CHADS_2$ 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 |

# Stroke and Bleed Risk Scoring Tools

## Calculate Your NVAF Patient's Stroke and Bleeding Risk

**$CHA_2DS_2VASc$ Score**

Use the $CHADS_2$ and $CHA_2DS_2VASc$ calculator to determine your patients AF stroke risk based on specific criteria

### $CHA_2DS_2VASc$ 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 |
| V | Vascular disease (PAD,MI) | 1 |
| A | Age 65-74 years | 1 |
| $S_c$ | 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 |

# Stroke and Bleed Risk Scoring Tools

## Calculate Your NVAF Patient's Stroke and Bleeding Risk

**HAS-BLED Score**

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

### 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 Stroke Risk (%) |
|---|---|
| 0 | 1.13 |
| 1 | 1.02 |
| 2 | 1.88 |
| 3 | 3.74 |
| 4 | 8.7 |
| 5+ | Not well validated |

## Important Information

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 rendered.**

It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers which can be updated frequently. 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.

This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved. The Health Care Provider (HCP) is solely responsible for selecting the site of service and treatment modalities appropriate for the patient based on medically appropriate needs of that patient and the independent medical judgement of the HCP.



**WATCHMAN FLX Pro Brief Summary**
watchman.com/en-us-implanter/watchman-flx-pro-brief-summary.html

Boston Scientific
*Advancing science for life™*

**Interventional Cardiology**
300 Boston Scientific Way
Marlborough, MA 01752-1234
**www.bostonscientific.com**

*Medical Professionals:*
*1.800.CARDIAC (227.3422)*
*Patients and Families:*
*1.866.484.3268*



SH-433408-AB

WATCHMAN™
INTEGRATED LAAC SOLUTIONS

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