

## Patient Screening Form

PATIENT NAME \_\_\_\_\_ DOB \_\_\_\_\_

PHONE NUMBER \_\_\_\_\_ EMAIL \_\_\_\_\_

OAC REGIMEN \_\_\_\_\_ CHA<sub>2</sub>DS<sub>2</sub>-VASc \_\_\_\_\_ HAS-BLED \_\_\_\_\_

### Patient has Non-Valvular Atrial Fibrillation (NVAF) and:

- 1 Is at increased risk for stroke based on CHA<sub>2</sub>DS<sub>2</sub>-VASc scores and is recommended for anticoagulation therapy  
*See CHA<sub>2</sub>DS<sub>2</sub>-VASc table on back page*
- 2 Is suitable for short-term anticoagulation therapy\*
- 3 Has an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy  
*Note: Does not apply to patients who receive the WATCHMAN Implant concomitantly or sequentially with an AFib ablation† Coverage remains unchanged. Under the CMS NCD, the patient must be deemed unable to take long-term OAC and meet all criteria in NCD 20.34 to be eligible for coverage. Commercial payer coverage policy requirements will vary.*

### Patient meets any of the following example scenarios with documentation supporting medical necessity\*\*: (select all that apply)

#### Past Bleed:

- History of intracranial bleeding (intracerebral or subdural) where benefits of LAAC outweigh risks
- History of spontaneous bleeding other than intracranial (e.g. retroperitoneal bleeding)

#### Increased Risk of Stroke:

- Documented poor compliance with anticoagulant therapy after patient education
- Inability or significant difficulty with maintaining in therapeutic anticoagulation range with use of guidelines

Other situations for which anticoagulation is inappropriate.

#### Increased Risk of Future Bleed:

- Intolerance of warfarin and new oral anticoagulants (NOACs)
- High risk of recurrent falls
- Cognitive impairment
- Severe renal failure
- Occupation related high bleeding risk
- Need for prolonged dual antiplatelet therapy
- Increased bleeding risk not reflected by the HAS-BLED score (e.g. thrombocytopenia, cancer, or risk of tumor associated bleeding in case of systemic anticoagulation)

\*\*ACC, HRS and SCAI issued a consensus memorandum to CMS in 2015 recognizing these example scenarios that support alternatives to long-term OAC. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=281&bc=AAAAAAAAQAAA&%20>

### CHA<sub>2</sub>DS<sub>2</sub>-VASc Score (Stroke Risk)<sup>a</sup>

	Condition	Points
C	Congestive heart failure	1
H	Hypertension	1
A	Age ≥ 75 years	2
D	Diabetes mellitus	1
S <sub>2</sub>	Prior stroke, TIA, or thromboembolism	2
V	Vascular disease (PAD, MI)	1
A	Age 65-74 years	1
Sc	Sex category (Female)	1
<b>Total Points</b>		

Score	Yearly Stroke Risk (%)		
	No Warfarin	With Aspirin <sup>b</sup>	With Warfarin <sup>b</sup>
0	0	0	0
1	1.3	1.0	0.5
2	2.2	1.8	0.8
3	3.2	2.6	1.1
4	4.0	3.2	1.4
5	6.7	5.4	2.3
6	9.8	7.8	3.4

Elevated Risk = CHA<sub>2</sub>DS<sub>2</sub>-VASc ≥ 2 in men, ≥ 3 in women.

CMS coverage criteria requires a CHA<sub>2</sub>DS<sub>2</sub>-VASc score ≥ 3. Providers are encouraged to read the decision memo in its entirety for additional detail. Commercial Policies' medical criteria may vary.

### HAS-BLED Score (Bleeding Risk)<sup>c</sup>

	Condition	Points
H	Hypertension (SBP > 160)	1
A	Abnormal renal/liver function (1 pt each)	1 or 2
S	Stroke	1
B	Bleeding history or disposition	1
L	Labile INR	1
E	Elderly (e.g. age > 65 years)	1
D	Current drugs (medication) or alcohol use (1 pt each)	1 or 2
<b>Total Points</b>		

Score	Yearly Major Bleeding Risk (%)**
0	1.13
1	1.02
2	1.88
3	3.74
4	8.70
5+	12.5

Elevated risk = ≥ 3.

#### References

- a. CHA<sub>2</sub>DS<sub>2</sub>-VASc: *Chest*. 2010;137(2):263-272.
- b. Warfarin Stroke Reduction: *Ann Intern Med*. 2007;146:857-867.
- c. HAS-BLED: *Chest*. 2010;138(5):1093-1100.

<sup>\*</sup>Option for immediate DAPT-only post-implant drug regimen for standalone WATCHMAN procedures

<sup>†</sup>In the OPTION trial, sequential LAAC was a minimum of 90 days post AF ablation (as a protocol-driven blanking period) and less than 6 months post-AF ablation.

<sup>\*\*</sup>Major Bleed = ICH or bleeding resulting in a hospitalization, a hemoglobin drop > 2 g/dL, or a blood transfusion.

#### Formal Shared Decision Making

The patient must have a formal shared decision making interaction with an independent, non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAf prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record. THIS IS NOT A FORMAL SHARED DECISION MAKING DOCUMENT AND CANNOT BE USED FOR RECORDING THE SHARED DECISION MAKING INTERACTION.



**WATCHMAN FLX™ Pro LAAC Device Indications, Safety and Warnings**  
<https://www.watchman.com/en-us-hcp/watchman-flx-pro-brief-summary.html>