

Patient Screening and Referral Form

PATIENT NAME _____ DOB _____

PHONE NUMBER _____ EMAIL _____

OAC REGIMEN _____ CHA₂DS₂-VASc _____ HAS-BLED _____

Patient with Non-Valvular Atrial Fibrillation (NVAF) who:

- 1 Has an increased risk for stroke and is recommended for oral anticoagulation (OAC)
See table on back page.
- 2 Is suitable for OAC therapy for at least 45 days
DAPT-Only Post-Implant Drug Regimen Now Available
- 3 Has an appropriate rationale to seek a non-pharmacologic alternative to OACs

Patients with Non-Valvular Atrial Fibrillation (NVAF) who: (select all that apply)

Source: ACC, HRS, SCAI LAAC NCD Consensus Memo to CMS

Bleed Risk:

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

Future Bleed Risk:

- High risk of recurrent falls
- Cognitive impairment
- Severe renal failure
- 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)

Compliance:

- Documented poor compliance with anticoagulant therapy
- Inability or significant difficulty with maintaining therapeutic anticoagulation range

Drug Interactions:

- Intolerance of warfarin and NOACs
- Need for prolonged dual antiplatelet therapy
- Avoidance of triple therapy after PCI or TAVR

Lifestyle:

- Occupation related high bleeding risk
- Other situations for which anticoagulation is inappropriate

I recommend this patient for a WATCHMAN FLX Implant Consult. Do Not Substitute LAAC Device

HEALTHCARE PROVIDER _____ DATE _____

PHONE or EMAIL _____

NOTES _____

Post-Implant Drug Regimen Preference: Short-Term OAC DAPT-Only Either OAC or DAPT-Only

CHA₂DS₂-VASc Score (Stroke Risk)^a

	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 (%)		
	No Warfarin	With Aspirin ^b	With Warfarin ^b
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 = CHA₂DS₂-VASc ≥ 2 in men, ≥ 3 in women.

CMS coverage criteria requires a CHA₂DS₂-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)^c

	Condition	Points
H	Hypertension	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
Total Points		

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

- CHA₂DS₂-VASc: *Chest*. 2010;137(2):263-272.
- Warfarin Stroke Reduction: *Ann Intern Med*. 2007;146:857-867.
- HAS-BLED: *Chest*. 2010;138(5):1093-1100.

^{*}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.

Please visit watchman.com/hcp for complete warnings, precautions and instructions for use.