HEALTH ECONOMICS & REIMBURSEMENT

Shared Decision-Making Guide for Left Atrial Appendage Occlusion (LAAO) Using Amplatzer™ Amulet™ Left Atrial Appendage Occluder Device

Patient-centered shared decision-making occurs when a healthcare provider and a patient work together to assess treatment modalities and make the optimal decision tailored to the patient's treatment goals, lifestyle, and current health status. The Centers for Medicare & Medicaid Services emphasizes the criticality of this process while determining the eligibility for the Left Atrial Appendage Occlusion (LAAO) procedure.[1]

This document is a step-by-step guide that walks you through a shared decision-making process with patients who could be eligible for the LAAO procedure using the Amplatzer™ Amulet™ Left Atrial Appendage Occluder*.

Please note that the ultimate decision to determine the eligibility for LAAO procedure is at the discretion of the healthcare provider and patient. This guidance should not be considered a formal documentation of shared decision making; evidence of formal shared decision making must be documented in the patient's medical records.

Patients with Non-Valvular Atrial Fibrillation (NVAF) should meet **all - three criteria below** to be eligible for the LAAO procedure[1]:

	Criteria	Specifications	Met?
I	Suitable for short-term warfarin therapy **but deemed unable to take long-term oral anticoagulation (OAC) therapy**	Refer to Step 1 below to determine whether the patient is unable to take long-term OAC (lifestyle, bleeding risk, other complications) Step 3 (HAS-BLED score) could be utilized if eligibility is due to bleeding risk	☐
II	Patient's stroke risk: CHA_2DS_2-VASc **≥ 3** or $CHADS_2$ **≥ 2**	Refer to Step 2 below (patient's score should be documented to show the annual stroke risk)	☐
III	**Documented** evidence of formal interaction between the patient and an independent non-interventional physician using an OAC evidence-based decision tool.	Non-interventional cardiologists, primary care providers, and neurologists caring for stroke patients are examples of non-interventional physicians.	☐

Step 1. Assess current/prior oral anticoagulation (OAC) regimen, bleeding history, and lifestyle impacting OAC therapy.

Click and type the answer in the cell below the question.

- **Currently on OAC therapy? If yes, document the regimen details.**

- **If not on OAC therapy, document the date stopped and the reason why.**

- **Does the patient have an absolute contraindication, allergy, hypersensitivity, or intolerance to OAC medications or excipients?**

Bleeding risk:

Click and type the answer in the cell below the question.

- **History of bleeding while taking OAC (intracranial, retroperitoneal, and other spontaneous bleedings)? If yes, what was the cause and has it been treated?**

- **History of falls or dizziness while taking OAC?**

- **History of severe kidney or liver failure?**

- **A career or lifestyle that increases the risk of bleeding?**

- **Other medications that increase the risk of bleeding (i.e., antiplatelets, NSAIDs, glucocorticoids)?**

- **History of chronic alcohol abuse associated with binge drinking?**

Medication adherence and monitoring compliance:

Click and type the answer in the cell below the question.

- **History of poor adherence to oral anticoagulants (i.e., missed doses)?**

- **Inability to maintain stable INR?**

- **Inability to comply with regular INR monitoring and/or unavailability of an alternative OAC for the patient (include any medical or lifestyle-specific factors such as dementia or transportation access)?**

Step 2. Calculate and record the patient's CHA_2DS_2-VASc and $CHADS_2$ scores using the tables below.[2,5] $CHADS_2$ refers to the first 5 factors included in the table.[3,5]

Condition		CHA_2DS_2-VASc Possible Points	$CHADS_2$ Possible Points	Your Input (CHA_2DS_2-VASc)	Your Input ($CHADS_2$)
C	Congestive heart failure	1	1		
H	Hypertension (Resting BP > 140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment)	1	1		
A	Age ≥ 75 years	2	1		
D	Diabetes mellitus	1	1		
S	Prior stroke, TIA, or thromboembolism	2 (if any is present)	2		
V	History of vascular disease (PAD, MI, or aortic plaque)	1	N/A		N/A
A	Age 65-74 years	1	N/A		N/A
Sc	Sex Category (Female)	1 (0 for male)	N/A		N/A
Patient's Scores		Max score: 9	Max score: 6	0	0

Using the tables below, determine and document the annual stroke risk (Use **both** CHA_2DS_2-VASc and $CHADS_2$ scores).[3,5]

Click in the cell below to enter text.

CHA_2DS_2-VASc Score	Annual 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	12.5
9	15.2

$CHADS_2$ Score	Annual Stroke Risk (%)
0	1.9
1	2.8
2	4.0
3	5.9
4	8.5
5	12.5
6	18.2

Step 3. Calculate and record the patient's HAS-BLED score to determine the risk of major bleeding using the tables below.[4] The patient's eligibility reasons may or may not include the risk of major bleeding, however, discussing this risk is vital for shared decision-making.

Click in the cell below to enter text.

Condition		Possible Points	Your Input
H	Hypertension (Uncontrolled BP, >160 mmHg systolic, or current antihypertensive pharmacologic treatment)	1	
A	Abnormal renal (Dialysis, transplant, Cr >2.26 mg/dL or >200 µmol/L) **OR** Liver function (Cirrhosis or bilirubin >2x normal with AST/ALT/AP >3x normal)	1 point for each (max 2)	
S	Stroke history	1	
B	Bleeding history or predisposition to bleeding	1	
L	Labile INR (Unstable/high INRs, time in therapeutic range <60%)	1	
E	Elderly (age > 65 years)	1	
D	Current drugs (e.g. Aspirin, clopidogrel, NSAIDs) **OR** Alcohol use (1 point for drug and 1 point for alcohol use ≥8 drinks/week)	1 point for each (max 2)	
Patient's HAS-BLED Score		Max score: 9	0

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

Rx Only

Important Safety Information

AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

Indication for Use
The Amplatzer™ Amulet™ Left Atrial Appendage Occluder is a percutaneous transcatheter device intended to reduce the risk of thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation and who are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores, are suitable for short term anticoagulation therapy, and have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.

Contraindications
The Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder is contraindicated for patients:
- With the presence of intracardiac thrombus.
- With active endocarditis or other infections producing bacteremia.
- Where placement of the device would interfere with any intracardiac or intravascular structures.

Potential Adverse Events
Potential adverse events associated with the device or implant procedure include, but are not limited to, the following: Air embolism; Airway trauma; Allergic reaction; Anemia; Anesthesia reaction (nausea, vasovagal reaction, confusion/altered mental status or other); Arrhythmia; Atrial septal defect; Bleeding; Cardiac arrest; Cardiac tamponade; Chest pain/discomfort; Congestive heart failure; Death; Device embolization; Device erosion; Device malfunction; Device malposition; Device migration; Device-related thrombus; Fever; Hematuria; Hypertension/hypotension; Infection; Multi-organ failure; Myocardial infarction; Perforation; Pericardial effusion; Pleural effusion; Renal failure/dysfunction; Respiratory failure; Seizure; Significant residual flow; Stroke; Thrombocytopenia; Thromboembolism: peripheral and pulmonary; Thrombus formation; Transient ischemic attack; Valvular regurgitation/insufficiency; Vascular access site injury (hematoma, pseudoaneurysm, arteriovenous fistula, groin pain or other); Vessel trauma/injury.

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