

Department of Origin: Integrated Healthcare Services	Effective Date: 01/01/22
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 12/07/21
Clinical Policy Document: Cardiac Devices & Procedures for Occlusion of Left Atrial Appendage	Replaces Effective Clinical Policy Dated: 12/07/21
Reference #: MC/A008	Page: 1 of 4

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria – Requests for left atrial appendage closure (LAAC) when the device has received U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication (eg, Watchman and Amplatzer Amulet device) - Must satisfy all of the following: I and II

- I. Member has nonvalvular atrial fibrillation (NVAf); and
- II. Member has all of the following: A - C
 - A. Is at high-risk for developing an embolic stroke as evidenced by either of the following:
 1. *CHADS₂* score equal to or greater than 2 (congestive heart failure, hypertension, age >75, diabetes, stroke/transient ischemia attack/thromboembolism); or
 2. *CHA₂DS₂-VAsC* score equal to or greater than 3 (congestive heart failure, hypertension, age ≥ 65, diabetes, stroke/transient ischemia attack/thromboembolism, vascular disease, sex category).
 - B. There is documentation of a formal shared decision making discussion with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in persons with NVAf prior to LAAC; and
 - C. Anticoagulation status - must satisfy the following: 1 – 2
 1. Is able to take short-term warfarin and long-term aspirin; and
 2. Is unable to take long term oral anticoagulation - must satisfy any of the following: a - c
 - a. Has a history of any of the following while on an oral anticoagulant despite INR in a therapeutic range – as evidenced by either of the following: 1) – 2)
 - 1) Experienced a thromboembolism; or
 - 2) Had a major bleed (intracranial bleed, significant gastrointestinal bleeding (not just guaiac positive stools).
 - b. Has an elevated risk of bleeding on oral anticoagulant with a *HAS-BLED* score equal to or greater than 3; or
 - c. Has other absolute contraindication(s) to long-term anticoagulation.



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NOT ROUTINELY COVERED:

Combination of transcatheter aortic valve implantation (TAVI) and left atrial appendage occlusion procedure

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:

CHADS₂:

Estimates stroke risk in patients with atrial fibrillation. Each letter in the name represents something that may increase the chances of having a stroke. For each one that applies, add 1 or 2 points:

C: Congestive heart failure (when your heart can't pump blood the way it should). If you have this, it counts for 1 point.

H: High blood pressure. If present, add a point.

A: Age. Are you 75 years old or older? If so, add a point.

D: Diabetes. If present, add a point

S: Stroke. History of stroke or a transient ischemic attack (TIA), add 2 points.

Score will be between 0 and 6 points:

Zero: Low risk for a stroke.

One point: Medium risk of stroke.

Two or more points: Medium to high risk of stroke.

CHA₂DS₂-VASc:

Estimates stroke risk in patients with atrial fibrillation. Includes CHADS₂ elements plus 3 additional measures.

V: Vascular disease (a problem with your blood vessels). If present, add a point.

A: Age. Are you 65 to 74 years old? If so, add a point.

Sc: Sex category If you're a woman, add 1 point.

The total of these plus the CHADS₂ score can be up to 9 points. The results scale is the same as for CHADS₂.

<https://www.webmd.com/heart-disease/atrial-fibrillation/chads-score-overview>

HAS-BLED Score:

Estimates bleeding risk based on the following

- Hypertension (1 point)
- Abnormal liver function (1 point)
- Abnormal renal function (1 point)
- Stroke (1 point)
- Bleeding tendency or predisposition (1 point)
- Labile INRs in patients taking warfarin (1 point)
- Elderly: age greater than 65 years (1 point)
- Drugs: concomitant antiplatelet agent(s) or NSAIDs (1 point)
- Drugs: alcohol abuse (1 point)



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HAS-BLED Score Interpretation:

0 points:	1.13 bleeds per 100 patient-years
1 point:	1.02 bleeds per 100 patient-years
2 points:	1.88 bleeds per 100 patient-years
3 points:	3.74 bleeds per 100 patient-years
4 points:	8.70 bleeds per 100 patient-years
5 to 9 points:	Insufficient data (high risk)

<https://www.merckmanuals.com/medical-calculators/HASBLED.htm>

BACKGROUND:

Atrial fibrillation (AF) is one of the most common cardiac arrhythmias and a leading cause of stroke. Individuals with AF have a higher risk for stroke due to the possibility of thrombus (blood clot) formation in coronary arteries. The left atrial appendage (LAA) of the heart was previously considered to have little purpose or activity; however, due to the shape of the appendage and lack of blood flow in the area, it is believed that thrombi could develop in certain individuals. While current standard treatment for non-valvular AF focuses on anticoagulation; it is suggested that closure by exclusion or occlusion of the LAA may reduce the risk for embolic stroke from atrial thrombi. Exclusion of the LAA may be performed at the same time as another open cardiac surgical procedure.

Stroke is one of the leading causes of death and disability in developed countries. Atrial fibrillation (AF), one of the most common cardiac arrhythmias, is a well-known predisposing factor for stroke, raising the risk significantly. Patients with AF have a 5-fold increased risk for stroke due to the possibility of thrombus (blood clot) formation in coronary arteries. The left atrial appendage (LAA) of the heart was previously considered to have little purpose or activity; however, due to the shape of the appendage and lack of blood flow in the area, it is believed that thrombi could develop in certain individuals. While current standard treatment for non-valvular AF focuses on anticoagulation; it is suggested that closure by exclusion or occlusion of the LAA may reduce the risk for embolic stroke from atrial thrombi.



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Prior Authorization: Yes, per network provider agreement

CODING:

CPT® or HCPCS

33267 Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

33268 Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)

33269 Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

33340 Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transeptal puncture, catheter placement(s), left angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

C1760 Closure device, vascular (implantable/insertable)

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REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. American College of Cardiology. 2019 AHA/ACC/HRS Focused Update of the 2014 Guideline for Management of Patients with Atrial Fibrillation. *JACC*. 2019;74(1). Retrieved from: <https://www.acc.org/Guidelines#/doctype=Guidelines>. Accessed 08-26-21.
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5. Comparative Effectiveness Review of Percutaneous Left Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation. Feb 13, 2018. Annual Review Apr 30, 2021. Hayes, Inc. Retrieved from: <https://evidence.hayesinc.com/report/dir.percutaneous2367>. Accessed 08-26-21.
6. Piayda K, Hellhammer K, Nielsen-Kudsk JE, et al. Clinical outcomes of patients undergoing percutaneous left atrial appendage occlusion in general anaesthesia or conscious sedation: data from the prospective global Amplatzer Amulet Occluder Observational Study. (2021). *BMJ Open*. 2021 Mar 24;11(3):e040455. Retrieved from: <https://pubmed.ncbi.nlm.nih.gov/33762228/>. Accessed 09-10-21.
7. Freiza X, Schmidt B, Mazzone P, et al. Comparative data on left atrial appendage occlusion efficacy and clinical outcomes by age group in the Amplatzer™ Amulet™ Occluder Observational Study. (2021). *Europace* 2021 Feb 5;23(2):238-246. Retrieved from: <https://pubmed.ncbi.nlm.nih.gov/33279979/>. Accessed 09-10-21.

DOCUMENT HISTORY:

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Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

We will:

- Provide free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provide free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية 1.866.631.5404 (رقم هاتف الصم والبك : 1.866.631.8597) متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف
Arabic

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.866.631.5404 (ATS : 1.866.631.8597).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 1.866.631.8597).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1-800-332-650 (TTY: 1.866.631.8597) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 1.866.631.8597) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 1.866.631.8597).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 1.866.631.8597).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 1.866.631.8597).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 1.866.631.8597).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY : 1.866.631.8597)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 1.866.631.8597).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 1.866.631.8597).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທສ 1.866.631.5404 (TTY: 1.866.631.8597).