



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 01/03/23
LAST REVIEW DATE: 10/01/24
CURRENT EFFECTIVE DATE: 10/01/24
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025

SURGICAL LEFT ATRIAL APPENDAGE OCCLUSION DEVICES FOR STROKE PREVENTION IN ATRIAL FIBRILLATION

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia. Stroke associated with AF is primarily embolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment.

Treatment with anticoagulant medications is a first-line approach to stroke prevention in individuals with AF, although occlusion of the left atrial appendage (LAA) may offer a non-pharmacological alternative to anticoagulant medications for those with a contraindication or intolerance to long-term anticoagulant use or with poor anticoagulant adherence.

Multiple surgical techniques may be used to excise or occlude the LAA. One device, the AtriClip Left Atrial Appendage Exclusion System, has approval from the U.S. Food and Drug Administration for surgical LAA occlusion for stroke prevention in patients with AF. Surgical occlusion of the LAA with AtriClip may be a treatment option for those with contraindications or intolerance to anticoagulants, or in those with poor anticoagulant adherence. Surgical LAA occlusion methods other than the AtriClip device include epicardial stapling and excision and suture closure.

Criteria:

- Surgical left atrial appendage occlusion devices, for the treatment of stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

These devices include, *but are not limited to*:

- AtriClip device

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➤ Surgical left atrial appendage occlusion devices for the treatment of stroke prevention as a stand-alone procedure are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:

1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
3. Insufficient evidence to support improvement of the net health outcome; or
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
5. Insufficient evidence to support improvement outside the investigational setting

These devices include, *but are not limited to*:

- AtriClip device

Resources:

Literature reviewed 10/01/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 10/03/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Abrich VA, Narichania AD, Love WT, Lanza LA, Shen WK, Sorajja D. Left atrial appendage exclusion during mitral valve surgery and stroke in atrial fibrillation. *J Interv Card Electrophysiol*. Dec 2018;53(3):285-292. doi:10.1007/s10840-018-0458-4
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3. Aryana A, Singh SK, Singh SM, et al. Association between incomplete surgical ligation of left atrial appendage and stroke and systemic embolization. *Heart Rhythm*. Jul 2015;12(7):1431-7. doi:10.1016/j.hrthm.2015.03.028
4. AtriClip Left Atrial Appendage Exclusion Concomitant to Structural Heart Procedures (ATLAS). Accessed June 14, 2024. <https://clinicaltrials.gov/ct2/show/NCT02701062>
5. AtriCure. AtriClip LAA Exclusion System. Accessed June 14, 2024. <https://www.atricure.com/healthcare-professionals/therapies/LAAM/atriclip-exclusion-system>

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9. Caliskan E, Sahin A, Yilmaz M, et al. Epicardial left atrial appendage AtriClip occlusion reduces the incidence of stroke in patients with atrial fibrillation undergoing cardiac surgery. *Europace.* Jul 1 2018;20(7):e105-e114. doi:10.1093/europace/eux211
10. Cartledge R, Suwalski G, Witkowska A, et al. Standalone epicardial left atrial appendage exclusion for thromboembolism prevention in atrial fibrillation. *Interact Cardiovasc Thorac Surg.* Mar 31 2022;34(4):548-555. doi:10.1093/icvts/ivab334
11. Collado FMS, Lama von Buchwald CM, Anderson CK, et al. Left Atrial Appendage Occlusion for Stroke Prevention in Nonvalvular Atrial Fibrillation. *J Am Heart Assoc.* Nov 2 2021;10(21):e022274. doi:10.1161/JAHA.121.022274
12. Dewland TA, Olgin JE, Vittinghoff E, Marcus GM. Incident atrial fibrillation among Asians, Hispanics, blacks, and whites. *Circulation.* Dec 3 2013;128(23):2470-7. doi:10.1161/CIRCULATIONAHA.113.002449
13. Franciulli M, De Martino G, Librera M, et al. Stand-Alone Thoracoscopic Left Atrial Appendage Closure in Nonvalvular Atrial Fibrillation Patients at High Bleeding Risk. *Innovations (Phila).* Nov/Dec 2020;15(6):541-546. doi:10.1177/1556984520960116
14. Friedman DJ, Piccini JP, Wang T, et al. Association Between Left Atrial Appendage Occlusion and Readmission for Thromboembolism Among Patients With Atrial Fibrillation Undergoing Concomitant Cardiac Surgery. *JAMA.* Jan 23 2018;319(4):365-374. doi:10.1001/jama.2017.20125
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16. Gardener H, Sacco RL, Rundek T, Battistella V, Cheung YK, Elkind MSV. Race and Ethnic Disparities in Stroke Incidence in the Northern Manhattan Study. *Stroke.* Apr 2020;51(4):1064-1069. doi:10.1161/STROKEAHA.119.028806

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23. Kewcharoen J, Shah K, Bhardwaj R, et al. Surgical left atrial appendage occlusion in patients with left ventricular assist device. *Pacing Clin Electrophysiol*. Apr 2022;45(4):567-570. doi:10.1111/pace.14471
24. Kurfirst V, Mokracek A, Canadyova J, Bulava A, Pesl L. Effectivity of Left Atrial Appendage Occlusion with AtriClip in 155 Consecutive Patients - Single Center Study. *Cor et Vasa*. Aug 2017;59(4):e376-e380.
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39. Wyler von Ballmoos MC, Hui DS, Mehaffey JH, et al. The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation. *Ann Thorac Surg*. Aug 2024;118(2):291-310. doi:10.1016/j.athoracsur.2024.01.007



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40. Yao X, Gersh BJ, Holmes DR, Jr., et al. Association of Surgical Left Atrial Appendage Occlusion With Subsequent Stroke and Mortality Among Patients Undergoing Cardiac Surgery. *JAMA*. May 22 2018;319(20):2116-2126. doi:10.1001/jama.2018.6024

Coding:

CPT: 33267, 33268, 33269

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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	10/01/24	Review with revisions
Medical Policy Panel	10/03/23	Review with no revisions
Medical Policy Panel	01/03/23	Approved guideline
Medical Director (Dr. Deering)	11/13/22	Development

Policy Revisions:

10/01/24 Updated: Resources section



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has 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: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights 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, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید].

Assyrian: . . . Blue Cross Blue Shield of Arizona . . . 877-475-4799 . . .

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคน หรือคนทอดกลางช่วยเหลื่อมคาถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คนสมททหจะไตรบความช่วยเหลอและขอมลในภาษา ของคนใดโดยไมมคาไขจาย พตคยภมลาม โทร 877-475-4799