7.01.172	Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation		
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Section:	7.0 Surgery	**Page:**	Page 1 of 20

Policy Statement

I. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures is considered **investigational**.

II. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
See the Codes table for details.

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.

Related Policies

- Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In June 2010, the AtriClip LAA Exclusion System (Atricure) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K093679). The FDA determined that this device was substantially equivalent to existing devices for occlusion of the LAA. The AtriClip has gone through numerous iterations since 2010, primarily relating to changes in the clip material composition and refinements of the clip applicator. The current FDA-cleared indication is unchanged from the original 2010 indication, which states that the AtriClip is indicated for "exclusion of the LAA, performed under direct visualization, in conjunction with other cardiac surgical procedures."[11] The FDA clearance documentation notes that direct visualization "requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc. or other appropriate viewing technologies." As of 2022, AtriCure markets 7 different versions of the AtriClip device, whose use varies according to LAA size and type of concomitant surgical procedure.[12]

Rationale

Background

Atrial Fibrillation

Nonvalvular atrial fibrillation (AF) is the most common type of cardiac arrhythmia, affecting at least 2.7 million people in the United States. The risk of AF has been found to be lower in Black, Hispanic, and Asian patients relative to White patients, following adjustment for demographic and AF risk factors.[1,2] AF is typically described according to frequency and duration and includes paroxysmal (duration up to 1 week), persistent (>1 week), long-term persistent (>1 year), or permanent (normal sinus rhythm cannot be restored despite treatment).[3] Stroke is the most serious complication of AF. The estimated incidence of stroke in non-treated patients with AF is 5% per year. Despite a lower risk of AF, Black and Hispanic patients have an increased risk of stroke compared with White patients.[4,5] Although this paradox may be partially attributable to clinical factors (e.g., congestive heart failure, hypertension, type 2 diabetes), Black and Hispanic patients with AF are less likely than White patients to receive stroke prevention therapy.[6] Stroke associated with AF is primarily thromboembolic, 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.

Stroke Prevention

The risk for stroke among patients with AF is evaluated using several factors. Two commonly used scores, the $CHADS_2$ score and the CHA_2DS_2-VASc score are described in Table 1:

Table 1. $CHADS_2$ and CHA_2DS_2-VASc Scores to Predict Ischemic Stroke Risk in Patients with Atrial Fibrillation

Letter	Clinical Characteristics	Points Awarded
C	Congestive heart failure (signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction)	1
H	Hypertension (resting blood pressure >140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment)	1
A	Age ≥75 y	1 ($CHADS_2$) 2 (CHA_2DS_2-VASc)
D	Diabetes (fasting glucose >125 mg/dL or treatment with oral hypoglycemic agent and/or insulin)	1
S	Stroke or transient ischemic attack (includes any history of cerebral ischemia)	2
V	Vascular disease (prior myocardial infarction, peripheral arterial disease, or aortic plaque)	1
A	Age 65-74 y	1
Sc	Sex category of female (female sex confers higher risk)	1

Adapted from Lip et al (2018)[7] and January et al (2014)[8]

Stroke in AF occurs primarily as a result of thromboemboli from the left atrium. The erratic atrial contractions in AF lead to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The first-line treatment for stroke prevention in AF is long-term anticoagulation, which has proven efficacy.[9] Warfarin, a vitamin K antagonist, is the predominant agent in clinical use. Several newer direct oral anticoagulant (DOAC) agents, including dabigatran, rivaroxaban apixaban, and edoxaban, have received U.S. Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. Warfarin requires frequent monitoring and adjustments as well as lifestyle changes; DOACs do not require the frequent monitoring seen with warfarin therapy. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Reversal agents can be used to counter the effects of life-threatening bleeding in individuals using warfarin or DOAC therapy. Such agents carry their own risk of inducing life-threatening thrombosis. For individuals with AF who have a contraindication to warfarin and DOACs, dual antiplatelet therapy with aspirin and clopidogrel is an option for stroke prevention, though it is less protective than either warfarin or DOACs.

The area of the left atrium with the lowest blood flow in AF, and therefore the highest risk of thrombosis, is the left atrial appendage (LAA). The LAA is a small extension of the left atrium that can vary widely in both size and shape (morphology). LAA morphologies are described according to their appearance and include: the chicken wing, which is the most common morphology and features a prominent bend in the dominant lobe; the cactus, characterized by a dominant central lobe with superior and inferior secondary lobes; the windsock, which features one dominant lobe; and the cauliflower, which is the least common morphology and features numerous lobes with none being dominant. It has been estimated that over 90% of left atrial thrombi occur in the LAA. Surgical removal or exclusion of the LAA is often performed in patients with AF who are undergoing open heart surgery. Surgical techniques to exclude the LAA include resection or occlusion through stapling or clipping.[9,10]

Percutaneous LAA occlusion is discussed in policy 2.02.26.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these

groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Surgical Left Atrial Appendage Occlusion with the AtriClip Device Concomitant with an Open or Thoracoscopic Cardiac Procedure

Clinical Context and Therapy Purpose

The purpose of surgical left atrial appendage (LAA) occlusion with the AtriClip device in patients with atrial fibrillation (AF) at risk for embolic stroke is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Use of anticoagulants is the first-line therapy for the reduction of the risk of stroke in individuals 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.

The following PICO was used to select literature to inform this review.

Populations

The relevant population(s) of interest are individuals with AF at increased risk for embolic stroke undergoing LAA occlusion concomitant with open or thoracoscopic cardiac surgical procedures.

Interventions

The therapy being considered is surgical LAA occlusion with the AtriClip device.

The efficacy of surgical LAA occlusion performed in conjunction with other cardiac procedures has been assessed in several systematic reviews and a large (N>10,000) observational study, which have generally found surgical LAA occlusion to be associated with a reduction in the risk of stroke or systemic embolism without an increased risk of post-procedural complications.[13,14,15,16,] This review focuses on surgical LAA occlusion with AtriClip. This review does not consider the net health benefit of surgical LAA occlusion in general, nor does it address the net health benefit of surgical LAA occlusion techniques other than AtriClip placement.

Comparators

The following therapies are currently being used for the prevention of stroke in individuals with AF at increased risk for embolic stroke: anticoagulation therapy, other surgical LAA occlusion methods, and no occlusion.

Warfarin is the predominant anticoagulant agent in clinical use. Several newer anticoagulant medications, including dabigatran, rivaroxaban apixaban, and edoxaban have received U.S. Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. Warfarin requires frequent monitoring and adjustments as well as lifestyle changes; direct oral anticoagulants (DOACs) do not require the frequent monitoring seen with warfarin therapy. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Reversal agents can be used to counter the effects of life-threatening bleeding in individuals using warfarin or DOAC therapy. Such agents carry their own risk of inducing life-threatening thrombosis.

Surgical LAA occlusion methods other than the AtriClip device include epicardial stapling and excision and suture closure.

Outcomes

The general outcomes of interest are overall survival, morbid events, and treatment-related morbidity. The primary outcome of interest is the rate of ischemic stroke during follow-up, along with rates of systemic embolization, cardiac events, and mortality. Surgical success, defined as complete

LAA occlusion, is not a direct health outcome, although evidence on surgical success is reported here as incomplete LAA occlusion, which may be associated with an increased risk of stroke.[17,]

Follow-up of 6 to 12 months or longer is required to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

A number of studies were excluded from this evidence review because they did not specifically assess surgical LAA occlusion with the Atriclip device.[18,19,16,20,21,22,23,24,25,26,]

Systematic Reviews

Toale et al (2019)[27,] conducted a systematic review assessing outcomes of LAA occlusion using the AtriClip device in individuals with AF either as a concomitant or stand-alone procedure. The review included 11 uncontrolled cohort studies and case series with a total population of 922 individuals (n ranged from 5 to 291; median n=40). Follow-up among the included studies ranged from time of hospital discharge to 4 years (median 1 year). Results from the largest studies (N>100) with the longest duration (>1 year) are discussed below (see Case Series section). The review found a surgical success rate of 97.8% (902/922) based on varying methods of assessing occlusion completion. When stratified according to surgical approach, success rates were slightly lower for AtriClip placement via a thoracoscopic approach (4 studies; 95.3%) than for an open approach (7 studies; 99.2%). This difference was statistically significant (p=.0002). At least one of the thoracoscopic studies[28,] attributed their lower success rate to a learning curve associated with AtriClip placement (see Case Series, below). Within the 30-day postoperative period, 20 individuals underwent surgical revision due to bleeding, 4 had a postoperative ischemic stroke and there were 29 deaths. In follow-up greater than 6 months, there were 5 cases of ischemic stroke, and 42 deaths. Among 798 individuals with data, 477 (60%) had discontinued anticoagulant use.

Randomized Controlled Trials

Whitlock et al (2021)[29,] reported the results of The Left Atrial Appendage Occlusion Study (LAAOS) III that randomized 4,811 individuals to LAA occlusion or no occlusion scheduled to undergo cardiac surgery (Table 2). Following post-randomization exclusions prior to surgery, 2,379 individuals were included in the occlusion group and 2,411 were included in the no occlusion group (N=4,770). Demographic and clinical characteristics for the intervention and control groups were similar at baseline. Indications for cardiac surgery included isolated coronary artery bypass graft (CABG; 21%), isolated valve replacement (23%), or other cardiac surgical procedures (55%). Thirty-three percent of the enrolled population underwent surgical ablation for AF. Data on occlusion method were reported for 71% (1,685/2,379) of those randomized to the occlusion group. Occlusion method was selected by the treating surgeon. Among those with data regarding the occlusion method, 15% underwent LAA occlusion with an epicardial closure device (e.g., AtriClip). The primary outcome was the incidence of ischemic stroke or systemic arterial embolism. The results of the trial are summarized in Table 3. At a mean 3.8 years follow-up, occlusion was associated with a significant reduction in risk of the primary outcome when compared with no occlusion, without an increased risk of post-procedural bleeding or

mortality. Occlusion appeared to result in greater risk reduction among those using either DOAC (hazard ratio [HR], 0.54; 95% CI, 0.34 to 0.86) or vitamin K antagonist therapy (HR, 0.62; 95% CI, 0.39 to 1.00) at baseline than in those not on anticoagulant therapy (HR, 0.79; 95% CI, 0.56 to 1.12). Anticoagulant use was 83% in the occlusion group and 81% in the no occlusion group at the time of hospital discharge, and the majority of study participants in both groups continued to use anticoagulants at 1- (80% and 79%), 2- (77% and 78%), and 3-year follow-up (75% and 78%). There was no subgroup analysis by occlusion method. Reporting of harms after the perioperative period was limited, but the risk of a major bleeding event (HR, 0.93; 95% CI, 0.78 to 1.11), hospitalization for heart failure (HR, 1.13; 95% CI, 0.92 to 1.40), and myocardial infarction (HR, 0.82; 95% CI, 0.57 to 1.18) were similar between occlusion and no occlusion groups.

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Surgical LAA Occlusion	No Surgical LAA Occlusion
Whitlock et al (2021)[29], LAAOS III	Multinational (27 countries in Asia, Australia, Europe, North America or South America)	105	2012-2018	Adults with a history of AF scheduled to undergo cardiac surgery with cardiopulmonary bypass and CHA_2-DS_2-VASc score ≥2 • Mean age 72 years • 33% female • Race/ethnicity NR • Mean CHA_2-DS_2-VASc score 4.2 • 29% DOAC use; 23% vitamin K antagonist use • 33% concomitant surgical ablation for AF	n=2,379 (15.1% epicardial clip [255/1685])[a]	n=2,391

AF: atrial fibrillation; DOAC: direct-acting oral anticoagulant; LAA: left atrial appendage; NR: not reported; RCT: randomized controlled trial.
[a] Data on occlusion method were reported for 1,685 (of 2,379) study participants

Table 3. Summary of Key RCT Results

Study	Ischemic Stroke or Systemic Arterial Embolism	Any Stroke	All-cause Mortality	Post-procedural Bleeding Requiring Reoperation[a]	Post-procedural Mortality (≤30 days)
Whitlock et al (2021)[29],LAAOS III	N=4,770	N=4,770	N=4,770	N=4,770	N=4,770
Occlusion	114/2379 (4.8%)	113/2379 (4.7%)	538/2379 (22.6%)	94/2379 (4.0%)	89/2379 (3.7%)
No occlusion	168/2391 (7.0%)	176/2391 (7.4%)	537/2391 (22.5%)	95/2391 (4.0%)	95/2391 (4.0%)

Study	Ischemic Stroke or Systemic Arterial Embolism	Any Stroke	All-cause Mortality	Post-procedural Bleeding Requiring Reoperation[a]	Post-procedural Mortality (≤30 days)
HR/Diff/RR (95% CI)	HR 0.67 (0.53 to 0.85)	HR 0.63 (0.50 to 0.80)	HR 1.00 (0.89 to 1.13)	RR 0.99 (0.75 to 1.32)	RR 0.94 (0.71 to 1.25)

CI: confidence interval; HR: hazard ratio; RCT: randomized controlled trial; RR: relative risk.
[a] Reoperation within 48 hours of initial surgery

Study relevance and design and conduct limitations are summarized in Tables 4 and 5. The purpose of the study limitations tables is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

The LAAOS III trial had some other important limitations not captured in Tables 4 and 5. Only 15% underwent LAA occlusion with an epicardial closure device (e.g., AtriClip). No subgroup analysis was conducted according to occlusion method. According to the study's authors, this was due to the lack of randomization for occlusion method. Consequently, the study authors noted "we cannot discern from our results whether all surgical closure methods are comparable" and no conclusions about the effectiveness of AtriClip placement relative to other occlusion methods can be drawn from the trial. In addition, due to the lack of an anticoagulant control group, no conclusions can be drawn from the trial about the comparative effectiveness of AtriClip versus first-line therapy (anticoagulants). The fact that 75% or more of study participants were still using anticoagulants up to 3 years following LAA occlusion also limits the applicability of the study results for those individuals with AF and a contraindication to anticoagulant use.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Whitlock et al (2021)[29], LAAOS III	5. Race/ethnicity not reported	2. No stratified analysis according to occlusion method			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Whitlock et al (2021)[29], LAAOS III						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

The AtriClip® Left Atrial Appendage Exclusion Concomitant to Structural Heart Procedures (ATLAS) RCT compared the AtriClip device (n=376) with medical management (standard of care anticoagulant therapy; n=186) in individuals undergoing a valve or CABG procedure.[30,] The study population did not have a history of AF, but had CHA_2DS_2-VASc of 2 or more (mean score, 3.4). The study completion date was June 2019. Full study results have not been published, but some 1 year results have been reported on ClinicalTrials.gov. Rates of postoperative AF were similar between AtriClip (47.3%) and medical management (40.3%) groups. Rates were also similar between groups (8.5% vs. 8.6%) for a composite outcome that included thromboembolic and hemorrhagic events (e.g., ischemic or hemorrhagic stroke, transient ischemic attack [TIA], peripheral ischemia, bleeding event). The rate of all-cause mortality in the AtriClip group (5.32%) was more than double that in the medical management group (2.15%). Full publication of these results would provide direct evidence on the effectiveness of AtriClip versus standard of care management with anticoagulation therapy.

Nonrandomized Studies

A retrospective database study conducted by Soltesz et al (2021)[31,] compared outcomes in 931 Medicare patients who underwent concomitant CABG and LAA occlusion with AtriClip with 3,279 patients who underwent CABG only without AtriClip placement (Table 6). The study was funded by the AtriClip manufacuter and was designed to assess both health outcomes and resource utilization. Anticoagulant use was not reported and it is unclear if baseline use was similar between the 2 groups. Surgical LAA occlusion with AtriClip was associated with a lower risk of thromboembolism, and a nonsignificant reduction in risk of ischemic stroke. There was no difference between AtriClip occlusion and no occlusion groups in post-surgical mortality (≤90 days), but LAA occlusion with AtriClip was associated with a lower risk of death at 90 days or more post-surgery (Table 7).

Table 6. Summary of Key Observational Comparative Studies

Study	Study Type	Country	Dates	Participants	Surgical LAA Occlusion	No Surgical LAA Occlusion	Follow-Up
Soltesz et al (2021)[31,]	Registry	U.S.	2015-2017	N=4,210 Individuals age ≥65 years included in a Medicare database with AF who underwent concomitant isolated CABG (without ablation) • Mean age 74 years • 26% female • Mean CHA_2-DS_2-VASc score 3.6	n=931 Surgical LAA occlusion with the AtriClip device	n=3,279	2 years

AF: atrial fibrillation; CABG: coronary artery bypass graft; LAA: left atrial appendage.

Table 7. Summary of Key Observational Comparative Study Results

Study	Ischemic Stroke[a]	Thromboembolism[a]	Mortality, 0-90 Days	Mortality, 91-730 Days[a]
Soltesz et al (2021)[31,]	N=4,210	N=4,210	N=4,210	N=4,210
Surgical LAA occlusion with AtriClip	2.3%	4.4%	NR	3.7%
No surgical LAA occlusion	3.1%	5.9%	NR	6.9%
HR (95% CI)	sHR 0.74 (0.49 to 1.11)	sHR 0.74 (0.54 to 1.00)	HR 1.05 (0.79 to 1.40)	HR 0.55 (0.32 to 0.95)

CI: confidence interval; HR: hazard ratio; NR: not reported; sHR: subhazard ratio
[a] Proportions represent annual risk, not absolute event rates

Case Series

As noted above, the 2019 Toale et al[27,] systematic review included 11 uncontrolled cohort studies or case series of AtriClip placement either as a concomitant or stand-alone procedure. Of the 11 studies in the review, 2 studies[32,33,] included more than 100 individuals who had AtriClip placement concomitant to cardiac surgery with follow-up of a year or more (Table 8). Both studies found AtriClip placement associated with successful occlusion rates of 98% or greater and stroke rates of 1% or fewer in the postoperative period and 2% or fewer in the long-term follow-up (Table 9). Kurfirst et al (2017)[33,] attributed their less than 100% success rate to a learning curve associated with AtriClip placement; 2 of the 3 failures were among the first 10 cases receiving AtriClip placement. An additional case series published by Heijden et al (2022) was identified, which included 119 individuals with AF treated by minimally invasive thoracoscopic epicardial ablation; the majority of patients were occluded with Atriclip (n=103; 90%), but the remaining patients were occluded with a different device (Lariat, Watchman, or stapler) or were not occluded due to complications.[34,] No stroke or mortality occurred post-operatively or through 2 years of follow-up (Table 9).

Table 8. Summary of Key Case Series Characteristics

Study	Country	Participants	Follow-Up
Caliskan et al (2018)[32,]	U.S., Switzerland, Germany	N=291 Individuals with AF undergoing cardiac surgery • Mean age 71 years • 32% female • Mean CHA_2-DS_2-VASc score 3.1 • 67% DOAC use • 20% isolated CABG; 22% combined CABG and valve procedure; 42% single or multiple valve procedures • 67% surgical ablation	3 years
Kurfirst et al (2017)[33,]	Czech Republic	N=155[a] • Mean age 67 years • 34% female • Mean CHA_2-DS_2-VASc score 2.7 • Anticoagulant use NR • 25% valve procedure; 21% CABG; 4% combined procedure • 46% thoracoscopic ablation	2 years
Heijden et al (2022)[34,]	The Netherlands, Belgium	N=119[b] • Mean age 64 years • 28% female • Mean CHA_2-DS_2-VASc score 2 • Anticoagulant use NR • unilateral left-sided, minimally invasive bilateral thoracoscopic epicardial ablation; 100%	2 years

AF: atrial fibrillation; CABG: coronary artery bypass graft; DOAC: direct-acting oral anticoagulants; NR: not reported.
[a] 4.5% (7/155) underwent AtriClip placement as a stand-alone procedure
[b] A minority of the patients (10%) utilized an occlusion device other than Atriclip. These devices included: Lariat (n=4), stapler (n=2), Watchman device (n=6) and no closure due to complications (n=5).

Table 9. Summary of Key Case Series Results

Study	Successful Occlusion	Continued Anticoagulant Use	Stroke	Mortality	Post-procedural Adverse Events	>30 Day Adverse Events
Caliskan et al (2018)[32,]	291/291 (100%)	109/275 (39.6%)	Post-operative (in hospital): 3/291 (1.0%) Follow-up: 2/291 (1.7%)	Post-operative (in hospital): 18/291 (6.2%) Follow-up: 36/291 (12.4%)	0/291 (0%)	0/291 (0%)
Kurfirst et al (2017)[33,]	152/155 (98.0%)	Anticoagulant or antiplatelet use: 75/142 (52.8%)	Post-operative (in hospital): 1/155 (0.6%) Follow-up: 1/155 (0.7%)	Post-operative (in hospital): 13/155 (8.4%) Follow-up: NR	Revision due to bleeding: 10/155 (6.4%)	NR
Heijden et al (2022)[34,]	NR	NR	Post-operative (in hospital): 0/119 (0%) Follow-up 0/119 (0%)	Post-operative (in hospital): 0/119 (0%) Follow-up 0/119 (0%)	Revision due to bleeding: 1(0.8%) Cardiac tamponade: 1(0.8%) Myocardial Infarction: 1(0.8%) Pacemaker implantation 1(0.8%) Pneumothorax: 1(0.8%) Minor complications: 6(5%)	Follow-up through 24 months: Late cardiac tamponade: 2(1.7%) diaphragm paresis: 1 (0.8%) hemothorax: 1 (0.8%) Pacemaker or cardioverter-defibrillator implantation: 3 (2.5%) Pericarditis requiring medication: 4 (3.4%) Pericardiocentesis: 2(1.7%) Pleural effusion: 2 (1.7%) Pneumonia: 1 (0.8%) Hospital readmission due to decompensation cordis: 2 (1.7%)

NR: not reported.

Section Summary: Surgical Left Atrial Appendage Occlusion with the AtriClip Device Concomitant with an Open or Thoracoscopic Cardiac Procedure

Evidence comparing surgical LAA occlusion with an AtriClip device with anticoagulation, another surgical occlusion method, or no occlusion in individuals undergoing concomitant cardiac procedures

is limited. LAA occlusion was associated with a reduced risk of stroke versus no occlusion in the LAAOS III trial, but the trial was not designed to assess the net health benefit of LAA occlusion with an AtriClip device specifically, nor was it designed to assess whether surgical LAA occlusion is suitable as a replacement for long-term anticoagulant use. An industry-sponsored retrospective database study that compared LAA occlusion with AtriClip with no occlusion found that AtriClip placement was associated with a lower risk of ischemic stroke that was not statistically significant, and a reduced risk of thromboembolism that was of marginal statistical significance. Large (N>100) case series with 2- to 3- years follow-up reported stroke rates 1% or fewer in the postoperative period and 2% or fewer in the long-term follow-up. Well-designed RCTs with follow-up of 1 year or more comparing AtriClip with anticoagulation, another surgical occlusion method, and/or no occlusion are needed to provide adequate evidence for assessment of net health benefit.

Surgical Left Atrial Appendage Occlusion with the AtriClip Device as a Stand-Alone Procedure

Clinical Context and Therapy Purpose

The purpose of surgical LAA occlusion with AtriClip in patients with AF at risk for embolic stroke is to provide a treatment option that is an alternative to or an improvement on existing therapies.

As noted above, use of anticoagulants is the first-line therapy for the reduction of the risk of stroke in individuals 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.

The following PICO was used to select literature to inform this review.

Populations

The relevant population(s) of interest are individuals with AF at increased risk for embolic stroke undergoing LAA occlusion as a stand-alone procedure.

Interventions

The therapy being considered is surgical LAA occlusion with the AtriClip device.

The efficacy of surgical LAA occlusion performed in conjunction with other cardiac procedures has been assessed in several systematic reviews and a large (N>10,000) observational study, which have generally found surgical LAA occlusion to be associated with a reduction in the risk of stroke or systemic embolism without an increased risk of post-procedural complications.[13,14,15,16,] This review focuses on surgical LAA occlusion with AtriClip. This review does not consider the net health benefit of surgical LAA occlusion in general, nor does it address the net health benefit of surgical LAA occlusion techniques other than AtriClip placement.

Comparators

The following therapies are currently being used for the prevention of stroke in individuals with AF at increased risk for embolic stroke: anticoagulation therapy or percutaneous LAA occlusion.

Warfarin is the predominant anticoagulant agent in clinical use. Several newer anticoagulant medications, including dabigatran, rivaroxaban apixaban, and edoxaban have received U.S. FDA approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. Warfarin requires frequent monitoring and adjustments as well as lifestyle changes; DOACs do not require the frequent monitoring seen with warfarin therapy. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Reversal agents can be used to counter the effects of life-threatening bleeding in individuals using warfarin or DOAC therapy. Such agents carry their own risk of inducing life-threatening thrombosis.

Percutaneous LAA occlusion devices have been developed as a nonpharmacologic alternative for stroke prevention in AF. These devices are delivered through a catheter guided by transesophageal

echocardiography or fluoroscopy. Percutaneous LAA occlusion requires the use of anticoagulation therapy during the perioperative period, followed by antiplatelet therapy. Percutaneous LAA occlusion devices are further discussed in policy 2.02.26.

Outcomes

The general outcomes of interest are overall survival, morbid events, and treatment-related morbidity. The primary outcome of interest is the rate of ischemic stroke during follow-up, along with rates of systemic embolization, cardiac events, and mortality. Surgical success, defined as complete LAA occlusion, is not a direct health outcome, although evidence on surgical success is reported here as incomplete LAA occlusion may be associated with an increased risk of stroke.[17,]

Follow-up of 6 to 12 months or longer is required to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Nonrandomized Studies

Branzoli et al (2022)[35,] conducted a retrospective cohort study of 40 individuals with AF and a contraindication to anticoagulant use managed by a Heart Team. Participants had a mean age of 74 years, 35% were female and had a mean CHA_2DS_2VASc score of 5.1 at baseline. Between 2017 and 2020, 20 individuals underwent surgical (thoracoscopic) LAA occlusion with the AtriClip device and 20 received percutaneuous LAA occlusion with the Watchman device. Perioperative outcomes (procedure duration, length of hospital stay) were similar between groups with no serious adverse events or deaths. At a mean follow-up of 33 months, there were no instances of hospitalization due to cardiovascular or neurological events in either group.

Case Series

Cartledge et al (2022),[36,] and Franciulli et al (2020)[37,] reported on the use of AtriClip as a stand-alone LAA occlusion procedure in individuals at high-risk of stroke (Table 10). In both studies, AtriClip placement was achieved via a thoracoscopic approach. LAA occlusion was successful in nearly all cases, with few post-procedural events. No incidence of stroke was reported in either study after 6-months or 1-year follow-up (Table 11). There were 6 deaths in the Cartledge et al study after 1 year, but the study authors deemed none device or procedure related.

Table 10. Summary of Key Case Series Characteristics

Study	Country	Participants	Follow-Up
Cartledge et al 2022[36,]	U.S., Poland	N=175 Individuals with AF at high-risk of stroke with a contraindication to anticoagulants (intolerance or failure) who were not candidates for ablation or other cardiac procedures • Mean age not reported; 51% ≥75 years • 49% female • Mean CHA_2-DS_2-VASc score 4.0	1 year

Study	Country	Participants	Follow-Up
		• 78% history of bleeding; 26% prior stroke or TIA • 66% oral anticoagulant or low molecular weight heparin	
Franciulli et al 2020[37,]	Italy	N=20 Individuals with AF at high bleeding risk evaluated by a Heart Team • Mean age 75 years • 20% female • Mean CHA_2-DS_2-VASc score 3.6 • 30% prior ischemic stroke	6 months

AF: atrial fibrillation; TIA: transient ischemic attack

Table 11. Summary of Key Case Series Results

Study	Successful Occlusion	Anticoagulant Use	Stroke	Mortality	Post-procedural Adverse Events	>30-day Adverse Events
Cartledge et al 2022[36,]	174/175 (99.4%)	22/173 (12.7%) Oral anticoagulant or low molecular weight heparin at time of hospital discharge	No events	6/165 (3.6%)	1/173 (0.6%) Acute heart failure 1/173 (0.6%) Hemorrhagic stroke	No major bleeding events, device migration or intercardiac thrombi in the area of the occluder reported
Franciulli et al 2020[37,]	20/20 (100.0%)	NR	0/20 (0%)	0/20 (0%)	1/20 (5.0%) Reoperation due to bleeding	NR

NR: not reported

Section Summary: Surgical Left Atrial Appendage Occlusion with the AtriClip Device as a Stand-Alone Procedure

Evidence on surgical LAA occlusion with the AtriClip device as a stand-alone procedure is limited. One small (N=40) retrospective observational study found use of AtriClip as a stand-alone procedure resulted in similar outcomes as percutaneous LAA occlusion; the evidence is too limited to draw definitive conclusions. Well-designed RCTs with follow-up of 1 year or more comparing AtriClip LAA occlusion with anticoagulants or percutaneous LAA occlusion are needed to provide adequate evidence for the assessment of net health benefit. The ongoing SALAMANDER study (NCT05144958; completion anticipated in 2025) should provide direct comparative evidence of stand-alone AtriClip LAA occlusion with percutaneous occlusion when published.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association et al

In 2023, the American Heart Association, in conjunction with the American College of Cardiology, the American College of Clinical Pharmacy, and the Heart Rhythm Society, issued a joint guideline on the management of individuals with atrial fibrillation (AF).[38,] The following are the recommendations provided on performing LAAC for patients undergoing cardiac surgery:

- In patients with AF undergoing cardiac surgery with a CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, surgical LAA exclusion, in addition to continued anti-coagulation, is indicated to reduce the risk of stroke and systemic embolism. (Class of recommendation I: Level of evidence: A)
- In patients with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in the absence of flow across the suture line and a stump of <1 cm as determined by intraoperative trans-esophageal echocardiography should be used. (Class of recommendation I: Level of evidence: A)
- In patients with AF undergoing cardiac surgery with CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, the benefit of surgical LAA exclusion in the absence of continued anticoagulation to reduce the risk of stroke and systemic embolism is uncertain. (Class of recommendation IIb: Level of evidence: A)

No recommendation was made regarding the method of surgical LAA occlusion.

Society for Cardiovascular Angiography & Interventions et al

In 2023, the Society for Cardiovascular Angiography & Interventions (SCAI) and Heart Rhythm Society (HRS) issued a consensus statement on transcatheter endovascular left atrial appendage closure (LAAC).[39,] The following are the recommendations on patient selection and physician experience prior to receiving or performing LAAC:

- Transcatheter LAAC is appropriate for patients with nonvalvular atrial fibrillation with high thromboembolic risk who are not suited for long-term oral anticoagulation and who have adequate life expectancy (minimum >1 year) and quality of life to benefit from LAAC. There should be patient-provider discussion for shared decision making.
- Physicians performing LAAC should have a prior experience, including 50 or more prior left-sided ablations or structural procedures and 25 or more transseptal punctures (TSPs). Interventional imaging physicians should have experience in guiding 25 or more TSPs before supporting any LAAC procedures independently.

No recommendation was made regarding the method of surgical LAA occlusion.

Society for Thoracic Surgeons

In 2023, the Society for Thoracic Surgeons (STS) published guidelines for the surgical treatment of atrial fibrillation.[40,] The following are the recommendations on patient selection and physician experience prior to receiving or performing LAAC:

- Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time nonemergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.
- Isolated surgical left atrial appendage obliteration may be considered in patients with longstanding persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation. (Class of recommendation IIb: Level of evidence: B)

No recommendation was made regarding the method of surgical LAA occlusion.

American College of Chest Physicians

Guidance from the American College of Chest Physicians in 2018[7,] recommends:

- In patients with AF at high risk of ischemic stroke who have absolute contraindications for oral anticoagulants (OAC), we suggest using LAA occlusion (weak recommendation, low quality evidence).
- In AF patients at risk of ischemic stroke undergoing cardiac surgery, we suggest considering surgical exclusion of the LAA for stroke prevention, but the need for long-term OAC is unchanged (weak recommendation, low quality evidence).

No guideline statement recommends a specific occlusion method or approach.

U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force (USPSTF) recommendations for surgical LAA occlusion have been identified.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05101993	VClip Post-Market Study	156	Aug 2023
NCT05144958	Stand-Alone Left Atrial Appendage Occlusion for throMboembolism Prevention in Nonvalvular Atrial fibrillatioN DiseasE Registry (SALAMANDER)	400	Mar 2025
NCT03838341	Stand-Alone Thoracoscopic Epicardial Left Atrial Appendage Occlusion with AtriClip® Device for Thromboembolism Prevention in Nonvalvular Atrial Fibrillation - the Polish Nationwide Registry.	100	Jan 2025
NCT05723536	PLAI-AF Trial: Hybrid Endo-epicardial Partial Left Atrial Isolation vs. Endocardial Ablation in Patients with Persistent Atrial Fibrillation (PLAI-AF)	80	Dec 2025
NCT05478304	Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction Trial	6500	Apr 2032

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	33267	Exclusion of left atrial appendage, open, any method (e.g., 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 (e.g., 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 (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
10/01/2022	New policy.
10/01/2023	Annual review. No change to policy statement. Literature review updated.
10/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation 7.01.172 **Policy Statement:** I. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures is considered **investigational**. II. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered **investigational**.	**Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation 7.01.172** **Policy Statement:** I. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures is considered **investigational**. II. The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered **investigational**.