



Medical Coverage Policy

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Coverage Policy Number 0469

Left Atrial Appendage Closure or Exclusion

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Overview

This Coverage Policy addresses procedures intended to close or exclude the left atrial appendage (LAA) including transcatheter and surgical approaches, and closure of residual peridevice leak.

Coverage Policy

Percutaneous Left Atrial Appendage Occlusion (pLAAO)

1. Percutaneous transcatheter closure of the left atrial appendage (CPT® code 33340) for non-valvular atrial fibrillation using a U.S. Food and Drug Administration (FDA) approved device is considered **medically necessary** for the prevention of stroke in an individual with **BOTH** of the following (a and b):
 - a. a moderate to high risk of stroke (CHA₂DS₂-VASc score $\geq 2^*$), and
 - b. a contraindication to long-term oral anticoagulation due to a nonreversible cause (e.g., arteriovenous malformation (AVM) in intestine or brain that is not treatable, recurrent duodenal ulcer, recurrent falls when cause of falls is not felt to be treatable).

**Note: CHA₂DS₂-VASc is a clinical risk score for prediction of stroke and systemic embolism: Congestive heart failure, hypertension, age greater than or equal to 65, diabetes, stroke/transient ischemia attack/thromboembolism, vascular disease, sex category.*

2. Percutaneous transcatheter closure of the left atrial appendage for **ANY** other indication including hypertrophic cardiomyopathy is considered **not medically necessary**.

Surgical Left Atrial Appendage (LAA) Exclusion

3. Surgical exclusion or excision of the left atrial appendage (CPT® codes 33267, 33269) performed as a standalone procedure is considered **not medically necessary**.

Peridevice Leak Closure

4. The closure of a peridevice leak (PDL) after a left atrial appendage occlusion (CPT® code 33999) is considered **experimental, investigational or unproven**.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

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Percutaneous Left Atrial Appendage Occlusion (pLAAO)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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

Surgical Left Atrial Appendage (LAA) Exclusion

Considered Not Medically Necessary when used to report-surgical exclusion or excision of the left atrial appendage performed as a standalone procedure:

CPT®* Codes	Description
33267	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
33269	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

Peridevice Leak Closure

Considered Experimental/Investigational/Unproven when used to report closure of a peridevice leak (PDL) after a left atrial appendage occlusion:

CPT®* Codes	Description
33999	Unlisted procedure, cardiac surgery

***Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.**

Background and Supporting Information

Atrial fibrillation (AF) is a cardiac arrhythmia (abnormal heart rhythm) characterized by rapid, irregular, and disorganized electrical activity in the atria. AF is associated with substantial morbidity and mortality, including increased risks of stroke, heart failure, hospitalization, cognitive dysfunction, and death. In 2010, the prevalence of AF in the United States was estimated to be between 2.1 and 6.1 million individuals and is projected to increase to approximately 12.1 million by 2030 (Calkins et al., 2026).

Prevention of thromboembolic complications, particularly ischemic stroke, is a cornerstone of AF management. The left atrial appendage (LAA) is a small pouch arising from the left atrium of the heart and plays an important role in AF-related thromboembolism. Among individuals with nonvalvular AF (i.e., AF occurring in the absence of mechanical heart valves or moderate-to-severe mitral stenosis), approximately 90% of left atrial thrombi (blood clots) are located within the LAA. During AF, ineffective atrial contractions cause blood to pool within the LAA, and the

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appendage's narrow opening and deep cavity further increase the risk of thrombus formation. AF is associated with an approximately fivefold increase in stroke risk; however, the risk of thromboembolism varies considerably among individuals. Current clinical practice guidelines recommend the use of validated risk assessment tools, such as the CHA₂DS₂-VASc score, to estimate stroke risk and guide treatment decisions. The strongest predictors of ischemic stroke and systemic thromboembolism include a history of heart failure, hypertension, advanced age, diabetes mellitus, stroke or transient ischemic attack, and chronic kidney disease (Cox et al., 2027; Calkins et al., 2026; Hijazi & Saw, 2026).

Oral anticoagulation (OAC) is the standard approach for reducing the risk of stroke and systemic embolism in individuals with nonvalvular AF who are considered at elevated thromboembolic risk. Current evidence demonstrates that anticoagulants are substantially more effective than antiplatelet agents (e.g., aspirin or clopidogrel) for the prevention of AF-related thromboembolic complications. Direct oral anticoagulants (DOACs), including dabigatran, rivaroxaban, apixaban, and edoxaban, are generally preferred over warfarin because they provide comparable or greater efficacy for stroke prevention, are associated with a lower risk of intracranial hemorrhage, and do not require routine international normalized ratio (INR) monitoring. Despite its effectiveness, anticoagulation may not be appropriate for all individuals. Contraindications or circumstances that may limit long-term anticoagulant use include prior major bleeding events (e.g., intracranial hemorrhage), recurrent gastrointestinal, genitourinary, or respiratory tract bleeding, thrombocytopenia or other bleeding disorders, or excessive fall risk despite safety interventions. For individuals at elevated risk of thromboembolic events who are unable to receive long-term anticoagulation, alternative nonpharmacologic approaches to stroke prevention have been developed, including procedures and devices intended to occlude, exclude, or remove the LAA (Cox et al., 2027; Calkins et al., 2026; Hijazi & Saw, 2026).

Percutaneous Left Atrial Appendage Occlusion (pLAAO)

Percutaneous left atrial appendage occlusion (pLAAO) is a minimally invasive transcatheter procedure designed to reduce thromboembolic risk by isolating the left atrial appendage from the systemic circulation using an implanted occlusion device. By preventing blood flow into and out of the appendage, pLAAO may reduce thrombus formation and the migration of clots from the LAA to other parts of the body. However, pLAAO is associated with potential procedural and device-related complications including pericardial effusion, vascular access complications, bleeding, stroke, procedure-related death, device-related thrombus, peri-device leak (residual blood flow around the device), and device embolization. In addition, because AF-related thrombi may originate outside the LAA, occlusion of the appendage reduces but does not completely eliminate thromboembolic risk. Contraindications to the procedure include preexisting thrombus in the LAA or left atrium, sensitivity to Nitinol (a nickel-titanium alloy) or other device components, and inability to tolerate short-term oral anticoagulation for at least 6 weeks following implantation (Calkins et al., 2026; Hijazi & Saw, 2026).

U.S. Food and Drug Administration (FDA): Percutaneous left atrial appendage occlusion devices are Class III medical devices regulated by the FDA through the Premarket Approval (PMA) process. These devices are indicated to reduce the risk of thromboembolism from the LAA in individuals with nonvalvular atrial fibrillation who are at increased risk of stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-VASc risk assessment, are considered appropriate candidates for anticoagulation therapy or short-term anticoagulation therapy, and have an appropriate rationale to seek a nonpharmacologic alternative to long-term oral anticoagulation while taking into account the safety and effectiveness of the device (FDA, 2026).

Device or Product	Identifier	Manufacturer
Amplatzer™ Amulet™ Left Atrial Appendage Occluder	P200049	Abbott

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Device or Product	Identifier	Manufacturer
WATCHMAN® Left Atrial Appendage Closure Devices (e.g., WATCHMAN™, WATCHMAN FLX™, WATCHMAN FLX™ Pro)	P130013	Boston Scientific

*FDA product codes: NGV

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Several additional percutaneous left atrial appendage closure or exclusion technologies have been evaluated in clinical studies but have not received FDA approval for stroke prevention in atrial fibrillation. Examples include the WaveCrest™ LAA Occlusion System (Biosense Webster), which was evaluated in the WAVECREST 2 randomized clinical trial that was subsequently terminated, and the LAMBRE™ Left Atrial Appendage Closure System (Lifetech Scientific), for which the United States clinical study was withdrawn prior to completion. The LARIAT® snare device (SentreHEART) is FDA-approved for soft tissue approximation as a substantial equivalent to devices used during laparoscopic surgery and vein harvesting and has been used for transcatheter LAA exclusion through a unique epicardial approach; however, published evidence has raised concerns regarding procedural complications and incomplete closure. Additionally, the AMPLATZER™ Vascular Plug (Abbott) has been used for LAA occlusion, however, it is indicated for arterial and venous embolization procedures in the peripheral vasculature, and the safety and effectiveness of the device for cardiac applications has not been established (Abbott, 2026; ClinicalTrials.gov, 2026a; ClinicalTrials.gov, 2026b; Hijazi & Saw, 2026; Chatterjee et al., 2015).

Literature Review: Evidence evaluating percutaneous left atrial appendage occlusion (pLAAO) for stroke prevention in individuals with nonvalvular atrial fibrillation includes systematic reviews and meta-analyses, randomized controlled trials (RCTs), and large multicenter observational registry studies. Comparators have primarily consisted of vitamin K antagonist therapy (warfarin) and direct oral anticoagulants (DOACs). Across the available literature, study populations range from approximately 400 participants in randomized trials to more than 73,000 participants in pooled analyses, with follow-up extending from one to five years. Participants enrolled in randomized trials and large observational studies generally had elevated thromboembolic risk, with mean CHA₂DS₂-VASc scores ranging from approximately 3.5 to 4.7, and many contemporary studies enrolled individuals with increased bleeding risk, prior clinically relevant bleeding events, or other clinical circumstances in which long-term anticoagulation may be undesirable, with mean HAS-BLED scores generally ranging from 2.7 to 3.3. Available evidence consistently demonstrates that pLAAO provides stroke and systemic embolism prevention comparable to oral anticoagulation in appropriately selected individuals with nonvalvular atrial fibrillation. Several studies have also reported lower rates of hemorrhagic stroke, nonprocedural clinically relevant bleeding, and cardiovascular or all-cause mortality compared with long-term anticoagulation, while maintaining durable effectiveness over extended follow-up. Randomized and real-world studies evaluating FDA-approved devices have demonstrated high implantation success rates, sustained freedom from oral anticoagulation, and low rates of device-related complications. Limitations of the available literature include heterogeneity in study populations, evolving device generations and post-procedural antithrombotic regimens, and limited long-term randomized evidence comparing pLAAO with contemporary DOAC therapy. (Lakkireddy et al., 2026; Lakkireddy et al., 2025; Oliva et al., 2024; Osmancik et al., 2022; Reddy et al., 2017). Overall, the available evidence supports pLAAO as an effective nonpharmacologic strategy for stroke risk reduction in appropriately selected individuals with nonvalvular atrial fibrillation.

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Other Indications: Additional uses of pLAAO beyond individuals with nonvalvular atrial fibrillation who are at increased risk of stroke and systemic embolism and have an appropriate rationale to seek a nonpharmacologic alternative to long-term oral anticoagulation continue to be investigated. Areas of ongoing study include use of pLAAO as an adjunct to anticoagulation following thromboembolic events despite anticoagulation, as an alternative to lifelong oral anticoagulation in individuals who are eligible for long-term anticoagulation but prefer to avoid it, and in populations not currently addressed by established indications, including individuals with hypertrophic cardiomyopathy and those with persistent left atrial appendage thrombus. Emerging clinical applications and ongoing trials evaluating these approaches include CHAMPION-AF, CATALYST, OPTION, ELAPSE, and LAAOS-4 (Hijazi & Saw, 2026; Shinohara et al., 2025; Aglan et al., 2024; Zhang et al., 2024; Khawaja et al., 2023; Marroquin et al., 2022).

Literature Review: Published evidence evaluating pLAAO for indications beyond its currently established use consists of randomized controlled trials, systematic reviews, multicenter registries, propensity-matched observational studies, and retrospective cohort studies. Comparators have included direct oral anticoagulation (DOAC), intensified antithrombotic therapy, oral anticoagulation alone, and alternative pLAAO treatment strategies, with follow-up ranging from several months to approximately three years. However, findings remain heterogeneous across indications. Important limitations of the evidence base include reliance on observational data for most indications, variability in patient populations and postprocedural antithrombotic regimens, and limited long-term follow-up. Additional high-quality studies are needed to better define long-term safety, effectiveness, and optimal patient selection for these emerging applications (Doshi et al., 2026; Chatani et al., 2025; Galea et al., 2025a, 2025b; Aarnink et al., 2024; Aglan et al., 2024; Zhang et al., 2024; Khawaja et al., 2023; Marroquin et al., 2022).

Adjunct to Anticoagulation / Hybrid Treatment: Chatani et al. (2025) conducted a retrospective observational study evaluating management strategies for individuals with atrial fibrillation-related ischemic stroke despite oral anticoagulation (AFIDA). A total of 236 individuals were included, including 141 treated with oral anticoagulation (OAC) alone and 95 treated with additional left atrial appendage closure (LAAC). AFIDA was defined as ischemic stroke occurring despite at least 3 weeks of continuous anticoagulation. Compared with individuals treated with OAC alone, those undergoing additional LAAC were younger (mean age 75 vs. 82 years) and had higher bleeding risk scores (mean HAS-BLED score 3.5 vs. 3.0), while mean CHA₂DS₂-VASc scores were similar between groups (5.7 vs. 5.7). The WATCHMAN FLX device was used in 79% of LAAC procedures. After 3 years of follow-up, rates of ischemic stroke were similar between the OAC-alone and additional-LAAC groups (p=0.75). Rates of major bleeding were also similar between groups (p=0.38); however, fatal bleeding occurred less frequently among individuals who underwent additional LAAC (p=0.03). Rates of fatal or disabling stroke were numerically lower in the additional-LAAC group (p=0.06). Subgroup analyses suggested that continued anticoagulation following LAAC may be associated with lower rates of fatal or disabling stroke without increasing major bleeding. Limitations included the retrospective single-center design, limited sample size, heterogeneous postprocedural antithrombotic regimens, and lack of long-term follow-up. The authors concluded that additional LAAC may represent a potential management strategy for selected individuals with AFIDA, particularly those at elevated bleeding risk, although randomized controlled trials are needed to confirm these findings.

Galea et al. (2025b) conducted a multicenter retrospective observational study evaluating percutaneous left atrial appendage closure (LAAC) in individuals with nonvalvular atrial fibrillation who experienced a cardioembolic ischemic stroke despite adequate oral anticoagulation (OAC). A total of 95 individuals with confirmed cardioembolic breakthrough stroke underwent LAAC at four European centers. Participants had a mean age of 74.1 years, a mean CHA₂DS₂-VASc score of 5.4, and a mean HAS-BLED score of 3.0. LAAC was performed a median of 120 days after the index stroke. Most participants remained on long-term OAC following the procedure, including

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83% at follow-up. After a median follow-up of approximately 2 years (713 days), recurrent ischemic stroke occurred in 4% of participants, cerebrovascular events occurred in 7%, and all-cause mortality occurred in 5%. Procedure-related complications were uncommon (1%), while device-related thrombus and peri-device leak were reported in 2% and 9% of participants, respectively. The authors noted that recurrent stroke rates appeared lower than those previously reported in observational studies of breakthrough stroke managed with OAC alone and suggested that LAAC in combination with OAC may provide additional thromboembolic protection. Limitations included the retrospective observational design, small sample size, and variation in postprocedural antithrombotic management. The authors concluded that LAAC appeared feasible and safe in individuals with cardioembolic breakthrough stroke despite adequate anticoagulation and supported further investigation of LAAC combined with OAC in this high-risk population.

Aarnink et al. (2024) conducted an international retrospective observational study evaluating left atrial appendage occlusion (LAAO) in individuals with atrial fibrillation who experienced a thrombotic event despite oral anticoagulation therapy (OAT). A total of 439 individuals who underwent LAAO because of ischemic stroke, transient ischemic attack (TIA), systemic embolism, or left atrial appendage thrombus despite OAT were compared with 438 propensity-matched individuals from the EWOLUTION registry who underwent LAAO because of a contraindication to long-term anticoagulation. After propensity matching, rates of ischemic stroke were similar between groups (2.5% vs. 1.9%). Recurrent thromboembolic events occurred more frequently among individuals with anticoagulation failure ($p=0.043$), while major bleeding occurred less frequently ($p=0.016$). Approximately one-third of participants remained on long-term anticoagulation following LAAO as part of a hybrid treatment strategy. Limitations included the retrospective observational design, comparison with another LAAO cohort rather than continued anticoagulation alone, uncertainty regarding stroke mechanism, and variability in postprocedural antithrombotic management. The authors concluded that LAAO in individuals with thrombotic events despite anticoagulation resulted in ischemic stroke rates comparable to those observed among individuals undergoing LAAO because of anticoagulation contraindications and suggested that LAAO may be considered in selected individuals with anticoagulation failure while awaiting randomized trial data.

Eligible for Long-Term Anticoagulation: Doshi et al. (2026) reported the primary 3-year outcomes of the ongoing CHAMPION-AF multicenter randomized controlled trial comparing percutaneous left atrial appendage closure (LAAC) using the WATCHMAN FLX device with direct oral anticoagulant (DOAC) therapy in individuals with nonvalvular atrial fibrillation who remained suitable candidates for long-term anticoagulation. Eligible participants had a CHA₂DS₂-VASc score ≥ 2 for men or ≥ 3 for women and were considered appropriate candidates for both device-based and pharmacologic therapy. Individuals with contraindications to oral anticoagulation, requirements for chronic anticoagulation for another indication, recent stroke, recent major bleeding, active bleeding, mechanical heart valves, or other contraindications to transcatheter LAA closure were excluded. A total of 3000 participants were randomized 1:1 to LAAC or DOAC therapy. Participants had a mean CHA₂DS₂-VASc score of 3.5 and a mean HAS-BLED score of 1.3. After 3 years of follow-up, rates of cardiovascular death, stroke, or systemic embolism were similar between the LAAC and DOAC groups (5.7% vs. 4.8%; $p<0.001$ for noninferiority). Non-procedure-related bleeding occurred less frequently among participants assigned to LAAC ($p<0.001$), and the composite net clinical benefit outcome favored LAAC (15.1% vs. 21.8%; HR, 0.66; 95% CI, 0.56-0.79). Numerically higher rates of stroke were observed in the LAAC group (3.6% vs. 2.5%), while cardiovascular mortality was similar between groups. Pericardial effusion requiring intervention occurred in 0.7% of participants undergoing device implantation, and device-related thrombus was identified in 4.8% of assessed participants. Interpretation is limited by ongoing follow-up, as final ischemic stroke and systemic embolism outcomes are not expected until completion of the planned 5-year analysis. The authors concluded that among individuals who remained candidates for long-term anticoagulation, LAAC using the WATCHMAN FLX device

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provided stroke and systemic embolism prevention comparable to DOAC therapy and was associated with lower rates of non-procedure-related bleeding.

Galea et al. (2025a) conducted a retrospective multicenter observational cohort study evaluating left atrial appendage closure (LAAC) in individuals with atrial fibrillation who refused long-term oral anticoagulation (OAC). Among 2649 individuals who underwent LAAC, 119 (4.5%) underwent the procedure due to refusal to take OAC lifelong despite medical recommendations and were compared with 238 individuals who underwent LAAC for more established indications, including prior major bleeding, high bleeding risk, or OAC failure. Individuals who underwent LAAC because of OAC refusal were younger (mean age 69.1 vs. 75.7 years) and had lower thromboembolic and bleeding risk scores than those undergoing LAAC for established indications (mean CHA₂DS₂-VASc score 3.4 vs. 4.5; mean HAS-BLED score 2.2 vs. 3.4). After approximately 3 years of follow-up, the composite outcome of cardiovascular death, stroke, or systemic embolism occurred less frequently in the OAC refusal group (4.2% vs. 17.2%; adjusted HR, 0.37; p=0.048). Procedural success and complication rates were similar between groups. Limitations included the retrospective observational design, absence of an oral anticoagulation comparator group, small sample size of the OAC refusal cohort, and substantial baseline differences between study groups. The authors concluded that OAC refusal represented an uncommon indication for LAAC and that outcomes in this population appeared favorable, although prospective studies are needed to better define the role of LAAC among individuals who remain candidates for long-term anticoagulation.

Hypertrophic Cardiomyopathy: Aglan et al. (2024) conducted a retrospective observational study to evaluate outcomes associated with percutaneous left atrial appendage closure (LAAC) in individuals with hypertrophic cardiomyopathy (HCM) and atrial fibrillation (AF). A total of 14,867 individuals with HCM and AF were identified, including 364 (2.5%) who underwent percutaneous LAAC and 14,503 who received oral anticoagulation (AC) alone. Propensity score matching yielded 354 matched individuals in each treatment group. The primary outcome was ischemic stroke; secondary outcomes included systemic embolism, all-cause mortality, hospitalization, and major bleeding. Follow-up extended to 3 years. After propensity matching, individuals who underwent percutaneous LAAC experienced higher rates of ischemic stroke compared with those treated with anticoagulation alone (p=0.006). Rates of systemic thromboembolism were also higher in the LAAC group (p<0.01). No significant differences were observed between groups for all-cause mortality, hospitalization, or major bleeding. The authors noted that thrombus formation in HCM may occur throughout the left atrium and not exclusively within the left atrial appendage, potentially limiting the effectiveness of appendage closure alone for thromboembolic risk reduction. Limitations include the retrospective design, inability to assess anticoagulation adherence, lack of data regarding AF burden or duration, and reliance on administrative and electronic health record data. The authors concluded that the findings did not support percutaneous LAAC as a primary stroke prevention strategy in individuals with HCM and AF when long-term oral anticoagulation is feasible.

Khawaja et al. (2023) conducted a retrospective observational cohort study of 71,980 individuals with hypertrophic cardiomyopathy (HCM) and atrial fibrillation (AF), including 1351 who underwent left atrial appendage closure (LAAC), of whom 287 (21.2%) received transcatheter LAAC. Median follow-up was 165 days. After propensity matching, LAAC was associated with lower rates of a composite outcome of ischemic stroke, hemorrhagic stroke, transient ischemic attack (TIA), and all-cause mortality (2.5% vs. 5.4%; HR, 0.38; p=0.024), as well as lower rates of a composite outcome of major bleeding and pericardial complications (2.9% vs. 6.8%; HR, 0.39; p=0.001). Rates of ischemic stroke and all-cause mortality were numerically lower in the LAAC group but did not reach statistical significance individually. Limitations included the retrospective observational design, short follow-up duration, and limited applicability to transcatheter LAAC because most LAAC procedures were surgical. The authors concluded that surgical and transcatheter LAAC were associated with lower thromboembolic and bleeding-related event rates

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in individuals with HCM and AF, although prospective randomized studies are needed to confirm these findings.

Persistent LAAT: Zhang et al. (2024) conducted a systematic review evaluating left atrial appendage closure (LAAC) in individuals with persistent left atrial appendage thrombus (LAAT), a condition generally considered a contraindication to LAAC and commonly excluded from major clinical trials. The review included 136 individuals from 26 publications who underwent LAAC despite the presence of LAAT. Median age was 70.5 years, median CHA₂DS₂-VASc score was 4.4, and median HAS-BLED score was 3. Prior bleeding and prior stroke were reported in 47.1% and 39.0% of individuals, respectively. The Amulet device was the most commonly used closure device (48.5%), and cerebral protection devices were used in 34.6% of cases. All procedures were reported as technically successful. During a mean follow-up of 13.2 ± 11.5 months, one stroke (0.7%), one death (0.7%), three major bleeding events (2.2%), three device-related thrombi (2.2%), and eight peri-device leaks (5.9%) were reported. Modified procedural techniques, particularly "no-touch" approaches designed to minimize manipulation within the appendage, were frequently employed. Limitations included reliance on case reports and observational studies, publication and selection bias, limited characterization of thrombus morphology and location, and lack of long-term follow-up data. The authors concluded that LAAC may be feasible in carefully selected individuals with persistent LAAT; however, larger prospective studies are needed to better define safety and effectiveness in this population.

Marroquin et al. (2022) conducted a multicenter retrospective observational registry evaluating management strategies and outcomes among 126 individuals with nonvalvular atrial fibrillation and left atrial appendage thrombus (LAAT) identified during preprocedural evaluation for percutaneous left atrial appendage closure (pLAAO). Historically, LAAT has been considered a contraindication to pLAAO. Treatment strategies included intensification of antithrombotic therapy (IAT) followed by deferred pLAAO (57.9%) or direct pLAAO (42.1%). Individuals undergoing direct pLAAO were older (mean age 74.7 vs. 70.9 years; $p=0.042$), had higher bleeding risk scores (mean HAS-BLED score 3.6 vs. 3.0; $p=0.014$), more prior bleeding events (77.4% vs. 60.3%; $p=0.043$), and were more likely to have an absolute contraindication to anticoagulation (45.3% vs. 21.9%; $p=0.005$). Initial IAT resulted in complete thrombus resolution in 60.3% of individuals, increasing to 75.3% following additional treatment lines. However, bleeding and stroke occurred during IAT in 9.6% and 2.9% of individuals, respectively. Direct pLAAO achieved a procedural success rate of 96.2%, with no intraprocedural stroke, systemic embolism, or death. After a median follow-up of 22.1 months, major adverse events occurred in 29.3% of individuals, with no significant difference between management strategies. Device-related thrombosis was identified in 12.8% of individuals who underwent follow-up imaging. Limitations included the retrospective nonrandomized design, variability in procedural techniques and antithrombotic regimens, and incomplete imaging follow-up. The authors concluded that both deferred and direct pLAAO were feasible management strategies in selected individuals with LAAT, although intensification of antithrombotic therapy was associated with a relatively high rate of bleeding and device-related thrombosis remained an important concern following pLAAO.

Professional Societies/Organizations: Current professional society recommendations regarding pLAAO are informed by evidence from systematic reviews, randomized controlled trials, observational studies, real-world registries, and expert consensus. Contemporary recommendations from cardiology, cardiovascular interventional, and stroke organizations generally support pLAAO as a stroke prevention strategy in appropriately selected individuals with nonvalvular atrial fibrillation who are unable to tolerate or have an appropriate rationale to avoid long-term oral anticoagulation. Available guidance generally concludes that current evidence supports the safety and effectiveness of pLAAO in these populations while acknowledging ongoing questions regarding patient selection and postprocedural antithrombotic management. Current recommendations primarily address individuals with nonvalvular atrial fibrillation and do not

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provide specific recommendations regarding use of pLAAO as an adjunct to anticoagulation following thromboembolic events despite anticoagulation, in individuals eligible for long-term anticoagulation or with hypertrophic cardiomyopathy, and in those with persistent left atrial appendage thrombus (Goldsweig et al., 2025; Cronin et al., 2025; Joglar et al., 2024; Ommen et al., 2024; Kleindorfer et al., 2021).

American Heart Association (AHA)/American Stroke Association (ASA) 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack (Kleindorfer et al., 2021)		
Recommendation	COR*	LOE*
5.4.1. Atrial Fibrillation		
In patients with stroke or TIA in the setting of nonvalvular AF who have contraindications for lifelong anticoagulation but can tolerate at least 45 days, it may be reasonable to consider percutaneous closure of the left atrial appendage with the Watchman device to reduce the chance of recurrent stroke and bleeding.	I Ib	B-R
5.4.4. Cardiomyopathy		
In patients with ischemic stroke or TIA and left atrial or left atrial appendage thrombus in the setting of ischemic, nonischemic, or restrictive cardiomyopathy and LV dysfunction, anticoagulant therapy with warfarin is recommended for at least 3 months to reduce the risk of recurrent stroke or TIA.	I	C-EO

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR*	LOE*
6.5.1. Percutaneous Approaches to Occlude the left atrial appendage (LAA)		
In patients with Atrial Fibrillation (AF), a moderate to high risk of stroke (CHA2DS2-VASc score ≥ 2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAA occlusion (pLAAO) is reasonable.	IIa	B-NR
In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive.	I Ib	B-R
6.6.1. Management of Patients With AF and ICH		
In patients with AF and conditions associated with high risk of recurrent intracranial hemorrhage (ICH) (eg, cerebral amyloid angiopathy) anticoagulation-sparing strategies (eg, LAAO) may be considered to reduce the risk of recurrent hemorrhage (ACC/Joglar, et al., 2024).	I Ib	B-NR
Table 14 Situations in Which Long-Term Anticoagulation Is Contraindicated and Situations When It Remains Reasonable		
Long-Term Anticoagulation Contraindicated:		

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American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation (Joglar et al., 2024)		
Recommendation	COR*	LOE*
- Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems - Spontaneous intracranial/intraspinal bleeding due to a nonreversible cause - Serious bleeding related to recurrent falls when cause of falls is not felt to be treatable		
Long-Term Anticoagulation Is Still Reasonable: - Bleeding involving the gastrointestinal, pulmonary, or genitourinary systems that is treatable - Bleeding related to isolated trauma - Bleeding related to procedural complications		

The Class (Strength) of Recommendation (COR) indicates the strength of recommendation, encompassing the estimated magnitude and certainty of benefit in proportion to risk.

- Class I – Strong (is recommended)
- Class 2a – Moderate (is reasonable)
- Class 2b – Weak (may/might be reasonable)
- Class 3 – No benefit (Moderate) (is not recommended)
- Class 3 – Harm (Strong) (potentially harmful)

The Level (Quality) of Evidence (LOE) rates the quality of scientific evidence supporting the intervention on the basis of the type, quantity, and consistency of data from clinical trials and other sources.

- Level A – High quality evidence from more than one randomized clinical trial, Meta-analyses of high-quality randomized clinical trials, One or more randomized clinical trials corroborated by high-quality registry.
- Level B-R – Randomized. Moderate quality evidence from one or more randomized clinical trials, Meta-analyses of moderate-quality randomized clinical trials.
- Level B-NR – Non-randomized. Moderate quality evidence from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies, Meta-analyses of such studies.
- Level C-LD – Limited data. Randomized or nonrandomized observational or registry studies with limitations of design or execution, Meta-analyses of such studies, Physiological or mechanistic studies of human subjects.
- Level C-EO – Expert Opinion. Consensus expert opinion based on the clinical experience.

American Heart Association (AHA)/American College of Cardiology (ACC)/American Medical Society for Sports Medicine (AMSSM)/Heart Rhythm Society (HRS)/Pediatric and Congenital Electrophysiology Society (PACES)/Society for Cardiovascular Magnetic Resonance (SCMR) Guideline for the Management of Hypertrophic Cardiomyopathy: The 2024 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy recommends anticoagulation for individuals with hypertrophic cardiomyopathy and atrial fibrillation irrespective of CHA₂DS₂-VASc score but does not provide recommendations regarding percutaneous left atrial appendage occlusion as an alternative stroke prevention strategy (Ommen et al., 2024).

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Society for Cardiovascular Angiography (SCAI) and Heart Rhythm Society (HRS) Clinical Practice Guidelines on Transcatheter Left Atrial Appendage Occlusion (Goldsweig, et al., 2025)		
	Recommendations	*Strength of a recommendation
1	In adults with nonvalvular atrial fibrillation (NVAF) and contraindication to oral anticoagulation (OAC), should left atrial appendage occlusion (LAAO) be performed rather than no therapy? 1.1 For patients with NVAF and contraindication to OAC, the SCAI/HRS guideline panel suggests LAAO over no therapy (neither OAC nor LAAO)	1.1 Conditional recommendation, very low certainty evidence.
2	In adults with NVAF, should LAAO be performed rather than OAC? 2.1 For patients with NVAF who have decided to pursue stroke prevention treatment, the SCAI/HRS guideline panel suggests OAC or LAAO as treatment options.	2.1 Strength rating not stated. The overall level of certainty is moderate.

*Interpretation of strong and conditional recommendations:

The strength of a recommendation is expressed as either strong ("the guideline panel recommends.") or conditional ("the guideline panel suggests.") and has the following interpretation:

- Strong recommendation
 - For patients: Most patients in this situation would want the recommended course of action, and only a small proportion would not.
 - For clinicians: Most patients should receive the recommended treatment or test. Formal decision aids are likely not needed to assist individual patients in making decisions consistent with their values and preferences.
 - For policymakers: The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality metric or performance indicator.
- Conditional recommendation
 - For patients: The majority of individuals in this situation would want the suggested course of action, but a sizable minority would not.
 - For clinicians: Recognize that different choices will be appropriate for individual patients and that patients should receive unbiased information to help them arrive at a management decision consistent with their values and preferences. Decision aids may be useful to help individuals make decisions consistent with their values and preferences.
 - For policymakers: Policymaking will require substantial debate and involvement of various stakeholders. Performance measures about the suggested course of action should focus on documentation of an appropriate decision-making process

Society for Cardiovascular Angiography & Interventions (SCAI)/Heart Rhythm Society (HRS): The SCAI/HRS Technical Review on Transcatheter Left Atrial Appendage Occlusion systematically reviewed the evidence supporting percutaneous left atrial appendage occlusion (LAAO) in individuals with nonvalvular atrial fibrillation. The review concluded that randomized controlled trial evidence demonstrates that LAAO likely reduces all-cause mortality, cardiovascular mortality, and nonprocedural bleeding compared with oral anticoagulation, while providing similar

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rates of major bleeding and stroke. However, the authors noted that evidence addressing many aspects of patient selection, imaging strategies, postprocedural antithrombotic therapy, and management of peridevice leak and device-related thrombus is primarily derived from nonrandomized studies and remains subject to uncertainty. The review identified the need for additional research regarding appropriate candidate selection, imaging protocols, postprocedural management, and long-term outcomes following LAAO (Cronin et al., 2025).

Surgical Left Atrial Appendage (LAA) Exclusion

Surgical left atrial appendage occlusion (sLAAO) or excision encompasses a variety of techniques intended to exclude or remove the appendage, including excision, amputation, suturing, stapling, and epicardial clipping. These procedures are most commonly performed as an adjunct to other cardiac operations, such as coronary artery bypass grafting (CABG), valve surgery, or as part of the operation during surgical ablation for atrial fibrillation (e.g., Maze procedures). Available evidence, including randomized controlled trials, systematic reviews, and meta-analyses, suggests that concomitant surgical LAA exclusion performed during cardiac surgery is associated with reductions in ischemic stroke and other thromboembolic events without a corresponding increase in major complications, supporting its use as an adjunctive stroke-prevention strategy in individuals with AF undergoing cardiac surgery (Calkins et al., 2026; Hijazi & Saw, 2026; Bahar et al., 2025).

The demonstrated benefits of appendage exclusion, combined with limitations associated with both long-term oral anticoagulation and transcatheter LAA closure, have led to growing interest in stand-alone surgical approaches performed in the absence of another cardiac surgical indication. Although randomized clinical trials have demonstrated that transcatheter LAA closure provides stroke prevention comparable to oral anticoagulation in appropriately selected individuals, device-based approaches may be associated with complications such as device-related thrombus, residual peri-device flow, and the need for postprocedural antithrombotic therapy (Wang et al., 2021). In contrast, thoracoscopic and other epicardial surgical techniques remove the appendage and eliminate the need for an intracardiac implant and may allow shorter duration of antithrombotic therapy following the procedure (Wańha et al., 2026; Wang et al., 2021). In addition, minimally invasive thoracoscopic epicardial exclusion has been investigated for individuals with appendage characteristics that may be less favorable for transcatheter closure, including large appendages, difficult ostial orientation, multilobed anatomy, or proximal lobes (Rose et al., 2024). These proposed advantages have prompted investigation of stand-alone surgical LAA exclusion as an alternative to both long-term anticoagulation and transcatheter closure. However, unlike concomitant surgical exclusion performed during cardiac surgery, stand-alone surgical approaches have been evaluated primarily in smaller studies and heterogeneous populations, and uncertainty remains regarding long-term effectiveness, comparative outcomes, and optimal patient selection (Hijazi & Saw, 2026; Wańha et al., 2026; Rose et al., 2024; Wang et al., 2021).

U.S. Food and Drug Administration (FDA): Surgical left atrial appendage exclusion/excision techniques are procedures and therefore are not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation.

FDA-cleared left atrial appendage exclusion systems are regulated as Class II medical devices through the 510(k) premarket notification pathway. These devices are indicated for exclusion of the heart's left atrial appendage under direct visualization and use in conjunction with other cardiac surgical procedures (FDA, 2026).

Device or Product	Identifier	Manufacturer
ECLIPTIS Left Atrial Appendage Exclusion System	K254232	Edwards Lifesciences

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Device or Product	Identifier	Manufacturer
ATLAAS (Atraumatic Left Atrial Appendage System)	K252917	Genesee Biomedical, Inc.
AtriClip PRO-Mini LAA Exclusion System	K243860	AtriCure, Inc.
Syntheon Left Atrial Appendage Exclusion System	K220305	Syntheon LLC
AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip	K160454	AtriCure, Inc.

*FDA product codes: PZX

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review: Published evidence evaluating stand-alone surgical left atrial appendage exclusion (LAAE) for stroke prevention consists primarily of prospective and retrospective cohort studies, registry studies, and retrospective comparative analyses. Most studies evaluated minimally invasive thoracoscopic epicardial exclusion using clip-based or stapling techniques in individuals with contraindications to oral anticoagulation (OAC), prior bleeding, high bleeding risk, or other factors limiting long-term anticoagulant therapy. Comparators have included propensity score-matched control populations that did not undergo LAAE, and transcatheter left atrial appendage closure (LAAO). Available studies consistently report high procedural success and appendage closure rates, low rates of procedure-related complications, and frequent discontinuation of anticoagulation following successful exclusion. Low rates of stroke and thromboembolic events have also been reported during short- to intermediate-term follow-up. However, the current evidence base is limited by reliance on nonrandomized observational study designs, small sample sizes, and short follow-up durations (Nakayama et al., 2025; Rose et al., 2024; Cartledge et al., 2022; Wang et al., 2021; Branzoli et al., 2020).

Nakayama et al. (2025) reported outcomes from a multicenter Japanese registry evaluating isolated thoracoscopic left atrial appendage occlusion (LAAO) performed without concomitant surgical ablation. The study population was comprised of 136 individuals with atrial fibrillation (AF) that underwent isolated thoracoscopic LAAO. The intervention consisted of thoracoscopic exclusion of the left atrial appendage using either stapling (78%) or epicardial clipping (22%), with intraoperative transesophageal echocardiography (TEE) used to confirm appendage exclusion. Technical success was defined as absence of residual stump or residual flow. Outcomes included procedural success, postoperative imaging-confirmed closure, oral anticoagulation (OAC) discontinuation, and cerebrovascular events. Procedural success was achieved in 100% of participants with no operative deaths or procedural conversions reported. Postoperative imaging demonstrated consistently high closure rates and oral anticoagulation was discontinued immediately after the procedure in 24% of participants, within one month in 63%, and continued beyond one month in 13%. During a median follow-up of 12 months, cerebrovascular event-free survival was 99.27%, and no thromboembolic deaths were reported. One postoperative ischemic stroke occurred in an 84-year-old participant with a CHADS₂ score of 5 prior to postoperative imaging confirmation. Study limitations include the retrospective observational design, absence of a comparator group, small sample size, and short follow-up duration.

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Rose et al. (2024) conducted a retrospective Medicare claims analysis evaluating thromboembolic outcomes among individuals with nonvalvular atrial fibrillation (AF) who underwent minimally invasive thoracoscopic epicardial left atrial appendage exclusion (LAAE) using an epicardial clip compared with a propensity score-matched control cohort that did not undergo LAAE. Eligible participants were not receiving oral anticoagulation before or after the index date and had no concomitant cardiac surgery or atrial fibrillation ablation procedure. The intervention group included 243 participants who underwent thoracoscopic epicardial LAAE and was matched 1:4 to a control cohort of 972 participants with similar baseline characteristics. Mean age was 75 years, 61% were male, 70% had nonparoxysmal AF, the mean CHA₂DS₂-VASc score was 5.38, and the mean HAS-BLED score was 4.20 in the LAAE cohort. Outcomes included thromboembolic events, defined as ischemic stroke, transient ischemic attack (TIA), and systemic embolism. During follow-up, thromboembolic events occurred less frequently among participants who underwent LAAE compared with matched controls. One-year adjusted thromboembolic event rates were 7.3% in the LAAE cohort and 12.1% in the control cohort, corresponding to an absolute risk reduction of 4.8% (p=0.028). However, when additional statistical analyses were performed to adjust for differences between groups, the results were not statistically significant. Major bleeding rates within 30 days were not significantly different between cohorts. The most commonly reported safety event following LAAE was pleural effusion (6.9%). Study limitations include the retrospective claims-based design, reliance on administrative coding, absence of randomization, and short follow-up duration.

Cartledge et al. (2022) conducted a retrospective multicenter cohort study evaluating the safety, feasibility, and clinical outcomes of standalone thoracoscopic epicardial left atrial appendage exclusion (LAAE) using an epicardial clip in individuals with nonvalvular atrial fibrillation (AF) at high risk for thromboembolism who were not candidates for catheter ablation or other cardiac surgery. Eligible participants included individuals with contraindications, intolerance, or complications related to oral anticoagulation (OAC), prior thromboembolic events despite OAC, high bleeding risk, or clinical characteristics associated with a low likelihood of successful AF ablation. Individuals with left atrial appendage thrombus, prior left-sided pleural surgery, or anatomic factors precluding a thoracoscopic approach were excluded. The intervention consisted of totally thoracoscopic epicardial clip placement using three unilateral thoracoscopic ports without cardiopulmonary bypass. There was no concurrent control group; observed clinical outcomes were compared with predicted stroke risk based on CHA₂DS₂-VASc scores. Primary outcomes included procedural success, periprocedural adverse events, thromboembolic events, bleeding events, mortality, and durability of appendage exclusion. A total of 175 participants underwent the procedure. Median CHA₂DS₂-VASc score was 4.0 and median HAS-BLED score was 4.0; 77.7% had a history of bleeding and 26.1% had a prior stroke, transient ischemic attack (TIA), or thromboembolic event. Procedural success was achieved in 174 of 175 participants (99.4%). Periprocedural complications were uncommon and included pleural effusion (2.3%), conversion to sternotomy (0.6%), and hemorrhagic stroke (0.6%); no phrenic nerve palsy or cardiac tamponade occurred. Follow-up was available for 165 participants (92%) at a median of 12.5 months. No ischemic strokes were reported during follow-up, compared with a predicted annual stroke rate of 4.8 per 100 patient-years based on CHA₂DS₂-VASc risk estimates. Six all-cause deaths occurred, although none were device- or procedure-related. At discharge, 90.3% of participants were no longer receiving OAC and no major bleeding events were reported during follow-up. Postprocedural CT or transesophageal echocardiography (TEE) was performed in a subset of participants (n=36), with no device migration, leaks, or device-related thrombi identified. Study limitations include retrospective observational design, lack of a control group, comparison of observed stroke rates with predicted rather than actual comparator outcomes, and relatively short follow-up duration.

Wang et al. (2021) conducted a prospective cohort study that assessed the safety and efficacy of minimally invasive thoracoscopic left atrial appendage occlusion compared to transcatheter left

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atrial appendage closure for stroke prevention in recurrent nonvalvular atrial fibrillation patients after radiofrequency ablation. Adults (n=209) age ≥ 18 years with recurrent atrial fibrillation after radiofrequency ablation and CHADS2 score ≥ 2 were included in the study. No health disparities were identified by the investigators. Patients were placed into two groups, the thoracoscopic LAA occlusion group (n=138) and the transcatheter LAA closure group (n=71). The thoracoscopic LAA group had the atrial appendages sutured with a modern stapler and the transcatheter LAA closure group received the WATCHMAN device. Patients were followed up by telephone or at the outpatient clinic at 1 week/45 days/3 months/6 months/12 months/twice annually after one year. Neurologic examinations were performed 12 months/once annually after one year. The efficacy outcomes measured the composite endpoint for stroke/SE and death and the composite endpoint for events from the 3rd month after surgery to the end of follow-up. Additionally, safety was measured using operation-related stroke and the differences in complications between the two groups. The study reported that the length of hospital stay in thoracoscopic LAA occlusion group was significantly longer than that in transcatheter LAA closure group ($p < 0.001$). The two groups had similar nonsignificant results regarding the efficacy endpoints and the incidence of TIA/stroke ($p = 0.559$; $p = 0.496$, respectively). The incidence of bleeding in the thoracoscopic LAA occlusion group was significantly lower than that in the intervention group ($p = 0.022$). The incidence of operative complications was 3/138 (2.17%) in thoracoscopic LAA occlusion group and 1/71 (1.41%) in transcatheter LAA closure group. Author noted limitations included the single-center study design and the type of local treatment to the LAA was chosen by the patient with a full explanation from the physician. Additional limitations included the small patient population, short term follow-up and the population only included patients in China and the results may not be applicable to other races or ethnic groups. The authors concluded that the groups had similar effects in preventing stroke. Thoracoscopic LAA occlusion has the advantage of low risk of bleeding, but it is accompanied by longer hospital stays. Randomized controlled studies with large patient populations and long-term follow-up are needed.

Branzoli et al. (2020) conducted a prospective study that evaluated the safety and effectiveness of a stand-alone thoracoscopic exclusion of the LAA using an epicardial clip for stroke prevention in patients with permanent AF with an absolute contraindication to OAC. Patients (n=45) with non-valvular atrial fibrillation (NVAf) and CHA2DS2-VASc of 6.5 ± 1.1 with contraindications to long-term OAC or at high risk of life-threatening bleeding if on antiplatelet therapy (APT) with HAS-BLED mean 4.9 ± 0.9 were included in the study. No health disparities were identified by the investigators. All patients were implanted with an LAA epicardial clip, guided by preoperative computed tomography (CT) and intraoperative transesophageal echocardiography (TEE). The thoracoscopic access was evaluated at 10 days and clinical evaluations were scheduled at two months, six months, and yearly thereafter, including electrocardiogram, laboratory workout, and physical examination. The Questionnaire for Verifying Stroke-Free Status (QVSFS) was used at each scheduled visit and the latest follow-up as a validated screening tool to identify the occurrence of neurological events occurrence. Clinical and CT/TEE follow-up was complete for all 45 patients and ranged from 2–34 months (mean follow-up period: 16.4 ± 9.1 months). There were not any procedure-related complications and intraprocedural transesophageal echocardiography (TEE) showed complete LAA occlusion in all patients. At a mean follow-up of 16.4 ± 9.1 months (range, 2–34), with all patients off oral anticoagulation (OAC), novel oral anticoagulation (NOAC) or antiplatelet therapy (APT), no ischemic stroke or hemorrhagic complications occurred. Computed tomography or TEE at follow-up demonstrated a correct LAA occlusion in all patients. Author noted limitations included the small patient population and limited follow-up. The authors concluded that thoracoscopic epicardial closure of the LAA with the AtriClip PRO2 device is a potentially safe and efficient treatment for stroke prevention in patients with NVAf contraindicated for anticoagulant therapy or APT. However, the effect of the therapy with regard to the reduction of ischemic stroke and hemorrhagic complications in the long-term should be evaluated. Further studies in large, diverse populations with long-term follow-up are needed to evaluate efficacy, optimize protocols and outcomes.

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Professional Societies/Organizations: Current professional society recommendations regarding surgical left atrial appendage exclusion for stroke prevention in atrial fibrillation are informed by randomized controlled trials, observational studies, meta-analyses, and expert consensus. Professional societies recognize a role for surgical LAA exclusion in reducing thromboembolic risk when performed in conjunction with cardiac surgery in appropriately selected individuals with atrial fibrillation. However, guidance specific to stand-alone surgical LAA exclusion remains limited, and uncertainty persists regarding its comparative safety, effectiveness, and role relative to established stroke-prevention strategies such as oral anticoagulation and transcatheter LAA closure (Joglar et al., 2024; Wyler von Ballmoos et al., 2024).

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS): In Section 6.5.2, Cardiac Surgery – LAA Exclusion/Excision, the ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation recommends surgical left atrial appendage (LAA) exclusion in individuals with atrial fibrillation undergoing cardiac surgery and elevated stroke risk, when performed in addition to continued anticoagulation therapy, to reduce the risk of stroke and systemic embolism. The guideline also recommends use of a surgical technique that results in complete exclusion of the appendage without residual flow and acknowledges that the benefit of surgical LAA exclusion in the absence of continued anticoagulation remains uncertain. The recommendations address LAA exclusion performed during cardiac surgery; no recommendations are provided regarding stand-alone surgical left atrial appendage exclusion performed in the absence of another cardiac surgical procedure (Joglar et al., 2024).

The Society of Thoracic Surgeons (STS) Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos et al., 2024)		
Recommendation	COR*	LOE*
Recommendations for concomitant left atrial appendage management:		
Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time non emergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.	I	A
Recommendations regarding stand-alone left atrial appendage management:		
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.	I Ib	B-NR

*Classes of Recommendation (COR) and Levels of Evidence (LOE)

Classification of strength of recommendation

Class I (strong; benefit >>> risk): procedure is useful, effective, and beneficial.

Recommendation: procedure should be performed.

Class IIA (moderate; benefit >> risk): procedure can be useful, effective, and beneficial. Recommendation: procedure is reasonable.

Class IIB (weak; benefit equal to or greater than risk): effectiveness is unknown, unclear, or uncertain. Recommendation: procedure might be reasonable.

Level of quality of evidence

Level A: high-quality evidence from more than one randomized controlled trial (RCT); meta-analyses or high-quality RCTs; or one or more RCTs corroborated by high-quality registry studies.

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Level B randomized: moderate quality evidence from one or more RCTs or meta-analyses of moderate quality.

Level B nonrandomized: moderate quality of evidence from one or more well-designed, well-executed nonrandomized studies, registries, or observational analyses; meta-analyses of such studies.

The efficacy and safety of stand-alone thoracoscopic LAA appendectomy has not been established. Randomized controlled trials with larger patient populations and long-term follow-up are needed.

Peridevice Leak (PDL) Closure

Peridevice leak (PDL) is a recognized complication of transcatheter left atrial appendage occlusion (LAAO) characterized by residual blood flow around an implanted occlusion device that may be associated with an increase in adverse thromboembolic and bleeding events. PDL may be detected during implantation or on follow-up imaging, most commonly with transesophageal echocardiography (TEE) or cardiac computed tomography (CT). There is no standardized definition of PDL; however, leaks have been described in the literature as minor (< 1 mm), moderate (3-5 mm), or major (> 5 mm). Reported rates of PDL may occur in up to 40.9% of individuals undergoing LAAO. The clinical significance of PDL, whether leak size should influence management decisions, and the optimal treatment strategy remain uncertain. Reported management approaches include continued antithrombotic therapy, leak surveillance via imaging, and percutaneous closure of the residual leak using devices and techniques such as the Amplatzer Patent Foramen Ovale (PFO) occluder, Hookless ACP, Amplatzer Vascular Plug II, embolic coils, and detachable vascular coils (Hijazi & Saw, 2026; Helal et al., 2024).

U.S. Food and Drug Administration (FDA): A review of FDA databases did not identify any devices approved or cleared for closure of a peridevice leak (PDL) following left atrial appendage occlusion (LAAO). Although a variety of occlusion devices and techniques have been described in the literature for management of PDL, FDA-approved indications for these devices do not include closure of residual peridevice leaks following LAAO (FDA, 2026).

Literature Review: Published evidence evaluating the clinical significance of residual peridevice leak (PDL) following left atrial appendage occlusion (LAAO) consists primarily of observational registry studies, post hoc analyses of randomized controlled trials, and post-market surveillance data. These studies evaluate the frequency, size, timing, and clinical implications of residual leak identified following LAAO and investigate associations between PDL and outcomes such as ischemic stroke, transient ischemic attack (TIA), systemic embolism, bleeding events, mortality, and major adverse events. Reported rates of PDL vary across studies according to differences in device type, imaging modality, timing of assessment, and leak definition (Saito et al., 2025; Alkhouli et al., 2022; Dukkipati et al., 2022; Ledesma et al., 2021). Large registry studies and post hoc analyses have reported higher rates of thromboembolic events among individuals with residual PDL, including leaks measuring ≤ 5 mm and ≤ 3 mm (Saito et al., 2025; Alkhouli et al., 2022; Dukkipati et al., 2022). Post-market surveillance data demonstrate that most identified leaks have historically been managed conservatively, although a variety of management approaches, including repeat intervention, have been reported (Ledesma et al., 2021). Available evidence remains limited by variability in PDL definitions, imaging protocols, follow-up intervals, and management strategies. Although residual PDL has been associated with adverse clinical outcomes in some studies, the relationship between leak size and clinical risk remains incompletely understood, and the optimal management strategy for persistent PDL has not been established (Saito et al., 2025; Alkhouli et al., 2022; Dukkipati et al., 2022; Ledesma et al., 2021).

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Studies evaluating closure of residual peridevice leaks (PDLs) following left atrial appendage occlusion (LAAO) consist primarily of multicenter registries, retrospective case series, case reports, and systematic reviews of those studies (Helal et al., 2024; Sleiman et al., 2021). Available studies have evaluated percutaneous closure using embolic coils, detachable vascular coils, vascular plugs, septal occluders, secondary LAA occlusion devices, and device replacement strategies for treatment of leaks identified following percutaneous LAAO, surgical ligation, and Lariat procedures (Helal et al., 2024; Sleiman et al., 2021; Della Rocca et al., 2020). Outcomes commonly reported include procedural success, reduction or elimination of residual leak, procedural complications, continuation or discontinuation of oral anticoagulation, and short-term clinical follow-up (Musikantow et al., 2021; Piayda et al., 2021; Sleiman et al., 2021). Across studies, percutaneous PDL closure has generally been reported as technically feasible, with high procedural success rates and low rates of periprocedural complications (Musikantow et al., 2021; Piayda et al., 2021; Sleiman et al., 2021; Della Rocca et al., 2020). However, the available evidence is limited by small sample sizes, heterogeneous patient populations, variability in closure devices and techniques, short follow-up durations, and the absence of randomized or comparative studies evaluating closure versus continued antithrombotic therapy or observation (Helal et al., 2024; Musikantow et al., 2021; Piayda et al., 2021; Sleiman et al., 2021). While published studies report successful reduction or elimination of residual leaks, evidence evaluating the effect of PDL closure on clinically meaningful outcomes such as stroke, systemic embolism, bleeding events, mortality, and overall net health outcomes remains limited (Helal et al., 2024; Musikantow et al., 2021; Piayda et al., 2021; Sleiman et al., 2021; Della Rocca et al., 2020).

Professional Societies/Organizations: Current professional society guidance addressing peridevice leak (PDL) following left atrial appendage occlusion (LAAO) consists of expert consensus statements and clinical practice guidelines informed by systematic evidence reviews, observational studies, registry data, post hoc analyses, and expert consensus. Available guidance recognizes PDL as a known complication of LAAO and acknowledges uncertainty regarding its clinical significance and optimal management. Recommendations generally emphasize minimizing residual leak at the time of implantation and performing post-procedural imaging surveillance when appropriate. While some guidelines address imaging and anticoagulation considerations for selected clinical scenarios, such as cardioversion following LAAO, professional societies consistently identify management of persistent PDL as an area of ongoing uncertainty and additional research. Current guidance does not provide specific recommendations supporting or opposing routine percutaneous closure of residual PDL (Goldsweig et al., 2025; Joglar et al., 2024; Saw et al., 2023; Wyler von Ballmoos et al., 2024).

American College of Cardiology (ACC)/American Heart Association (AHA)/American College of Chest Physicians (ACCP)/Heart Rhythm Society (HRS): The ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation addresses residual leak following left atrial appendage occlusion (LAAO) in the setting of cardioversion. The guideline notes that residual leak and device-related thrombus may be identified following surgical or percutaneous LAAO and recommends that imaging may be reasonable in selected individuals with prior LAAO undergoing cardioversion to assess the adequacy of appendage exclusion and exclude device-related thrombus. For individuals with a residual leak following LAAO, the guideline states that pericardioversion anticoagulation may be considered and continued thereafter. The recommendations do not address percutaneous closure of residual peridevice leaks (Joglar et al., 2024).

Society for Cardiovascular Angiography and Interventions (SCAI)/Heart Rhythm Society (HRS): The SCAI/HRS Expert Consensus Statement on Transcatheter Left Atrial Appendage Closure acknowledges that the clinical impact and optimal management of peridevice leaks (PDLs) are not fully understood and recommends that all efforts be made to minimize residual leak at the time of device implantation. The document notes that PDLs are common following left atrial

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appendage occlusion (LAAO), that leaks >5 mm are generally considered significant and are often managed with continued oral anticoagulation, and that percutaneous leak closure using occlusion devices, vascular plugs, or coil embolization has been reported in case reports and small case series. However, the statement notes that data are lacking regarding the long-term clinical impact of these interventions and whether oral anticoagulation can be safely discontinued following leak closure. The consensus statement also recommends transesophageal echocardiography (TEE) or cardiac computed tomography (CT) surveillance 45 to 90 days following LAAO to evaluate for peridevice leak and device-related thrombus (Saw et al., 2023).

In the subsequent **SCAI/HRS Clinical Practice Guidelines on Transcatheter Left Atrial Appendage Occlusion**, management of peridevice leak was identified as an area of uncertainty and ongoing practice variation. The guideline panel reviewed available evidence regarding oral anticoagulation for individuals with PDL following LAAO and issued no recommendation regarding the use of oral anticoagulation because of insufficient evidence. The guideline further identified management of PDL as a knowledge gap requiring additional research. The guideline notes that observational evidence suggests an association between PDL and thromboembolic events; however, the benefit of oral anticoagulation, follow-up imaging strategies, and percutaneous leak closure remains uncertain. The guideline also notes that percutaneous closure of PDL using vascular plugs or coils has been described in case reports and small series, but comparative evidence evaluating safety, efficacy, or stroke prevention outcomes is lacking (Goldsweig et al., 2025).

The Society of Thoracic Surgeons (STS): The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation focus primarily on surgical atrial fibrillation ablation and surgical left atrial appendage (LAA) management. The guideline acknowledges that residual peridevice leak following percutaneous LAA occlusion is common and cites evidence associating PDL with an increased risk of thromboembolic events. However, the guideline does not provide recommendations regarding percutaneous closure of residual leaks and instead focuses on surgical LAA occlusion/obliteration and management of atrial fibrillation in surgical populations (Wyller von Ballmoos et al., 2024).

There is insufficient evidence in the published medical literature to demonstrate the safety and effectiveness of peridevice leak closure, using any method, for the treatment of residual blood flow around an implanted left atrial occlusion device.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Several studies have evaluated sex-related differences in outcomes following left atrial appendage occlusion (LAAO). Observational studies and registry analyses have reported higher rates of in-hospital and periprocedural adverse events among women undergoing LAAO compared with men, including mortality, stroke, major bleeding, and pericardial complications (Darden et al., 2021; Sanjoy et al., 2021). A subsequent systematic review and meta-analysis of 16 studies involving

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111,775 individuals undergoing transcatheter LAAO similarly found that women experienced higher rates of periprocedural complications; however, no statistically significant sex-related differences were identified for long-term outcomes including ischemic stroke, major bleeding, device-related thrombus, cardiovascular mortality, or all-cause mortality (Mathai et al., 2023). The authors noted that women remain underrepresented in clinical trials evaluating LAAO and emphasized the need for additional research to better understand factors associated with sex-related differences in outcomes and to improve representation in future studies (Mathai et al., 2023).

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Revised policy title from Atrial Fibrillation: Nonpharmacological Treatments to Left Atrial Appendage Closure or Exclusion and moved policy statements unrelated to LAA closure or exclusion procedures to CP 0532 Cardiac Electrophysiological (EP) Studies and Cardiac Ablation of Abnormal Electrical Rhythms	10/15/2026

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Annual Review	- Revised policy statement for cardiac surgery – LAA exclusion/excision (surgical closure of the left atrial appendage) - Revised policy statement for surgical ablation (surgical Maze or modified Maze procedure)	11/15/2025
Focused Review	- Revised policy statement for cardiac catheter ablation - Revised policy statements for surgical ablation (surgical Maze or modified Maze procedure)	5/15/2025
Focused Review	Revised policy statements for percutaneous transcatheter closure of the left atrial appendage (LAA)	3/15/2025
Annual Review	Revised policy statements for surgical ablation (surgical Maze or modified Maze procedure)	10/15/2024
Annual Review	- Title change from Nonpharmacological Treatments for Atrial Fibrillation - Added policy statement for repeat cardiac catheter ablation - Added policy statement for active esophageal cooling device - Revised policy statements for: ➤ Cardiac catheter ablation ➤ Percutaneous transcatheter closure of the left atrial appendage (LAA) ➤ Surgical ablation (surgical Maze or modified Maze procedure)	3/15/2024

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