Left Atrial Appendage Closure (Occlusion) (for Ohio Only)

Policy Number: CS255OH.C
Effective Date: August 1, 2025

Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Members 18 Years of Age and Older

Percutaneous endovascular and surgical closure (occlusion) of the left atrial appendage (LAA) is medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Left Atrial Appendage Closure.

Click here to view the InterQual® criteria.

When medical necessity cannot be determined using the above InterQual criteria, percutaneous endovascular closure (occlusion) of the left atrial appendage (LAA) is proven and medically necessary to reduce the risk of stroke when using a U.S. Food and Drug Administration (FDA) approved device, when all of the following criteria are met:

- Device is used according to FDA labeled indications, contraindications, warnings, and precautions
- Diagnosis of nonvalvular atrial fibrillation (AF)
- Moderate to high risk of embolic stroke (CHA_2DS_2-VASc Score ≥ 2)
- Documented medical contraindication to long-term anticoagulation

When medical necessity cannot be determined using the above InterQual criteria, surgical closure (occlusion) of the LAA as part of cardiac surgery with cardiopulmonary bypass for a different indication is proven and medically necessary to reduce the risk of stroke when all of the following criteria are met:

- Age 18 years or above
- History of AF
- CHA_2DS_2-VASc Score ≥ 2
- Device is used according to FDA labeled indications, contraindications, warnings, and precautions, when applicable

Note: Thoracoscopic closure (occlusion) of the LAA is not addressed in this policy.

Members Under 18 Years of Age

Percutaneous endovascular closure (occlusion) of the left atrial appendage (LAA) is proven and medically necessary to reduce the risk of stroke when using a U.S. Food and Drug Administration (FDA) approved device, when all of the following criteria are met:

- Device is used according to FDA labeled indications, contraindications, warnings, and precautions
- Diagnosis of nonvalvular atrial fibrillation (AF)
- Moderate to high risk of embolic stroke (CHA_2DS_2-VASc Score ≥ 2)
- Documented medical contraindication to long-term anticoagulation

Note: Thoracoscopic closure (occlusion) of the LAA is not addressed in this policy.

Definitions

CHA_2DS_2-VASc Score: Also known as the Birmingham schema, is a risk stratification score used to estimate the long-term systematic embolization risk in patients with atrial fibrillation (AF) (Lip, 2010).

2009 Birmingham Schema Expressed as a Point-Based Scoring system, with the Acronym CHA_2DS_2-VASc:

Risk Factor	Points
Congestive Heart Failure Associated signs and symptoms, or left ventricular systolic dysfunction	1
Hypertension	1
Age ≥ 75 years	2
Diabetes mellitus	1
Stroke, transient ischemic attack, or thromboembolism	2
Vascular Disease (prior myocardial infarction, peripheral artery disease or aortic plaque) Myocardial infarction, peripheral artery disease, or aortic plaque	1
Age 65–74 years	1
Sex category (i.e., female gender)	1

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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)
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

Description of Services

Atrial fibrillation (AF) is a common cause of cardioembolic ischemic strokes, many of them resulting from a thrombus that originated at the left atrial appendage (LAA). Anticoagulation is the most common approach to AF related cardioembolic

ischemic stroke prevention but poses a risk for bleeding complications. An alternative or in addition to chronic anticoagulation is percutaneous endovascular closure (occlusion) and surgical closure (occlusion) of the LAA. Percutaneous LAA closure or occlusion involves the use of a catheter-inserted, implanted device to close the LAA and exclude it from systemic circulation. Open surgical closure is performed at the same time another open cardiac surgical procedure is being performed for a different indication (Whitlock, 2021).

Clinical Evidence

Percutaneous Endovascular Left Atrial Appendage Closure (Occlusion)

Labori et al. (2021) conducted a systematic review and meta-analysis of observational studies on the long-term clinical effectiveness of percutaneous endocardial left atrial occlusion (LAAO) for stroke prevention in patients with atrial fibrillation (AF), and contraindication to oral anticoagulation (OAC). The authors note that this study differs from the PROTECT AF and PREVAIL RCTs where participants were excluded if they had contraindications to OACs. The authors used Poisson random effect models to estimate the incidence rate (events per 100 patient-years) of ischemic stroke, transient ischemic attack, major bleeding, and all-cause death after LAAO treatment. They also calculated the risk reduction of ischemic stroke with LAAO compared with no stroke prevention estimated through a predicted risk in an untreated population (5.5 per 100 patient-years). There were 29 observational studies in the meta-analysis, including 7951 individuals and 12211 patient-years. The mean CHA_2DS_2-VASc score among the patients in the included studies was 4.32. The pooled incidence rate of ischemic stroke was 1.38 per 100 patient-years (95% CI 1.08; 1.77). According to a meta-regression model, the estimated incidence rate of ischemic stroke at CHA_2DS_2-VASc 4 was 1.39 per 100 patient-years. This suggests a risk reduction of 74.7% with LAAO compared to predicated risk with no stroke prevention. Results suggest that LAAO is effective in preventing ischemic stroke for patients with AF that are at increased risk of stroke and have contraindications to OAC. This review is limited by inclusion of observational studies only and comparisons to historical controls.

An ECRI Clinical Evidence Assessment compared Watchman and Watchman FLX with other LAA closure devices or warfarin for thrombosis and stroke prevention and concluded that the evidence is somewhat favorable in support of the Watchman devices. The assessment found no head-to-head randomized controlled trial (RCT) comparisons of Watchman to other devices. Based on two RCTs, Watchman devices reduced all-cause mortality compared to warfarin, but all-stroke or systemic embolism and major bleeding did not differ statistically between groups at 5-year follow-up. No studies were included that compared Watchman or Watchman FLX to novel OACs that have less adverse events than warfarin (ECRI, 2021a).

Watchman/Watchman FLX

The prospective, multicenter case series PINNACLE FLX study (n = 400) evaluated the safety and effectiveness of the next-generation Watchman FLX LAA closure device in patients with nonvalvular AF in whom OAC is not contraindicated, but who have an appropriate rationale to seek a nonpharmaceutical alternative. The primary safety end point was the occurrence of one of the following events within seven days after the procedure or by hospital discharge: death, ischemic stroke, systemic embolism, or device- or procedure-related events requiring cardiac surgery. The primary effectiveness end point was the incidence of effective LAA closure (peri-device flow ≤ 5 mm), as assessed by transesophageal echocardiography. At one-year, effective closure was seen in 100% of patients who had a Watchman FLX successfully implanted, and the incidence of the primary safety end point was 0.5%. Device-related thrombus was reported in seven patients, no patients experienced pericardial effusion requiring open cardiac surgery, and there were no device embolizations. This study is limited by lack of comparison group, in particular, one that uses newer OACs. Additionally, the study was not designed to evaluate non-inferiority or superiority of the Watchman FLX device versus long-term anticoagulation in terms of mortality and stroke (Kar et al., 2021). NCT02702271. A clinical trial is in progress to compare the safety and efficacy of the Watchman FLX device to novel OACs. NCT04394546.

Both the PROTECT-AF and PREVAIL studies noted below had accompanying registries designed to continue accrual of data on longer-term outcomes. These registries, CAP (Continued Access to PROTECT-AF) and CAP2 (Continued Access to PREVAIL) represent the largest number and longest follow-up of patients implanted with the Watchman device. Holmes et al. (2019) reported on the final 5-year total experience of CAP and the 4-year follow-up of CAP2. The nonrandomized CAP registry included 566 patients who continued follow-up through their 5-year visit or until study exit. The nonrandomized CAP2 registry enrolled 578 patients with follow-up data available through 4 years on all patients remaining in the trial. CAP2 patients were significantly older and had higher CHA_2DS_2-VASc score scores (4.51 versus 3.88; $p < 0.001$). Procedural success was similar in both (94%). The primary composite endpoint occurred at a rate of 3.05 per 100 patient-years in CAP and 4.80 per 100 patient-years in CAP2. Events contributing to this endpoint were most commonly cardiovascular/unexplained death (1.69 per 100 patient-years for CAP and 2.92 per 100 patient-years for CAP2). Hemorrhagic stroke was significantly less than ischemic stroke (0.17 per 100 patient-years in CAP and 0.09 per

100 patient-years in CAP2), and total stroke rates were significantly less than predicted by CHA_2DS_2-VASc score (78% reduction with CAP, 69% reduction with CAP2).

Reddy et al. (2017a) evaluated 5-year outcomes of the PREVAIL trial, combined with the 5-year outcomes of the PROTECT AF trial. In participants with AF undergoing LAA closure using the Watchman device, protection against ischemic stroke and systemic embolism was similar to that achieved with warfarin, but LAA closure was associated with substantial reductions in hemorrhagic, disabling, and fatal stroke. Additional studies may be advantageous comparing the benefit of LAA occlusion against OACs other than warfarin in patients with AF, and to assess advantages for those with contraindications to anticoagulation.

Reddy et al. (2017b) evaluated the acute procedural performance and complication rates for all Watchman implants performed in the United States since FDA approval. In 3,822 consecutive cases, implantation was successful in 3,653 patients (95.6%), with a median procedure time of 50 minutes. Implanting physicians (n = 382) included 71% new, nonclinical trial implanters, who performed 50% of the procedures. Procedural complication rates included 39 pericardial tamponades (1.02%) (24 treated percutaneously, 12 surgically and 3 fatal); 3 procedure-related strokes (0.078%); 9 device embolization's (0.24%) (6 requiring surgical removal); and 3 procedure-related deaths (0.078%).

The prospective, multicenter EWOLUTION registry (Boersma et al., 2016) reported 30-day periprocedural outcomes with the Watchman device. Implant data were available for 1021 patients at high risk of stroke and moderate-to-high risk of bleeding. The device was successfully implanted in 98.5% of patients with no flow or minimal residual flow achieved in 99.3% of implanted patients. Twenty-eight patients experienced 31 serious adverse events within 1 day of the procedure. The most common serious adverse event occurring within 30 days of the procedure was major bleeding requiring transfusion. Incidence of serious adverse events within 30 days was significantly lower for subjects deemed to be ineligible for OAC therapy compared with those eligible for OAC therapy (6.5 versus 10.2%). The overall 30-day mortality rate was 0.7%. The authors reported that improvement in implantation techniques has led to a reduction of periprocedural complications previously limiting the net clinical benefit of the procedure.

Holmes et al. (2015) performed a meta-analysis on composite data from the PROTECT AF and PREVAIL trials and their respective registries comparing warfarin to the Watchman device for the prevention of stroke, systemic embolism, and cardiovascular death in patients with nonvalvular AF. The analysis included 2,406 patients with 5,931 patient-years of follow-up. A total of 1,877 patients were treated with Watchman (1,145 registry patients) and 382 received warfarin. Patients receiving the Watchman device had significantly fewer hemorrhagic strokes, cardiovascular/unexplained death and nonprocedural bleeding compared with warfarin; however, there were more ischemic strokes in the device group. All-cause stroke or systemic embolism was similar between both strategies. The composite efficacy endpoint favored participants receiving the Watchman device, but this did not reach statistical significance. The authors reported that further studies are needed to define risk thresholds for thromboembolism and bleeding at which patients with AF benefit from LAA occlusion therapy for stroke prevention and to compare the safety and efficacy of this strategy with target specific OACs.

Briceno et al. (2015) conducted a systematic review and meta-analysis evaluating the safety and efficacy of different approaches for preventing stroke in patients with nonvalvular AF. The three groups investigated were novel OACs, the Watchman LAA occlusion device and warfarin. Efficacy outcomes were stroke or systemic embolism, and all-cause mortality. Safety outcome was major bleeding and procedure-related complications. Seven RCTs (n = 73,978) were included in the analysis. There was a significant difference favoring novel OACs for systemic embolism, all-cause mortality and safety outcomes compared with warfarin. No difference was seen between the Watchman device and warfarin for efficacy end points; however, there were a few safety concerns. (Studies by Holmes 2009 and 2014 are included in this systematic review.)

The PREVAIL study (Holmes et al., 2014) was a multicenter, prospective RCT to assess the safety and efficacy of LAA occlusion using the Watchman device for stroke prevention compared with long-term warfarin therapy. Patients with nonvalvular AF who had a $CHADS_2$ (congestive heart failure, hypertension, age > 75 years, diabetes mellitus and previous stroke/TIA) score ≥ 2 or 1 and another risk factor were eligible. Participants were randomly assigned (in a 2:1 ratio) to undergo LAA occlusion and subsequent discontinuation of warfarin (n = 269) or receive chronic warfarin therapy (n = 138). There were three primary endpoints (two effectiveness and one safety): 1) the composite of ischemic stroke, hemorrhagic stroke, systemic embolism and cardiovascular or unexplained death; 2) the composite of ischemic stroke and systemic embolism, excluding events occurring in the first seven days following randomization; and 3) the occurrence of all-cause mortality, ischemic stroke, systemic embolism or device or procedure-related events requiring open cardiac surgery or major endovascular intervention between the time of randomization and seven days of the procedure or by hospital discharge, whichever is later. Due to the low overall trial event rates, there was limited power with the planned sample size to establish noninferiority for the primary efficacy endpoint and the prespecified criteria noninferiority was not

achieved for this outcome. At 18 months, LAA occlusion was noninferior to warfarin for the second primary efficacy endpoint. Event rates were low and comparable in both arms. Early safety events occurred in 2.2% of the Watchman arm, significantly lower than in PROTECT AF, satisfying the safety performance goal. Using a broader, more inclusive definition of adverse effects, these still were lower in the PREVAIL trial than in PROTECT AF (4.2% versus 8.7%). Pericardial effusions requiring surgical repair decreased from 1.6% to 0.4%, and those requiring pericardiocentesis decreased from 2.9% to 1.5%. The authors concluded that these results provide additional data that LAA occlusion is a reasonable alternative to warfarin therapy for stroke prevention in patients with nonvalvular AF who do not have an absolute contraindication to short-term warfarin therapy. However, the primary hypothesis of the study was not demonstrated.

The PROTECT AF trial (Holmes et al., 2009) included 707 participants with nonvalvular AF who had at least one risk factor for stroke. Patients were randomized to chronic warfarin treatment (n = 244) or percutaneous placement of the LAA device (n = 463). The clinical endpoint of the study was a composite measure of stroke, cardiovascular death, and embolism. The safety assessment included serious adverse events, including major bleeding, pericardial effusion, and device embolization. After 1065 patient-years of follow-up, the efficacy event rate was 3.0 per 100 patient-years in the device group compared with 4.9 in the warfarin group - a relative reduction of 38%. However, serious safety events were more common in the device group (7.4 events per 100 patient-years) compared with the warfarin group (4.4). Most of these safety events were related to the procedural implant and pericardial effusion. Statistical analysis demonstrated that the LAA was 99.9% likely to be noninferior to warfarin alone. At two years, both treatment groups had a similar intention-to-treat cumulative event rate. Since warfarin therapy is burdensome and carries risks of its own, the authors concluded that closure of the LAA might provide an alternative strategy to chronic warfarin therapy for stroke prophylaxis in patients with nonvalvular AF. However, these data likely do not justify routine LAA occlusion in all patients with nonvalvular AF, primarily because the trial did not demonstrate prevention of embolism and stroke in high-risk patients. In addition, the short duration of follow-up does not offer enough information regarding long-term safety and efficacy.

Reddy et al. (2011) reported a significant improvement in the safety of the Watchman device with increased operator experience. In a 2.3-year follow-up to the PROTECT AF trial, Reddy et al. (2013b) reported primary efficacy event rates of 3.0 per 100 patient-years in the Watchman group and 4.3 in the warfarin group which indicated the Watchman device met criteria for both noninferiority and superiority, compared with warfarin, for preventing the combined outcome of stroke, systemic embolism, and cardiovascular death, as well as superiority for cardiovascular and all-cause mortality. Participants in the device group had lower rates of both cardiovascular and all-cause mortality.

In the ASAP trial, Reddy et al. (2013a) conducted a multicenter case series to assess the safety and efficacy of the Watchman LAA closure device in patients with nonvalvular AF (n = 150) ineligible for warfarin therapy. The primary efficacy endpoint was the combined events of ischemic stroke, hemorrhagic stroke, systemic embolism, and cardiovascular/unexplained death. History of hemorrhagic/bleeding tendencies (93%) was the most common reason for warfarin ineligibility. Serious procedure- or device-related safety events occurred in 13 patients (8.7%). All-cause stroke or systemic embolism occurred in four patients (2.3% per year): ischemic stroke in three patients (1.7% per year) and hemorrhagic stroke in one patient (0.6% per year). The authors concluded that the Watchman device is a reasonable alternative for patients at high risk for stroke but with contraindications to systemic OAC.

Amulet

Lakkireddy et al. (2023) reported 3-year outcomes of the Amulet IDE trial (Lakkireddy et al., 2021) included in the Bing and Chen systematic review and meta-analysis noted below. The Amulet occluder demonstrated continued safety and effectiveness with over 96% free of OAC usage through three years in a high-risk population compared to the Watchman device.

Bing and Chen (2023) performed a systematic review and meta-analysis on the efficacy and safety of the Watchman vs. ACP/Amulet devices for nonvalvular AF (NVAF) patients. A total of 19 articles (three RCTs and sixteen non-RCTs) were included in the study. The effective outcomes were stroke and systemic embolism. Safety outcomes were all-cause death, cardiovascular death, and major bleeding. The Watchman and ACP/Amulet groups comprised 3267 and 2957 patients, respectively. The authors observed that no statistical differences were detected between the Watchman and the ACP/Amulet group in terms of stroke, systematic embolism. The all-cause death and cardiogenic death were similar between the two groups. Watchman group had a potential trend of higher occurrences of major bleeding than ACP/Amulet group, though it did not have statistically significant difference. The Watchman group had a significantly higher incidence of device-related thrombus (DRT) and (peri-device leaks) PDL > 5 mm than ACP/Amulet group. The authors concluded effective and safety outcomes were comparable between two groups. Limitations identified in this study were this was a study-level meta-analysis, the range of studies occurrence was long, and the experience of the operators may influence the results, and the follow-up time of the included studies ranged from 3−48 months, and different follow-up times can affect the effective and safety endpoints. Furthermore, the analyses were not separated between RCTs and observational

studies. (Publications by Galea 2022 and Lakkireddy 2021, which were previously cited in this policy, are included in this systematic review.)

An ECRI Clinical Evidence Assessment concluded that the evidence on Amplatzer Amulet LAA occluder's safety and effectiveness for treating AF complications, and how it compared with OAC therapies and the Watchman device, was inconclusive due to the lack of high-quality studies. The evidence suggests that Amplatzer Amulet implantation has a very high technical success rate and reduces major bleeding for up to two years compared with OAC therapy. The evidence also suggests the Amplatzer device death and thrombosis rates may be similar to those for the Watchman LAA Closure device, but studies are very low quality. Large RCTs comparing Amplatzer Amulet with medical therapy and other LAA devices and reporting longer-term (> 2 years) data are needed (ECRI, 2022).

In a systematic review and meta-analysis of observational studies, Basu Ray et al. (2020) compared the safety and efficacy of the Amplatzer and Watchman LAA closure devices. Six studies, with 342 patients in the Watchman group and 274 patients in the Amplatzer group, were included in the meta-analysis. Of the six studies, two were prospective nonrandomized studies and four were retrospective studies. No RCTs were identified. Overall, both devices had relatively low complication rates. No significant differences between the devices were found in safety outcomes or in the rates of all-cause mortality, cardiac death, stroke/TIA, or device-related thrombosis. The total bleeding rate was significantly lower in the Watchman group, yet no significant differences were found when the bleeding rate was categorized into major and minor bleeding. Total peridevice leakage rate and insignificant peridevice leakage rate were significantly higher in the Watchman group. However, significant peridevice leakages were similar in both the devices. The authors noted that observations were limited by the small number of available studies.

Surgical Closure (Occlusion) of the LAA as Part of Cardiac Surgery With Cardiopulmonary Bypass for a Different Indication

A Hayes Health Technology Assessment concluded that a very low-quality body of evidence from single arm studies demonstrated a high rate of complete LAA occlusion; however, the specific impact of AtriClip on relevant clinical outcomes including stroke risk cannot be determined due to the lack of comparative studies and the confounding effect of concurrent cardiac interventions. Well-designed comparative studies with sufficient follow-up duration are needed to determine whether the AtriClip system is a safe and effective preventive measure for stroke (Hayes, 2021; updated 2024).

Nso et al. (2022) conducted a systematic review and meta-analysis and compared the outcomes of surgical LAAO with those of no LAAO and the use of direct OACs and vitamin K antagonists (VKAs) using the PRISMA guidelines. A total of 20 selected randomized and observational studies met inclusion criteria. The meta-analysis found a significant reduction in incidence of embolic events and a significant reduction in risk of MACE in patients who underwent LAAO. The authors concluded LAAO is potentially superior to no LAAO in terms of reducing the incidence of embolic events and MACE in patients undergoing cardiac surgery for AF. However, complete replacement of direct OACs and warfarin therapy with surgical LAAO is unlikely despite its non-inferiority in terms of minimizing all-cause mortality, embolic events, MACE, major bleeding, and stroke in patients on OAC therapies. Limitations in the study include selection and performance bias, limited availability of RCTs, results were not stratified on whether LAAO was surgery – based versus percutaneously administered, and limited validity for young adults in this meta-analysis findings. (Studies by Healey 2005 and Whitlock 2013 are included in this systematic review.)

Prasad et al. (2022) conducted a systematic review and meta-analysis which compared left atrial appendage closure (LAAC) and placebo arm during cardiac surgery in patients with AF. Five RCTs and 22 observational studies were included with a total of 540,111 patients. The results from the study identified LAAC group had significantly decreased postoperative stroke/embolic events as compared to the no LAAC group with all cardiac surgeries, isolated valvular surgery. However, CABG insignificantly favored the LAAC group for stroke/embolic events. There was no difference between both groups in all-cause mortality in the perioperative period but was significantly lower in the LAAC arm after two years. There was no difference in major bleeding, all-cause rehospitalizations, or cross-clamp time between both groups. The bypass and the cross-clamp time were longer in the LAAC group. The authors concluded in patients with AF, LAAC during cardiac surgery significantly decreased the risk of stroke and long-term all-cause mortality. Furthermore, there was no difference in major bleeding, all-cause rehospitalizations, or cross-clamp time. Limitations found in the studies included a meta-analysis design but most of the studies were observational. Additionally, the included studies utilized different surgical techniques for LAAC. Next, incomplete LAAC has been linked with increased adverse effects, but the included studies did not report enough data to perform statistical analysis. Finally, the role of anticoagulation post-LAAC was not evaluated as it was not included in most studies. (Studies by Healey 2005 and Whitlock 2013 are included in this systematic review.)

An ECRI Clinical Evidence Assessment concluded that the evidence for AtriClip Flex-V and Pro-V is limited to reported clinical experiences on five patients that may not represent typical outcomes of LAA occlusion with these devices. Large clinical studies are needed to assess AtriClip Flex-V and Pro-V safety and effectiveness (ECRI, 2021b).

Whitlock et al. (2021) conducted the Left Atrial Appendage Occlusion Study (LAAOS III) after the LAAO I (Healey 2005) and LAOOS II (Whitlock 2013) trials. The LAAOS I and LAAOS II indicated LAA was a promising approach to stroke prevention in AF, although larger trials were needed to support its safety and efficacy. The LAAOS III is a multicenter, RCT that evaluated the efficacy and safety of concomitant left atrial appendage occlusion in participants with a history of AF undergoing cardiac surgery with cardiopulmonary bypass for another indication. The authors aimed to specifically determine whether concomitant occlusion would prevent ischemic stroke or systemic embolism in participants who continued to receive usual care, including anticoagulation. This multicenter, randomized trial involved adults with AF who had a CHA_2DS_2-VASc score of at least 2 (on a scale from 0 to 9, with higher scores indicating greater risk of stroke) who were scheduled to undergo cardiac surgery for another indication. The participants were randomly assigned to undergo, using a range of procedures, or not undergo occlusion of the LAA during surgery; all the participants were expected to receive usual care, including OAC, during follow-up. The primary outcome was the occurrence of ischemic stroke (including transient ischemic attack with positive neuroimaging) or systemic embolism. The participants, research personnel, and primary care physicians were unaware of the trial-group assignments. The study population included 2379 participants in the occlusion group and 2391 in the no-occlusion group, with a mean age of 71 years and a mean CHA_2DS_2-VASc score of 4.2. The participants were followed for a mean of 3.8 years. A total of 92.1% of the participants received the assigned procedure, and at 3 years, 76.8% of the participants continued to receive OAC. Stroke or systemic embolism occurred in 114 participants (4.8%) in the occlusion group and in 168 (7.0%) in the no-occlusion group (hazard ratio, 0.67; 95% confidence interval, 0.53 to 0.85; p = 0.001). The incidence of perioperative bleeding, heart failure, or death did not differ significantly between the trial groups. Limitations included lack of comparison of the efficacy of LAAO compared with OAC and that the findings from LAAOS III apply primarily to surgical occlusion of the appendage performed as a concomitant procedure and not to stand-alone surgical or endovascular occlusion. The study design did not allow to determine whether all surgical closure methods were comparable. The results indicated that among patients with AF who are scheduled to undergone cardiac surgery with cardiopulmonary bypass for another indication, most of whom continued to take ongoing antithrombotic therapy, the risk of stroke or systemic embolism was lower when LAAO that was performed at the time of the cardiac surgery.

Toale et al. (2019) conducted a systematic review of 11 studies (n = 922) evaluating the safety, efficacy, and durability of LAA occlusion using the AtriClip device in the management of patients with AF. Rates of total LAA occlusion compared favorably to conventional surgical and percutaneous closure methods. No device-related adverse events were reported across the studies. The reported incidence of stroke or TIA post-procedure ranged from 0.2 to 1.5/100 patient-years. Four hundred and seventy-seven of 798 patients (59.7%) had ceased anticoagulation on follow-up. Limitations include heterogenous studies of differing design and methodology, use of various procedural approaches and inconsistent post-operative anticoagulation. Most of the included studies appeared to be case series without a comparator, limiting the conclusions that can be drawn from this review. The authors noted that future trials comparing AtriClip with established surgical and percutaneous methods of LAA closure are needed.

Ando et al. (2018) conducted a systematic review and meta-analysis of studies comparing patients who underwent open cardiac surgery with or without LAA closure. Seven studies were included in the analysis. There were 1,963 patients in the LAA closure group and 1,934 patients in the non-LAA closure group. Of the seven studies, three were RCTs, three were propensity-matched studies and one was a case-matching study. At 30-day/in-hospital follow-up, LAA closure was significantly associated with decreased risk of mortality and cerebrovascular accident. The authors concluded that concomitant surgical LAA closure should be considered at the time of open cardiac surgery, particularly among those with preoperative AF. The benefit of LAA closure for patients without preoperative AF and for those undergoing nonvalvular surgery is still unclear. Additionally, the findings are mostly based on included observational studies, with the findings of the three RCTs being less conclusive.

Atti et al. (2018) conducted a systematic review and meta-analysis to evaluate the safety and efficacy of concomitant surgical left atrial appendage occlusion (s-LAAO) during cardiac surgery versus no occlusion during cardiac surgery. Twelve studies met inclusion criteria (three RCTs and nine observational studies). The analysis identified 13,535 patients received s-LAAO during cardiac surgery while the other group with 26,572 patients did not receive s-LAAO. The meta-analysis identified the s-LAAO group was associated with lower rates of embolic events and stroke; and there was no significant difference in the incidence of all-cause mortality, postoperative complications, or reoperations for bleeding between the two groups. The authors concluded concomitant s-LAAO during cardiac surgery was associated with lower risk of follow-up thromboembolic events and stroke, especially in those with AF without significant increase in adverse events. Further randomized trials to evaluate long-term benefits of s-LAAO are warranted. (Studies by Healey 2005 and Whitlock 2013 are included in this systematic review.)

Caliskan et al. (2018) in an observational study with historical controls, evaluated the safety, effectiveness, and durability of the AtriClip implanted in patients undergoing open heart surgery. A total of 291 AtriClip devices were implanted epicardially in patients (mean CHA_2DS_2-VASc-Score: 3.1 ±1.5) undergoing open-heart surgery (including isolated coronary artery bypass grafting, valve, or combined procedures) comprising of forty patients from a first-in-man device trial (NCT00567515) and 251 patients from a consecutive institutional registry afterwards. In all patients (n = 291), the LAA was successfully excluded, and overall mean follow-up (FU) was 36 ±23months (range: 1-97 months). No device-related complications were detected throughout the FU period. Long-term imaging work-up (computed tomography) in selected patients ≥ 5 years post-implant (range: 5.1-8.1 years) displayed complete LAA occlusion with no signs of residual reperfusion or significant LAA stumps. Subgroup analysis of patients with discontinued OAC during FU (n = 166) revealed a relative risk reduction of 87.5% with an observed ischemic stroke-rate of 0.5/100 patient-years compared with what would have been expected in a group of patients with similar CHA_2DS_2-VASc scores (expected rate of 4.0/100 patient-years). No strokes occurred in the subgroup with OAC. The study had several limitations, including lack of contemporary controls, wide range of follow-up, and concomitant surgical ablations performed in some patients which likely impacted outcomes. In addition, long-term data (5-year analyses) was only reported on 32 patients. While the study results support the safety and effectiveness of the AtriClip system, well-designed controlled trials are needed to evaluate the AtriClip device in regard to stroke-prevention compared with current pharmacological and interventional therapies.

Emmert et al. (2014) evaluated the AtriClip device in 40 patients with AF undergoing elective cardiac surgery with planned concomitant ablation. Early mortality was 10% due to non-device-related reasons; however, the remaining 36 patients were evaluated at 3, 12, 24 and 36 months. After imaging, clips were found to be stable, showing no secondary dislocation 36 months after surgery. No intracardial thrombi, LAA perfusion or LAA stump were detected. Apart from one unrelated TIA that occurred two years after surgery in a patient with carotid plaque, no other strokes and/or neurological events were reported. While the results were promising, the study is limited by lack of randomization and small sample size.

Clinical Practice Guidelines

American Heart Association (AHA)/American College of Cardiology (ACC)/American College of Clinical Pharmacy (ACCP)/Heart Rhythm Society (HRS)

The AHA/ACC/HRS guideline for the diagnosis and management of patients with atrial fibrillation (AF) states the following regarding LAA occlusion:

- In individuals with AF, a moderate to high risk of stroke, and a contraindication to long-term anticoagulation due to a nonreversible cause, percutaneous closure of the LAA is reasonable (Class 2a; Level of Evidence B-NR).
- In individuals with AF, a moderate to high risk of stroke, and a high risk of major bleeding on OAC, percutaneous closure of the LAA may be a reasonable alternative to OAC, with careful consideration of procedural risk and with the understanding that the evidence for OAC is more extensive (Class 2b; Level of Evidence B-R).
- In individuals with AF undergoing cardiac surgery with a CHA_2DS_2-VASc score ≥ 2 or equivalent stroke risk, surgical LAA exclusion, in addition to continued anticoagulation, is indicated to reduce the risk of stroke and systemic embolism (Class 1, Level of Evidence A).
- In individuals with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in absence of flow across the suture line and a stump of < 1 cm as determined by intraoperative transesophageal echocardiography should be used (Class 1, Level of Evidence A).
- In individuals 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 2b, Level of Evidence A) (Joglar et al., 2024).

European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS)

The ESC guidelines for the diagnosis and management of AF, developed in collaboration with EACTS, make the following recommendations regarding LAA occlusion:

- LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (e.g., intracranial bleeding without a reversible cause).
- Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery. Multiple observational studies indicate the feasibility and safety of surgical LAA occlusion/exclusion, but only limited controlled trial data are available (Hindricks et al., 2021).

National Institute for Health and Care Excellence (NICE)

The NICE guidelines for the diagnosis and management of AF state the following:

- Consider LAA occlusion if anticoagulation is contraindicated or not tolerated and discuss the benefits and risks with the individual.
- Do not offer LAA as an alternative to anticoagulation unless anticoagulation is contraindicated or not tolerated (NICE, 2021).

Society of Thoracic Surgeons (STS)

The Society of Thoracic Surgeons clinical practice guidelines for the surgical treatment of AF make the following recommendations:

- LAA 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 (Class I, Level of Evidence A).
- Isolated surgical LAA obliteration may be considered in patients with long-standing persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term OAC (Class IIb, Level of Evidence B-NR) (Wyler von Ballmoos et al., 2024).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

FDA approval status for percutaneous left atrial appendage (LAA) closure devices can be found by searching the FDA's Premarket Approval (PMA) database using a product name or Product Code NGV: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed June 25, 2024)

FDA approval status for surgical LAA closure devices can be found by searching the FDA's 510(k) Premarket Notification database using a product name or Product Code PZX: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 25, 2024)

Product Information

- Amplatzer™ Amulet™ - Abbott
- AtriClip® - AtriCure
- Penditure™ - Medtronic/Syntheon
- Watchman™ - Boston Scientific

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Policy History/Revision Information

Date	Summary of Changes
08/01/2025	**Coverage Rationale** ***Members 18 Years of Age and Older*** • Replaced language indicating "percutaneous endovascular closure (occlusion) of the left atrial appendage (LAA) *is proven and* medically necessary in certain circumstances *to reduce the risk of stroke when using a U.S. Food and Drug Administration (FDA) approved device*" with "percutaneous endovascular and surgical closure (occlusion) of the left atrial appendage (LAA) is medically necessary in certain circumstances" • Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® CP: Procedures, Left Atrial Appendage Closure, *Percutaneous*" with "InterQual® CP: Procedures, Left Atrial Appendage Closure" • Added language to clarify the criteria listed in the policy must be met *when medical necessity cannot be determined using the InterQual® criteria [listed in the policy]* for: o Percutaneous endovascular closure (occlusion) of the LAA o Surgical closure (occlusion) of the LAA as part of cardiac surgery with cardiopulmonary bypass for a different indication ***Members Under 18 Years of Age*** • Added language to indicate percutaneous endovascular closure (occlusion) of the LAA is proven and medically necessary to reduce the risk of stroke when using a U.S. Food and Drug Administration (FDA) approved device, when all of the following criteria are met: o Device is used according to FDA labeled indications, contraindications, warnings, and precautions o Diagnosis of nonvalvular atrial fibrillation (AF) o Moderate to high risk of embolic stroke (CHA_2DS_2-VASc Score ≥ 2) o Documented medical contraindication to long-term anticoagulation

Date	Summary of Changes
	Supporting Information • Archived previous policy version CS255OH.B

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.