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

Policy # 00296
Original Effective Date: 05/18/2011
Current Effective Date: 09/11/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of a device with U.S. Food and Drug Administration (FDA) approval for percutaneous left atrial appendage closure (e.g., the Watchman or Amplatzer Amulet)™‡ for the prevention of stroke in individuals with atrial fibrillation (AF) to be **eligible for coverage**** when the following criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered when the following criteria has been met:

- There is an increased risk of stroke and/or systemic embolism based on $CHADS_2$ score ($\geq$ 2) or CHA_2DS_2-VASc score ($\geq$ 2), and systemic anticoagulation therapy is recommended; AND
- The long-term risks of systemic anticoagulation outweigh the risks of the device implantation (e.g., HAS-BLED score $\geq$ 3, see Policy Guidelines section for additional details).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of a device with FDA approval for percutaneous left atrial appendage closure (eg, the Watchman or Amplatzer Amulet) for stroke prevention in individuals who do not meet the above criteria to be **investigational.***

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

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Based on review of available data, the Company considers the use of other percutaneous left atrial appendage closure devices, including but not limited to the Lariat®‡, and Amplatzer Cardiac Plug devices, for stroke prevention in individuals with atrial fibrillation (AF) to be **investigational.***

Policy Guidelines

The balance of risks and benefits associated with implantation of the Watchman or Amplatzer Amulet device for stroke prevention, as an alternative to systemic anticoagulation must be made on an individual basis.

Bleeding is the primary risk associated with systemic anticoagulation. A number of risk scores have been developed to estimate the risk of significant bleeding in individuals treated with systemic anticoagulation. An example is the HAS-BLED score, which is validated to assess the annual risk of significant bleeding in individuals with atrial fibrillation treated with warfarin. Scores range from 0 to 9, based on a number of clinical characteristics (see Table PG1).

Table PG1. Clinical Components of the HAS-BLED Bleeding Risk Score

Letter	Clinical Characteristics	Points Awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile international normalized ratios	1
E	Elderly (>65 y)	1
D	Drugs or alcohol (1 point each)	1 or 2

Adapted from Pisters et al (2010)

HAS-BLED: Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR (international normalized ratio), Elderly, Drugs/alcohol concomitantly.

The risk of major bleeding in individuals with scores of 3, 4, and 5 has been reported at 3.74 per 100 patient-years, 8.70 per 100 patient-years, and 12.5 per 100 patient-years, respectively. Scores of 3 or greater are considered to be associated with a high risk of bleeding, potentially signaling the need for closer monitoring of individuals for adverse events, closer monitoring of international normalized ratio, or differential dose selections of oral anticoagulants or aspirin.

Following individuals may have an unacceptably high risk of bleeding with long-term oral anticoagulation:

- Thrombocytopenia or known coagulation defect associated with bleeding
- Recurrent bleeding, including gastrointestinal, genitourinary, respiratory
- Prior severe bleeding, including intracranial hemorrhage
- Combined use of dual antiplatelet and anticoagulant therapy
- Poor compliance or intolerance with anticoagulant therapy
- High risk of the patient falling or prior falls resulting in injury

Background/Overview

Atrial Fibrillation and Stroke

Atrial fibrillation (AF) is the most common type of irregular heartbeat, affecting at least 2.7 million people in the U.S. Risk of AF has been found to be lower in Black, Hispanic and Asian individuals relative to White individuals, including following adjustment for demographic and AF risk factors. Stroke is the most serious complication of AF. The estimated incidence of stroke in nontreated individuals with AF is 5% per year; despite a lower risk of AF, Black and Hispanic individuals have an increased risk of stroke compared with White individuals. Stroke associated with AF is primarily embolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is a main goal of AF treatment.

Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The area of the left atrium with the lowest blood flow in AF, and, therefore, the highest risk of thrombosis is the left atrial appendage (LAA). It has been estimated that 90% of left atrial thrombi occur in the LAA.

Treatment

Pharmacologic

The main treatment for stroke prevention in AF is anticoagulation, which has proven efficacy. The risk for stroke among individuals with AF is evaluated using several factors. Two commonly used scores, the $CHADS_2$ score and the CHA_2DS_2-VASc score are described below in Table 1. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban apixaban, and edoxaban have received U.S. Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Also, warfarin requires frequent monitoring and adjustments as well as lifestyle changes. Newer agents do not require the frequent monitoring seen with warfarin therapy; however, specific reversal agents do not exist for all of these agents. The 2018 American College of Chest Physicians guidelines (updated from 2012) recommend that CHA_2DS_2VASc be used to evaluate stroke risk, and individuals initially identified as having a low stroke risk should not be given antithrombotic therapy. In addition, they recommend bleeding risk assessments be given to every patient at every patient contact and that "potentially modifiable bleeding risk factors" should be the initial focus.

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

Letter	Clinical Characteristics	Points Awarded
C	Congestive heart failure (signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction)	1
H	Hypertension (resting blood pressure >140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment)	1
A	Age ≥75 y	1 ($CHADS_2$) 2 (CHA_2DS_2-VASc)

D	Diabetes (fasting glucose >125 mg/dL or treatment with oral hypoglycemic agent and/or insulin)	1
S	Stroke or transient ischemic attack (includes any history of cerebral ischemia)	2
V	Vascular disease (prior myocardial infarction, peripheral arterial disease, or aortic plaque)	1
A	Age 65-74 y	1
Sc	Sex category of female (female sex confers higher risk)	1

Adapted from Lip et al (2018) and January et al (2014).

Bleeding is the primary risk associated with systemic anticoagulation. Risk scores have been developed to estimate the risk of significant bleeding in individuals treated with systemic anticoagulation, such as the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in individuals with AF treated with warfarin. The score ranges from 0 to 9, based on clinical characteristics, including the presence of hypertension, renal and liver function, history of stroke, bleeding, labile international normalized ratios, age, and drug/alcohol use. Scores of 3 or greater are considered to be associated with a high risk of bleeding, potentially signaling the need for closer monitoring of individuals for adverse risks, closer monitoring of international normalized ratios, or differential dose selections of oral anticoagulants or aspirin.

Surgery

Surgical removal, or exclusion, of the LAA is often performed in individuals with AF who are undergoing open heart surgery for other reasons. Percutaneous left atrial appendage closure (LAAC) devices have been developed as a nonpharmacologic alternative to anticoagulation for stroke prevention in AF. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation.

Several versions of LAA occlusion devices have been developed. The PLAATO system (ev3 Endovascular) was the first device to be approved by the FDA for LAA occlusion. The device was discontinued in 2007 for commercial reasons, and intellectual property was sold to manufacturers of the Watchman system. The Watchman Left Atrial Appendage System (Boston Scientific) is a self-

expanding nickel titanium device. It has a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, using venous access and transseptal puncture to enter the left atrium. Transesophageal echocardiography and fluoroscopy are used to guide the procedure. Following implantation, individuals receive anticoagulation with warfarin or alternative agents for approximately 1 to 2 months. After this period, individuals are maintained on antiplatelet agents (ie, aspirin and/or clopidogrel) indefinitely. The Watchman FLX device is a next-generation Watchman device that is also FDA-approved for LAAC. This device is based on the design of the Watchman device, is fully recapturable and repositionable, and was made to occlude a wider size range of LAA than the original Watchman device. The Amplatzer cardiac plug (St. Jude Medical), is FDA-approved for closure of atrial septal defects but not for LAAC. A second-generation device developed for the specific indication of LAAC, the Amplatzer Amulet (Abbott), received FDA approval in August 2021. The Amplatzer Amulet consists of a nitinol mesh disc to seal the ostium of the LAA and a nitinol mesh distal lobe, to be positioned within the LAA. The device is preloaded within a delivery sheath. The Percutaneous LAA Transcatheter Occlusion device (ev3) has also been evaluated in research studies but has not received FDA approval. The Occlutech ™‡ (Occlutech) Left Atrial Appendage Occluder has received a CE mark for coverage in Europe. The Cardioblate™‡ closure device (Medtronic) is currently being tested in clinical studies.

The Lariat Loop Applicator is a suture delivery device approved by the FDA, intended to close a variety of surgical wounds. It is not specifically approved for LAAC. While the Watchman and other devices are implanted in the endocardium, the Lariat is a non-implant epicardial device.

In September 2021, the FDA sent a letter to healthcare providers indicating that women undergoing percutaneous LAA closure may be at higher risk of adverse procedural outcomes than men. This was based on an analysis of registry data from 49,357 individuals who underwent LAA closure with the Watchman device. When adjusted for multiple confounding factors, the study found women were more likely than men to experience any adverse event, major adverse events, and major bleeding. Women also had a significantly higher risk of death (adjusted odds ratio [OR], 2.01; 95% confidence interval [CI] 1.31 to 3.09) but absolute risk was low for both women and men (0.3% vs. 0.1%). In their letter, the FDA stated that they believe the benefits continue to outweigh the risks for approved LAA closure devices when used in accordance with their instructions for use.

Outcome Measures
The optimal study design for evaluating the efficacy of percutaneous LAAC for the prevention of stroke in AF is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. The rate of ischemic stroke during follow-up is the primary outcome of interest, along with rates of systemic embolization, cardiac events, bleeding complications, and death. For the LAAC devices, the appropriate comparison group could be oral anticoagulation, no therapy (for individuals who have a prohibitive risk for oral anticoagulation), or open surgical repair.

Ideally, percutaneous LAAC devices would represent an alternative to oral anticoagulation for the prevention of stroke in individuals with AF However, during the post implantation period the LAAC device may be associated with increased thrombogenicity, therefore, anticoagulation is used during the periprocedural period. Most studies evaluating percutaneous LAAC devices have included individuals who are eligible for anticoagulation.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 2002, the PLAATO system (ev3 Endovascular) was the first device to be approved by the FDA for LAA occlusion. The device was discontinued in 2007 for commercial reasons, and intellectual property was sold to manufacturers of the Watchman system.

In 2015, the Watchman™‡ Left Atrial Appendage Closure Technology (Boston Scientific) was approved by the FDA through the premarket approval process by the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Individuals with Atrial Fibrillation randomized controlled trial. In 2020, the Watchman FLX device (Boston Scientific) was approved by the FDA based on the single-arm, nonrandomized PINNACLE FLX study. The Amplatzer™‡ Amulet™‡ Left Atrial Appendage Occluder (Abbott) received FDA approval in 2021 through the premarket approval process based on results from the Amplatzer Amulet Left Atrial Appendage Occluder Randomized Controlled Trial (Amulet IDE Trial). The Watchman and Amplatzer Amulet devices are indicated to reduce the risk of thromboembolism from the LAA in individuals with nonvalvular AF who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and

- Have an appropriate rationale to seek a nonpharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

FDA product code: NGV.

Several other devices are being evaluated for LAA occlusion but are not approved in the U.S. for percutaneous LAAC. In 2006, the Lariat™‡ Loop Applicator device (SentreHEART), a suture delivery system, was cleared for marketing by the FDA through the 510(k) process. The intended use is to facilitate suture placement and knot tying in surgical applications where soft tissues are being approximated or ligated with a pretied polyester suture. The Amplatzer Cardiac Plug device (St. Jude Medical) and WaveCrest™‡ (Johnson & Johnson Biosense Webster) have CE approval in Europe for LAAC but are not currently approved in the U.S. for this indication.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Stroke prevention in individuals with atrial fibrillation (AF) is an important goal of treatment. Treatment with anticoagulant medications is the most common approach to stroke prevention. Because most embolic strokes originate from the left atrial appendage, occlusion of the left atrial appendage may offer a nonpharmacologic alternative to anticoagulant medications to lower the risk of stroke. Multiple percutaneously deployed devices are being investigated for left atrial appendage closure (LAAC). Two types of left atrial appendage devices (the Watchman and Amplatzer Amulet devices) have approval from the U.S. Food and Drug Administration (FDA) for stroke prevention in individuals with AF.

Summary of Evidence

For individuals who have atrial fibrillation (AF) who are at increased risk for embolic stroke who receive an FDA-approved percutaneous left atrial appendage closure (LAAC) device (e.g., the

Watchman or Amulet device), the evidence includes randomized controlled trials (RCTs) and observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. The most relevant evidence for the Watchman device comes from 2 industry-sponsored RCTs comparing the Watchman device with anticoagulation alone. One trial reported noninferiority on a composite outcome of stroke, cardiovascular/unexplained death, or systemic embolism after 2 years of follow-up, with continued benefits with the Watchman device after 4 years of follow-up. The second trial did not demonstrate noninferiority for the same composite outcome but did demonstrate noninferiority of the Watchman device to warfarin for late ischemic stroke and systemic embolization. Patient-level meta-analyses at 5-year follow-up for the 2 Watchman trials reported that the Watchman device is noninferior to warfarin on the composite outcome of stroke, systemic embolism, and cardiovascular death. Also, the Watchman was associated with lower rates of major bleeding, particularly hemorrhagic stroke, and mortality over the long term. Evidence for the Amplatzer Amulet device comes from 2 RCTs comparing the Amulet and Watchman devices, one of which was a short-term trial that assessed periprocedural outcomes at 45 days. The second trial comparing the Amulet and Watchman devices found the Amulet device to be noninferior to the Watchman device after 18 months of follow-up for a composite efficacy outcome that included ischemic stroke or systemic embolism and for a composite safety outcome that included all-cause mortality, major bleeding or procedure-related complications. One additional RCT evaluated the use of either the Amplatzer Amulet or Watchman device versus anticoagulants; subgroup analyses according to device were not performed. After up to 4 years of follow-up, the study found LAAC with either the Watchman or Amulet was noninferior to anticoagulants for a composite outcome that included stroke, transient ischemic attack (TIA), systemic embolism, clinically significant bleeding, significant periprocedural or device-related complications, or cardiovascular mortality. Among individuals in which the long-term risk of systemic anticoagulation exceeds the procedural risk of device implantation, the net health outcome will be improved. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have AF who are at increased risk for embolic stroke who receive a percutaneous LAAC device other than the Watchman device or Amplatzer Amulet device (eg, Lariat or Amplatzer Cardiac Plug), the evidence includes several nonrandomized comparator studies and uncontrolled observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. One nonrandomized study that compared outcomes among individuals undergoing LAAC with the Lariat device with individuals receiving anticoagulant or antiplatelet therapy reported fewer thromboembolic events in the group receiving the Lariat device. Evidence

from other observational studies of these devices which report high procedural success but also numerous complications. In addition, these devices do not have U.S. FDA approval for LAAC. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from 1 physician specialty society (2 responses) and 4 academic medical centers, 1 of which provided 4 responses, for a total of 8 responses, while this policy was under review in 2015. Input generally supported the use of a left atrial appendage closure device approved by the U.S. Food and Drug Administration for individuals with an increased risk of stroke and systemic embolism, based on $CHADS_2$ or CHA_2DS_2-VASc score. Systemic anticoagulation therapy was recommended, but the long-term risks of systemic anticoagulation outweigh the risks of the device implantation.

Practice Guidelines and Position Statements

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

American College of Chest Physicians

In 2018, the American College of Chest Physicians (CHEST) guideline made the following recommendation regarding left atrial appendage (LAA) occlusion and oral anticoagulation: "In individuals with AF at high risk of ischemic stroke who have absolute contraindications for OAC

[oral anticoagulation], we suggest using LAA occlusion (Weak recommendation, low-quality evidence)."

American Heart Association
In 2019, the American Heart Association (AHA), in collaboration with the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS), published an update of their guideline for the management of individuals with atrial fibrillation (AF). A new recommendation in the guideline states: "Percutaneous LAA [left atrial appendage] occlusion may be considered in individuals with AF at increased risk of stroke who have contraindications to long-term anticoagulation." The class of recommendation is IIb and the level of evidence is B_NR (moderate quality of evidence, nonrandomized). No other LAA closure devices are mentioned in the guideline. The AHA also released a scientific statement in 2021 about managing AF in individuals with heart failure and reduced ejection fraction. They state that, "It is reasonable to consider LAA closure in individuals with AF and heart failure with reduced ejection fraction (HFrEF) with moderate to high stroke risk and contraindications to long-term oral anticoagulation", however, they also note that the role of LAA therapies in individuals with AF with HFrEF needs to be better understood, and this is an opportunity for future research.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Since 2016, the Centers for Medicare & Medicaid Services has a national coverage determination under coverage with evidence development for percutaneous LAAC in AF, as follows:

> "LAAC devices are covered when the device has received U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meet all of the conditions specified below:

The patient must have:

- A $CHADS_2$ score ≥2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA_2DS_2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category).

- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in individuals with NVAF [nonvalvular atrial fibrillation] prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.
- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.

The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon(s) that meet the following criteria:

- Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,
- Has performed ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum; and,
- Continues to perform ≥ 25 interventional cardiac procedures that involve transseptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period."

Individuals must be enrolled in approved registries that track outcomes for procedures and devices.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this policy are listed in Table 2

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02513797[a]	aMAZE Study: LAA Ligation with the LARIAT Suture Delivery System as Adjunctive to	600	Mar 2022

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Pulmonary Vein Isolation for Persistent Atrial Fibrillation (aMAZE)		
NCT03204695[a]	A Prospective, Multicenter, Non-Randomized, Post-market Clinical Follow-up Study to Confirm Safety and Performance of the Coherex WaveCrest Left Atrial Appendage Occlusion System in Individuals with Non-valvular Atrial Fibrillation	65	Mar 2023
NCT03463317	Left Atrial Appendage CLOSURE in Individuals With Atrial Fibrillation at High Risk of Stroke and Bleeding Compared to Medical Therapy: a Prospective Randomized Clinical Trial	1512	Mar 2025
NCT02964208[a]	AMPLATZER LAA Occluder Post Approval Study (PAS)	1000	Jun 2023
NCT03302494[a]	WaveCrest Vs. Watchman Transseptal LAA Closure to Reduce AF-Mediated Stroke 2 (WAVECREST2)	1550	Dec 2029
NCT03309332[a]	OSB Lead-AMPLATZER PFO Occluder New Enrollment PAS	1214	Apr 2030
NCT03795298	Comparison of Anticoagulation with Left Atrial Appendage Closure After AF Ablation (OPTION)	1600	Nov 2024
NCT04394546	WATCHMAN FLX Versus NOAC for Embolic Protection in in the Management of Individuals With Non-Valvular Atrial Fibrillation	3000	Dec 2027
NCT04226547	Clinical Trial of Atrial Fibrillation Individuals Comparing Left Atrial Appendage Occlusion Therapy to Non-vitamin K Antagonist Oral Anticoagulants	2650	April 2029

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03276169	Left Atrial Function Changes after Left Atrial Appendage Closure in Individuals with Persistent Atrial Fibrillation	105	Nov 2020 (updated Mar 2021)
NCT01118299	AMPLATZER Cardiac Plug Clinical Trial	3000	Dec 2018 (updated Apr 2020)
NCT02681042	Left Atrial Appendage Closure with SentreHeart Lariat Device	9	May 2018 (updated Feb 2021)

NCT: national clinical trial.
[a] indicates industry-sponsored study.

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Policy History

Original Effective Date: 05/18/2011
Current Effective Date: 09/11/2023

05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. New policy.
05/03/2012	Medical Policy Committee review
05/16/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. Percutaneous added to the title and coverage statement.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. An FDA-approved left atrial appendage closure device is considered medically necessary with conditions.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT Coding Update
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. No change to coverage.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. No change to coverage.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Added policy guidelines
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. No change to coverage.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Added to policy guideline section.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. No change to coverage.

Policy # 00296
Original Effective Date: 05/18/2011
Current Effective Date: 09/11/2023

08/04/2022 Medical Policy Committee review
08/10/2022 Medical Policy Implementation Committee approval. Policy statements updated to include the FDA-approved Amplatzer Amulet device.
08/03/2023 Medical Policy Committee review
08/09/2023 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 08/2024

Coding

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

Policy # 00296
Original Effective Date: 05/18/2011
Current Effective Date: 09/11/2023

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33340
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.