PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 2.02.26

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

BCBSA Ref. Policy:	2.02.26	
Effective Date:	Aug. 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	July 10, 2023	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

The heart is divided into two upper and two lower chambers. Atrial fibrillation, also called a-fib, occurs when the heart's upper chambers beat irregularly—and often rapidly. Because blood isn't pumped out the way that it should be, blood tends to pool in these two upper chambers. The pooling blood increases the risk of blood clots in the area of the heart called the left atrial appendage. If a blood clot comes loose, it may travel to the brain and cause a stroke. Blood thinners are the usual method of preventing blood clots in people with a-fib. If taking a blood thinner poses too much risk or a person can't tolerate this medication, placing a device in the heart is a different way of helping to prevent stroke. This device seals off the left atrial appendage. Should a clot develop, the device blocks it from entering the bloodstream. This policy describes when a left atrial appendage closure device is considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Medical Necessity
Percutaneous left atrial appendage closure device (e.g., the Watchman)	**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) may be considered medically necessary for the prevention of stroke in individuals with atrial fibrillation when the following criteria are met:** • There is an increased risk of stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc score (see **Table 2**) and systemic anticoagulation therapy is recommended **AND** • The long-term risks of systemic anticoagulation outweigh the risks of the device implantation (see **Related Information**) **The use of a device with FDA approval for percutaneous left atrial appendage closure (e.g., the Watchman or Amplatzer Amulet) for stroke prevention in individuals who do not meet the above criteria is considered investigational.**

Device	Investigational
Other percutaneous left atrial appendage closure devices	**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 is considered investigational.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include ALL of the following: • Name of the Food and Drug Administration (FDA) device to be used • $CHADS_2$ or CHA_2DS_2-VASc score documenting individual's increased risk of stroke and systemic embolism • Documentation that systemic anticoagulation therapy is recommended AND the long-term risks of systemic anticoagulation outweigh the risks of the device implantation

Coding

Code	Description
CPT	
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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

The balance of risks and benefits associated with percutaneous 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 has been 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 1**).

Table 1: Clinical Components of the HAS-BLED Bleeding Risk Score

Letter	Clinical Characteristic	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 risks, closer monitoring of international normalized ratio, or differential dose selections of oral anticoagulants or aspirin.

Evidence Review

Description

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 device (the Watchman and Amplatzer Amulet devices) have approval from the U.S. Food and Drug Administration (FDA)for stroke prevention in individuals with AF.

Background

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.[1,2] 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.[3,4] 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 $CHADS_2$ and the CHA_2DS_2-VASc score, are described below in **Table 2**. 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 individual at every individual contact and that "potentially modifiable bleeding risk factors" should be the initial focus.

Table 2. $CHADS_2$ and CHA_2DS_2-VASc Scores to Predict Ischemic Stroke Risk in Patients with Atrial Fibrillation

Letter	Clinical Characteristics	Points Awarded
C	Congestive heart failure (signs/symptoms of heart failure confirmed with objective evidence of cardiac dysfunction)	1

Letter	Clinical Characteristics	Points Awarded
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)[5] and January et al (2014).[6]

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.[7] 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.[6]

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) closure 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 (i.e., 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.[8] 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.[9] 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.[10] This was based on an analysis of registry data from 49,357 individuals who underwent LAA closure with the Watchman device.[11] 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 postimplantation 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.

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 two 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 two years of follow-up, with continued benefits with the Watchman device after four 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 five-year follow-up for the two 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 in 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 four years of follow-up, the study found LAAC closure 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 (e.g., 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 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 3**.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02513797[a]	aMAZE Study: LAA Ligation with the LARIAT Suture Delivery System as Adjunctive to Pulmonary Vein Isolation for Persistent Atrial Fibrillation (aMAZE)	600	Mar 2022
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 Patients with Non-valvular Atrial Fibrillation	65	Mar 2023
NCT03463317	Left Atrial Appendage CLOSURE in Patients 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 Patients With Non-Valvular Atrial Fibrillation	3000	Dec 2027
NCT04226547	Clinical Trial of Atrial Fibrillation Patients Comparing Left Atrial Appendage Occlusion Therapy to Non-vitamin K Antagonist Oral Anticoagulants	2650	April 2029
Unpublished			
NCT03276169	Left Atrial Function Changes after Left Atrial Appendage Closure in Patients 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

Clinical Input Received 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.

In response to requests, input was received from one physician specialty society (two responses) and four academic medical centers, one of which provided four responses, for a total of eight 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

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. 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 LAA occlusion and oral anticoagulation (OAC): "In patients with AF at high risk of ischemic stroke who have absolute contraindications for OAC, we suggest using LAA occlusion (Weak recommendation, low quality evidence)."[5]

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 patients with AF.[77]

A new recommendation in the guideline states:

"Percutaneous LAA occlusion may be considered in patients 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, non-randomized). No other LAA closure devices are mentioned in the guideline.

The AHA also released a scientific statement in 2021 about managing AF in patients with heart failure and reduced ejection fraction.[78] They state that, "It is reasonable to consider LAA closure in patients 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 patients with AF with HFrEF needs to be better understood, and this is an opportunity for future research.

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[79]:

"LAAC devices are covered when the device has received 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 patients 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 meets 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."

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

Regulatory Status

In 2002, the PLAATO system (ev3 Endovascular) was the first device to be approved by 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 Patients with Atrial Fibrillation (PROTECT-AF) randomized controlled trial.[12] In 2020, the Watchman FLX device (Boston Scientific) was approved by the FDA based on the single-arm, nonrandomized PINNACLE FLX study.[8] 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).[9] The Watchman and

Amplatzer Amulet devices are indicated to reduce the risk of thromboembolism from the LAA in patients 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.

References

1. Mou L, Norby FL, Chen LY, et al. Lifetime Risk of Atrial Fibrillation by Race and Socioeconomic Status: ARIC Study (Atherosclerosis Risk in Communities). Circ Arrhythm Electrophysiol. Jul 2018; 11(7): e006350. PMID 30002066
2. Dewland TA, Olgin JE, Vittinghoff E, et al. Incident atrial fibrillation among Asians, Hispanics, blacks, and whites. Circulation. Dec 03 2013; 128(23): 2470-7. PMID 24103419
3. Gardener H, Sacco RL, Rundek T, et al. Race and Ethnic Disparities in Stroke Incidence in the Northern Manhattan Study. Stroke. Apr 2020; 51(4): 1064-1069. PMID 32078475
4. Guo J, Gabriel N, Magnani JW, et al. Racial and Urban-Rural Difference in the Frequency of Ischemic Stroke as Initial Manifestation of Atrial Fibrillation. Front Public Health. 2021; 9: 780185. PMID 34805085
5. Lip GYH, Banerjee A, Boriani G, et al. Antithrombotic Therapy for Atrial Fibrillation: CHEST Guideline and Expert Panel Report. Chest. Nov 2018; 154(5): 1121-1201. PMID 30144419
6. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. Dec 02 2014; 64(21): e1-76. PMID 24685669
7. Lip GY, Frison L, Halperin JL, et al. Comparative validation of a novel risk score for predicting bleeding risk in anticoagulated patients with atrial fibrillation: the HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or

Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) score. J Am Coll Cardiol. Jan 11 2011; 57(2): 173-80. PMID 21111555

8. Food and Drug Administration. Summary of Safety and Effectiveness Data. WATCHMAN Left Atrial Appendage Closure Device with Delivery System and WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System. **https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013S035B.pdf**. Accessed June 12, 2023,
9. Food and Drug Administration. Approval Letter: Amplatzer Amulet Left Atrial Appendage Occluder; 2021. **https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200049A.pdf**. Accessed June 12, 2023.
10. Food and Drug Administration. Left Atrial Appendage Occlusion (LAAO) Devices Potentially Associated with Procedural Outcome Differences Between Women and Men: Letter to Health Care Providers. Accessed March 23, 2023.
11. Darden D, Duong T, Du C, et al. Sex Differences in Procedural Outcomes Among Patients Undergoing Left Atrial Appendage Occlusion: Insights From the NCDR LAAO Registry. JAMA Cardiol. Nov 01 2021; 6(11): 1275-1284. PMID 34379072
12. Food and Drug Administration. Approval Letter: WATCHMAN LAA Closure Technology. 2015; **http://www.accessdata.fda.gov/cdrh_docs/pdf13/p130013a.pdf**. Accessed June 12, 2023.
13. Reddy VY, Doshi SK, Kar S, et al. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. J Am Coll Cardiol. Dec 19 2017; 70(24): 2964-2975. PMID 29103847
14. Bode WD, Patel N, Gehi AK. Left atrial appendage occlusion for prevention of stroke in nonvalvular atrial fibrillation: a meta-analysis. J Interv Card Electrophysiol. Jun 2015; 43(1): 79-89. PMID 25711953
15. Briceno DF, Villablanca P, Cyrille N, et al. Left Atrial Appendage Occlusion Device and Novel Oral Anticoagulants Versus Warfarin for Stroke Prevention in Nonvalvular Atrial Fibrillation: Systematic Review and Meta-Analysis of Randomized Controlled Trials. Circ Arrhythm Electrophysiol. Oct 2015; 8(5): 1057-64. PMID 26226997
16. Holmes DR, Doshi SK, Kar S, et al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient-Level Meta-Analysis. J Am Coll Cardiol. Jun 23 2015; 65(24): 2614-2623. PMID 26088300
17. Li X, Wen SN, Li SN, et al. Over 1-year efficacy and safety of left atrial appendage occlusion versus novel oral anticoagulants for stroke prevention in atrial fibrillation: A systematic review and meta-analysis of randomized controlled trials and observational studies. Heart Rhythm. Jun 2016; 13(6): 1203-14. PMID 26724488
18. Lip GY, Lane DA. Stroke prevention in atrial fibrillation: a systematic review. JAMA. May 19 2015; 313(19): 1950-62. PMID 25988464
19. Price MJ, Reddy VY, Valderrábano M, et al. Bleeding Outcomes After Left Atrial Appendage Closure Compared With Long-Term Warfarin: A Pooled, Patient-Level Analysis of the WATCHMAN Randomized Trial Experience. JACC Cardiovasc Interv. Dec 28 2015; 8(15): 1925-1932. PMID 26627989
20. Noelck N, Papak J, Freeman M, et al. Effectiveness of Left Atrial Appendage Exclusion Procedures to Reduce the Risk of Stroke: A Systematic Review of the Evidence. Circ Cardiovasc Qual Outcomes. Jul 2016; 9(4): 395-405. PMID 27407055
21. Sahay S, Nombela-Franco L, Rodes-Cabau J, et al. Efficacy and safety of left atrial appendage closure versus medical treatment in atrial fibrillation: a network meta-analysis from randomised trials. Heart. Jan 15 2017; 103(2): 139-147. PMID 27587437
22. Wei Z, Zhang X, Wu H, et al. A meta-analysis for efficacy and safety evaluation of transcatheter left atrial appendage occlusion in patients with nonvalvular atrial fibrillation. Medicine (Baltimore). Aug 2016; 95(31): e4382. PMID 27495048
23. Tereshchenko LG, Henrikson CA, Cigarroa J, et al. Comparative Effectiveness of Interventions for Stroke Prevention in Atrial Fibrillation: A Network Meta-Analysis. J Am Heart Assoc. May 20 2016; 5(5). PMID 27207998
24. Bajaj NS, Kalra R, Patel N, et al. Comparison of Approaches for Stroke Prophylaxis in Patients with Non-Valvular Atrial Fibrillation: Network Meta-Analyses of Randomized Controlled Trials. PLoS One. 2016; 11(10): e0163608. PMID 27706224
25. Hanif H, Belley-Cote EP, Alotaibi A, et al. Left atrial appendage occlusion for stroke prevention in patients with atrial fibrillation: a systematic review and network meta-analysis of randomized controlled trials. J Cardiovasc Surg (Torino). Feb 2018; 59(1): 128-139. PMID 28215062

26. Baman JR, Mansour M, Heist EK, et al. Percutaneous left atrial appendage occlusion in the prevention of stroke in atrial fibrillation: a systematic review. Heart Fail Rev. Mar 2018; 23(2): 191-208. PMID 29453694

27. Takeda K, Tsuboko Y, Iwasaki K. Latest outcomes of transcatheter left atrial appendage closure devices and direct oral anticoagulant therapy in patients with atrial fibrillation over the past 5 years: a systematic review and meta-analysis. Cardiovasc Interv Ther. Oct 2022; 37(4): 725-738. PMID 35098478

28. Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. Lancet. Aug 15 2009; 374(9689): 534-42. PMID 19683639

29. Reddy VY, Doshi SK, Sievert H, et al. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) Trial. Circulation. Feb 12 2013; 127(6): 720-9. PMID 23325525

30. Reddy VY, Sievert H, Halperin J, et al. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial. JAMA. Nov 19 2014; 312(19): 1988-98. PMID 25399274

31. Alli O, Doshi S, Kar S, et al. Quality of life assessment in the randomized PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) trial of patients at risk for stroke with nonvalvular atrial fibrillation. J Am Coll Cardiol. Apr 30 2013; 61(17): 1790-8. PMID 23500276

32. Holmes DR, Kar S, Price MJ, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. J Am Coll Cardiol. Jul 08 2014; 64(1): 1-12. PMID 24998121

33. Osmancik P, Herman D, Neuzil P, et al. Left Atrial Appendage Closure Versus Direct Oral Anticoagulants in High-Risk Patients With Atrial Fibrillation. J Am Coll Cardiol. Jun 30 2020; 75(25): 3122-3135. PMID 32586585

34. Osmancik P, Herman D, Neuzil P, et al. 4-Year Outcomes After Left Atrial Appendage Closure Versus Nonwarfarin Oral Anticoagulation for Atrial Fibrillation. J Am Coll Cardiol. Jan 04 2022; 79(1): 1-14. PMID 34748929

35. Lam YY, Yip GW, Yu CM, et al. Left atrial appendage closure with AMPLATZER cardiac plug for stroke prevention in atrial fibrillation: initial Asia-Pacific experience. Catheter Cardiovasc Interv. Apr 01 2012; 79(5): 794-800. PMID 21542102

36. Montenegro MJ, Quintella EF, Damonte A, et al. Percutaneous occlusion of left atrial appendage with the Amplatzer Cardiac PlugTM in atrial fibrillation. Arq Bras Cardiol. Feb 2012; 98(2): 143-50. PMID 22286325

37. Park JW, Bethencourt A, Sievert H, et al. Left atrial appendage closure with Amplatzer cardiac plug in atrial fibrillation: initial European experience. Catheter Cardiovasc Interv. Apr 01 2011; 77(5): 700-6. PMID 20824765

38. Reddy VY, Holmes D, Doshi SK, et al. Safety of percutaneous left atrial appendage closure: results from the Watchman Left Atrial Appendage System for Embolic Protection in Patients with AF (PROTECT AF) clinical trial and the Continued Access Registry. Circulation. Feb 01 2011; 123(4): 417-24. PMID 21242484

39. Swaans MJ, Post MC, Rensing BJ, et al. Percutaneous left atrial appendage closure for stroke prevention in atrial fibrillation. Neth Heart J. Apr 2012; 20(4): 161-6. PMID 22231152

40. Reddy VY, Möbius-Winkler S, Miller MA, et al. Left atrial appendage closure with the Watchman device in patients with a contraindication for oral anticoagulation: the ASAP study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology). J Am Coll Cardiol. Jun 25 2013; 61(25): 2551-6. PMID 23583249

41. Boersma LV, Schmidt B, Betts TR, et al. Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry. Eur Heart J. Aug 2016; 37(31): 2465-74. PMID 26822918

42. Dukkipati SR, Kar S, Holmes DR, et al. Device-Related Thrombus After Left Atrial Appendage Closure: Incidence, Predictors, and Outcomes. Circulation. Aug 28 2018; 138(9): 874-885. PMID 29752398

43. Jazayeri MA, Vuddanda V, Turagam MK, et al. Safety profiles of percutaneous left atrial appendage closure devices: An analysis of the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database from 2009 to 2016. J Cardiovasc Electrophysiol. Jan 2018; 29(1): 5-13. PMID 28988455

44. Lakkireddy D, Thaler D, Ellis CR, et al. Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial. Circulation. Nov 09 2021; 144(19): 1543-1552. PMID 34459659

45. Galea R, De Marco F, Meneveau N, et al. Amulet or Watchman Device for Percutaneous Left Atrial Appendage Closure: Primary Results of the SWISS-APERO Randomized Clinical Trial. Circulation. Mar 08 2022; 145(10): 724-738. PMID 34747186

46. Landmesser U, Schmidt B, Nielsen-Kudsk JE, et al. Left atrial appendage occlusion with the AMPLATZER Amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study. EuroIntervention. Sep 20 2017; 13(7): 867-876. PMID 28649053

47. Landmesser U, Tondo C, Camm J, et al. Left atrial appendage occlusion with the AMPLATZER Amulet device: one-year follow-up from the prospective global Amulet observational registry. EuroIntervention. Aug 03 2018; 14(5): e590-e597. PMID 29806820

48. Hildick-Smith D, Landmesser U, Camm AJ, et al. Left atrial appendage occlusion with the Amplatzer™ Amulet™ device: full results of the prospective global observational study. Eur Heart J. Aug 07 2020; 41(30): 2894-2901. PMID 32243499

49. Nielsen-Kudsk JE, Korsholm K, Damgaard D, et al. Clinical Outcomes Associated With Left Atrial Appendage Occlusion Versus Direct Oral Anticoagulation in Atrial Fibrillation. JACC Cardiovasc Interv. Jan 11 2021; 14(1): 69-78. PMID 33413867

50. Gloekler S, Shakir S, Doblies J, et al. Early results of first versus second generation Amplatzer occluders for left atrial appendage closure in patients with atrial fibrillation. Clin Res Cardiol. Aug 2015; 104(8): 656-65. PMID 25736061

51. Al-Kassou B, Omran H. Comparison of the Feasibility and Safety of First- versus Second-Generation AMPLATZER™ Occluders for Left Atrial Appendage Closure. Biomed Res Int. 2017; 2017: 1519362. PMID 29085833

52. Chatterjee S, Herrmann HC, Wilensky RL, et al. Safety and Procedural Success of Left Atrial Appendage Exclusion With the Lariat Device: A Systematic Review of Published Reports and Analytic Review of the FDA MAUDE Database. JAMA Intern Med. Jul 2015; 175(7): 1104-9. PMID 25938303

53. Price MJ, Gibson DN, Yakubov SJ, et al. Early safety and efficacy of percutaneous left atrial appendage suture ligation: results from the U.S. transcatheter LAA ligation consortium. J Am Coll Cardiol. Aug 12 2014; 64(6): 565-72. PMID 25104525

54. Bartus K, Han FT, Bednarek J, et al. Percutaneous left atrial appendage suture ligation using the LARIAT device in patients with atrial fibrillation: initial clinical experience. J Am Coll Cardiol. Jul 09 2013; 62(2): 108-118. PMID 23062528

55. Massumi A, Chelu MG, Nazeri A, et al. Initial experience with a novel percutaneous left atrial appendage exclusion device in patients with atrial fibrillation, increased stroke risk, and contraindications to anticoagulation. Am J Cardiol. Mar 15 2013; 111(6): 869-73. PMID 23312129

56. Miller MA, Gangireddy SR, Doshi SK, et al. Multicenter study on acute and long-term safety and efficacy of percutaneous left atrial appendage closure using an epicardial suture snaring device. Heart Rhythm. Nov 2014; 11(11): 1853-9. PMID 25068574

57. Gafoor S, Franke J, Bertog S, et al. Left atrial appendage occlusion in octogenarians: short-term and 1-year follow-up. Catheter Cardiovasc Interv. Apr 01 2014; 83(5): 805-10. PMID 24259397

58. Lakkireddy D, Afzal MR, Lee RJ, et al. Short and long-term outcomes of percutaneous left atrial appendage suture ligation: Results from a US multicenter evaluation. Heart Rhythm. May 2016; 13(5): 1030-1036. PMID 26872554

59. Bartus K, Bednarek J, Myc J, et al. Feasibility of closed-chest ligation of the left atrial appendage in humans. Heart Rhythm. Feb 2011; 8(2): 188-93. PMID 21050893

60. Stone D, Byrne T, Pershad A. Early results with the LARIAT device for left atrial appendage exclusion in patients with atrial fibrillation at high risk for stroke and anticoagulation. Catheter Cardiovasc Interv. Jul 2015; 86(1): 121-7. PMID 23765504

61. Fink T, Schlüter M, Tilz RR, et al. Acute and long-term outcomes of epicardial left atrial appendage ligation with the second-generation LARIAT device: a high-volume electrophysiology center experience. Clin Res Cardiol. Dec 2018; 107(12): 1139-1147. PMID 29881879

62. Dar T, Afzal MR, Yarlagadda B, et al. Mechanical function of the left atrium is improved with epicardial ligation of the left atrial appendage: Insights from the LAFIT-LARIAT Registry. Heart Rhythm. Jul 2018; 15(7): 955-959. PMID 29477973

63. Litwinowicz R, Bartus M, Burysz M, et al. Long term outcomes after left atrial appendage closure with the LARIAT device-Stroke risk reduction over five years follow-up. PLoS One. 2018; 13(12): e0208710. PMID 30566961

64. Litwinowicz R, Bartus M, Malec-Litwinowicz M, et al. Left Atrial Appendage Occlusion for Secondary Stroke Prevention in Patients with Atrial Fibrillation: Long-Term Results. Cerebrovasc Dis. 2019; 47(3-4): 188-195. PMID 31121584

65. Litwinowicz R, Bartus M, Kapelak B, et al. Reduction in risk of stroke and bleeding after left atrial appendage closure with LARIAT device in patients with increased risk of stroke and bleeding: Long term results. Catheter Cardiovasc Interv. Nov 15 2019; 94(6): 837-842. PMID 30884101

66. Nietlispach F, Gloekler S, Krause R, et al. Amplatzer left atrial appendage occlusion: single center 10-year experience. Catheter Cardiovasc Interv. Aug 01 2013; 82(2): 283-9. PMID 23412815

67. Kefer J, Vermeersch P, Budts W, et al. Transcatheter left atrial appendage closure for stroke prevention in atrial fibrillation with Amplatzer cardiac plug: the Belgian Registry. Acta Cardiol. Dec 2013; 68(6): 551-8. PMID 24579432

68. Guérios EE, Schmid M, Gloekler S, et al. Left atrial appendage closure with the Amplatzer cardiac plug in patients with atrial fibrillation. Arq Bras Cardiol. Jun 2012; 98(6): 528-36. PMID 22584492

69. Danna P, Proietti R, Sagone A, et al. Does left atrial appendage closure with a cardiac plug system reduce the stroke risk in nonvalvular atrial fibrillation patients? A single-center case series. Pacing Clin Electrophysiol. Mar 2013; 36(3): 347-53. PMID 23252940

70. Lopez-Minguez JR, Eldoayen-Gragera J, Gonzalez-Fernandez R, et al. Immediate and one-year results in 35 consecutive patients after closure of left atrial appendage with the Amplatzer Cardiac Plug. Rev Esp Cardiol. Feb 2013;66(2):90-97. PMID 22939161

71. Streb W, Szymała M, Kukulski T, et al. Percutaneous closure of the left atrial appendage using the Amplatzer Cardiac Plug in patients with atrial fibrillation: evaluation of safety and feasibility. Kardiol Pol. 2013; 71(1): 8-16. PMID 23348528

72. Cruz-González I, González-Ferreiro R, Freixa X, et al. Left atrial appendage occlusion for stroke despite oral anticoagulation (resistant stroke). Results from the Amplatzer Cardiac Plug registry. Rev Esp Cardiol (Engl Ed). Jan 2020; 73(1): 28-34. PMID 31036510

73. Santoro G, Meucci F, Stolcova M, et al. Percutaneous left atrial appendage occlusion in patients with non-valvular atrial fibrillation: implantation and up to four years follow-up of the AMPLATZER Cardiac Plug. EuroIntervention. Feb 2016; 11(10): 1188-94. PMID 25354761

74. Meerkin D, Butnaru A, Dratva D, et al. Early safety of the Amplatzer Cardiac Plug™ for left atrial appendage occlusion. Int J Cardiol. Oct 09 2013; 168(4): 3920-5. PMID 23890886

75. Wiebe J, Bertog S, Franke J, et al. Safety of percutaneous left atrial appendage closure with the Amplatzer cardiac plug in patients with atrial fibrillation and contraindications to anticoagulation. Catheter Cardiovasc Interv. Apr 01 2014; 83(5): 796-802. PMID 24327462

76. Urena M, Rodés-Cabau J, Freixa X, et al. Percutaneous left atrial appendage closure with the AMPLATZER cardiac plug device in patients with nonvalvular atrial fibrillation and contraindications to anticoagulation therapy. J Am Coll Cardiol. Jul 09 2013; 62(2): 96-102. PMID 23665098

77. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. Aug 2019; 16(8): e66-e93. PMID 30703530

78. Gopinathannair R, Chen LY, Chung MK, et al. Managing Atrial Fibrillation in Patients With Heart Failure and Reduced Ejection Fraction: A Scientific Statement From the American Heart Association. Circ Arrhythm Electrophysiol. Jun 2021; 14(6): HAE0000000000000078. PMID 34129347

79. Center for Medicare & Medicaid Services. National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34). 2016; **https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=367&ncdver=1&NCAId=281&bc=AAAAAAAACAAAAA%3d%3d&**. Accessed June 12, 2023.

History

Date	Comments
06/13/11	Add to Cardiology Section - New medical policy created with literature search; procedure considered investigational.
12/29/11	Code 0281T added.
05/22/12	Replace policy. Policy updated with literature review, references 2-4, 6-9, 11, 12 added. Policy title and policy statements revised to include percutaneous – no other change to policy statement.
09/17/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
05/28/13	Replace policy. Policy updated with literature review through January 2013, references 2, 12-20 added. Policy statement unchanged.
09/23/14	Annual Review. Policy updated with literature review through June 5, 2014. References 1-3, 12-14, 17, 25-29, 31-32, and 34 added. Policy statement unchanged.
12/08/15	Annual Review. Policy updated with literature review through May 29, 2015; references 2-3, 6, 9, 12, 21, 33, and 43 added; clinical input reviewed. An FDA-approved left atrial appendage closure device is considered medically necessary with conditions.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through April 30, 2016; references 6-7, 9-11, and 25-27 added. Policy statements unchanged.
01/01/17	Coding update, added new code 33340 effective 1/1/17.
07/01/17	Annual Review, approved June 22, 2017. Policy moved into new format. Policy updated with literature review through March 23, 2017; references 13-18 and 55-56 added. Policy statements unchanged.
01/01/18	Removed code CPT code 0281T as it was terminated 1/1/17 and replaced with 33340.
08/01/18	Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 16 and 53 added. PLAATO device removed from the policy statement; statements otherwise unchanged. Removed CPT codes 33999 and 93799.
08/01/19	Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019; several references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.

Date	Comments
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through March, 2020; references added. Policy statements unchanged.
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through March 18, 2021; references added. Policy statements unchanged.
08/01/22	Annual Review, approved July 12, 2022. Policy updated with literature review through March 12, 2022; references added. Policy statements updated to include the FDA-approved Amplatzer Amulet device.
08/01/23	Annual Review, approved July 10, 2023. Policy updated with literature review through March 23, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator ─ Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-607-0546 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-607-0546 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-607-0546 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-607-0546 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-607-0546 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-607-0546 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-607-0546 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-607-0546 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-607-0546 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-607-0546 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-607-0546 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-607-0546 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-607-0546 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-607-0546 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-607-0546 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-607-0546 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-607-0546 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-607-0546 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-607-0546 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-607-0546 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-607-0546 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-607-0546 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-607-0546 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-607-0546 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-607-0546 (TTY: 711) تماس بگیرید.