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

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Percutaneous left atrial appendage closure device (eg, the Watchman) | The use of a device with U.S. Food and Drug Administration (FDA) approval for percutaneous left atrial appendage closure (eg, the Watchman) may be considered medically necessary for the prevention of stroke in patients with atrial fibrillation when the following criteria are met:  
  - There is an increased risk of stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-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 (eg, the Watchman) for stroke prevention in patients who do not meet the above criteria is considered 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 devices, for stroke prevention in patients with atrial fibrillation is considered investigational. |

### Documentation Requirements

The patient’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
- CHADS₂ or CHA₂DS₂-VASc score documenting patient’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
The balance of risks and benefits associated with implantation of the Watchman device for stroke prevention, as an alternative to systemic anticoagulation with warfarin, 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 patients treated with systemic anticoagulation. An example is the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in patients with atrial fibrillation treated with warfarin (Pisters et al, 2010)\textsuperscript{1}. 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

<table>
<thead>
<tr>
<th>Letter</th>
<th>Clinical Characteristic</th>
<th>Points Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>Hypertension</td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>Abnormal renal and liver function (1 point each)</td>
<td>1 or 2</td>
</tr>
<tr>
<td>S</td>
<td>Stroke</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>Bleeding</td>
<td>1</td>
</tr>
<tr>
<td>L</td>
<td>Labile international normalized ratios</td>
<td>1</td>
</tr>
<tr>
<td>E</td>
<td>Elderly (&gt;65 y)</td>
<td>1</td>
</tr>
<tr>
<td>Letter</td>
<td>Clinical Characteristic</td>
<td>Points Awarded</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>D</td>
<td>Drugs or alcohol (1 point each)</td>
<td>1 or 2</td>
</tr>
</tbody>
</table>

Adapted from Pisters et al (2010)\(^1\) HAS-BLED: Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR (international normalized ratio), Elderly, Drugs/alcohol concomitantly.

Risk of major bleeding in patients 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 patients for adverse risks, closer monitoring of international normalized ratio, or differential dose selections of oral anticoagulants or aspirin (January et al, 2014).\(^2\)

### Evidence Review

#### Description

Stroke prevention in patients 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). One left atrial appendage device (the Watchman device) has approval from the U.S. Food and Drug Administration for stroke prevention in patients 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. Stroke is the most serious complication of AF. The estimated incidence of stroke in nontreated patients with AF is 5% per year. Stroke associated with AF is primarily embolic in nature, 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 patients with AF is evaluated using several factors. Two commonly used scores, the CHADS₂ and the CHADS₂-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, and apixaban, 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. Dabigatran does not require monitoring. However, unlike warfarin, the antithrombotic effects of dabigatran are not reversible with any currently available hemostatic drugs. 2018 American College of Chest Physicians guidelines (updated from 2012) recommend that CHA2DS2VASc be used to evaluate stroke risk, and patients 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 2. CHADS₂ and CHADS₂-VASc Scores to Predict Ischemic Stroke Risk in Patients with Atrial Fibrillation

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

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 patients treated with systemic anticoagulation, such as the HAS-BLED score, which has been validated to assess the annual risk of significant bleeding in patients 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 three or greater are considered to be associated with high risk of bleeding, potentially signaling the need for closer monitoring of patients 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 patients 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, patients receive anticoagulation with warfarin or alternative agents for approximately one to two months. After this period, patients are maintained on antiplatelet agents (ie, aspirin and/or clopidogrel) indefinitely. The Amplatzer cardiac plug (St. Jude Medical), is FDA-approved for closure of atrial septal defects but not for LAAC. A second-generation device, the Amplatzer Amulet, has been developed for the specific indication of LAAC, but currently does not have the FDA approval. 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 the 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.

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 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 patients who have a prohibitive risk for oral anticoagulation), or open surgical repair.

Although the Watchman device and other LAAC devices would ideally represent an alternative to oral anticoagulation for the prevention of stroke in patients with AF, during the postimplantation period, the device may be associated with increased thrombogenicity and, therefore, anticoagulation is used during the periprocedural period. Most studies evaluating the Watchman device have included patients who are eligible for anticoagulation.
Summary of Evidence

For individuals who have AF who are at increased risk for embolic stroke who receive the Watchman percutaneous LAAC device, the evidence includes two RCTs and meta-analyses of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. The most relevant evidence comes from two industry-sponsored RCTs that compared 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 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. The evidence also indicates that the Watchman device is efficacious in preventing stroke in the subset of patients with AF who are at increased risk for embolic stroke. Among patients 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 a meaningful 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 (eg, the Lariat or Amplatzer), the evidence includes several nonrandomized comparator studies and uncontrolled case series. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity. One nonrandomized study which compared outcomes among patients undergoing LAAC with the Lariat device with patients receiving anticoagulant or antiplatelet therapy, reported fewer thromboembolic events in the group receiving the Lariat device. Two nonrandomized studies compared the Amplatzer cardiac plug with the Amplatzer amulet. While the amulet may be technically easier to implant, clinical outcomes were similar between the two groups. The remaining evidence consists of case series of these devices which report high procedural success but also numerous complications. In addition, these devices do not have Food and Drug Administration approval for LAAC. The evidence is insufficient to determine the effects of the technology on health outcomes.
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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02681042</td>
<td>Left Atrial Appendage Closure with SentreHeart Lariat Device</td>
<td>50</td>
<td>Mar 2019</td>
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<tr>
<td>NCT03276169</td>
<td>Left Atrial Function Changes after Left Atrial Appendage Closure in Patients with Persistent Atrial Fibrillation</td>
<td>105</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>NCT02513797a</td>
<td>aMAZE Study: LAA Ligation with the LARIAT Suture Delivery System as Adjunctive to Pulmonary Vein Isolation for Persistent Atrial Fibrillation (aMAZE)</td>
<td>600</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT03204695a</td>
<td>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</td>
<td>65</td>
<td>Mar 2021</td>
</tr>
<tr>
<td>NCT02426944</td>
<td>Left Atrial Appendage Closure vs Novel Anticoagulation Agents in Atrial Fibrillation</td>
<td>400</td>
<td>May 2020</td>
</tr>
<tr>
<td>NCT03463317</td>
<td>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</td>
<td>1512</td>
<td>Feb 2023</td>
</tr>
<tr>
<td>NCT02964208a</td>
<td>AMPLATZER LAA Occluder Post Approval Study (PAS)</td>
<td>1000</td>
<td>Oct 2023</td>
</tr>
<tr>
<td>NCT02879448</td>
<td>AMPLATZER™ Amulet™ Left Atrial Appendage Occluder Randomized Controlled Trial</td>
<td>1878</td>
<td>Dec 2023</td>
</tr>
<tr>
<td>NCT03399851</td>
<td>Comparison of Amplatzer Amulet vs. Watchman Device in Patients Undergoing Left Atrial Appendage Closure: the SWISS-APERO Randomized Clinical Trial</td>
<td>200</td>
<td>Feb 2025</td>
</tr>
<tr>
<td>NCT03302494a</td>
<td>WAveCrest Vs. Watchman TransssEptal LAA Closure to REDuce AF-Mediatd STroke 2 (WAVECREST2)</td>
<td>1250</td>
<td>Dec 2025</td>
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<tr>
<td>NCT03309332a</td>
<td>OSB Lead-AMPLATZER PFO Occluder New Enrollment PAS</td>
<td>1214</td>
<td>Dec 2027</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------</td>
<td>--------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>NCT01118299</td>
<td>AMPLATZER Cardiac Plug Clinical Trial</td>
<td>3000</td>
<td>Dec 2018 (updated 02/01/19)</td>
</tr>
</tbody>
</table>

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 Food and Drug Administration for patients with an increased risk of stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-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

American Heart Association

In 2019, the American Heart Association, in collaboration with the American College of Cardiology and the Hearth Rhythm Society published an update of their guideline for the management of patients with atrial fibrillation. 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.
Guideline Comparison

In 2017, Andrade et al provided the following summary (see Table 4) comparing guidelines by American, Canadian, and European societies on left atrial appendage exclusion and closure for the management of atrial fibrillation.66

Table 4. Comparison of American, Canadian, and European Guidelines on LAA Exclusion/Closure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>AHA/ACC/HRS</th>
<th>CCS</th>
<th>ESC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical LAA closure (excision or obliteration of LAA)</td>
<td>May be considered in patients undergoing cardiac surgery (IIb)</td>
<td>Should be considered as part of surgical ablation of AF associated with mitral, aortic valve, or coronary artery bypass surgery</td>
<td>May be considered in patients undergoing cardiac surgery (IIb) More data are needed to confirm safety and efficacy of thoracoscopic exclusion</td>
</tr>
<tr>
<td>Percutaneous LAA exclusion</td>
<td>No recommendation</td>
<td>Not to be used, except in research or in systematically documented use protocols in patients at high risk of stroke (CHADS2 ≥2) and antithrombotic therapy precluded</td>
<td>May be considered in patients with contraindications for long term anticoagulant treatment (IIb)</td>
</tr>
</tbody>
</table>

Adapted from Andrade et al (2017).66

ACC: American College of Cardiology; AF: atrial fibrillation; AHA: American Heart Association; CCS: Canadian Cardiovascular Society; CHADS2: Congestive Heart Failure, Hypertension, Age, Diabetes, Stroke/transient Ischemic Attack; ESC: European Society of Cardiology; HRS: Heart Rhythm Society; LAA: left atrial appendage

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 follows67:

“LAAC devices are covered when the device has received 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 CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age > 75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-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. This device is 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 CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin; and
- Have an appropriate rationale to seek a nonpharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

FDA product code: NGV.

Several other devices are being evaluated for LAA occlusion but are not approved in the United States for percutaneous LAAC. In 2006, the Lariat® Loop Applicator device (SentreHEART), a suture delivery system, was cleared for marketing by 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 Amulet® device (St. Jude Medical) and WaveCrest® (Johnson & Johnson Biosense Webster) have CE approval in Europe for LAAC but are not currently approved in the United States for this indication.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/13/11</td>
<td>Add to Cardiology Section - New medical policy created with literature search; procedure considered investigational.</td>
</tr>
<tr>
<td>12/29/11</td>
<td>Code 0281T added.</td>
</tr>
<tr>
<td>05/22/12</td>
<td>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.</td>
</tr>
<tr>
<td>09/17/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>05/28/13</td>
<td>Replace policy. Policy updated with literature review through January 2013, references 2, 12-20 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>12/08/15</td>
<td>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.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update, added new code 33340 effective 1/1/17.</td>
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<tr>
<td>01/01/18</td>
<td>Removed code CPT code 0281T as it was terminated 1/1/17 and replaced with 33340.</td>
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<tr>
<td>08/01/18</td>
<td>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.</td>
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<tr>
<td>08/01/19</td>
<td>Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019; several references added. Policy statements unchanged.</td>
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<tr>
<td>04/01/20</td>
<td>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.</td>
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<tr>
<td>07/02/20</td>
<td>Delete policy.</td>
</tr>
</tbody>
</table>

**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). ©2020 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 complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • 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, or sex, 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 800-842-5357
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 Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

 العربية (Arabic):
لا يمكن للشركة منع أو التمييز ضد أي شخص بناءً على العرق أو الجنس أو اللغة أو اللغة الرئيسية. يحق للأشخاص ذوي الإعاقة التعرف على وسائل التواصل الصوتية أو الكتابية أو المعرفة باللغات الأخرى.

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga imporman pagganpee iti aplikasyon noy uno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramideng nga adda sambay dagiti partikular a naituding nga adda aldaw tapno mapagtalaineyo ti coverage ti salan-atyo weno tungol kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormanon ken tungol iti bukodyo a pagasao nga uwan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross

Prezentuje, że ważna jest znajomość języków obcych, aby móc poradzić sobie w sytuacji kryzysowej. Wszystkim, którzy mają problem z zrozumieniem polskiego, możemy pomóc, pokazując im, jak się porozmawiać w języku obcym. Warto również zwrócić na uwagę, że wiedza języków obcych jest kluczowa w przyszłości, gdy będziemy musieli zwalczać pandemie.