MASSACHUSETTS

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Medical Policy

Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation

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Policy Number: 176

BCBSA Reference Number: 7.01.172 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation, #334

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention in individuals with atrial fibrillation undergoing open or thoracoscopic cardiac procedures is considered investigational. **INVESTIGATIONAL**.

The use of surgical left atrial appendage occlusion devices, including the AtriClip device, for stroke prevention as a stand-alone procedure for stroke prevention in individuals with atrial fibrillation is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting
Medicare HMO Blue℠	This procedure is performed in the inpatient setting
Medicare PPO Blue℠	This procedure is performed in the inpatient setting

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

According to the policy statement above, the following CPT codes are considered investigational for the conditions listed for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
33267	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)
33269	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

Description

Atrial Fibrillation

Nonvalvular atrial fibrillation (AF) is the most common type of cardiac arrhythmia, affecting at least 2.7 million people in the United States. The risk of AF has been found to be lower in Black, Hispanic, and Asian patients relative to White patients, following adjustment for demographic and AF risk factors.[1,2,] AF is typically described according to frequency and duration and includes paroxysmal (duration up to 1 week), persistent (>1 week), long-term persistent (>1 year), or permanent (normal sinus rhythm cannot be restored despite treatment).[3,] Stroke is the most serious complication of AF. The estimated incidence of stroke in non-treated patients with AF is 5% per year. Despite a lower risk of AF, Black and Hispanic patients have an increased risk of stroke compared with White patients.[4,5,] Although this paradox may be partially attributable to clinical factors (e.g., congestive heart failure, hypertension, type 2 diabetes), Black and Hispanic patients with AF are less likely than White patients to receive stroke prevention therapy.[6,] Stroke associated with AF is primarily thromboembolic, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment.

Stroke Prevention

The risk for stroke among patients with AF is evaluated using several factors. Two commonly used scores, the $CHADS_2$ score and the CHA_2DS_2-VASc score are described in Table 1:

Table 1. $CHADS_2$ 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
H	Hypertension (resting blood pressure >140/90 mmHg on at least 2 occasions or current antihypertensive pharmacologic treatment)	1

A	Age ≥75 y	1 (CHADS2) 2 (CHA2DS2-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)[7,] and January et al (2014)[8,]

Stroke in AF occurs primarily as a result of thromboemboli from the left atrium. The erratic atrial contractions in AF lead to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The first-line treatment for stroke prevention in AF is long-term anticoagulation, which has proven efficacy.[9,] Warfarin, a vitamin K antagonist, is the predominant agent in clinical use. Several newer direct oral anticoagulant (DOAC) agents, 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. Warfarin requires frequent monitoring and adjustments as well as lifestyle changes; DOACs do not require the frequent monitoring seen with warfarin therapy. While anticoagulation is effective for stroke prevention, it carries an increased risk of bleeding. Reversal agents can be used to counter the effects of life-threatening bleeding in individuals using warfarin or DOAC therapy. Such agents carry their own risk of inducing life-threatening thrombosis. For individuals with AF who have a contraindication to warfarin and DOACs, dual antiplatelet therapy with aspirin and clopidogrel is an option for stroke prevention, though it is less protective than either warfarin or DOACs.

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). The LAA is a small extension of the left atrium that can vary widely in both size and shape (morphology). LAA morphologies are described according to their appearance and include: the chicken wing, which is the most common morphology and features a prominent bend in the dominant lobe; the cactus, characterized by a dominant central lobe with superior and inferior secondary lobes; the windsock, which features one dominant lobe; and the cauliflower, which is the least common morphology and features numerous lobes with none being dominant. It has been estimated that over 90% of left atrial thrombi occur in the LAA. Surgical removal or exclusion of the LAA is often performed in patients with AF who are undergoing open heart surgery. Surgical techniques to exclude the LAA include resection or occlusion through stapling or clipping.[9,10,]

Percutaneous LAA occlusion is discussed in policy #334

Summary

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia. 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 one of the main goals of AF treatment. Treatment with anticoagulant medications is a first-line approach to stroke prevention in individuals with AF, although occlusion of the left atrial appendage (LAA) may offer a non-pharmacological alternative to anticoagulant medications for those with a contraindication or intolerance to long-term anticoagulant use or with poor anticoagulant adherence. Multiple surgical techniques may be used to excise or occlude the LAA. One device, the AtriClip Left Atrial Appendage Exclusion System, has approval from the U.S. Food and Drug Administration for surgical LAA occlusion for stroke prevention in patients with AF.

Summary of Evidence

For individuals with atrial fibrillation (AF) at increased risk for embolic stroke undergoing left atrial appendage (LAA) occlusion with an AtriClip device concomitant with open or thoracoscopic cardiac surgical procedures, the evidence includes a randomized controlled trial (RCT), a controlled observational study, and case series. Relevant outcomes are ischemic stroke, cardiac events, and mortality. Although evidence from several systematic reviews and a large (N>10,000) observational study found surgical LAA occlusion was associated with a reduction in the risk of stroke without an increase in the risk of adverse events, direct evidence specifically comparing the AtriClip Left Atrial Appendage Exclusion System with anticoagulation, another surgical occlusion method, or no occlusion is limited. LAA occlusion was associated with a reduced risk of stroke versus no occlusion in the Left Atrial Appendage Occlusion Study (LAAOS) III trial, but the trial was not designed to specifically assess the net health benefit of LAA occlusion with an AtriClip device. A retrospective database study that compared the AtriClip device with no occlusion found that AtriClip placement was associated with a lower risk of ischemic stroke, which was not statistically significant, and a reduced risk of thromboembolism that was of marginal statistical significance. Large (N>100) case series of AtriClip device use with 2- to 3-year follow-up reported stroke rates of 1% or fewer in the postoperative period and 2% or fewer in the long-term follow-up. Well-designed RCTs with follow-up of 1 year or more comparing the AtriClip device with anticoagulation, other surgical occlusion methods, and/or no occlusion are needed to provide adequate evidence for assessment of net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with AF at increased risk for embolic stroke undergoing LAA occlusion with an AtriClip device as a stand-alone procedure, the evidence includes a controlled observational study and case series. Relevant outcomes are ischemic stroke, cardiac events, and mortality. One small (N=40) industry-sponsored retrospective observational study reported that use of the AtriClip device as a stand-alone procedure resulted in similar outcomes compared to percutaneous LAA occlusion. This evidence is too limited to draw definitive conclusions. Well-designed RCTs with follow-up of 1 year or more comparing stand-alone AtriClip device placement with percutaneous LAA occlusion are needed to provide adequate evidence for assessment of net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
5/2024	Clarified coding language above code table
10/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2023	New medical policy describing investigational indications. Effective 1/1/2023.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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