Medical Coverage Policy | Surgical Left Atrial Appendage Occlusion Devices for Stroke Prevention in Atrial Fibrillation

EFFECTIVE DATE: 12|01|2022
POLICY LAST UPDATED: 09|20|2023

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

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 not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

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 not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

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 not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

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 not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

BACKGROUND

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. 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). 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. 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. 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 CHADS2 score and the CHA2DS2-VASc score are described in Table 1:

Table 1. $CHADS_2$ and $CHADS_2$-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	2
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

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. 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 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.

Regulatory Status

In June 2010, the AtriClip LAA Exclusion System (Atricure) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K093679). The FDA determined that this device was substantially equivalent to existing devices for occlusion of the LAA. The AtriClip has gone through numerous iterations since 2010, primarily relating to changes in the clip material composition and refinements of the clip applicator. The current FDA cleared indication is unchanged from the original 2010 indication, which states that the AtriClip is indicated for "exclusion of the LAA, performed under direct visualization, in conjunction with other cardiac surgical procedures." The FDA clearance documentation notes that direct

visualization "requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc. or other appropriate viewing technologies." As of 2022, AtriCure markets 7 different versions of the AtriClip device, whose use varies according to LAA size and type of concomitant surgical procedure.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

33267 Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

33269 Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

RELATED POLICIES

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

PUBLISHED

Provider Update, September 2023
Provider Update, October 2022

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