

# Left Atrial Appendage and Cardiac Structural Defect Closure for Stroke Prevention



INDEPENDENT CARE HEALTH PLAN

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## Medicare Advantage Medical Coverage Policy

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#### Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

## Related Documents

Please refer to [CMS website](#) for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

There are no NCD and/or LCDs for atrial septal defect or patent foramen ovale repair.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories
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			Administrative Contractors (MACs)	
NCD	Percutaneous Left Atrial Appendage Closure (LAAC)	<a href="#">20.34</a>		

## Description

### Left Atrial Appendage

The left atrial appendage (LAA) is a finger-like extension originating from the left atrium (upper chamber) in the heart. Atrial fibrillation (AF), one of the most common clinically significant cardiac arrhythmias, is associated with substantial stroke risk due to thrombus (clot) formation. The weak contractions during atrial fibrillation and blood pooling in the LAA often result in thrombus formation that may interrupt blood flow to the brain leading to a stroke.

Closure by exclusion or occlusion of the LAA may reduce the risk for ischemic stroke and is either performed surgically at the same time as another open cardiac procedure, or via a less invasive, percutaneous approach. Left atrial appendage imaging using either transesophageal echocardiogram (TEE) or cardiac computed tomographic angiography (CCTA) is used for preprocedural planning. An individual with nonvalvular AF may be a candidate for LAA closure when long-term anticoagulation medication (eg, warfarin or other oral anticoagulants) is contraindicated due to a history of bleeding or increased bleeding risk, noncompliance with medication regimen or comorbidity treatment, lifestyle or occupation that is incompatible with oral anticoagulants.

**Surgical or open closure** generally involves clipping or suturing the LAA during open cardiac procedures such as mitral valve surgery. Examples of US Food & Drug Administration (FDA) approved devices used for this approach include, but are not limited to, the AtriClip, AtriClip Flex-V and AtriClip Pro-V. These are approved for use under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope or other appropriate viewing technologies.

The Lariat suture delivery device is intended to facilitate suture placement and knot tying in surgical applications where soft tissue is being approximated or tied off with a pre-tied polyester suture. It has been used percutaneously to tie off or exclude the LAA. It has not been FDA-approved specifically for this indication.

**Percutaneous (transcatheter) closure** is performed with a specialized catheter used to insert the device through a vein in the individual's leg and advanced through the atrial septum to the LAA where it opens and creates an occlusion of the appendage. Over time, the area develops a thin layer of tissue which inhibits future clot formation.

The WATCHMAN FLX and WATCHMAN FLX Pro are examples of FDA-approved percutaneous LAA closure devices that use a single seal closure mechanism. The use of the WATCHMAN devices requires the ability to tolerate individualized oral antithrombotic therapy following LAA closure. Expanded FDA labelling for the WATCHMAN FLX and WATCHMAN FLX Pro now allows for oral antithrombotic therapy for the initial 45-day

post-procedure period using either oral anticoagulation (eg, warfarin, direct oral anticoagulant [DOAC]) or dual antiplatelet therapy ([DAPT] and may or may not be limited to aspirin, clopidogrel or other oral antiplatelet). This is followed by DAPT for approximately 6 months. Shared decision-making between the healthcare provider and the individual may determine that DAPT for 6 months or less (without the initial period of oral anticoagulation) following LAA closure is indicated due to elevated bleeding risk.

The Amplatzer Amulet is another FDA-approved percutaneously implanted LAA closure device that differs from the WATCHMAN devices in that it uses a dual seal mechanism to form a complete seal in the LAA opening and eliminates the need for postimplantation anticoagulation. Dual antiplatelet therapy (may or may not be limited to aspirin, clopidogrel or other oral antiplatelets) is recommended for up to 6 months following the procedure.

### **Patent Foramen Ovale**

A patent foramen ovale (PFO) is a hole in the heart that remains open after birth. The small, flap-like foramen ovale is found between the right and left atria of the fetal heart and allows blood to bypass the lungs prior to birth. The foramen ovale usually closes when a newborn takes the first breath; however, for some individuals it remains patent (open). This condition generally does not cause symptoms, although there is a risk of thrombus formation and subsequent stroke from the blood that could leak from this opening.

**PFO occlusion** devices were developed to reduce the risk of recurrent stroke in individuals between 18 and 60 years of age who have had a cryptogenic (unknown cause) stroke due to a presumed paradoxical embolism that crosses an intracardiac defect into systemic circulation. This is determined by a neurologist and a cardiologist following an evaluation to exclude known causes of ischemic stroke. The PFO is occluded (closed) during a transcatheter procedure, which stops leakage of blood from the foramen ovale. The Amplatzer Talisman PFO occluder and the GORE CARDIOFORM Septal Occluder are examples of FDA-approved devices for PFO closure.

### **Atrial Septal Defect**

An atrial septal defect (ASD) is a failure of the septal tissue to form between the atria before birth. This congenital heart defect increases the amount of blood that flows through the lungs which can elevate stroke risk. An individual may have no symptoms; however, the risk for clot formation exists and repair may be recommended to prevent stroke. An ASD may be repaired via transcatheter approach using a device specifically designed to occlude the opening. Examples of FDA-approved devices for ASD closure include the Amplatzer Septal Occluder and the GORE CARDIOFORM Septal Occluder.

NobleStitch EL is an endovascular suture tool intended for use during cardiovascular procedures, including PFO closure and potentially LAA and ASD closures.

## **Coverage Determination**

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

Please refer to the above CMS guidance for **left atrial appendage closure**.

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:*

[Left Atrial Appendage and Cardiac Structural Defect Closure for Stroke Prevention](#)

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

**Coverage Limitations**

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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)	
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transeptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	
33999	Unlisted procedure, cardiac surgery	

93580	Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant	
<b>CPT® Category III Code(s)</b>	<b>Description</b>	<b>Comments</b>
No code(s) identified		
<b>HCPCS Code(s)</b>	<b>Description</b>	<b>Comments</b>
C1817	Septal defect implant system, intracardiac	

## References

- Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Percutaneous left atrial appendage closure (LAAC) (20.34). <https://www.cms.gov>. Published February 8, 2016. Accessed November 14, 2023.

## Change Summary

- 01/01/2024 New Policy.
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