Medicare Medical Policy

Left Atrial Appendage Devices Closure

MEDICARE MEDICAL POLICY NUMBER: 74

Effective Date: 6/1/2024

Last Review Date: 5/2024

Next Annual Review: 5/2025

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Percutaneous *left atrial appendage closure (LAAC) for the treatment of non-valvular atrial fibrillation*	National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) **NOTE:** See "Policy Guidelines" for different types of devices (percutaneous vs. non-percutaneous) and Table 1 in "Regulatory Status" for the FDA approval status of select devices.
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below)* • **Medicare Coverage Manuals:** Medicare does not have criteria for surgical (thoracoscopic or open) LAAC in a coverage manual. • **National Coverage Determination (NCD):** While Medicare does have an NCD for ***percutaneous*** LAAC, Medicare does not have an NCD for ***non-percutaneous*** LAAC. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractor (MAC) has an applicable LCD or LCA. • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making.	
Non-percutaneous *surgical LAA procedures (open or thoracoscopic)*	Company medical policy for Left Atrial Appendage Devices I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those

considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Cardiac: Left Atrial Appendage Devices, MP66
- Clinical Trials and IDE Studies, MP233

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Patients with atrial fibrillation (AF), an irregular heartbeat, are at an increased risk of stroke. The left atrial appendage (LAA) is a tubular structure that opens into the left atrium and has been shown to be one potential source for blood clots that can cause strokes. While thinning the blood with anticoagulant medications has been proven to prevent strokes, percutaneous LAA closure (LAAC) has been studied as a non-pharmacologic alternative for patients with AF.

The Medicare NCD 20.34 allows for allows for coverage of ***percutaneous*** left atrial appendage (LAA) closure under Coverage with Evidence Development (CED) with certain conditions. A link to current registries and clinical trials approved by CMS can be found within the NCD directly, as well as on the Percutaneous Left Atrial Appendage Closure (LAAC) Coverage with Evidence Development website. To view participants of the Left Atrial Appendage Occlusion (LAAO) Registry that is sponsored by the American College of Cardiology, the participant directory for the National Cardiovascular Data Registry (NCDR) can be viewed to look for individual facilities.

For more information, please see the "Clinical Trials and IDE Studies (Medicare Only)" policy in the Medical Policy Cross References section above.

There is no Medicare coverage guidance for ***non-percutaneous*** procedures to occlude the LAA. Therefore, Company policy criteria will be applied.

Percutaneous Devices

Watchman (Boston Scientific Corp.)

The Watchman LAA closure device is a self-expandable, open-ended nitinol basket that is permeable to blood. The device is permanently anchored into the ostium of the LAA to trap blood clots before they exit the LAA in patients with non-valvular atrial fibrillation. The three-part system consists of a transseptal access sheath, a delivery catheter, and a self-expanding nitinol frame with fixation barbs covered with a permeable polyester fabric and preloaded into a proprietary delivery catheter, which is

designed to allow device recapture if necessary. This device is approved as a percutaneous device approved by the United States Food & Drug Administration (FDA) LAA closure/occlusion. It is intended for use in patients for whom anticoagulation therapy is recommended but seek a non-pharmacologic alternative to long-term anticoagulation therapy.

AMPLATZER™ Cardiac Plug (ACP) (St. Jude Medical / Abbott)

The AMPLATZER™ Cardiac Plug (ACP) is a transcatheter, self-expanding device that is anchored into the neck of the LAA. The device requires an LAA depth of 10 mm and includes a left atrial disc designed to completely seal the LAA orifice. The ACP consists of nitinol and interwoven polyester materials in an effort to promote occlusion and tissue in-growth. The technique for implanting this device is also similar to that of the Watchman system.

AMPLATZER™ Amulet™ (St. Jude Medical / Abbott)

The AMPLATZER™ S Amulet™ is a self-expanding, second-generation device made of the same components and inserted in the same location in the LAA as its predecessor, the AMPLATZER™ ACP. The device has additional features intended to reduce the occurrence of embolization and incomplete LAA exclusion that has been reported with the ACP, including availability in a broader size range (11 to 31 mm in diameter).

LARIAT® Suture Delivery Device (SentreHEART Inc.)

The LARIAT® Suture delivery device is a remote suture delivery system that utilizes a 40mm pre-tied suture loop and collapsible snare to close soft tissues without the use of metal, clip or implant. According to the FDA, its intended use is to facilitate suture placement and knot tying in surgical applications where soft tissues are being ligated with a polyester suture. The technical approach differs from that of the Watchman system in that the suture loop ligates the LAA from the epicardial space, with assistance of catheters and balloons in the left atrium.

Non-Percutaneous Devices

AtriClip® (AtriCure, Inc.)

AtriClip LAA Exclusion Systems include a clip device that is placed at the base of the LAA to permanently occlude it from the circulating blood in the left atrium.

The AtriClip LAA exclusion systems have been approved by the FDA for the occlusion of the LAA, under direct visualization and in conjunction with other open cardiac surgical procedures. The FDA 510(k) premarket notification states that direct visualization, in this context, requires “that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).”

MEDICARE AND MEDICAL NECESSITY

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

FDA-Approved Devices

Note: The list of devices below may not be conclusive. Additionally, approved indications and contraindications may change before the policy is annually reviewed. For the most current information of approved devices and supplemental approval order statements, please refer to the U.S. Food and Drug Administration's Premarket Approval (PMA) website (product code: NGV).

Table 1: FDA-Approved Devices

Device	Indications	Contraindications
Watchman™ Left Atrial Appendage Closure Technology/	Patients with non-valvular atrial fibrillation who:	• Intracardiac thrombus is present. • An atrial septal defect repair or closure device or a patent

Watchman FLX device (Boston Scientific)	• 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 non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.	foramen ovale repair or closure device is present. • The LAA anatomy will not accommodate a Closure Device. • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device or WATCHMAN FLX Device is contraindicated. • Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present. • There are contraindications to the use of anticoagulation therapy, aspirin, or P2Y12 inhibitor.
Amplatzer Amulet® device (St. Jude Medical)	In patients who have nonvalvular atrial fibrillation and who: • Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores; • Are suitable for short term anticoagulation therapy; • And have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.	The Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder is contraindicated for patients: • With the presence of intracardiac thrombus • With active endocarditis or other infections producing bacteremia • Where placement of the device would interfere with any intracardiac or intravascular structures
AtriClip® LAA Exclusion System (AtriCure, Inc)	The AtriClip® LAA Exclusion System in indicated for the occlusion of the heart's left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures. Direct visualization, in this context, requires that the	• The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.

	surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy, (full or partial) as well as thoracotomy (single or multiple).	• AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.

BILLING GUIDELINES AND CODING

GENERAL

Additional billing guidance can be found in the following resources:

- CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 3515, SUBJECT: Percutaneous Left Atrial Appendage Closure (LAAC)
- Medicare Claims Processing Manual Chapter 32, Section 69.6 - Requirements for Billing Routine Costs of Clinical Trials

CODES*		
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
	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)
HCPCS	C1760	Closure device, vascular (implantable/insertable)
	C2628	Catheter, occlusion

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
8/2022	Annual review (converted to new format 2/2023)
6/2023	Interim update; "Investigational" to "not medically necessary" change; added additional regulatory information
7/2023	Annual review, no significant changes to criteria
6/2024	Annual review, no change to criteria