MEDICAL POLICY	Cardiac: Left Atrial Appendage Devices Closure (Medicare Only)
Effective Date: 8/1/2022  8/1/2022 Medical Officer Date	Medical Policy Number: 74 Medical Policy Committee Approved Date: 10/16; 12/17; 7/18; 8/19; 05/2020; 06/2021; 11/2021; 6/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
Percutaneous *left atrial appendage closure for the treatment of non-valvular atrial fibrillation*	National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34)
Non-percutaneous *surgical LAA procedures (open or thoracoscopic)*	Company medical policy for Cardiac: Left Atrial Appendage Devices (All Lines of Business Except Medicare) I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.*

POLICY GUIDELINES

Medicare and Medical Necessity

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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

General

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. The current registries and clinical trials approved by CMS can be found at the Percutaneous Left Atrial Appendage Closure (LAAC) Coverage with Evidence Development website. See the NCD for additional details.

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

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

BILLING GUIDELINES

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.

CPT/HCPCS CODES

Medicare Members Only	
No Prior Authorization Required	
The only supply code that is appropriate to bill with the CPT code 33340 is C1760.	
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
C1760	Closure device, vascular (implantable/insertable)
The code below is not covered when billed with 33340	
C2628	Catheter, occlusion
Not Covered	
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)

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

MEDICAL POLICY CROSS REFERENCES

- Cardiac: Left Atrial Appendage Devices (All Lines of Business Except Medicare), MP66
- Clinical Trials and IDE Studies (Medicare Only), MP233