

**Prior Authorization Review Panel
MCO Policy Submission**

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Plan: PA Health & Wellness (PHW)	Submission Date: 1/1/2025
Policy Number: PA.CP.MP.151	Effective Date: 09/2018 Revision Date: 11/2024
Policy Name: Transcatheter Closure of Patent Foramen Ovale	
Type of Submission – <u>Check all that apply</u>: ☐ New Policy ☐ Revised Policy* ☐ Annual Review – No Revisions ☐ Statewide PDL ☒ Retiring Policy	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: Revised for retirement	
Name of Authorized Individual (Please type or print): Dr. Craig A. Butler, MD.	Signature of Authorized Individual: <i>Craig A Butler MD</i>

CLINICAL POLICY

Transcatheter Closure of Patent Foramen Ovale

Clinical Policy: Transcatheter Closure of Patent Foramen Ovale

Reference Number: PA.CP.MP.151

Effective Date: 09/2018

Date of Last Revision: 11/2024

[Coding Implications](#)

[Revision Log](#)

Description

Patent foramen ovale (PFO) is a congenital cardiac lesion which is generally asymptomatic and affects up to a quarter of the population. PFO can present with an array of significant clinical complications, including cryptogenic stroke. This policy describes the medical necessity requirements for the percutaneous transcatheter closure of a PFO. Currently, three devices have been approved by the U.S. Food and Drug Administration (FDA) for percutaneous PFO closure and include the Amplatzer™ PFO Occluder, the Amplatzer™ Talisman™ PFO Occluder, and the Gore® Cardioform Septal Occluder.^{1,2,3,4}

Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness® (PHW) that the percutaneous transcatheter closure of patent foramen ovale (PFO) is **medically necessary** to reduce the risk of recurrent ischemic stroke, when used according to United States Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and meet all the following:
 - A. Age ≥ 18 and ≤ 60 years;
 - B. Both a neurologist and a cardiologist confirm all of the following:
 1. PFO with a right-to-left interatrial shunt detected by bubble study;
 2. Cryptogenic stroke caused by a presumed paradoxical embolism and at least one of the following:
 - a. Possible, probable, or definite likelihood that the stroke was causally related to PFO based on the PFO-associated stroke causal likelihood (PASCAL) classification system;
 - b. Risk of Paradoxical Embolism (RoPE) score > 6 , and/or there is a large shunt or atrial septal aneurysm;
 3. Absence of other risk factors of ischemic stroke, including but not limited to, any of the following:
 - a. Atherosclerosis;
 - b. Small vessel occlusion;
 - c. Hypercoagulable state;
 - d. Atrial fibrillation;
 - e. Arterial dissection;
 - C. Device is FDA-approved for percutaneous transcatheter closure of PFO (e.g. Amplatzer™ PFO Occluder, Amplatzer™ Talisman™ PFO Occluder, and the Gore® Cardioform Septal Occluder).
- II. It is the policy of PHW® that there is insufficient evidence in the published peer-reviewed literature to support the use of percutaneous transcatheter closure of PFO for the following:
 - A. Devices not currently FDA-approved for PFO, including any of the following:
 1. CardioSEAL STARFlex Septal Closure System;
 2. Buttoned Device;
 3. Atrial Septal Defect Occluding System;

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- B. Migraine prophylaxis;
- C. Primary stroke prevention;
- D. Unexplained oxygen desaturation.

Background

The foramen ovale is a particular structure of the fetal circulation that fails to close and is present in 25% of the adult population, forming a patent foramen ovale (PFO).^{5,6} The biological significance of PFOs has been widely debated in the literature for the last decade.^{7,8,9} Case control studies have established an association between an increased risk of ischemic stroke and the PFO.⁵ The CLOSURE I study, the PC study, and the RESPECT study are three initial randomized controlled trials (RCTs) that, along with a meta-analysis of 14 trials, collectively demonstrate that there is no significant advantage for surgical PFO closure to improve ischemic stroke prevention over medical therapy.^{10,11,12,13}

However, four additional published articles in *The New England Journal of Medicine* expand the body of work and extend analyses of the advantage of PFO closure.^{6,14,15,16,17} In the CLOSE study, investigators assessed 663 patients with cryptogenic stroke attributed to PFO and demonstrated reduced recurrent stroke rates in those treated with PFO closure and antiplatelet therapy compared to those treated with antiplatelet therapy alone.⁶ This finding was also validated by the Gore REDUCE investigators in their analysis of 664 patients, which concluded that the risk of recurrent ischemic stroke was lower for patients who had PFO closure combined with antiplatelet therapy than in patients who were treated with antiplatelet therapy alone.¹⁵ Furthermore, the RESPECT investigators recapitulate earlier results in a multicenter trial, noting that closure of PFO among patients who had a cryptogenic stroke was associated with a lower rate of recurrent ischemic stroke compared to medical therapy alone during an extended follow-up of 980 patients for a median of 5.9 years.¹⁴ A meta-analysis of six RCTs demonstrated benefits of PFO closure for secondary prevention of stroke among patients with cryptogenic stroke and small increase in risk of new onset atrial fibrillation.¹⁸

Mounting evidence suggests that PFO device closure is more effective than medical therapy alone for select patients aged ≤ 60 years with a PFO-associated stroke (i.e., a nonlacunar ischemic stroke in the setting of a PFO with a right-to-left interatrial shunt and no other source of stroke despite a comprehensive evaluation).^{19,20}

The American Heart Association published a 2018 review that states that recent RCTs have demonstrated the superiority of PFO closure over pharmacological treatment alone in reducing the risk of recurrent ischemic stroke in certain patients, and that governing societies should rewrite their guidelines accordingly.²¹

2021 guidelines from the American Heart Association/ American Stroke Association consider it reasonable to percutaneously close PFO in patients who meet each of the following criteria: age 18 to 60 years, nonlacunar stroke, no other identified cause, and high risk PFO features.¹⁸

The American Academy of Neurology Practice advisory 2020 update summary on PFO and secondary stroke prevention include the following recommendations²²:

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- “In patients being considered for PFO closure, clinicians should ensure that an appropriately thorough evaluation has been performed to rule out alternative mechanisms of stroke (level B).
- In patients with a higher risk alternative mechanism of stroke identified, clinicians should not routinely recommend PFO closure (level B).
- Clinicians should counsel patients that having a PFO is common; that it occurs in about 1 in 4 adults in the general population; that it is difficult to determine with certainty whether their PFO caused their stroke; and that PFO closure probably reduces recurrent stroke risk in select patients (level B).
- In patients younger than 60 years with a PFO and embolic-appearing infarct and no other mechanism of stroke identified, clinicians may recommend closure following a discussion of potential benefits (absolute recurrent stroke risk reduction of 3.4% at 5 years) and risks (periprocedural complication rate of 3.9% and increased absolute rate of non-periprocedural atrial fibrillation of 0.33% per year) (level C).
- In patients who opt to receive medical therapy alone without PFO closure, clinicians may recommend an antiplatelet medication such as aspirin or anticoagulation (level C).”

Due to the low risk of stroke related to PFO combined with the high prevalence of PFO in the general population, there is often uncertainty regarding the relationship between PFO and a cryptogenic embolic-appearing ischemic stroke. In order to guide decisions about PFO management and secondary stroke prevention, it is essential to determine whether a PFO is pathogenic or incidental in relation to an ischemic stroke. To determine the likelihood that PFO is the cause of paradoxical embolism, it is recommended to evaluate PFO features, other possible causes of ischemic stroke, and utilize methods such as the Risk of Paradoxical Embolism (RoPE) score and PFO-associated stroke causal likelihood (PASCAL) classification system.^{20,23}

The RoPE score is a major component of the PASCAL classification system and helps in estimating the likelihood that a PFO is incidental or pathogenic for a cryptogenic stroke. High RoPE scores indicate pathogenic, higher risk PFOs and are typically found in younger patients who do not have vascular risk factors. Low RoPE scores suggest incidental, lower risk PFOs and are typically seen in older patients with vascular risk factors.²³

The PASCAL classification system estimates the likelihood that PFO is the mechanism of embolic stroke when there are no other major sources of ischemic stroke. The PASCAL classification system is based on the RoPE score as well as anatomic features and clinical factors such as shunt size, presence of an atrial septal aneurysm, and presence of venous thromboembolism.²³

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage.

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Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant

HCPCS Codes	Description
C1817	Septal defect implant system, intracardiac

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Reviews, Revisions, and Approvals	Review Date	Approval Date
Policy developed	09/18	
Added “but not limited to” to criteria regarding absence of other risk factors for ischemic stroke. Added hypercoagulation, arterial dissection, and atrial fibrillation as conditions that must be ruled out. Added contraindications per instruction manual. Updated background.	12/18	01/28/18
Annual review. Added Gore Cardioform as an FDA-approved device appropriate for medically necessary closure of PFO. References reviewed and updated. Reviewed by specialist.	6/2020	
Background updated with no impact on clinical criteria. References reviewed and updated. Replaced “member” with “member/enrollee” in all instances.	7/2021	
Annual review. Reworded policy statement, adding “when used according to FDA labeled indications, contraindications, warnings and precautions. Removed contraindications (I.B.4) since they are specific to the Amplatzer PFO device. Updated background with 2021 AHA/ASA recommendations. Added AAN recommendation for patients who opt to receive medical therapy alone without PFO closure. “Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” References reviewed, updated, and reformatted. Reviewed by specialist.	7/28/2022	
Annual review. Updated description to include newest FDA-approved device: Amplatzer™ Talisman™ PFO Occluder. Clarified in I.B. that age requirements are in years. Updated Criteria I.B. # 2 to state that cryptogenic stroke caused by a presumed paradoxical embolism, and a possible, probable, or definite likelihood that the stroke was causally related to PFO based on the PFO-associated stroke causal likelihood (PASCAL) classification system with a Risk of Paradoxical Embolism (RoPE) score > 6, and/or there is a large shunt or atrial septal aneurysm. Updated Criteria to include Criteria C. Device is FDA-approved for percutaneous transcatheter closure of PFO (e.g., Amplatzer™ PFO Occluder, Amplatzer™ Talisman™ PFO Occluder, and the Gore® Cardioform Septal Occluder). Background updated and includes information on PASCAL classification system and RoPE score. Removed ICD-10 codes. References reviewed and updated. Reviewed by internal specialist and external specialist.	12/8/2022	
Annual review. Minor rewording in Background section with no impact on criteria. References reviewed and updated.	11/2023	01/2024

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Reviews, Revisions, and Approvals	Review Date	Approval Date
Revised for retirement	11/2024	12/23/2024

References

1. St. Jude Medical Corporation. Amplatzer PFO Occluder Instructions for Use. 2016. <https://www.fda.gov/media/97980/download>. Accessed September 19, 2024.
2. Abbott. Amplatzer™ Talisman™ PFO Occluder for Patent Foramen Ovale Closure. <https://www.cardiovascular.abbott/us/en/hcp/products/structural-heart/structural-interventions/amplatzer-talisman.html>. Accessed September 19, 2024.
3. W.L. Gore & Associates, Inc. GORE® CARDIOFORM Septal Occluder – Product Overview. <https://www.goremedical.com/products/cardioform/septal-occluder>. Accessed September 19, 2024.
4. U.S. Food and Drug Administration. Premarket Approval (PMA) - Amplatzer™ Talisman™ PFO Occluder. Published September 27, 2021. Updated October 03, 2022. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120021S020>. Accessed September 19, 2024.
5. Nakanishi K, Yoshiyama M, Homma S. Patent foramen ovale and cryptogenic stroke. *Trends Cardiovasc Med*. 2017;27(8):575 to 581. doi:10.1016/j.tcm.2017.06.016
6. Mas JL, Derumeaux G, Guillon B, et al. Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke. *N Engl J Med*. 2017;377(11):1011 to 1021. doi:10.1056/NEJMoA1705915
7. Smer A, Salih M, Mahfood Haddad T, et al. Meta-analysis of Randomized Controlled Trials on Patent Foramen Ovale Closure Versus Medical Therapy for Secondary Prevention of Cryptogenic Stroke. *Am J Cardiol*. 2018;121(11):1393 to 1399. doi:10.1016/j.amjcard.2018.02.021
8. Lee PH, Song JK, Kim JS, et al. Cryptogenic Stroke and High-Risk Patent Foramen Ovale: The DEFENSE-PFO Trial. *J Am Coll Cardiol*. 2018;71(20):2335 to 2342. doi:10.1016/j.jacc.2018.02.046
9. Nasir UB, Qureshi WT, Jogu H, et al. Updated meta-analysis of closure of patent foramen ovale versus medical therapy after cryptogenic stroke. *Cardiovasc Revasc Med*. 2019;20(3):187-193. doi: 10.1016/j.carrev.2018.06.001
10. Carroll JD, Saver JL, Thaler DE, et al. Closure of patent foramen ovale versus medical therapy after cryptogenic stroke. *N Engl J Med*. 2013;368(12):1092 to 1100. doi:10.1056/NEJMoA1301440
11. Meier B, Kalesan B, Mattle HP, et al. Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N Engl J Med*. 2013;368(12):1083 to 1091. doi:10.1056/NEJMoA1211716
12. Furlan AJ, Reisman M, Massaro J, et al. Closure or medical therapy for cryptogenic stroke with patent foramen ovale. *N Engl J Med*. 2012;366(11):991 to 999. doi:10.1056/NEJMoA1009639
13. Wolfrum M, Froehlich GM, Knapp G, et al. Stroke prevention by percutaneous closure of patent foramen ovale: a systematic review and meta-analysis. *Heart*. 2014;100(5):389 to 395. doi:10.1136/heartjnl-2013-304394

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14. Saver JL, Carroll JD, Thaler DE, et al. Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke. *N Engl J Med.* 2017;377(11):1022 to 1032. doi:10.1056/NEJMoA1610057
15. Søndergaard L, Kasner SE, Rhodes JF, et al. Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke [published correction appears in *N Engl J Med.* 2020 Mar 5;382(10):978. doi: 10.1056/NEJMc200001]. *N Engl J Med.* 2017;377(11):1033-1042. doi:10.1056/NEJMoA1707404
16. Farb A, Ibrahim NG, Zuckerman BD. Patent Foramen Ovale after Cryptogenic Stroke - Assessing the Evidence for Closure. *N Engl J Med.* 2017;377(11):1006 to 1009. doi:10.1056/NEJMp1700218
17. Ropper AH. Tipping Point for Patent Foramen Ovale Closure. *N Engl J Med.* (2017);377(11):1093 to 1095. doi:10.1056/NEJMe1709637
18. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published correction appears in *Stroke.* 2021 Jul;52(7):e483 to e484. doi: 10.1161/STR.0000000000000383]. *Stroke.* 2021;52(7):e364-e467. doi:10.1161/STR.0000000000000375
19. Kuijpers T, Spencer FA, Siemieniuk RAC, et al. Patent foramen ovale closure, antiplatelet therapy or anticoagulation therapy alone for management of cryptogenic stroke? A clinical practice guideline. *BMJ.* 2018;362:k2515. Published 2018 Jul 25. doi:10.1136/bmj.k2515
20. Messé SR, Brecker SJD. Stroke associated with patent foramen ovale (PFO): Management. UpToDate. www.uptodate.com. Published February 27, 2023. Accessed September 20, 2024.
21. Collado FMS, Poulin MF, Murphy JJ, Jneid H, Kavinsky CJ. Patent Foramen Ovale Closure for Stroke Prevention and Other Disorders. *J Am Heart Assoc.* 2018;7(12):e007146. Published 2018 Jun 17. doi:10.1161/JAHA.117.007146
22. Messé SR, Gronseth GS, Kent DM, et al. Practice advisory update summary: Patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. *Neurology.* 2020;94(20):876 to 885. doi:10.1212/WNL.00000000000009443
23. Messé SR, Brecker SJD. Stroke associated with patent foramen ovale (PFO): Evaluation. UpToDate. www.uptodate.com. Published February 28, 2023. Accessed September 20, 2024.
24. Connolly, HM, Taggart, N. Surgical and percutaneous closure of atrial septal defects in adults. UpToDate. www.uptodate.com. Published December 20, 2023. Accessed September 24, 2024.