Clinical Policy: Transcatheter Closure of Patent Foramen Ovale

Reference Number: PA.CP.MP.151
Effective Date: 09/2018
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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.[1-5]

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 the all of the following indications:

A. Age ≥ 18 and ≤ 60;

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 the percutaneous transcatheter closure of PFO is **experimental/investigational** 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;
4. Helex Septal Occluder;

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 PFO.[1,2] The biological significance of PFOs has been widely debated in the literature for the last decade. Case control studies have established an association between an increased risk of ischemic stroke and the PFO.[1] Three initial randomized controlled trials (*e.g.* the CLOSURE I study, the PC study, and the RESPECT study), as well as a meta-analysis of 14 trials, collectively demonstrate that that there is no significant advantage for surgical PFO closure to improve ischemic stroke prevention over medical therapy.[7-10]

However, four additional published articles in *The New England Journal of Medicine* expand the body of work and extend analyses.[2-6] In the CLOSE study, investigators assessed 663 patients and demonstrated reduced recurrent stroke rates after PFO closure compared to oral anticoagulation with antiplatelet medical therapy in patients with cryptogenic stroke.[2] This finding was also validated by the Gore REDUCE investigators in their analysis of 664 patients[4.] Furthermore, the RESPECT investigators recapitulate earlier results in a multicenter trial, noting that closure of PFO was associated with a lower rate of recurrent ischemic stroke, after having followed 980 patients for a median of 5.9 years.[3] A meta-analysis of 6 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.[24]

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).[20]

The American Heart Association published a 2018 review that stated that recent RCTs have demonstrated the superiority of PFO closure over pharmacological treatment in reducing risk of recurrent ischemic stroke in certain patients, and that governing societies should rewrite their guidelines accordingly.[15]

2021 guidelines from the American Heart Association/ American Stroke Association considers it reasonable to percutaneously close PFO in patients who meet each of the following criteria: age 18–60 years, nonlacunar stroke, no other identified cause, and high risk patent foramen ovale features.[24]

The American Academy of Neurology Practice advisory update summary on patent foramen ovale and secondary stroke prevention include the following recommendations:

- 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)[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 2021, 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. 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

Reviews, Revisions, and Approvals	Review Date	Approval Date
Policy developed	09/18	

Reviews, Revisions, and Approvals	Review Date	Approval Date
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	12/18	01/28/18

Reviews, Revisions, and Approvals	Review Date	Approval Date
must be ruled out. Added contraindications per instruction manual. Updated background.		
Annual review. Added Gore Cardioform as an FDA-approved device appropriate for medic	6/2020	

Reviews, Revisions, and Approvals	Review Date	Approval Date
ally necessary closure of PFO. References reviewed and updated. Reviewed by specialist.		
Background updated with no impact on clinical criteria. References reviewed and updated. Repla	7/2021	

Reviews, Revisions, and Approvals	Review Date	Approval Date
ced "member" with "member/enrollee" in all instances.		
Annual review. Reworded policy statement, adding "when used according to FDA labeled indications, contraindications, warni	7/28/2022	

Reviews, Revisions, and Approvals	Review Date	Approval Date
ngs 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 reco		

Reviews, Revisions, and Approvals	Review Date	Approval Date
mmendation 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		

Reviews, Revisions, and Approvals	Review Date	Approval Date
header to "revision date." References reviewed, updated, and reformatted. Reviewed by specialist.		
Annual review. Updated description to include newest FDA-approved device: Ampl	12/8/2022	

Reviews, Revisions, and Approvals	Review Date	Approval Date
atzer™ 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		

Reviews, Revisions, and Approvals	Review Date	Approval Date
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		

Reviews, Revisions, and Approvals	Review Date	Approval Date
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 transcathete		

Reviews, Revisions, and Approvals	Review Date	Approval Date
r closure of PFO (e.g., Amplatzer™ PFO Occluder, Amplatzer™ Talisman™ PFO Occluder, and the Gore® Cardioform Septal Occluder). Background updated and includes infor		

Reviews, Revisions, and Approvals	Review Date	Approval Date
mation on PASCAL classification system and RoPE score. Removed ICD-10 codes. References reviewed and updated. Reviewed by internal specialist and external specialist.		

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