Clinical Policy: Transcatheter Closure of Patent Foramen Ovale

Reference Number: CP.MP.151 Coding Implications
Date of Last Revision: 11/22 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 health plans affiliated with Centene Corporation® 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;

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).[6-7] The biological significance of PFOs has been widely debated in the literature for the last decade.[8-10] Case control studies have established an association between an increased risk of ischemic stroke and the PFO.[6] 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.[11-14]

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.[7,15-18] 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.[7] 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.[16] 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.[15] 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.[19]

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).[20-21]

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.[22]

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 to 60 years, nonlacunar stroke, no other identified cause, and high risk PFO features.[19]

The American Academy of Neurology Practice advisory 2020 update summary on PFO and secondary stroke prevention include the following recommendations[23]:

- "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.[21,24]

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.[24]

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.[24]

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	Description
C1817	Septal defect implant system, intracardiac

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	11/17	12/17
Removed the phrase "to reduce the risk of ischemic stroke" from the medical necessity statement in II. Specified that the "stroke prevention" in section II is "primary stroke prevention."	06/18	
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.	11/18	11/18
Annual review. Added Gore Cardioform as an FDA-approved device appropriate for medically necessary closure of PFO. Reviewed by specialist.	11/19	11/19
Background updated with no impact on clinical criteria. References reviewed and updated. Replaced "member" with "member/enrollee" in all instances.	11/20	11/20
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.	11/21	11/21
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.	11/22	11/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

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Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.