Clinical Policy: Transcatheter Closure of Patent Foramen Ovale

Reference Number: CP.MP.151 Coding Implications
Last Review Date: 11/19 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 patent foramen ovale with the Amplatzer™ PFO Occluder or Gore® Cardioform Septal Occluder.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that the percutaneous transcatheter closure of PFO with an FDA-approved device (Amplatzer PFO Occluder or Gore Cardioform) is **medically necessary** to reduce the risk of recurrent ischemic stroke when meeting 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;
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.
4. None of the following contraindications:
   a. Intra-cardiac mass, vegetation, tumor or thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the PFO is gained;
   b. Vasculature through which access to the PFO is gained is inadequate to accommodate the appropriate sheath size;
   c. Anatomy in which the Amplatzer PFO device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins;
   d. Other source of right-to-left shunts, including an atrial septal defect and/or fenestrated septum;
   e. Active endocarditis or other untreated infections.

II. It is the policy of health plans affiliated with Centene Corporation® 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;

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 have 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 more recently published articles in *The New England Journal of Medicine* expand the body of work and extend analyses.[2-6] Mas *et al.* for the CLOSE 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 Søndergaard for the Gore REDUCE investigators in their analysis of 664 patients[4.] Furthermore, Saver *et al.* for 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]

The 2014 American Heart Association / American Stroke Association have not yet been updated to include recent randomized controlled trials (RCTs), and the 2016 Practice Advisory Board of the American Academy of Neurology, does not recommend percutaneous transcatheter closure of PFO outside of research settings.[11-12] 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]

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 2019, 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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
Q21.1	Atrial septal defect

Reviews, Revisions, and Approvals	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

References

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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 policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, 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 members, 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.