

Clinical Policy: Transcatheter Closure of Patent Foramen Ovale

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[Revision Log](#)

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Description

Patent foramen ovale (PFO) is a congenital cardiac lesion which is generally asymptomatic that affects up to a quarter of the population. PFO can present 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.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that the percutaneous transcatheter closure of PFO with the Amplatzer PFO Occluder is **medically necessary** to reduce the risk of recurrent ischemic stroke for the following indications:
 - A. Age \geq 18 and \leq 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 any of the following:
 - a. Atherosclerosis;
 - b. Small vessel occlusion.
- II. It is the policy of health plans affiliated with Centene Corporation® that the percutaneous transcatheter closure of PFO is **experimental/investigational** to reduce the risk of ischemic stroke for the following indications:
 - 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. Stroke prevention;
 - D. Unexplained oxygen desaturation.

Background

The foramen ovale is a particular structure of the fetal circulation that fails to close 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 there is no significant advantage for surgical PFO closure to improve ischemic stroke prevention over medical therapy.⁷⁻¹⁰

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Consequently, the 2014 American Heart Association / American Stroke Association, as well as the 2016 Practice Advisory Board of the American Academy of Neurology, do not recommend percutaneous transcatheter closure of PFO outside of research settings.¹¹⁻¹²

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 patients⁴. 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

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 2017, 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

References

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12. Messé, Steven R., et al. "Practice advisory: Recurrent stroke with patent foramen ovale (update of practice parameter) Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology* 87.8 (2016): 815-821.

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 developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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

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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.

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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.

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