

Clinical Policy: Transcatheter Closure of Patent Foramen Ovale

Reference Number: WNC.CP.132

Last Review Date: 12/22

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Note: 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.

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. 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 WellCare of North Carolina® that the percutaneous transcatheter closure of PFO is medically necessary to reduce the risk of recurrent ischemic stroke, when used according to FDA labeled indications, contraindications, warnings and precautions and meet 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 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).

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- II.** It is the policy of WellCare of North Carolina® 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 PFO.⁶⁻⁷ The biological significance of PFOs have 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 risk of recurrent ischemic stroke in certain patients, and that governing societies should rewrite their guidelines accordingly.²²

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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.¹⁹

The American Academy of Neurology Practice advisory 2020 update summary on patent foramen ovale 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

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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 (i.e., Fontan fenestration, atrial septal defect) with implant

HCPCS®* Codes	Description
C1817	Septal defect implant system, intracardiac

Reviews, Revisions, and Approvals	Review Date	Approval Date
Original approval date	03/21	06/21
Reviewed CPT, HCPCS, and ICD-10-CM codes.	08/21	11/21
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. References reviewed, updated, and reformatted.	08/22	08/22
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 included information on PASCAL classification system and RoPE score. Removed ICD-10 codes. References reviewed and updated.	12/22	

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North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
 2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in this policy.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

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- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

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NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

EPSDT does not apply to NCHC beneficiaries.

Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the, NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

- a. Claim Type - as applicable to the service provided:
Professional (CMS-1500/837P transaction)
Institutional (UB-04/837I transaction)
Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report

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the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- d. Modifiers - Providers shall follow applicable modifier guidelines.
- e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments -
For Medicaid refer to Medicaid State Plan:
<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>
For NCHC refer to NCHC State Plan:
<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>
- g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>.

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 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

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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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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