Cohere Medical Policy - Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure

Clinical Policy for Medical Necessity Review

Version: 2
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Important Notices

Notices & Disclaimers:

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Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medical Policy - Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD) Closure

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
    - The medical necessity of each individual request
    - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
    - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Closure of a patent foramen ovale (PFO) and atrial septal defect (ASD) - congenital openings between the heart's upper chambers - is performed via endovascular, minimally invasive means. During closure of a PFO, a device (often a mesh disc) is implanted in the atrial septum to seal an abnormal opening between the atria that is suspected of contributing to stroke. The procedure requires transcatheter access to a large vein, typically the femoral vein in the groin.[1-3] ASD closure similarly involves transcatheter insertion and implantation of occluder devices to seal an abnormal opening in the atrial septum. However, because ASDs are typically larger, the occluder devices are often larger, and their insertion is more complex, requiring more extensive imaging, balloon sizing of the defect, and a larger device delivery system.[4]

Medical Necessity Criteria

Indications

Patent foramen ovale (PFO) or atrial septal defect (ASD) closure is considered appropriate if **ANY** of the following is **TRUE**:

- **PFO closure** is considered appropriate if **ANY** of the following is **TRUE**[1,5-9]:
  - **ALL** of the following:
    - The patient is 18 to 60 years of age with PFO with a right-to-left shunt; **AND**
    - Non-lacunar embolic stroke determined after comprehensive evaluation by a qualified radiologist or neurologist; **AND**
    - No other evident source of stroke[10-15]; **OR**
  - Systemic embolism without a prior PFO-associated stroke, in whom other embolic etiologies have been excluded[10,11,14,16]; **OR**
  - The patient has PFO with unexplained recurrent embolic stroke despite medical therapy (without another identified cause)[10,14]; **OR**
- **ASD closure** is considered appropriate if **ANY** of the following is **TRUE**[1,4,8,9,,18]:
  - Isolated secundum ASD and **ALL** of the following:
    - Impaired functional capacity; **AND**
    - RA or RV enlargement; **AND**
    - Hemodynamically significant net left-to-right shunt (Qp:Qs greater than or equal to 1.5:1); **OR**
  - The patient is asymptomatic and has **ALL** of the following:

        - Isolated atrial septal defect (ASD); **AND**
        - RA and RV enlargement; **AND**
        - Net left-to-right shunt sufficiently large to cause physiological sequelae (e.g., Qp:Qs 1.5:1 or greater); **OR**
    - Percutaneous closure may be considered for adults with **ANY** of the following:
        - ASD when net left-to-right shunt (Qp:Qs) is 1.5:1 or greater; **OR**
        - PA systolic pressure is 50% or more of systemic arterial systolic pressure; **OR**
        - Pulmonary vascular resistance is greater than one-third of the systemic resistance; **OR**
    - Patient with a fenestrated Fontan circuit[19-21]; **OR**
    - The patient can be considered for documented recurrent paradoxical embolization event on treatment (without another identified cause)[9]; **OR**
    - Unrepaired Ebstein anomaly with moderate-severe tricuspid regurgitation and impaired exercise tolerance.[22]

Non-Indications

Patent foramen ovale (PFO) or atrial septal defect (ASD) closure is not considered appropriate if **ANY** of the following is **TRUE**:

- **PFO closure** is not considered appropriate if the patient has **ANY** of the following[23]:
    - Irreversible severe pulmonary hypertension (e.g., Eisenmenger physiology [net right-to-left shunt], pulmonary artery pressure or pulmonary vascular resistance greater than ⅔ systemic)[5,16]; **OR**
    - Active endocarditis, sepsis, or other untreated infection; **OR**
    - Intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant; **OR**
    - PFO was discovered incidentally without associated symptoms; **OR**
    - Alternative cause of stroke identified (e.g., atherosclerotic lesions, atrial fibrillation)[12,14]; **OR**
    - Bleeding disorder or other contraindication to antiplatelet therapy[5,16]; **OR**
- **ASD closure** is not considered appropriate if the patient has **ANY** of the following[4,16]
    - Irreversible severe pulmonary hypertension (pulmonary artery pressure or pulmonary vascular resistance greater than ⅔ systemic); **OR**
    - Eisenmenger physiology, net right-to-left shunt; **OR**

- Bleeding disorder or other contraindication to antiplatelet therapy; **OR**
- Active endocarditis, sepsis, or other untreated infection; **OR**
- Known intracardiac thrombi.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant.

Medical Evidence

Amini (2025) reviewed findings on PFO and cryptogenic stroke, noting that while it may not be possible to definitively conclude whether a PFO was causally involved in a stroke, a high risk of paradoxical embolism (RoPE) score increases the likelihood that PFO was involved in the stroke. The RoPE score considers history of hypertension, diabetes, stroke, smoking, cortical infarct, and age. Similarly, the PFO-associated stroke causal likelihood (PASCAL) classification considers anatomical features of the PFO, including size of the defect and shunt type, to determine the likelihood that PFO was causally involved in a stroke. The author then reviewed studies showing that, in patients with high-risk PFOs, PFO closure decreased the recurrent stroke rate by up to 41%.[11]

In 2020, Messe et al. updated the 2016 American Academy of Neurology's practice advisory guidelines on the treatment of patients with PFO and stroke. They recommended thorough patient evaluation prior to PFO closure. Specific recommendations included the elimination of any other cause of stroke, exercising particular caution when alternative stroke mechanisms are identified, and the importance of advising patients that PFO is common and that it is not possible to definitively determine whether the PFO was causally involved in their stroke.[14] In 2019, a panel of neurologists and cardiologists published recommendations on PFO closure as a treatment for cryptogenic stroke. Their recommendations included age between 16-60, ischemic stroke within the last 6 months attributable to the PFO after examination with a stroke specialist, and specific PFO characteristics - including atrial septal aneurysm, a right-to-left shunt greater than 20 microbubbles, or a diameter at least 2 mm.[13]

Collado et al. (2018) systematically reviewed PFO closure for stroke prevention and other disorders. The evidence showed that, while approximately 25% of the adult population has a PFO, the condition itself has not been proven to increase the risk of ischemic stroke. However, up to 40% of ischemic cryptogenic strokes occur in patients with PFOs, suggesting that paradoxical embolism through a PFO may be the cause of a significant percentage of cryptogenic strokes. The authors reviewed procedural complications, including transient ST elevations, transient ischemic attack, device

dislodgement, and large residual shunt, occurring in 3% of the 307 patients evaluated. Vascular injury at the access site was found to occur in as many as 30% of cases, though only 2.4% required surgical intervention. In a study of 1355 cases, major complications occurred in 1.5% of patients, and 7.9% experienced minor complications. Device embolization was a very rare complication at 0.7% overall.[1]

In the 2018 AHA/ACC guideline for the management of adults with congenital heart disease, Stout and colleagues discussed PFO in relation to Ebstein anomaly, in that an otherwise normal-appearing PFO may have a significant impact on Ebstein anomaly. Surgery for PFO or ASD, as well as tricuspid valve repair and arrhythmia surgery, may be beneficial to the patient. The committee stated that patients who do not undergo ASD closure have worse long-term outcomes, including atrial arrhythmia, eventual greater degrees of pulmonary arterial hypertension (PAH), and significantly reduced functional capacity. They stated that data suggest that ASD closure improves functional capacity, but the benefit is less clear in patients with preoperatively normal functional capacity. Until further studies are completed, the guidelines recommend closing a hemodynamically important ASD if significant PAH is absent.[4]

Kernan et al. (2014) developed guidelines for the prevention of stroke in patients with stroke and transient ischemic attack (TIA). In patients with a cryptogenic ischemic stroke or TIA who also have a PFO and no deep vein thrombosis, the available data do not support the benefits of PFO closure. Transcatheter PFO closure may be considered in the event of PFO with deep vein thrombosis (DVT), based on the risk of the DVT reoccurring.[8] However, Kavinsky CJ et al. (2022) recommended PFO closure in patients aged 18-60 with a PFO-associated stroke but not for TIA. Also, the same guideline recommended against PFO closure in persons with a history of DVT and without a prior PFO-associated stroke.[5]

References

1. Collado FM, Poulin MF, Murphy JJ, et al. Patent foramen ovale closure for stroke prevention and other disorders. *J Am Heart Assoc*. 2018;7:e007146. https://doi.org/10.1161/JAHA.117.007146

2. Luca F, Pino PG, Parrini I, et al. Patent foramen ovale and cryptogenic stroke: Integrated management. *J. Clin. Med. 2023*;12(5):1952

3. Sondergaard L, Kasner SE, Rhodes JF, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med*. 2017;377(11):1033-1042

4. Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC guideline for the management of adults with congenital heart disease. *J Am Coll Cardio*. 2019;73(12):81-192

5. Kavinsky CJ, Szerlip M, Goldsweig AM, et al. SCAI guidelines for the management of patent foramen ovale. *J Soc Cardiovasc Angiogr Interv*. 2022;1(4):100039. doi:10.1016/J.JSCAI.2022.100039

6. Mojadidi MK, Zaman MO, Elgendy IY, et al. Cryptogenic stroke and patent foramen ovale. *J Am Coll Cardiol*. 2018;71(9):1035-1043. doi:10.1016/J.JACC.2017.12.059

7. Mas JL, Derumeaux G, Guillon B, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med*. 2017;377(11):1011-1021. doi:10.1056/NEJMOA1705915

8. Kernan WN, Ovbiagele B, Black HR, et al. Guidelines for the prevention of stroke in patients with stroke and transient ischemic attack: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2014;45(7):2160-2236. doi:10.1161/STR.0000000000000024. Erratum in: *Stroke*. 2015;46(2):e54

9. Warnes CA, Williams RG, Bashore TM, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease. *J Am Coll Cardio*l. 2008;52(23). doi:10.1016/j.jacc.2008.10.001

10. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 guideline for the prevention of stroke in patients with stroke and transient ischemic attack. *Stroke*. 2021;52:e364–e467. doi: 10.1161/STR.0000000000000375

11. Amini T. Cryptogenic stroke and patent foramen ovale: Endeavoring for clarity. *Front Neurol*. 2024;15. doi:10.3389/fneur.2024.1533232

12. Saver JL, Carroll JD, Thaler DE, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med*. 2017;377(11):1022-1032. doi:10.1056/NEJMOA1610057

13. Mas JL, Derex L, Guérin P, et al. Transcatheter closure of patent foramen ovale to prevent stroke recurrence in patients with otherwise unexplained ischaemic stroke: Expert consensus of the French Neurovascular Society and the French Society of Cardiology. *Arch Cardiovasc Dis*. 2019;112(8-9):532-542. doi:10.1016/J.ACVD.2019.06.002

14. Messé SR, Gronseth GS, Kent DM, et al. Practice advisory update summary: Patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. *Neurology*. 2020;94(20):876-885. doi:10.1212/WNL.0000000000009443

15. Arboix A, Parra O, Alió J. Patent foramen ovale closure in non-lacunar cryptogenic ischemic stroke: Where are we now? *J Geriatr Cardiol*. 2021;18(1):67. https://doi.org/10.11909/j.issn.1671-5411.2021.01.009

16. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data: Amplatzer septal occluder. Published September 10, 2001. https://www.accessdata.fda.gov/cdrh_docs/pdf/P000039b.pdf

17. Othman F, Med B, Bailey B, et al. Platypnea-orthodeoxia syndrome in the setting of patent foramen ovale without pulmonary hypertension or major lung disease. *J Am Heart Assoc*. 2022;11:24609. doi:10.1161/JAHA.121.024609

18. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data: GORE CARDIOFORM septal occluder. Published March 30, 2018. https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050006s060b.pdf

19. Greenleaf CE, Lim ZN, Li W, et al. Impact on clinical outcomes from transcatheter closure of the Fontan fenestration: A systematic review and meta-analysis. *Front Pediatr*. 2022;10:915045. doi:10.3389/FPED.2022.915045/FULL

20. Gewillig M, Brown SC. The Fontan circulation after 45 years: Update in physiology. *Heart*. 2016 Jul 15;102(14):1081-6

21. Schumacher KR, Cedars A, Allen K, et al. Achieving consensus: Severity-graded definitions of Fontan-associated complications to characterize Fontan circulatory failure. *J Card Fail*. 2024 Dec 1;30(12):1595-603

22. Jost CHA, Connolly HM, Dearani JA, et al. Ebstein's anomaly. *Circulation*. 2007;115(2):277-285. doi:10.1161/CIRCULATIONAHA.106.619338

23. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data: Amplatzer PFO occluder. Published October 28, 2016. https://www.accessdata.fda.gov/cdrh_docs/pdf12/p120021b.pdf

24. O'byrne ML, Levi DS. State of the art ASD closure devices for congenital heart disease. *Interv Cardiol Clin*. 2019;8(1):11-21. doi:10.1016/j.iccl.2018.08.008

25. Amedro P, Soulatges C, Fraisse A. Infective endocarditis after device closure of atrial septal defects: Case report and review of the literature. *Catheter Cardiovasc Interv*. 2017;89(2):324-334. doi:10.1002/ccd.26784

Policy Revision History/Information

Original Date: April 5, 2024		
Review History		
Version 2	07/10/2025	Annual policy review & restructure. Minor reorganization of first PFO indication without altering the criteria itself Removed “or surgical closure” from ASD indication as this policy scope is limited to transcatheter intervention Removed qualifier of “worsening hypoxia” for patients with HLHS/Fontan palliation in adherence to society guidelines Removal of indication: orthodeoxia/platypnea syndrome. This indication was felt to be redundant and a potential area of risk if misinterpreted.