Cohere Medicare Advantage Policy - Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure

Clinical Policy for Medical Necessity Review

Version: 3
Revision Date: May 22, 2025

Important Notices

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Other Notices:

Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medicare Advantage Policy - Patent Foramen Ovale (PFO) and 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) and Atrial Septal Defect (ASD) Closure

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for patent foramen ovale (PFO) and atrial septal defect (ASD) closure

Description

Closure of a patent foramen ovale (PFO) and atrial septal defect (ASD) are procedures to seal an abnormal opening in the heart's atrial septum.
In PFO closure, mesh discs are implanted on the atrial septum to seal an abnormal opening between the atria that is suspected of contributing to stroke. The procedure is minimally invasive, involving transcatheter insertion of the device through 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 delivery system.[4]

Medical Necessity Criteria

Indications

Patent foramen ovale (PFO) and 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]:
  - 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 the patient has **ANY** of the following[1,4,8,9,5,18]:
    - 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**
    - Asymptomatic and **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 or surgical 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**
    - Worsening hypoxia in a patient with a fenestrated Fontan circuit[19]; **OR**
    - The patient can be considered for documented recurrent paradoxical embolization event on treatment (without another identified cause)[9]; **OR**
    - Orthodeoxia/platypnea syndrome[20,21]; **OR**
    - Unrepaired Ebstein anomaly with moderate-severe tricuspid regurgitation and impaired exercise tolerance.[22]

Non-Indications

Patent foramen ovale (PFO) and 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[23]; **OR**
  - Intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant[23]; **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[4,5,16]
  - 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.

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for PFO and ASD closure may include:

- Adverse effects from delayed or denied treatment for PFO include increased risk of recurrent stroke and other embolic events.[1,3] The 2022 Society for Cardiovascular Angiography & Interventions guidelines for the management of PFO emphasize careful patient evaluation in determining the appropriateness of PFO closure, noting that patient age and the presence of other conditions, including atrial fibrillation, thrombophilia, or high-risk anatomy, should all be considered when deciding whether to proceed with PFO closure.[5]
- Adverse effects from delayed or denied treatment for ASD include increased risk of right heart enlargement and heart failure, irreversible pulmonary hypertension, frequent pulmonary infections, fatigue, exercise intolerance, palpitations, and embolisms.[9]
    - Risks with surgical procedures include infection, bleeding, injury to neurovascular structures, anesthetic risk, the need for repeat or additional procedures, and other postoperative complications. The FDA summary of safety and effectiveness data for the Amplatzer PFO occluder highlights the importance of appropriate patient selection to minimize surgical risks and enhance the benefits of PFO and ASD closure.[6]
    - Increased risk of thrombotic complications, including atrial fibrillation and venous thromboembolism, after PFO closure.[3,5,6]
    - Risk of vascular disorders, including embolization, thrombus formation, erosion, and arrhythmias after ASD closure.[24]

The clinical benefits of using these criteria for PFO and ASD closure may include:

- Improved patient selection, resulting in better long-term outcomes. In appropriately selected patients with cryptogenic stroke, PFO closure can decrease the risk of recurrent stroke.[7,8,11,12] ASD closure may decrease atrial arrhythmias and increase functional capacity.[4] Guidelines on the use of PFO and ASD closure procedures emphasize the importance of accurate diagnostics, interdisciplinary collaboration involving cardiologists and neurologists, and appropriate patient selection in preventing complications.[7]
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with irreversible severe pulmonary hypertension who undergo PFO or ASD closure are at risk of hemodynamic deterioration due to the loss of a compensatory right-to-left shunt.[4,16,23]
- Patients with active endocarditis, sepsis, or other untreated infections who undergo PFO or ASD closure are at risk of infective endocarditis, delaying recovery and increasing the risk of complications.[23,25]
- Patients with unaddressed intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant who undergo PFO closure are at risk of infection and device failure.[4,23]
- Patients with bleeding disorders or other contraindications to antiplatelet therapy at the intended site of implant who undergo ASD closure are at increased risk of thrombosis.[23]

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 eliminating any other cause of stroke, taking extra caution when alternative stroke mechanisms are identified, and advising patients that PFO is common and that it is not possible to definitively determine whether the PFO was causally involved in stroke.[14] In 2019, a panel of neurologists and cardiologists published recommendations on using PFO closure to treat cryptogenic stroke. Their recommendations included age between 16-60, ischemic stroke within the last 6 months attributed 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 patent foramen ovale 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 are in patients with PFOs, suggesting that paradoxical embolism through a PFO may be the cause of a significant percentage of cryptogenic strokes. A study was reviewed regarding

procedural complications, including transient ST elevations, transient ischemic attack, device dislodgement, and large residual shunt in 3% of the 307 patients evaluated. Vascular injury at the access site was found to occur in as many as 30% of cases, with only 2.4% requiring 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 discuss 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 arrhythmias, 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 and a PFO in which there is 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. Accessed September 6, 2018. 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. Accessed May 22, 2024. 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. Shah AH, Osten M, Leventhal A, et al. Percutaneous intervention to treat platypnea–orthodeoxia syndrome: The Toronto experience. *JACC Cardiovasc Interv*. 2016;9(18):1928-1938. doi:10.1016/J.JCIN.2016.07.003

21. Akin E, Krüger U, Braun P, et al. 2599-26041 The platypnea-orthodeoxia syndrome. *Eur Rev Med Pharmacol Sci*. 2014;18(18):2599-2604. https://www.europeanreview.org/wp/wp-content/uploads/2599-26041.pdf

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. Accessed May 22, 2024 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

Clinical Guideline Revision History/Information

Original Date: MAY 24, 2024		
Review History		
Version 2	06/10/2024	422.101 Disclaimer added
Version 3	05/22/2025	Annual review. Change to medical necessity criteria: non-lacunar embolic stroke must be determined by a qualified radiologist or neurologist. No changes to procedure codes. Updated medical evidence and harms/benefits (including references).