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

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

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

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

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

Benefit Category

Not applicable.

Recommended Clinical Approach

Patent foramen ovale (PFO) refers to the nonclosure between the septum primum and secundum located at the superior and inferior margin of the foramen ovale. Closure can prevent stroke in appropriate patients.[1-3] Patients with reduced functional capacity caused by hemodynamically important isolated secundum atrial septal defect (ASD) benefit from surgical or transcatheter closure of the secundum ASD. Patients who do not undergo ASD closure may experience atrial arrhythmias, reduced functional capacity, and greater degrees of pulmonary arterial hypertension (PAH).[4] While secundum ASDs can be closed percutaneously, anatomy permitting, the primum, sinus venosus, and coronary sinus ASDs require surgical treatment.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of PFO and ASD closure procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of PFO and ASD closure can lead to increased symptoms and complications, especially in patients with a high risk of stroke. The 2021 guideline for the prevention of stroke in patients with stroke and

transient ischemic attack emphasizes the importance of timely intervention to prevent adverse outcomes in patients with significant heart conditions.[7]

- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to 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.[8]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of PFO and ASD closure criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The guidelines for the management of congenital heart disease support the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.[6]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to PFO and ASD closure procedures for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. The guidelines for the management of adults with congenital heart disease emphasize the diagnostic accuracy of imaging and monitoring procedures in managing patients with heart conditions.[4]
- Enhanced diagnostic accuracy: This is crucial for complex cardiovascular conditions where traditional diagnostic methods may pose additional risks. Advanced imaging and monitoring techniques offer the advantage of detailed vascular assessment, aiding in decision-making regarding interventions.[9]
- Reduction in complications and adverse effects: Proper use of PFO and ASD closure criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The guidelines on the use of PFO and ASD closure procedures emphasize the importance of accurate diagnostics in preventing complications.[11]

- Enhanced overall patient satisfaction: Ensuring that PFO and ASD closure procedures are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. The guidelines for the prevention of stroke in patients with stroke and transient ischemic attack support the necessity of appropriate use criteria to minimize healthcare costs and prevent complications.[5]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **PFO closure** is considered appropriate if **ANY** of the following is **TRUE**[1,5-8]:
- ◆ The patient is 18 to 65 years of age with PFO with a right-to-left shunt and non-lacunar embolic appearing ischemic stroke with no other evident source of stroke despite a comprehensive evaluation; **OR**
- ◆ Systemic embolism without a prior PFO-associated stroke, in whom other embolic etiologies have been excluded[9]; **OR**
- ◆ The patient has PFO with unexplained recurrent embolic stroke despite medical therapy (without another identified cause); **OR**
- ◆ The patient has orthodeoxia/platypnea syndromes after other causes of hypoxia have been excluded; **OR**

➔ **ASD closure** is considered appropriate if the patient has **ANY** of the following[1,5-6,10-11]:
- ◆ 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; **OR**
    - The patient can be considered for documented recurrent paradoxical embolization event on treatment (without another identified cause)[6]; **OR**
    - Orthodeoxia/platypnea syndrome; **OR**
    - Unrepaired Ebstein anomaly with moderate-severe tricuspid regurgitation and impaired exercise tolerance.

Non-Indications

- ➔ **PFO closure** is not considered appropriate if the patient has **ANY** of the following[4,8]:
    - Irreversible severe pulmonary hypertension (e.g., Eisenmenger physiology (net right-to-left shunt), pulmonary artery pressure or pulmonary vascular resistance greater than ⅔ systemic)[4,10-11]; **OR**
    - Active endocarditis, sepsis, or other untreated infections[8]; **OR**
    - Intracardiac mass, vegetation, tumor, or thrombus at the intended site of implant[8]; **OR**
    - PFO was discovered incidentally without associated symptoms; **OR**
    - Alternative cause of stroke identified (e.g., atherosclerotic lesions, atrial fibrillation); **OR**
    - Bleeding disorder or other contraindication to antiplatelet therapy[10-11]; **OR**
- ➔ **ASD closure** is not considered appropriate if the patient has **ANY** of the following:
    - Irreversible severe pulmonary hypertension (pulmonary artery pressure or pulmonary vascular resistance greater than ⅔ systemic)[4,10-11]; **OR**

- Eisenmenger physiology, net right to left shunt; **OR**
- Bleeding disorder or other contraindication to antiplatelet therapy[10-11]; **OR**
- Active endocarditis, sepsis, or other untreated infections[10-11]; **OR**
- Known intracardiac thrombi.[10-11]

Level of Care Criteria

Inpatient

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

Collado et al. (2018) conducted a systematic review of 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 suggests that ASD closure improves functional capacity, but in patients with preoperatively normal functional capacity, the benefit is less clear. Until further studies are completed, it is stated to be reasonable to close a hemodynamically important ASD if significant PAH is not present.[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, it was stated that the available data do not support the benefits of PFO closure. Transcatheter PFO closure may be considered in the event of PFO with DVT, based on the risk of the DVT reoccurring.[5] 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 deep vein thrombosis (DVT) and without a prior PFO-associated stroke.[11]

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Clinical Guideline Revision History/Information

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