



# **Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure – Single Service**

*Clinical Guidelines for Medical Necessity Review*

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## Guideline Information:

**Specialty Area:** Cardiovascular Disease

**Guideline Name:** Patent Foramen Ovale (PFO) and Atrial Septal Defect (ASD) Closure (Single Service)

**Literature review current through:** 4/5/2024

**Document last updated:** 4/5/2024

**Type:**  Adult (18+ yo) |  Pediatric (0-17yo)

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# Medical Necessity Criteria

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

### General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Patent foramen ovale (PFO) refers to the nonclosure between septum primum and secundum located at the superior and inferior margin of the foramen ovale. Closure can prevent stroke in appropriate patients.<sup>1-3</sup> 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).<sup>4</sup> While secundum ASDs can be closed percutaneously, anatomy permitting, the primum, sinus venosus, and coronary sinus ASDs require surgical treatment.
- **Exclusions:** Exclusions to percutaneous device closure may include the presence of an inferior vena cava filter, elevated bleeding risk or coagulopathy, and vascular, cardiac, or PFO anatomy that is unsuitable for device placement.

### Medical Necessity Criteria

#### Indications

- **PFO Closure** is considered appropriate if **ANY** of the following is **TRUE**.<sup>1,5-8</sup>
- ◆ The patient is 18 to 60 years of age with PFO with a right-to-left shunt and **ANY** of the following is **TRUE**:
    - 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<sup>11</sup>; **OR**
  - ◆ The patient is 18 to 60 years of age with 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<sup>1,5-6,9-10</sup>:
  - ◆ 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)<sup>6</sup>; **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<sup>4,8</sup>:
  - ◆ Irreversible severe pulmonary hypertension (e.g., Eisenmenger physiology (net right-to-left shunt), pulmonary artery pressure or pulmonary vascular resistance greater than  $\frac{2}{3}$  systemic)<sup>4,9-10</sup>; **OR**
  - ◆ Active endocarditis, sepsis, or other untreated infections<sup>8</sup>; **OR**
  - ◆ Intracardiac mass, vegetation, tumor or thrombus at the intended site of implant<sup>8</sup>; **OR**
  - ◆ Body size or vasculature too small for TEE probe<sup>8</sup>; **OR**
  - ◆ PFO was discovered incidentally without associated symptoms; **OR**

- ◆ Alternative cause of stroke identified (e.g., atherosclerotic lesions, atrial fibrillation); **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  $\frac{2}{3}$  systemic)<sup>4,9-10</sup>; **OR**
  - ◆ Eisenmenger physiology, net right to left shunt; **OR**
  - ◆ Bleeding disorder or other contraindication to antiplatelet therapy<sup>9-10</sup>; **OR**
  - ◆ Body size or vasculature too small for TEE probe<sup>9-10</sup>; **OR**
  - ◆ Active endocarditis, sepsis, or other untreated infections<sup>9-10</sup>; **OR**
  - ◆ Known intracardiac thrombi<sup>9-10</sup>.

### 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.<sup>1</sup>

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 significant impact in 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.<sup>4</sup>

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 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.<sup>5</sup> 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.<sup>11</sup>

# References

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# Clinical Guideline Revision History/Information

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<b>Review History</b>	