MASSACHUSETTS

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Medical Policy

Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

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Policy Number: 121

BCBSA Reference Number: 2.02.09 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

The percutaneous transcatheter closure of a patent foramen ovale using a device that has been approved by the U.S. Food and Drug Administration for that purpose may be considered **MEDICALLY NECESSARY** to reduce the risk of recurrent ischemic stroke if individual meets all of the following:

- Between 18 and 60 years of age
- Diagnosed with patent foramen ovale with a right-to-left interatrial shunt confirmed by echocardiography with at least 1 of the following characteristics:
    - PFO with large shunt, defined as >30 microbubbles in the left atrium within 3 cardiac cycles, after opacification of the right atrium.
    - PFO associated with atrial septal aneurysm on transesophageal examination: septum primum excursion >10 mm
- Documented history of cryptogenic ischemic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude any other identifiable cause of stroke, including large vessel atherosclerotic disease and small vessel occlusive disease.

AND none of the following are present:

- Uncontrolled vascular risk factors, including uncontrolled diabetes or uncontrolled hypertension
- Other sources of right-to-left shunts, including an atrial septal defect and/or fenestrated septum **not meeting the above criteria**
- Active endocarditis or other untreated infections
- Inferior vena cava filter.

Transcatheter closure of secundum atrial septal defects may be considered **MEDICALLY NECESSARY** when using a device that has been approved by the U.S. Food and Drug Administration for that purpose and used according to the labeled indications including:

- Individuals with echocardiographic evidence of ostium secundum atrial septal defect;

AND either of the following:

- Clinical evidence of right ventricular volume overload (ie, 1.5:1 degree of left-to-right shunt or right ventricular enlargement); **OR**
- Clinical evidence of paradoxical embolism.

Transcatheter closure of secundum atrial septal defects is considered **INVESTIGATIONAL** for all other indications not meeting the criteria outlined above.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.
Medicare HMO Blue℠	Prior authorization is **required**.
Medicare PPO Blue℠	Prior authorization is **required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
02U53JZ	Supplement Atrial Septum with Synthetic Substitute, Percutaneous Approach
02U54JZ	Supplement Atrial Septum with Synthetic Substitute, Percutaneous Endoscopic Approach
02Q53ZZ	Repair Atrial Septum, Percutaneous Approach
02Q54ZZ	Repair Atrial Septum, Percutaneous Endoscopic Approach

Description

Patent Foramen Ovale

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Before birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over the course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale (PFO) is a common finding in 25% of asymptomatic adults.[1,] In some epidemiologic studies, PFO has been associated with cryptogenic stroke, defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources. Studies have also shown an association between PFO and migraine headache.

Atrial Septal Defects

Unlike PFO, which represents the postnatal persistence of normal fetal cardiovascular physiology, atrial septal defects (ASDs) represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized by their anatomy. Ostium secundum describes defects located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and are within the spectrum of atrioventricular septal defects. Primum defects occur commonly in patients with Down syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins.

Ostium secundum ASDs are the third most common form of congenital heart disorder and among the most common congenital cardiac malformations in adults, accounting for 30% to 40% of these patients older than age 40 years. The ASD often goes unnoticed for decades because the physical signs are subtle and the clinical sequelae are mild. However, virtually all patients who survive into their sixth decade are symptomatic; fewer than 50% of patients survive beyond age 40 to 50 years due to heart failure or pulmonary hypertension related to the left-to-right shunt. Symptoms related to ASD depend on the size of the defect and the relative diastolic filling properties of the left and right ventricles. Reduced left ventricular compliance, and mitral stenosis will increase left-to-right shunting across the defect. Conditions that reduce right ventricular compliance and tricuspid stenosis will reduce left-to-right shunting or cause a right-to-left shunt. Symptoms of an ASD include exercise intolerance and dyspnea, atrial fibrillation, and less commonly, signs of right heart failure. Patients with ASDs are also at risk for paradoxical emboli.

Treatment of Atrial Septal Defects

Repair of ASDs is recommended for those with a pulmonary-to-systemic flow ratio (Q_p: Q_s) exceeding 1.5:1.0. Despite the success of surgical repair, there has been interest in developing a transcatheter-based approach to ASD repair to avoid the risks and morbidity of open heart surgery. A variety of devices have been researched. Technical challenges include minimizing the size of the device so that smaller catheters can be used, developing techniques to center the device properly across the ASD, and ensuring that the device can be easily retrieved or repositioned, if necessary.

Individuals with ASDs and a history of cryptogenic stroke are typically treated with antiplatelet agents, given an absence of evidence that systemic anticoagulation is associated with outcome improvements.

Transcatheter Closure Devices

Transcatheter PFO and ASD occluders consist of a single or paired wire mesh discs covered or filled with polyester or polymer fabric that are placed over the septal defect. Over time, the occlusion system is epithelialized. ASD occluder devices consist of flexible mesh discs delivered via catheter to cover the ASD.

Summary

Patent foramen ovale (PFO) and atrial septal defects (ASDs) are relatively common congenital heart defects that can be associated with a range of symptoms. PFOs may be asymptomatic but have been

associated with higher rates of cryptogenic stroke. PFOs have also been investigated for a variety of other conditions, such as a migraine. Depending on their size, ASDs may lead to left-to-right shunting and signs and symptoms of pulmonary overload. Repair of ASDs is indicated for patients with a significant degree of left-to-right shunting. Transcatheter closure devices have been developed to repair PFO and ASDs. These devices are alternatives to open surgical repair for ASDs or treatment with antiplatelet and/or anticoagulant medications in patients with cryptogenic stroke and PFO.

Summary of Evidence

For individuals who have PFO and cryptogenic stroke who receive PFO closure with a transcatheter device, the evidence includes multiple randomized controlled trials (RCTs) comparing device-based PFO closure with medical therapy, systematic reviews, meta-analyses, and observational studies. Relevant outcomes are symptoms, change in disease status, overall survival, morbid events, and treatment-related morbidity and mortality. The RCTs comparing PFO closure with medical management have suggested that PFO closure is more effective than medical therapy in reducing event rates. Although these results were not statistically significant by intention-to-treat analyses in earlier trials [ie, Amplatzer PFO Occluder with Medical Treatment in Patients with Cryptogenic Embolism (PC-Trial) and Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment (RESPECT; initial study)], they were statistically significant in later trials [ie, RESPECT (extended follow-up), Reduction in the Use of Corticosteroids in Exacerbated COPD (REDUCE), and Patent Foramen Ovale Closure or Anticoagulants versus Antiplatelet Therapy to Prevent Stroke Recurrence (CLOSE)]. Use of appropriate patient selection criteria to eliminate other causes of cryptogenic stroke in RESPECT, REDUCE, and CLOSE trials contributed to findings of the superiority of PFO closure compared with medical management. Of note, higher rates of atrial fibrillation were reported in a few of the individual trials and in the meta-analysis that incorporated evidence from RESPECT, REDUCE, and CLOSE trials. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have PFO and migraines who receive PFO closure with a transcatheter device, the evidence includes 3 RCTs of PFO closure and multiple observational studies reporting on the association between PFO and migraine. Relevant outcomes are symptoms, quality of life, medication use, and treatment-related morbidity and mortality. Two sham-controlled randomized trials did not demonstrate significant improvements in migraine symptoms after PFO closure. A third RCT with blinded endpoint evaluation did not demonstrate reductions in migraine days after PFO closure compared to medical management but likely was underpowered. Nonrandomized studies have shown highly variable rates of migraine reduction after PFO closure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have PFO and conditions associated with PFO other than cryptogenic stroke or migraine (eg, platypnea-orthodeoxia syndrome, myocardial infarction with normal coronary arteries, decompression illness, high-altitude pulmonary edema, obstructive sleep apnea) who receive PFO closure with a transcatheter device, the evidence includes small case series and case reports. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity and mortality. Comparative studies are needed to evaluate outcomes in similar patient groups treated with and without PFO closure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have ASD and evidence of left-to-right shunt or right ventricular overload who receive ASD closure with a transcatheter device, the evidence includes systematic reviews, nonrandomized comparative studies, and single-arm studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity and mortality. The available nonrandomized comparative studies and single-arm case series have shown rates of closure using transcatheter-based devices approaching the high success rates of surgery, which are supported by meta-analyses of these studies. The percutaneous approach has a low complication rate and avoids the morbidity and complications of open surgery. In systematic reviews, the risk of overall mortality was similar with transcatheter device versus surgical closure, whereas in-hospital mortality was significantly reduced with transcatheter device closure. If the percutaneous approach is unsuccessful, ASD closure can be achieved using surgery. Because of the benefits of percutaneous closure over open surgery, it can be determined that transcatheter ASD

closure improves outcomes in patients with an indication for ASD closure. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
7/2022	Annual policy review. Minor editorial corrections to policy statements; intent unchanged.
6/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Policy clarified. Statement on PFO for individuals with history of cryptogenic stroke who have failed conventional drug therapy was removed. Failed medical therapy is not a requirement for PFO closure.
7/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	Annual policy review. First policy statement revised to: the percutaneous transcatheter closure of a patent foramen ovale using a device that has been approved by the U.S. Food and Drug Administration for that purpose may be considered medically necessary to reduce the risk of recurrent ischemic stroke if patient meets all of the specified criteria. New investigational statement was added for situations not meeting criteria, and information on the appropriate patient population for ostium secundum atrial septal defect. Effective 10/1/2019.
4/2019	Prior authorization is required in the outpatient setting. Clarified coding information. Effective 4/1/2019.
10/2018	Annual policy review. New medically necessary indications described. Effective 10/1/2018.
1/2018	Clarified coding information.
7/2017	Annual policy review. New references added
5/2016	Annual policy review. New references added
1/2016	New medically necessary and investigational indications for transcatheter closure of a PFO described. Effective 1/1/2016.
9/2015	Added coding language.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
12/2013	Annual policy review. New references added
4/2013	Annual policy review. New references added
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
7/2010	Annual policy review. No changes to policy statements.
4/2010	Reviewed - Medical Policy Group – Cardiology. No changes to policy statements.
9/1/2009	Medical Policy 121 effective 9/1/2009.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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