MEDICAL POLICY

POLICY TITLE	CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (ASD)
POLICY NUMBER	MP-1.039

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**5/30/2018**
Effective Date:	**11/1/2018**

I. POLICY

The percutaneous transcatheter closure of a patent foramen ovale using Amplatzer PFO Occluder may be considered **medically necessary** to reduce the risk of recurrent ischemic stroke if patient 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 one 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;
- Active endocarditis or other untreated infections;
- Inferior vena cava filter.

Transcatheter closure of secundum atrial septal defects (ASD) may be considered **medically necessary** when using a device that has been U.S. Food and Drug Administration approved for that purpose and used according to the labeled indications.

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Policy Guidelines
Three devices have been approved by the U.S. Food and Drug Administration for atrial septal defect closure: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder.

The labeled indications for these devices are similar and include:

- Patients with echocardiographic evidence of ostium secundum atrial septal defect; AND
- Clinical evidence of right ventricular volume overload (ie, 1.5:1 degree of left-to-right shunt or right ventricular enlargement).

Generally recognized indications for closure include a pulmonary-to-systemic flow ratio of greater than 1.5, right atrial and right ventricular enlargement, and paradoxical embolism.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-2.02.09, Closure Devices for Patient Foramen Ovale and Atrial Septal Defects. The FEP Medical Policy Manual can be found at: https://www.fepblue.org.

III. DESCRIPTION/BACKGROUND

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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.

Treatment
Conventional therapy for cryptogenic stroke consists of antiplatelet therapy (aspirin, clopidogrel, or dipyridamole given alone or in combination) or oral anticoagulation with warfarin. In general,

patients with a known clotting disorder or evidence of preexisting thromboembolism are treated with warfarin, and patients without these risk factors are treated with antiplatelet agents. Closure devices are nonpharmacologic alternatives to medical therapy for cryptogenic stroke in patients with a PFO.

There has been interest in open surgery and transcatheter approaches to close the PFO in patients with a history of cryptogenic stroke to prevent recurrent stroke.

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

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.

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Transcatheter Closure Devices
Several devices have been developed to treat PFO and ASDs via a transcatheter approach, including the CardioSEAL STARFlex™ Septal Occlusion System, the Amplatzer PFO Occluder, the Figulla ASD Occluder (Occlutech GmbH), and the CeraFlex ASD Occluder (Lifetech Scientific).

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.

REGULATORY STATUS

PFO Closure Devices

In 2002, 2 transcatheter devices were cleared for marketing by the U.S. Food and Drug Administration (FDA) through a humanitarian device exemption as treatment for patients with cryptogenic stroke and PFO: the CardioSEAL® Septal Occlusion System (NMT Medical; device no longer commercially available) and the Amplatzer® PFO Occluder (Amplatzer, now St. Jude Medical). Following the limited FDA approval, use of PFO closure devices increased by more than 50-fold, well in excess of the 4000 per year threshold intended under the humanitarian device exemption,[2] prompting FDA to withdraw the humanitarian device exemption approval for these devices in 2007.

In November 2016, the Amplatzer® PFO Occluder was approved by FDA through the premarket approval process for the following indication[3]:

> "For percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke."

FDA product code: MLV.

ASD Closure Devices

Three devices have been approved by the FDA through the premarket approval process or a premarket approval supplement for transcatheter ASD closure (see Table 1) (FDA product code: MLV).

Table 1. ASD Closure Devices Approved by the Food and Drug Administration

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer™ Septal Occluder	St. Jude Medical	Dec 2001	• Occlusion of ASDs in the secundum position • Use in patients who have had a fenestrated Fontan procedure who require closure of the fenestration • Patients indicated for ASD closure have echocardiographic evidence of ostium secundum ASD and clinical evidence of right ventricular volume overload.
GORE HELEX Septal Occluder	W.L. Gore & Associates	Aug 2006 (discontinued)	• Percutaneous, transcatheter closure of ostium secundum ASDs
GORE CARDIOFORM Septal Occluder	W.L. Gore & Associates	Oct 2016 (supp.)	• Percutaneous, transcatheter closure of ostium secundum ASDs

ASD: atrial septal defect; PMA: premarket approval.

IV. RATIONALE

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Summary of Evidence

For individuals who have PFO and cryptogenic stroke who receive PFO closure with a transcatheter device, the evidence includes multiple, RCTs comparing device-based PFO closure with medical therapy, systematic reviews, and meta-analyses of these studies. Relevant outcomes are 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. While these results were not statistically significant by intention-to-treat analyses in the first 3 trials (ie, CLOSURE I, PC, and RESPECT [initial study]), they were statistically significant in later trials (ie, RESPECT [extended follow-up], REDUCE, and 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 a meaningful improvement in the net health outcome.

For individuals who have PFO and migraines who receive PFO closure with a transcatheter device, the evidence includes 2 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. The available sham-controlled randomized trial did not demonstrate significant improvements in migraine symptoms after PFO closure. A second RCT with blinded end point evaluation did not demonstrate reductions in migraine days after PFO closure but likely was underpowered. Nonrandomized studies have shown highly variable rates of migraine reduction after PFO closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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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. The body of evidence only consists of small case series and case reports. Comparative studies are needed to evaluate outcomes in similar patient groups treated with and without PFO closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 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. 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 a meaningful improvement in the net health outcome.

V. DEFINITIONS

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ANTICOAGULANT is an agent that delays or prevents blood coagulation.

ATRIA are the upper chambers of the heart.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible

for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when Medically Necessary

CPT Codes®								
93580								

HCPCS Code	Description
C1817	Septal defect implant system, intracardiac

ICD-10-CM Diagnosis Code	Description
I23.1	Atrial septal defect as current complication following acute myocardial infarction
Q21.1	Atrial septal defect
Q21.2	Atrioventricular septal defect

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.039	**CAC 1/28/03**
	CAC 11/30/04
	CAC 1/25/05
	CAC 1/31/06
	CAC 1/30/07
	CAC 1/29/08 Consensus
	CAC 5/26/09
	CAC 5/25/10 Consensus
	CAC 7/26/11 Adopted BCBA for PFO and ASD. Added list of labeled indications for Amplatzer Septal Occluder and GoreHelex Septal Occluder. Deleted information related to closure for PDA since it appears this procedure is a standard medical practice using an FDA approved device. Changed title to Closure Devices for Patent Foramen Ovale, and Atrial Septal Defects (ASD) (Formerly Closure Devices for Patent Foramen Ovale, Patent Ductus Arteriosis and Atrial Septal Defects). Minor wording changes to policy statements but intent is unchanged.
	CAC 8/28/12 Consensus review. References updated. No changes to policy statements. FEP variation added. Codes reviewed
	CAC 7/30/13 Consensus review. References updated. No changes to the policy statements. Policy guidelines added. Admin code review complete.
	CAC 3/25/14 Consensus review. References added. No changes to the policy statements. Rationale added. Policy coded.
	CAC 3/24/15 Consensus review. No change to policy statements. References

	and rationale updated. Policy coded.
	CAC 3/29/16 Consensus review. No change to policy statements. References and rationale updated. Removed the Medicare variation referencing IOM 100-02 Chapter 14 Medical Devices. No mention of coverage criteria for these devices. Coding reviewed.
	Admin Update 11/9/16 Variation Reformatting.
	Administrative update 11/18/16 Reference section update.
	CAC 9/26/17 Consensus review. Statement, "There are currently no transcatheter devices with the FDA approval or clearance for this indication," removed from investigational statement for PFO closure devices; policy statements otherwise unchanged. Policy Guidelines, Description/Background, Rationale and Reference sections updated. Coding updated C1817 added.
	5/30/18 Minor revision. Percutaneous transcatheter closure of a patent foramen ovale using the Amplatzer PFO Occluder may be considered medically necessary to reduce the risk of recurrent ischemic stroke when criteria is met. Policy Guidelines, Description/Background, Rationale and Reference sections updated. Coding reviewed.

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