MEDICAL POLICY

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

Clinical Benefit	**☒ Minimize safety risk or concern.** **☒ Minimize harmful or ineffective interventions.** **☐ Assure appropriate level of care.** **☐ Assure appropriate duration of service for interventions.** **☐ Assure that recommended medical prerequisites have been met.** **☐ Assure appropriate site of treatment or service.**
Effective Date:	**10/1/2024**

I. POLICY

The percutaneous transcatheter closure of a patent foramen ovale, using a device that has been approved by the U.S. Food and Drug Administration, 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 one of the following characteristics:
  - Observation of microbubbles in the left atrium within three (3) cardiac cycles, after opacification of the right atrium.
  - Atrial septal aneurysm on transesophageal examination: septum primum excursion greater than 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 individual has none of the following:

- 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.

MEDICAL POLICY

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

Transcatheter closure of atrial septal defects (ASD) may be considered **medically necessary** when using a device that has been approved by the U.S. Food and Drug Administration including:

- Closure of a fenestration as a result of the Fontan procedure **OR**
- Individuals with echocardiographic evidence of ostium secundum atrial septal defect **AND** one of the following:
  - Clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left-to-right shunt or right ventricular enlargement);
  - Clinical evidence of paradoxical embolism.

Transcatheter closure of atrial septal defects is considered **investigational** for all other indications not meeting criteria outlined above, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

Two devices approved by the U.S. Food and Drug Administration for patent foramen ovale closure and atrial septal defect closure are currently marketed: the Amplatzer Septal Occluder and the GORE CARDIOFORM Septal Occluder. The GORE HELEX Septal Occluder has been discontinued.

Cross-references:

MP 1.127 Left-Atrial Appendage Closure Device for Stroke Prevention in Atrial Fibrillation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

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 PFO is a common finding in 25% of asymptomatic adults. 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, 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.

Fontan Fenestration

The Fontan procedure is used as a palliative surgical procedure for patients with congenital heart disease with univentricular heart. Although about 85% of patients now reach adulthood following the Fontan procedure, in time, they develop a reduction of exercise capacity and multi-organ complications, including hepatic fibrosis, protein-losing enteropathy (PLE), and effects on respiratory function. Since 1971, when the first Fontan operation was performed, this procedure has undergone many modifications. Almost 30 years ago, in 1988, the technique of fenestration was developed, which is the creation of a small atrial septal defect (ASD) to allow a small right-to-left shunt. A fenestration is a communication between the right and left atrium that allows a reduction in pressure in the right atrium and the cavopulmonary bypass and improves the preload on the single ventricle. The cardiac surgical procedure of fenestration contributes to overcoming the period of low cardiac output in the early postoperative period, reduces the need for mechanical ventilation, and reduces the incidence of pleural effusion, but this is done at the expense of mild to moderate desaturation. The benefits of fenestration, beyond the early

postoperative period, include a reduction in fibrinous (plastic) bronchitis, PLE, and cardiac dysrhythmia. However, the potential risks of fenestration include cyanosis and thromboembolism.

Treatment
Repair of ASDs is recommended for those with a pulmonary-to-systemic flow ratio (Qp: Qs) 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.

REGULATORY STATUS

PFO Closure Devices
The U.S. Food and Drug Administration (FDA)has approved three devices for ASD closure through the premarket approval process or a premarket approval supplement: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder (see Table 1) (FDA product code: MLV).

In 2002, 2 transcatheter devices were cleared for marketing by the 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, prompting the FDA to withdraw the humanitarian device exemption approval for these devices in 2007. The Amplatzer PFO Occluder was approved through the premarket approval process in 2016.

In March 2018, the FDA granted an expanded indication to the Gore Cardioform Septal Occluder to include closure of PFO to reduce the risk of recurrent stroke (see Table 1). The new indication was based on results of the REDUCE pivotal clinical trial.

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

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer™ PFO Occluder	St. Jude Medical	Nov 2016	• 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.
GORE CARDIOFORM Septal Occluder	W.L. Gore & Associates	Mar 2018 (supplement)	• PFO closure 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

PFO: patent foramen ovale; PMA: premarket approval. FDA product code: MLV.

ASD Closure Devices

The FDA has approved three devices for ASD closure through the premarket approval process or a premarket approval supplement: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder (see Table 2) (FDA product code: MLV).

Table 2. ASD Closure Devices Approved by the Food and Drug Administration

Device	Manufacturer	PMA Approval Date	Indications

Amplatzer™ Septal Occluder	St. Jude Medical (Abbot 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 ASD Occluder	W.L. Gore & Associates	May 2019 (supplement)	• Percutaneous, transcatheter closure of ostium secundum ASDs
GORE CARDIOFORM Septal Occluder	W.L. Gore & Associates	Apr 2015 (supplement)	• 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. The 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 three trials (i.e., CLOSURE I, PC, and RESPECT [initial study]), they were statistically significant in later trials (i.e., 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 two RCTs of PFO closure and multiple observational studies reporting on the association between PFO and migraine. The 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 endpoint 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.

For individuals who have PFO, and conditions associated with PFO other than cryptogenic stroke or migraine (e.g., 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. The 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. The 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. Furthermore, consensus guidelines have recommended surgical or percutaneous ASD closure in adults with right heart enlargement, with or without symptoms. Similarly, patients who have undergone the Fontan procedure with fenestration benefit from closure of this opening later in

life. 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.

CRYPTOGENIC STROKE is an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources

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 health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' 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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross 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

Procedure Codes								
C1817	93580							

ICD-10-CM Diagnosis Code	Description
I21.B	Myocardial infarction with coronary microvascular dysfunction
I23.1	Atrial septal defect as current complication following acute myocardial infarction
I51.0	Cardiac septal defect, acquired
Q21.10	Atrial septal defect, unspecified
Q21.11	Secundum atrial septal defect
Q21.12	Patent foramen ovale
Q21.13	Coronary sinus atrial septal defect
Q21.14	Superior sinus venosus atrial septal defect
Q21.15	Inferior sinus venosus atrial septal defect
Q21.16	Sinus venosis atrial septal defect, unspecified
Q21.20	Atrioventricular septal defect, unspecified as to partial or complete
Q21.21	Partial atrioventricular septal defect
Q21.22	Transitional atrioventricular septal defect
Q21.23	Complete atrioventricular septal defect
Q21.19	Other specified atrial septal defect

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.039	**07/27/2020 Minor Review.** Change to criteria to remove “30 microbubbles to just observation of microbubbles”. Update to tables and references.
	11/17/2020 Administrative Update. Added new codes 33741, 33745, 33746

MEDICAL POLICY

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

	01/06/2021 Administrative Update. New codes 33741, 33745, 33746 have been removed.
	06/04/2021 Consensus Review. No change in policy statement. References updated and coding reviewed.
	07/11/2022 Minor Review. Added criteria of Fontan fenestration to be included in MN for ASD. Added ICD10 I50.1. Updated cross references, and definitions. Literature review. Updated references.
	08/01/2022 Administrative Update. ICD10 Codes updated
	06/20/2023 Consensus Review. No change in policy statement. References updated. Coding reviewed, no changes.
	09/07/2023 Administrative Update. Added ICD10 Code I21.B.
	06/05/2024 Consensus Review. No change in policy statement. References updated. Coding reviewed, no changes.

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