BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Transcatheter Closure Devices for Septal Defects

Policy #: 218
Latest Review Date: May 2024
Category: Cardiovascular

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **transcatheter closure of a patent foramen ovale (PFO) using an FDA-approved closure device** as a **covered benefit** to reduce the risk of recurrent ischemic stroke when all of the following are met:

- Diagnosis of PFO with a right to left shunt confirmed by echocardiography
- Diagnosis of cryptogenic stroke due to a presumed paradoxical embolism

Blue Advantage will treat **transcatheter closure of atrial septal defects (ASD) in adult or pediatric patients** as a **covered benefit** for any of the following indications:

- For the occlusion of ASDs in secundum position OR patients who have undergone a fenestrated Fontan procedure who now require closure of the fenestration;
- Have echocardiographic evidence of ostium secundum ASD AND clinical evidence of right ventricular volume overload (e.g. 1.5:1 degree of left to right shunt or RV enlargement).
- Have echocardiographic evidence of ostium secundum ASD AND clinical evidence of paradoxical embolism
- Documented platypnea- orthodeoxia
- Presence of net left-to-right shunting, pulmonary artery pressure less than two thirds systemic levels, PVR less than two-thirds systemic vascular resistance, or when responsive to either pulmonary vasodilator therapy or test occlusion of the defect

Blue Advantage will treat **transcatheter closure of atrial septal defects (ASD,) in all other situations, including but not limited to coronary sinus ASD, ostium primum ASD and sinus venosus ASD,** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **transcatheter closure of ventricular septal defects (VSD)** as a **covered benefit** for any of the following indications:

- Complex VSD of significant size to warrant closure (e.g. large volume left to right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) **AND** are considered to be at high risk for standard transarterial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.**
- Iatrogenic artifacts after surgical replacement of the aortic valve

**High-risk anatomical factors for transatrial or transarterial surgical closure include patients:

- Requiring left ventriculotomy or an extensive right ventriculotomy
- With a failed previous VSD closure
- With multiple apical and/or anterior muscular VSDs (Swiss Cheese Septum)
- With posterior apical VSDs covered by trabeculae

Blue Advantage will treat **transcatheter closure of ventricular septal defects (VSD)** as a **non-covered benefit** and as **investigational** including but not limited to, when the above criteria are not met and in patients with severe irreversible PAH.

Blue Advantage will treat **transcatheter closure of patent ductus arteriosus (PDA)** as a **covered benefit** when using an FDA-approved device for this indication.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Despite the success of standard open-heart surgery to repair cardiac defects, the risks and morbidity of open-heart surgery remain. Interventional cardiac catheterization techniques have advanced to a point where percutaneous transcatheter devices can be offered as an alternative for carefully selected patients. Transcatheter closure devices are permanent implants designed to close defects between chambers of the heart, including atrial septal defect (ASD), ventricular septal defect (VSD), and patent foramen ovale (PFO). Devices are also used for persistent patent ductus arteriosus (PDA), which is an opening between the descending thoracic aorta and the pulmonary artery which fails close after birth. These devices are self-expandable, self-centering umbrella-like devices. They are implanted in the defect through catheters inserted into either a vein or an artery using a transcatheter or percutaneous approach.

The standard for managing clinically significant cardiac defects mentioned above has been surgical closure, which except for complex ventricular septal defects, is associated with a very low mortality. Conventional surgical closure is done through a midline sternotomy. The transcatheter approach offers repair of the defect without major thoracic surgery, less post-operative pain, and decreased hospital stay without compromising outcomes in a select group of patients.

Patent Foramen Ovale (PFO)

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 un-inflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Prior to 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 arterial pressure and a decrease in right atrial pressure result in the permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale may be detected in up to 25% of asymptomatic adults. In some epidemiologic studies, patent foramen ovale (PFO) has been associated with cryptogenic stroke, a type of stroke defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources. Studies also show an association of PFO and migraine headaches.

Atrial Septal Defect (ASD)

Unlike PFOs, which represent 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 according to their anatomy. Ostium secundum describes defects that are located mid-septally 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 one of 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 (Qp: Qs) exceeding 1.5:1.0. Despite the success of operative repair, there has been interest in developing a catheter-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 device so that smaller catheters can be used, developing techniques to properly center the device 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 that are 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 disks that are delivered via catheter to cover the ASD.

Ventricular Septal Defect (VSD)
VSD is one of the most common congenital heart defects at birth and presents in approximately 42 out of every 10,000 births per year. Ventricular septal defects (VSDs) are usually present at birth but may also occur following myocardial infarction. Small VSDs may never be detected. A large VSD can allow blood to flow from the left to the right ventricle which increases load on the heart and lungs. this can cause symptoms such as shortness of breath, poor weight gain, and tiredness while feeding.

Treatment
Small VSDs may cause no problems and close on their own. If the VSD is large, open heart surgery or transcatheter closure may be required which is usually performed in infancy or childhood.

Patent Ductal Arteriosus (PDA)
PDA is another fairly common type of congenital heart defect (CHD). Although it can affect full-term babies, it is more common in premature babies. With this CHD, there is abnormal blood flow between the aorta and pulmonary artery. These two arteries are connected by the ductus arteriosus which is a normal and essential part of fetal blood circulation. Soon after birth, the vessel should close. When the vessel does not close, it allows oxygen rich blood from the aorta to mix with oxygen poor blood from the pulmonary artery which may strain the heart and increase blood pressure in lung arteries.

Treatment
A PDA may be treated with medications, catheter-based procedures or open surgery. Transcatheter closure of a PDA is an established treatment and is often the treatment of choice.

KEY POINTS:
The most recent update with literature review is through May 13, 2024.

Summary of Evidence
PFO
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 include 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 (i.e. Amplatzer PFO Occluder with Medical Treatment in Patients with Cryptogenic Embolism [PC-Trial]), they were statistically significant in later trials (i.e., RESPECT [extended follow-up], Reduction in the use of Corticosteroids in Exacerbated COD [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 randomized controlled trials of PFO closure, multiple observational studies reporting on the association between PFO and migraine, and systematic

reviews of these studies. Relevant outcomes are symptoms, quality of life, medication use, and treatment-related morbidity and mortality. Two sham-controlled RCTs did not demonstrate significant improvements in migraine symptoms after PFO closure. A third RCT with blinded endpoint evaluation did not demonstrate improvements in migraine days after PFO closure but was likely underpowered. Nonrandomized studies have shown highly variable rates of migraine improvement 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., 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, changes 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 the effects of the technology on health outcomes.

ASD
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, changes in disease status, and treatment-related morbidity and mortality. The available nonrandomized comparative studies and single-arm case series show high success rates of closure using closure 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.

VSD
For individuals who have a complex VSD of significant size and considered to be at high risk for surgical closure or have iatrogenic artifacts after surgical replacement of the aortic valve, the evidence includes prospective and retrospective studies. The relevant outcomes include symptoms, change in disease status, and treatment-related morbidity and mortality. The studies have shown for transcatheter closure of VSD high closure rates, low procedural mortality and positive short term results. Low complication rates and shorter hospital stays have made this procedure more favorable over the surgical treatment for appropriately selected individuals. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

PDA
For individuals who have a PDA and receive transcatheter closure with an FDA-approved PDA device, the evidence includes observational studies, single-arm multi-center studies, and retrospective reviews. The relevant outcomes include symptoms, changes in disease status, and treatment-related morbidity and mortality. Studies have shown that this is a well-established treatment, and is an efficient and safe procedure. Studies have shown excellent results for short and long-term studies. Low complication rates and shorter hospital stays have made this procedure more favorable over the surgical treatment when appropriate. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements
PFO
American College of Chest Physicians
In 2012, the American College of Chest Physicians updated its guidelines on antithrombotic therapy and the prevention of thrombosis, which made the following recommendations related to patent foramen ovale (PFO) and cryptogenic stroke:

> "We suggest that patients with stroke and PFO are treated with antiplatelet therapy following the recommendations for patients with noncardioembolic stroke…. In patients with a history of noncardioembolic ischemic stroke or TIA, we recommend long-term treatment with aspirin (75-100 mg once daily), clopidogrel (75 mg once daily), aspirin/extended-release dipyridamole (25 mg/200 mg bid), or cilostazol (100 mg bid) over no antiplatelet therapy (Grade 1A), oral anticoagulants (Grade 1B), the combination of clopidogrel plus aspirin (Grade 1B), or triflusal (Grade 2B)."

American Academy of Neurology
In 2020, the American Academy of Neurology (AAN) issued updated evidence-based guidelines about the management of patients with stroke and PFO to address whether percutaneous closure of PFO is superior to medical therapy alone. This update to the practice advisory published in 2016 was completed due to the approval of the Amplatzer PFO Occluder and the GORE CARDIOFORM Septal Occluder. Following a systematic review of the literature and structured formulation of recommendations, the AAN developed conclusions addressing percutaneous PFO closure as compared to medical therapy alone, for patients with cryptogenic stroke and PFO, percutaneous PFO closure:

- "probably reduces the risk of stroke recurrence with an HR [hazard ratio] of 0.41 (95% CI [confidence interval], 0.25–0.67, I2=12%) and an absolute risk reduction of 3.4% (95% CI, 2.0%–4.5%) at 5 years,"
- "probably is associated with a periprocedural complication rate of 3.9% (95% CI, 2.3%–5.7%)," and
- "probably is associated with the development of serious non-periprocedural atrial fibrillation, with a relative risk of 2.72 (95% CI,1.30–5.68, I2= 0%)."

The guidelines recommended:

> "In patients being considered for PFO closure, clinicians should ensure that an appropriately thorough evaluation has been performed to rule out alternative mechanisms of stroke, as was performed in all positive PFO closure trials (level B). In patients with a PFO detected after stroke and no other etiology identified after a thorough evaluation, clinicians should counsel that having a PFO is common; that it occurs in about 1 in 4 adults in the general population; that it is difficult to determine with certainty whether their PFO caused their stroke; and that PFO closure probably reduces recurrent stroke risk in select patients (level B)."
>
> "In patients younger than 60 years with a PFO and an embolic-appearing infarct and no other mechanism of stroke identified, clinicians may recommend closure following a discussion of potential benefits (reduction of stroke recurrence) and risks (procedural complication and atrial fibrillation) (level C). PFO closure may be offered in other populations, such as for a patient who is aged 60–65years with a very limited degree of traditional vascular risk factors (i.e., hypertension, diabetes, hyperlipidemia, or smoking) and no other mechanism of stroke detected following a thorough evaluation, including prolonged monitoring for atrial fibrillation (level C). PFO closure may be offered to younger patients (e.g., <30 years) with a single, small, deep stroke (<1.5 cm), a large shunt, and absence of any vascular risk factors that would lead to intrinsic small-vessel diseases such as hypertension, diabetes, or hyperlipidemia (level C)."

American Heart Association and American Stroke Association

In 2021, the American Heart Association (AHA) and American Stroke Association published updated guidelines on the prevention of stroke in patients with ischemic stroke or TIA. The guidelines list the following recommendations for device-based closure for patent foramen ovale (PFO):

- "In patients 18 to 60 years of age with a nonlacunar ischemic stroke of undetermined cause despite a thorough evaluation and a PFO with high-risk anatomic features* it is reasonable to choose closure with a transcatheter device and long-term antiplatelet therapy over anti-platelet therapy alone for preventing recurrent stroke (Class IIa; Level of Evidence B-Randomized)"
- "In patients 18 to 60 years of age with a nonlacunar ischemic stroke of undetermined cause despite a thorough evaluation and a PFO without high-risk anatomic features,* the benefit of closure with a transcatheter device and long-term antiplatelet therapy over antiplatelet therapy alone for preventing recurrent stroke is not well established(Class IIb; Level of Evidence C-Limited Data)"
- "In patients 18 to 60 years of age with a nonlacunar ischemic stroke of undetermined cause despite a thorough evaluation and a PFO, the comparative benefit of closure with a transcatheter device versus warfarin is unknown(Class IIb; Level of Evidence C-Limited Data)"

*The guideline notes that high-risk anatomic features are not uniformly described throughout the literature.

The guideline also defined the following relevant terms:

- "Cryptogenic stroke: An imaging-confirmed stroke with unknown source despite thorough diagnostic assessment (including, at a minimum, arterial imaging, echocardiography, extended rhythm monitoring, and key laboratory studies such as a lipid profile and hemoglobin A1c [HbA1c])."
- "Embolic stroke of undetermined source (ESUS): A stroke that appears nonlacunar on neuroimaging without an obvious source after a minimum standard evaluation (including arterial imaging, echocardiography, extended rhythm monitoring, and key laboratory studies such as a lipid profile and HbA1c) to rule out known stroke etiologies such as cardioembolic sources and atherosclerosis proximal to the stroke. A diagnosis of ESUS implies that the stroke is embolic in origin, given the nonlacunar location; however, the source of the embolus is unknown, despite a minimal standard evaluation. Although cryptogenic stroke similarly implies that the cause of the origin is unknown, the stroke is not necessarily embolic. Individuals with ESUS have cryptogenic stroke, but the converse is not always the case."

ASD
American College of Cardiology and American Heart Association

In 2018, the AHA and ACC published guidelines for the management of adults with congenital heart disease. Recommendations for surgical closure versus transcatheter closure are dependent on the underlying condition. The treatment recommendations are below:

American College of Cardiology and American Heart Association Recommendations for Treating Atrial Septal Defect

Condition	Recommendation	COR[a]/LOE[b]
Symptomatic isolated secundum ASD, right atrial and/or RV enlargement, and net left-to-right shunt sufficiency large enough to cause physiological sequelae, without cyanosis at rest or during exercise	Transcatheter or surgical closure	I1/B-NR2
Symptomatic primum ASD, sinus venosus defect, or coronary sinus defect, right atrial and/or RV enlargement, and net left-to-right shunt sufficiency large enough to cause physiological sequelae, without cyanosis at rest or during exercise	Surgical closure unless precluded by comorbidities	I1/B-NR2
Asymptomatic isolated secundum ASD, right atrial and RV enlargement, and net left-to-right shunt sufficiency large enough to cause physiological sequelae, without cyanosis at rest or during exercise	Transcatheter or surgical closure	IIa1/C-LD2

Secundum ASD when a concomitant surgical procedure is being performed and there is a net left-to-right shunt sufficiently large enough to cause physiological sequelae, and right atrial and RV enlargement without cyanosis at rest or during exercise	Surgical closure	IIa1/C-LD2
ASD when net left-to-right shunt is ≥1.5:1, PA systolic pressure and/or pulmonary vascular resistance is greater than of one-third of systemic resistance	Percutaneous or surgical closure	IIb1/B-NR2
ASD with PA systolic pressure greater than two-thirds systemic, pulmonary vascular resistance greater than two-thirds systemic, and/or a net left-to-right shunt	ASD closure should not be performed	III-Harm1/C-LD2

Adapted from Stout et al (2019)

ASD: atrial septal defect; COR: class (strength) of recommendation; LOE: level (quality) of evidence; PA: pulmonary artery; RCT: randomized controlled trial; RV: right ventricular.

[a] COR key: I=strong; IIa=moderate; IIb=weak; III: No Benefit=weak; III: Harm=strong. [b] LOE key: A=high quality from >1 RCT, meta-analyses of high-quality RCTs, ≥1 RCT corroborated by high-quality registry studies; B-R=randomized, moderate-quality evidence from ≥1 RCT or meta-analysis of moderate-quality RCTs; B-NR=nonrandomized, moderate-quality evidence from ≥1 well-designed, well-executed nonrandomized study, observational study, or registry study, or meta-analyses of such studies; C-LD: limited data, randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies in human subjects; C-EO: expert opinion

VSD

National Institute for Health and Care Excellence

In 2010, NICE issued a guideline that stated, "Current evidence on the safety and efficacy of transcatheter endovascular closure of perimembranous ventricular septal defect (VSD) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit."

American College of Cardiology and American Heart Association

In 2018, the AHA and ACC published guidelines for the management of adults with congenital heart disease. They did not have a specific recommendation for transcatheter VSD closure but stated that "Transcatheter device occlusion of muscular and perimembranous VSD is feasible, and trials have demonstrated a good safety and efficacy profile. The following are their recommendations for VSD:

Recommendations for Ventricular Septal Defect

Recommendation	COR	LOE

Adults with a VSD and evidence of left ventricular volume overload and hemodynamically significant shunts (Qp: Qs ≥1.5:1) should undergo VSD closure if PA systolic pressure is less than 50% systemic and pulmonary vascular resistance is less than one-third systemic.	I	B-NR
Surgical closure of perimembranous or supracristal VSD is reasonable in adults when there is worsening aortic regurgitation (AR) caused by VSD.	IIa	C-LD
Surgical closure of a VSD may be reasonable in adults with a history of IE caused by VSD if not otherwise contraindicated.	IIb	C-LD
Closure of a VSD may be considered in the presence of a net left-to-right shunt (Qp: Qs ≥1.5:1) when PA systolic pressure is 50% or more than systemic and/or pulmonary vascular resistance is greater than one-third systemic.	IIb	C-LD
VSD closure should not be performed in adults with severe PAH with PA systolic pressure greater than two-thirds systemic, pulmonary vascular resistance greater than two-thirds systemic and/or a net right-to-left shunt.	III	C-LD

PDA

In 2018, the AHA and ACC published guidelines for the management of adults with congenital heart disease. They did not have a specific recommendation for transcatheter PDA closure, but stated that:

"When signs of volume overload are indicative of significant left-to-right shunt, closing the PDA is likely to prevent further left atrial or LV enlargement, progression or development of PAH, and pulmonary hypertension secondary to left HF and will possibly provide symptom relief if symptoms are present. Closure is typically performed percutaneously with good success and minimal complications."

U.S. Preventive Services Task Force Recommendations

Use of closure devices are not a preventive service.

KEY WORDS:

Atrial Septal Defect, ASD, Ventricular Septal Defect, VSD, Patent Foramen Ovale, PFO, Patent Ductus Arteriosus, PDA, AMPLATZER Septal Occluder, Gore HELEX Septal Occluder, CardioSEAL Septal Occlusion System with Qwik Load, AMPLATZER Muscular VSO Occluder, CardioSEAL STAR Flex Septal Occlusion System, AMPLATZER PFO Occluder, Monodisc Occluder, Occlutech, OcclutechASD Occluder

APPROVED BY GOVERNING BODIES:

Patent Foramen Ovale

The U.S. Food and Drug Administration (FDA) has approved two devices for PFO closure through the premarket approval process or a premarket approval supplement: the Amplatzer PFO Occluder and the GORE CARDIOFORM Septal Occluder.

In 2002, two transcatheter devices were cleared for marketing by the FDA through a humanitarian device exemption as a 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. 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. The new indication was based on the results of the REDUCE pivotal clinical trial.

Patent Foramen Ovale Closure Devices Approved by the U.S. Food and Drug Administration

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer Talisman PFO Occluder	Abbott	Nov 2016	For percutaneous transcatheter closure of a 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 CARDIOFORMSeptal 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.

Atrial Septal Defect
Five devices have been approved by the FDA through the premarket approval process or a premarket approval supplement for transcatheter ASD closure.
ASD Closure Devices Approved by the Food and Drug Administration

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer Septal Occluder	St. Jude Medical (Abbott 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)	• Ppercutaneous, transcatheter closure of ostium secundum ASDs
GORE CARDIOFORM ASD Occluder	W.L. Gore & Associates	May 2019	• Percutaneous, transcatheter closure of ostium secundum ASDs
GORE CARDIOFORM Septal Occluder	W.L. Gore & Associates	Apr 2015 (supplement)	• Ppercutaneous, transcatheter closure of ostrium secundum ASDs
OcclutechASD Occluder	Occlutech	Dec 2023	• Percutaneous, transcatheter closure of ostium secundum ASDs

ASD: atrial septal defect; PMA: premarket approval.

Ventricular Septal Defect
AMPLATZER® Muscular VSD Occluder received FDA approval via premarket application (PMA) on September 7, 2007, for closure of complex VSD of significant size to warrant closure

on patients who are considered to be at high risk for standard transarterial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Patent Ductus Arteriosus
In October 2005, Abbott's Amplatzer Duct Occluder received FDA approval via PMA for non-surgical closure of PDA.

In August 2013, the Nit-Occlud® PDA (PFM medical) received FDA approval via PMA for percutaneous, transcatheter closure of PDA.

In August 2013, the Amplatzer™ Duct Occluder II (2nd generation) received FDA approval via PMA for non-surgical closure of PDAs.

In January 2019, the Amplatzer Piccolo™ Occluder received FDA approval via PMA for the non-surgical closure of PDAs.

BENEFIT APPLICATION:
Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

93799	Unlisted cardiovascular service or procedure
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant
93581	Percutaneous transcatheter closure of a congenital ventricular septal defect with implant
93582	Percutaneous transcatheter closure of patent ductus arteriosus
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (List separately in addition to code for primary procedure).
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (list separately in addition to code for primary procedure).

93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (list separately in addition to code for primary procedure)

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POLICY HISTORY:

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Medical Policy Group, December 2011
Medical Policy Group, October 2013
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