Cigna Medical Coverage Policy

Subject **Transcatheter Closure of Septal Defects**

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Hyperlink to Related Coverage Policies

Coverage Policy

Cigna covers transcatheter closure with a U.S. Food and Drug Administration (FDA)-approved device used according to FDA labeling as medically necessary for ANY of the following conditions:

- secundum atrial septal defect (ASD) (excludes patent foramen ovale ([PFO])
- patent ductus arteriosus (PDA)
- fenestration following a Fontan procedure
- complex ventricular septal defect (VSD) when BOTH of the following criteria are met:
  - The VSD is of significant size to warrant closure.
  - The individual is considered to be at high risk for standard transatrial or transarterial surgical closure.

Cigna does not cover transcatheter closure of patent foramen ovale (PFO) because there are not any PFO closure devices that have received U.S. Food and Drug Administration (FDA) approval for marketing. PFO closure devices are available only through an FDA Investigational Device Exemption (IDE). Transcatheter closure of PFO is therefore considered experimental investigational, or unproven.

Cigna does not cover transcatheter closure of ostium primum or sinus venosus atrial septal defects (ASDs) because it is considered experimental, investigational, or unproven.

Cigna does not cover perventricular (transmyocardial) closure of ventricular septal defects (VSDs) because it is considered investigational, experimental or unproven.

General Background

Atrial Septal Defect (ASD)

ASDs represent a communication between the left and right atria and account for 7–10% of all congenital heart defects. ASDs may be located at different sites in the septum and range in size from small to large. The three major types of ASD, ostium secundum, ostium primum and sinus venosus, are named for their position in the atrial septum. Ostium secundum ASD constitute 75–80% of all atrial septal defects and are located in the central portion of the septum (i.e., fossa ovalis). Ostium primum ASD account for 15% of all ASD and are located in the lower portion of the septum just above the atrioventricular valves. Sinus venosus or venous ASD, which constitute 10% of all ASD, occur at the junction of the superior vena cava and the right atrium. Moderate or large ASD may be associated with significant left-to-right shunting and increase in pulmonary blood flow, and right ventricular volume overload. Risk factors associated with increased mortality from untreated ASD include the development of pulmonary vascular obstructive disease (i.e., pulmonary arteries thicken from prolonged left-to-right shunting), right atrial or ventricular enlargement, tricuspid regurgitation, pulmonary hypertension, cardiac rhythm disturbances and stroke. Transcatheter closure using implantable occlusive devices has evolved as an alternative to open surgical intervention in selected patients with secundum septal defects. Transcatheter closure is not an option for ostium primum and sinus venosus ASD. These defects are located at the very lower and upper edges of the atrial septum, respectively, and are often associated with other valve abnormalities.

U.S. Food and Drug Administration (FDA): The Amplatzer® Septal Occluder (AGA Medical Corporation, Golden Valley, MN) received FDA approval through the PMA process on December 5, 2001, for the occlusion of atrial septal defects in secundum position and for patients who have undergone a fenestrated Fontan procedure and require closure of the fenestration. According to the FDA approval order, the Amplatzer system is indicated for patients who have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left-to-right shunt or right ventricle enlargement.

The GORE HELEX™ Septal Occluder (W.L. Gore & Associates, Flagstaff, AZ) received FDA approval through the PMA process on August 11, 2006, for the percutaneous transcatheter closure of ostium secundum atrial septal defects.

Literature Review: Du et al. (2002) conducted a nonrandomized controlled trial in 29 pediatric cardiology centers comparing the safety, efficacy and clinical utility of ASD closure of secundum ASD using the Amplatzer device to surgical repair. A total of 442 patients were in the device closure group, and 154 were in the surgical group. For the device group, the presence of a distance of > 5 mm from the margins of the ASD to the coronary sinus, atrioventricular valves and right pulmonary vein was required. Exclusion criteria included primum ASD, sinus venosus ASDs, and the presence of associated congenital cardiac anomalies requiring surgical repair. The authors reported success rates at discharge and at 12-month follow-up of 94.8% and 98.5%, respectively, for the device group and 96.1% and 100%, respectively, for the surgical group. The complication rate was 7.2% for the device group and 24% for the surgical group.

Transcatheter closure of secundum ASDs has been evaluated in several case series (Berger, et al., 1999; Chessa, et al., 2002; Fischer, et al., 2003). The consensus in these studies was that transcatheter closure is safe and effective in the majority of cases. Complications and complete closure rates were comparable to those seen with surgical closure and transcatheter closure offered the advantages of less morbidity and shorter hospitalizations.

Although the indications for the procedure are the same as for surgical closure, the selection criteria are stricter in terms of defect size and surrounding rim tissue. Depending on the device, transcatheter closure can be performed only for patients with a secundum ASD with a stretched diameter of less than 41 mm and with adequate rims to enable secure device deployment. This technique is generally precluded in patients with anomalous pulmonary venous connection or with proximity of the defect to the AV valves, coronary sinus or systemic venous drainage. Major complications occur in less than 1% of patients, and clinical closure is achieved in more than 90% of patients. Device closure of an ASD improves functional status in symptomatic patients and exercise capacity in asymptomatic and symptomatic patients. Based on intermediate follow-up data, ASD device closure is safe and effective, with better preservation of right ventricular function[1] and lower complication rates than with surgery. (Bonow: Braunwald's Heart Disease, 2011).

Professional Societies/Organizations: American College of Cardiology/American Heart Association Guidelines for the Management of Adults with Congenital Heart Disease (Warnes et al., 2008) include the following recommendations for closure of atrial septal defects:

Class I

- Closure of an ASD either percutaneously or surgically is indicated for right atrial and RV enlargement with or without symptoms. (*Level of Evidence: B*
- A sinus venosus, coronary sinus, or primum ASD should be repaired surgically rather than by percutaneous closure. (*Level of Evidence: B*)

Class IIa

- Surgical closure of secundum ASD is reasonable when concomitant surgical repair/replacement of a tricuspid valve is considered or when the anatomy of the defect precludes the use of a percutaneous device. (*Level of Evidence: C*)
- Closure of an ASD, either percutaneously or surgically, is reasonable in the presence of
  - Paradoxical embolism. (*Level of Evidence: C*)
  - Documented orthodeoxia-platypnea. (*Level of Evidence: B*)

Class IIb

- Closure of an ASD, either percutaneously or surgically, may be considered in the 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 (patients should be treated in conjunction with providers who have expertise in the management of pulmonary hypertensive syndromes). (*Level of Evidence: C*)

Summary—Atrial Septal Defects: Moderate or large atrial septal defects in secundum position may be associated with significant left-to-right shunting, right heart dilation, or volume overload. Transcatheter closure of these defects has been shown to be a safe and effective alternative to surgical intervention in selected patients with suitable anatomy when the defect shows no signs of spontaneous closure. . Transcatheter closure is not an option for ostium primum and sinus venosus ASD, located at the very lower and upper edges of the atrial septum, respectively. (Note: Patent foramen ovale, a variant of atrial septal defect, is discussed below.)

Patent Foramen Ovale (PFO)

The foramen ovale, a remnant of the fetal circulation, is a tunnel-like space between the overlying septum secundum and septum primum. In fetal life, this interatrial communication directs blood flow from the umbilical vein to the left atrium. After birth, the left atrial pressure increases and the valve to the fossa ovalis closes. In approximately 25% of people, however, this fusion is not complete. This persistent communication is a variant of atrial septal defect (ASD), but differs from ASD in morphology and associated signs and symptoms. With ASD an actual hole exists between the left and right atria. This defect, especially when large, may result in significant left-to-right shunting and right ventricular volume overload, as described above. The flap-like opening seen with PFO however, is usually not clinically significant in healthy adults, and is generally not treated unless conditions such as pulmonary hypertension, chronic obstructive pulmonary disease or pulmonary embolism are present. These conditions may cause the right atrial pressure to be elevated, causing an increased potential for right-to-left shunting through the PFO. PFOs have been scrutinized for their implication in the mechanism of cryptogenic stroke (i.e. stroke with no other known cause of cerebral ischemia). Although basic principles linking PFO and stroke are plausible, this link has not been demonstrated. It has been proposed that PFOs may serve as a conduit for paradoxical embolization from the venous side to the systemic circulation, or as a point of origin for thrombus formation because of their tunnel-like structure and tendency for stagnant flow. A coordinated series of events is necessary for a paradoxical embolism through a PFO to occur, however. Therefore, even in patients with a history of cryptogenic stroke, the risk of recurrence may not be high (Bonow: Braunwald's Heart Disease, 2011; Almekhlafi et al., 2009)

Antiplatelet therapy may be indicated for patients with PFO who have had a cryptogenic stroke or transient ischemic attack (TIA). Warfarin may be recommended for patients with other indications for oral anticoagulation, including patients with an underlying hypercoagulation state, or those with evidence of venous thrombosis. There is no clear evidence to demonstrate whether warfarin or aspirin is superior in preventing recurrent stroke or death. It is also unclear whether patients treated medically following a cryptogenic stroke are at increased risk for a subsequent stroke or death because of the presence of PFO. Transcatheter closure has been proposed as an alternative to medical therapy in patients with PFO associated with cryptogenic stroke (Messe, et al., 2004, reaffirmed 2007; Sacco et al., 2006, Valente and Rhodes, 2007)

Several other clinical conditions have been attributed to presence of a PFO. It has been proposed that PFO may be implicated in the pathophysiologic mechanism of migraine headaches, decompression sickness (arterial gas embolism from the venous side), and platypnoea-orthodeoxia syndrome (dyspnea and arterial desaturation in the upright position, which improves on lying down) (Bonow: Braunwald's Heart Disease, 2011; Mattle at al., 2010).

U.S. Food and Drug Administration (FDA): No FDA-approved PFO closure devices have been available to market in the United States since October 31, 2006. Two devices had previously received FDA Humanitarian Device Exemption (HDE) approval. The CardioSEAL® Septal Occlusion System (Nitinol Medical Technologies, Inc., Boston, MA) had received FDA HDE approval on February 1, 2000 for closure of a PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through the patent foramen ovale and who have failed conventional drug therapy. The Amplatzer® PFO Occluder (AGA Medical Corporation, Golden Valley, MN) had received HDE approval on April 5, 2002, for the nonsurgical closure of a PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy.

In order to receive HDE approval, a manufacturer must first be granted a Humanitarian Use Device (HUD) exemption by demonstrating that the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 people in the U.S. per year. Although data demonstrating the safety and probable clinical benefit are required for HDE approval, clinical trials evaluating the effectiveness of the device are not required. Following HDE approval, the hospital or health care facility institutional review board (IRB) must also approve the use of the device at that institution before the device may be used in a patient.

On August 14, 2006, the manufacturers of the Amplatzer PFO Occluder and the CardioSEAL Septal Occlusion System agreed to voluntarily withdraw their HDEs, effective October 31, 2006. The FDA had notified the manufacturers of its intent to formally propose to withdraw HDE approvals for these two devices because they no longer met the HDE criteria. The FDA determined that the target patient population described by the approved indication (i.e., patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy) is significantly in excess of 4,000 patients in the U.S. per year. These devices therefore are no longer eligible for HDE designation and no longer eligible for marketing under an HDE. Because of the larger number of patients eligible for these devices, the FDA concluded that a demonstration of reasonable assurance of both safety and effectiveness is required, as is the case with all class III (highest risk) devices not eligible for HDE status (FDA Information Sheet, Center for Devices and Radiological Health, Aug. 16, 2006).

As of October 31, 2006, the Amplatzer PFO Occluder and the CardioSEAL Septal Occlusion System were available in the United States only through an FDA-approved Investigational Device Exemption (IDE). NMT, manufacturer of the CardioSEAL device, ceased operations in 2011. An IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application submission to the FDA. A device being marketed through an IDE is not approved by the FDA or other appropriate regulatory agency to be lawfully marketed for the proposed use. An investigational device may also be available through an FDA compassionate use provision for a patient who does not meet the requirements for inclusion in clinical investigations, when the physician believes the device may provide a benefit in treating a serious disease or condition and no alternative treatments exist. The FDA uses its regulatory discretion to determine whether such investigational device use should occur. Prior FDA approval is needed before compassionate use occurs.

In 2007, the FDA convened a meeting of the Circulatory System Devices Panel (CSDP) to address several issues regarding PFO closure devices, and issued the following recommendations:

- Randomized controlled trials of PFO closure to prevent recurrent stroke are required.
- A "proof of principle" trial with pooled data demonstrating that PFO closure does prevent recurrent stroke could allow this question to be answered in a timely fashion, if sponsors are amenable to cooperating and sharing data. "Proof of device" trials demonstrating that an individual device effectively closes a PFO could be done separately.

- “Off-label” closure should be discouraged. Enrollment in ongoing trials should be encouraged.
- Patients and physicians should be educated about the lack of evidence of benefit of closure and the need for completion of trials. (Slottow et al., 2007)

Literature Review: Carroll et al., for the RESPECT Investigators (2013) conducted a prospective, multicenter randomized trial to evaluate whether PFO closure with the Amplatzer device is superior to medical therapy alone in preventing recurrent ischemic stroke or early death in patients 18 to 60 years of age (n=980). The medical therapy group received one or more antiplatelet medications (74.8%) or warfarin (25.2%). Treatment exposure was unequal between the two groups (21375 patient years for the closure group vs. 1184 in the medical therapy group). Patients were followed for an average of 2.5 years. No significant benefit of closure of the PFO was shown in the primary (intention-to-treat) analysis; Nine patients in the closure group had a recurrence of stroke compared to 16 in the medical therapy group (hazard ratio, 0.49; 95% confidence interval [CI], 0.22-1.11; p=0.08). Analysis of the per-prespecified per-protocol cohort showed a higher rate of stroke in the medical therapy group (14 events vs. 5 events, p=0.03) and in the as-treated cohort (16 events vs. 5 events). As the authors stated, results of the per-protocol and as-treated analyses need to be interpreted with caution, due to potential bias arising from nonrandom factors that may have accounted for nonadherence to the protocol.

Meier et al. for the PC Trial Investigators (2013) conducted a multicenter trial in 29 centers in Europe, Canada, Brazil and Australia to investigate whether closure is superior to medical therapy for secondary prevention of cryptogenic embolism in patients with PFO. The primary endpoint was a composite of death, nonfatal stroke, TIA, or peripheral embolism. The mean duration of follow-up was 4.1 years in the closure group and 4.0 years in the medical therapy group. The primary end point occurred in 7 of 204 patients in the closure group (3.4%) and 11 of 210 patients (5.2%) in the medical therapy group, (063; 95% CI, 0.24-1.62, p=0.34) One patient in the closure group and five patients in the medical-therapy group experienced nonfatal stroke. TIA occurred in five patients in the closure group and seven in the medical therapy group. The authors concluded that closure of a PFO for secondary prevention of cryptogenic embolism did not result in a significant reduction in the risk of recurrent embolic events or death as compared with medical therapy.

Closure 1 (Evaluation of the STARFlex Septal Closure System in Patients with a Stroke and/or Transient Ischemic Attack due to Presumed Paradoxical Embolism through a Patent Foramen Ovale) (n=909) was a prospective, multicenter, randomized, open-label two-group superiority trial designed to evaluate percutaneous device closure compared to medical therapy (Furlan et al., for the Closure 1 Investigators, 2012). Patients were randomly assigned on a 1:1 basis to percutaneous closure of the PFO with the STARFlex device followed by a standard antiplatelet regimen consisting of clopidogrel for six months and aspirin daily for two years (n=447) or to medical therapy alone, consisting of warfarin, aspirin, or both (n=462). Of the randomly assigned patients 402 underwent attempted device implantation, and 458 received medical therapy. The primary endpoint was a composite of stroke or transient ischemic attack during two years of follow-up, death from any cause during the first thirty days, or death from neurologic causes between 31days and two years. The cumulative incidence of the primary endpoint was 5.5% in the closure group (n=447) compared to 6.8% in the medical therapy group (adjusted hazard ratio, 0.78; 95% confidence interval, 0.45-1.35, p=0.37). The rate of stroke in the closure group was 2.9% compared to 3.1% in the medical treatment group (p=0.79), and rate of TIA was 3.1% in the closure group compared to 4.1% in the medical therapy group (p=0.44). There were no deaths at thirty days in either group, and no deaths from neurologic causes during the two-year follow-up. A cause other than paradoxical embolism was usually apparent in those who experienced recurrent neurological events. The authors concluded that in patients with cryptogenic stroke or TIA who had a patent foramen ovale, device closure did not offer a greater benefit than medical therapy alone for the prevention of recurrent stroke or TIA.

Almedhlafi et al. (2009) conducted a systematic review and meta-analysis of the literature to estimate the absolute risk of recurrent cerebrovascular events in medically treated patients with PFO, and to evaluate their relative risk of recurrent events compared to patients without a PFO. Of 15 identified eligible studies, four included a non-PFO comparison group. In these four studies, the pooled relative risk of recurrent ischemic stroke or TIA in patients with vs. without a PFO was 1.1. For ischemic stroke alone, the absolute relative risk was 0.8. The absolute rate for recurrent events in all 15 studies was also calculated. The pooled absolute rate of recurrent ischemic stroke or TIA in patients with PFO was 4.0 events per 100 person years, and the rate of recurrent ischemic stroke alone was 1.6 events per 100 person years. The authors concluded that the available evidence does not support an increased relative risk of recurrent ischemic events in those with vs. without a

PFO, and that PFO closure in these patients cannot be recommended until the results of ongoing clinical trials are reported.

Harms et al. (2007) conducted a case series to evaluate clinical outcomes and closure status following transcatheter PFO closure for prevention of recurrent stroke (n=237). The duration of follow-up was 568 ± 364 days. There were six deaths unrelated to the procedure or the presence of PFO, and one death due to a new neurologic event. Eight of 237 patients (3.4%) experienced clinically and radiographically confirmed strokes after PFO closure. All eight patients were taking aspirin at the time of recurrent stroke; two were taking clopidogrel and aspirin, and three were taking warfarin and aspirin. There was a significant difference in the rate of recurrent stroke based on age (≤ 55 years, 1.4%; > 55 years, 6.6%; 0=.03). In the overall group, three devices were explanted due to malalignment and large, persistent right-to-left shunt that required surgical closure. Complete closure or minimal residual right-to-left shunting was achieved in 66% of patients.

Demkow et al. (2004) evaluated the short- and mid-term results of transcatheter closure of PFO in 32 consecutive patients with a history of cryptogenic ischemic stroke. The procedure was effective in all patients, and no complications were observed. During a mean follow-up period of 25.9 months (>12 months in 22 patients), no new neurological events were recorded. Control TEE was performed in 28 patients a mean 22.3 months after the procedure and confirmed the correct positioning of the occluder. A significant residual shunt was detected in two patients. One patient developed episodes of paroxysmal supraventricular tachycardia which were effectively resolved by radiofrequency ablation.

Transcatheter closure of PFO has also been evaluated in the treatment of migraine. Migraine with aura has been associated with PFO and with other causes of right-to-left shunts. Dowson et al. (2008) conducted a prospective, double-blind, randomized controlled trial to evaluate the effectiveness of PFO closure in patients with migraine with aura who experienced frequent migraine attacks, had failed ≥ two classes of prophylactic treatments, and had moderate to large right-to-left shunts consistent with the presence of PFO. Patients were randomized to transcatheter closure with the STARFlex implant (NMT Medical, Inc., Boston MA) (n=74) or to a sham procedure (n=73). The primary efficacy endpoint was migraine headache cessation 91–180 days after the procedure. There was no significant difference in the primary outcome between the two groups; in the treatment group, 3 of 74 patients experienced headache cessation, compared to 3 of 73 patients in the sham group.

Schwedt et al. (2008) conducted a systematic review to evaluate the association of PFO and migraine and to assess the effect of PFO closure on migraine. Six retrospective studies met the inclusion criteria for the effect of PFO closure on migraine. The authors stated that the low-to-moderate grade of evidence from observational studies supports an apparent association between PFO and migraine, and that although PFO closure seemed to have a favorable effect on migraine patterns, the very low grade of available evidence to support this association precludes definitive conclusions.

Professional Societies/Organizations: The American College of Chest Physicians Evidence-Based Clinical Practice Guideline, Antithrombotic Therapy and Prevention of Thrombosis (9th ed., 2012) includes the following recommendations for patients with PFO and atrial septal aneurysms:

- In patients with cryptogenic stroke and PFO or atrial septal aneurysm, we recommend aspirin (50-100 mg) over no aspirin (Grade 1A, strong recommendation, high quality evidence)
- In patients with cryptogenic stroke and PFO or atrial septal aneurysm, who experience recurrent events despite aspirin therapy, we suggest treatment with vitamin K antagonist (VKA therapy), and consideration of device therapy over aspirin therapy (Grade 2C, weak recommendation, low or very low quality evidence)
- In patients with cryptogenic stroke and PFO, with evidence of deep vein thrombosis, we recommend VKA therapy for three months and consideration of device therapy over no VKA therapy or aspirin therapy (Grade 2C, weak recommendation, low-or very low quality evidence)

A science advisory on percutaneous device closure of patent foramen ovale for secondary stroke prevention was issued by the American Heart Association/American Stroke Association and the American College of Cardiology, and was affirmed by the American Academy of Neurology (O'Gara et al., 2009). According to the advisory, the optimal therapy for prevention of recurrent stroke or transient ischemic attack in patients with cryptogenic stroke and patent foramen ovale has not been defined. Although a strong association between patent foramen ovale and cryptogenic stroke has been suggested by numerous observational studies, a causal relationship has not been convincingly established for the majority of affected patients. The advisory further states:

> “The choice between medical therapy and percutaneous device closure has been the subject of intense debate over the past several years, albeit one that has not been adequately informed by randomized, prospective clinical trial data to permit an objective comparison of the relative safety and efficacy of these respective approaches. Enrollment in clinical trials has lagged considerably despite frequent calls for participation from the US Food and Drug Administration and major professional societies. Completion and peer review of ongoing trials are critical steps to establish an evidence base from which clinicians can make informed decisions regarding the best therapy for individual patients. The present advisory strongly encourages all clinicians involved in the care of appropriate patients with cryptogenic stroke and patent foramen ovale—cardiologists, neurologists, internists, radiologists, and surgeons—to consider referral for enrollment in these landmark trials to expedite their completion and help resolve the uncertainty regarding optimal care for this condition.”

Summary—Patent Foramen Ovale (PFO): PFO is a variant of atrial septal defect, but differs in morphology and associated signs and symptoms. PFO, a remnant of the fetal circulation, is a tunnel-like space between the overlying septum secundum and septum primum that usually closes shortly after birth. Fusion of this communication is incomplete in approximately 25% of adults, however. This persistent communication is usually not clinically significant. PFO has been scrutinized for its association with cryptogenic stroke (i.e., stroke with no other known cause). Although a direct causal relationship has not been established, it has been proposed that PFO may serve as a conduit for paradoxical embolization form the venous side to the systemic circulation, or as a point of origin for thrombus formation. A high rate of recurrence of cerebrovascular events has not been demonstrated, however, in patients with PFO. This is likely due to the fact that a coordinated series of events is necessary for a paradoxical embolism to occur. Randomized controlled trials are needed to definitively determine whether PFO closure prevents recurrent stroke**.** It has also been proposed that PFO may be implicated in several other conditions, including migraine headaches, decompression sickness, and platypnoea-orthodeoxia syndrome. There is insufficient evidence to determine whether the presence of a PFO is involved in the pathophysiologic mechanisms of these conditions or to determine the safety and efficacy of transcatheter PFO closure for these indications.

In addition, as detailed above in the U.S. Food and Drug Administration (FDA) section, there are currently no FDA-approved devices for transcatheter closure of PFO.

Patent Ductus Arteriosus (PDA)
The ductus arteriosus is the vessel leading from the bifurcation of the pulmonary artery to the aorta, just distal to the left subclavian artery. Under normal circumstances, this channel is open in the fetus and closes spontaneously during the first few days of life. PDA results from the failure of this duct to close following birth. It is a common finding in premature infants and progressively decreases in frequency with increasing gestational age. In premature infants with compromised respiratory status, closure may be attempted using fluid restriction, diuresis, maintenance of good oxygenation, medications such as indomethacin or by surgical ligation. Treatment of PDA in a preterm infant varies, depending on the degree of shunting and the severity of hyaline membrane disease. There is general agreement that closure of a hemodynamically significant PDA is indicated in children and adults. The safety and efficacy of transcatheter closure of PDA is established, with achievement of complete ductal closure in more than 85% of patients by one year, with a mortality rate of less than 1%. Surgical closure is generally reserved for patients in whom the defect is too large for device closure, or in centers without access to device closure. Surgical closure has a marginally greater closure rate than device closure, but is associated with slightly higher morbidity and mortality (Bonow: Braunwald’s Heart Disease, 2011).

U.S. Food and Drug Administration (FDA): On May 14, 2003, the Amplatzer Duct Occluder and 180° Delivery System (AGA Medical Corporation, Golden Valley, MN) received FDA approval through the PMA process for the nonsurgical closure of patent ductus arteriosus (PDA).

Literature Review: Butera et al. (2004) conducted a case series (n=197) to analyze the safety and efficacy of percutaneous closure of PDA using the Amplatzer Duct Occluder in very young symptomatic children. Physical examinations and echocardiograms were performed before the surgery and at follow-up (three, six and twelve months) and yearly thereafter. No deaths or major complications occurred. Two patients experienced mild inguinal hematomas, and one patient had femoral artery thrombosis successfully treated with intravenous urokinase. The mean follow-up was 12.8 months. Patients with recurrent respiratory infections had no significant recurrences, and children who had failed to thrive had significantly increased growth. The authors concluded that in experienced hands, percutaneous closure of moderate to large PDA in very young symptomatic children is safe, effectively closes the PDA and solves clinical problems.

A multicenter case series (n=484) by Pass et al. (2004) reported initial and one-year efficacy and safety results of the USA Amplatzer ductal occluder device trial. The device was not implanted in 45 patients because the PDA was too small or because of elevated pulmonary resistance. The Amplatzer occluder was successfully implanted in 435 of the 439 remaining patients. Angiographic demonstration of occlusion was seen in 329 (76%) of 435 patients, increasing to 384 (89%) of 433 patients on post-catheterization day one. Occlusion was documented in 359 (99.7%) of 360 patients at one year. There were two cases of partial left pulmonary artery occlusion after ADO implantation and no cases of significant aortic obstruction. The researchers concluded that moderate-to-large PDAs can be effectively and safely closed using the Amplatzer duct occluder, with excellent initial and one-year results.

The safety and efficacy of transcatheter device closure for ducts smaller than 8 mm has been established over the past 20 years, with complete ductal closure achieved in more than 85% of patients by one year with a mortality rate of less than 1%. Transcatheter closure has become the method of choice in centers with appropriate resources and experience. Although surgical closure has a marginally greater closure rate than device closure, the surgical mortality in adults is 1–3.5%, due to the presence of pulmonary arterial hypertension and difficult ductal morphology (e.g., calcified or aneurismal) frequently seen in adults. Surgical closure is therefore generally reserved for patients in whom the PDA is too large for device closure or centers without access to device closure (Bonow: Braunwald's Heart Disease, 2011).

Professional Societies/Organizations: American College of Cardiology/American Heart Association Guidelines for the Management of Adults with Congenital Heart Disease (Warnes et al., 2008) include the following recommendations for closure of PDA:

Class I

Closure of a PDA either percutaneously or surgically is indicated for the following:

- Left atrial and/or LV enlargement or if PAH is present, or in the presence of net left-to-right shunting. (*Level of Evidence: C*)
    - Prior endarteritis. (*Level of Evidence: C*)
    - Careful evaluation and consultation with ACHD interventional cardiologists is recommended before surgical closure is selected as the method of repair for patients with a calcified PDA. (*Level of Evidence: C*)
- Surgical repair, by a surgeon experienced in CHD surgery, is recommended when:
    - The PDA is too large for device closure. (*Level of Evidence: C*)
    - Distorted ductal anatomy precludes device closure (eg, aneurysm or endarteritis).42 (*Level of Evidence: B*)

Class IIa

- It is reasonable to close an asymptomatic small PDA by catheter device. (*Level of Evidence: C*)
- PDA closure is reasonable for patients with PAH with a net left-to-right shunt. (*Level of Evidence: C*)

Class III

- PDA closure is not indicated for patients with PAH and net right-to-left shunt. (*Level of Evidence: C*)

Summary—Patent Ductus Arteriosus (PDA): The ductus arteriosus is the vessel leading from the bifurcation of the pulmonary artery to the aorta, distal to the left subclavian artery. PDA results from the failure of this duct to close following birth. The safety and efficacy of transcatheter closure of PDA is well established. Surgical closure is generally reserved for patients in whom the defect is too large for device closure, or in centers without access to device closure, since although surgical closure has a slightly higher closure rate than device closure, it is associated with slightly higher morbidity and mortality.

Fenestration Following Fontan Procedure

The Fontan procedure is a palliation procedure that involves separating the pulmonary and systemic blood flows in patients with single ventricular defects. The technique reduces the mixing of unoxygenated and oxygenated blood by directing blood flow from the right atrium to the pulmonary artery, excluding the ventricle from right-sided circulation. The procedure is intended to produce a normal workload on the ventricle. One component of this procedure involves leaving a hole or fenestration in the septum of the repaired section of the heart, allowing for some mixing of blood for patients who are unable to tolerate the change in venous pressure. The size of the fenestration varies, and smaller holes can close spontaneously. Some patients require the creation of larger holes and, in many of these patients, the fenestration will remain patent. In patients with cyanosis in the setting of a fenestrated Fontan, surgical or preferably transcatheter closure of the fenestration can be attempted. Postoperative closure of Fontan fenestrations using a test occlusion and subsequent permanent closure with an intracardiac device evolved based on growing experience with transcatheter techniques to close various intracardiac defects. Early and late closure after test occlusion has been reported to reduce mortality and morbidity after the Fontan procedure, especially in high-risk patients.

U.S. Food and Drug Administration (FDA): The CardioSEAL Septal Occlusion System (Nitinol Medical Technologies, Inc., Boston, MA) received humanitarian device exemption (HDE) approval from the FDA on September 8, 1999, for the treatment of patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and required closure of the fenestration.

As stated above, the Amplatzer Septal Occluder received FDA approval through the PMA process on December 5, 2001, for the occlusion of secundum atrial septal defects and also for patients who have undergone a fenestrated Fontan procedure and require closure of the fenestration. According to the FDA approval order, the Amplatzer system is indicated for patients who have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left-to-right shunt or right ventricle enlargement.

Literature Review: The FDA PMA submission for the Amplatzer Septal Occluder included registry data that evaluated the safety and effectiveness in patients with fenestrated Fontan. According to the Summary of Safety and Effectiveness, the effectiveness of the device was demonstrated by results consistent with those obtained for treatment of ASD and by the primary efficacy at 12 months' follow-up. There was no need for additional surgical repair in the 32 patients. In addition, the adverse events rates at 12 months were within the protocol-defined acceptable limits. The mortality rate was zero, and the major adverse event rate was 4.2%.

Goff et al. (2000) published a multicenter registry study of patients who underwent catheter closure of a fenestrated Fontan with either the Clamshell (n=91) or CardioSEAL (n=63) device. All 63 patients who had their fenestrations treated with the CardioSEAL device achieved successful implantation. Late closure of the fenestration (at greater than six months after surgery) was followed by improved oxygenation, reduced need for anticongestive medication, and improved somatic growth at follow-up.

Because of the relative rarity of this condition, published studies that evaluate transcatheter closure for closure of fenestration following Fontan procedure are limited. There is sufficient evidence, however, to indicate that transcatheter septal occlusion is safe and effective for closure of a fenestration following a Fontan procedure in patients with single ventricle physiology.

Summary—Fenestration Following Fontan Procedure: The Fontan procedure is a palliation procedure that involves separating the pulmonary and systemic blood flows in patients with single ventricular defects. A hole, or fenestration, is left in the septum of the repaired section of the heart, to allow some mixing of blood for patients who are cannot tolerate the change in venous pressure. In some cases the fenestration will remain patent. Early and late transcatheter closure after test occlusion has been reported to reduce mortality and morbidity after the Fontan procedure, especially in high-risk patients.

Ventricular Septal Defect (VSD)

Congenital VSD can occur in isolation and as one part of a combination of cardiac anomalies. The natural history of congenital VSD may include spontaneous closure, development of pulmonary vascular obstruction, right ventricle outflow tract obstruction, aortic regurgitation, infective endocarditis, cardiomegaly, congestive cardiac failure and death in infancy. Many infants experience growth failure. Management of VSD is largely dependent on the size and pathophysiology of the defect. Patients with large defects and pulmonary hypertension are those at greatest risk of developing pulmonary vascular obstruction as well as respiratory infections. Large defects require correction early in life when pulmonary vascular disease is still reversible. Medical treatment may include diuretics, digitalis, and treatment of respiratory infections, as well as increased caloric density of feedings. Acquired VSD can occur post-myocardial infarction (MI), as well as following multiple trauma. It has been estimated that there is an 80–90% mortality rate within the first two months of the occurrence of a post-MI VSD with medical treatment alone. Rupture of the intraventricular septum is an uncommon but often fatal complication of acute MI or traumatic injury. Surgical closure of congenital and acquired ventricular septal defects is a well established procedure with low perioperative mortality and a high closure rate. Transcatheter closure has evolved as a less invasive alternative to surgical closure of VSD, particularly for patients who are considered at high-risk for standard surgical closure.

U.S. Food and Drug Administration (FDA): The CardioSEAL® Septal Occlusion System with QuikLoad™ (Nitinol Medical Technologies, Inc., Boston, MA) received FDA approval through the Premarket Approval (PMA) process on December 5, 2001, for use in patients with complex VSDs of significant size to warrant closure and who are considered at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or overall medical condition. According to the FDA approval order, high-risk anatomical factors for transatrial or transarterial surgical closure include:

- patients requiring a left ventriculotomy or an extensive right ventriculotomy
- patients with a failed previous VSD closure
- patients with multiple apical and/or anterior muscular VSDs ("Swiss cheese septum")
- patients with posterior apical VSDs covered by trabeculae

A modified version of the CardioSEAL device, to be marketed under the trade name STARFlex® Septal Occlusion System, received FDA PMA approval on March 5, 2009. The device as modified is indicated for use in patients with a complex ventricular septal defect of a significant size to warrant closure but that, based on location, cannot be closed with standard transatrial or transarterial approaches.

The Amplatzer Muscular VSD Occluder (AGA Medical Corporation, Golden Valley, MN) received FDA approval through the PMA process on September 7, 2007. The device is indicated for use in patients with a complex VSD of significant size to warrant closure (large volume, left to right shunt, pulmonary hypertension and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. The approval letter lists the same high-risk anatomical factors included in the approval letter for the CardioSEAL Septal Occlusion System with QuikLoad™, listed above.

Literature Review: Yang et al. (2010) conducted a single-center case series to evaluate the safety, efficacy, and long-term results of transcatheter closure of perimembranous ventricular septal defects (VSD) (n=848). The device was successfully placed in 832 patients (98.1%). The median follow-up was 37 months (range 6-78.7 months). There were 103 adverse events (12.4%) reported. The most frequent minor adverse events included hematoma, junctional rhythm, and right bundle branch block. Nine (8.7%) major adverse events were reported, including two instances of complete atrioventricular block requiring pacemaker implantation. The authors concluded that transcatheter closure is an effective method for treatment of perimembranous VSD in experienced hands, with a high success rate and favorable long-term results. The authors noted that 1798 patients were referred for surgery following screening and were not considered for transcatheter closure due to the strict inclusion/exclusion criteria, and stated that this may demonstrate the importance of patient selection in assuring the safety and effectiveness of the technique.

Butera et al. (2007) evaluated the safety and efficacy of transcatheter closure of perimembranous VSD in 104 patents who were treated between 1999 and 2006. The inclusion criteria were clinical and/or echocardiographic evidence of a significant left-to-right shunt through a perimembranous VSD. Two Amplatzer devices were used: the muscular VSD occluder, and the perimembranous VSD occluder. The latter device has not yet received FDA approval. The mean age at closure was 14 years. The device was successfully placed in 100 patients (96.2%). The total occlusion rate was 47% at the completion of the procedure and increased to 84% at discharge and 99% at follow-up. Early complications occurred in 13 patients (11.5%), but were transient in 11 patients. The median follow-up was 38 months. Complete atrioventricular (AV) block requiring pacemaker implantation occurred in six patients—two in the early phase and four during the follow-up period. The authors stated that the only variable that was significantly associated with complete AV block was age at the time of the procedure; all patients who experienced this complication were less than six years old (p=0.028).

Masura et al. (2005) conducted a case series to evaluate the Amplatzer membranous septal occluder in 186 patients age 3–51 years (average age 15.9 years) with an average weight of 43.5 kg. Patients were divided into three groups: single defects without aneurysm; single defects with aneurysm; and multiple defects with aneurysm. Immediate closure rates achieved in the three groups were 90%, 98%, and 89%, respectively. Complete closure rates at one year were 100%, 98%, and 89%, respectively. Complications included left anterior hemiblock, complete right bundle branch block, and incomplete right bundle branch block. Two patients developed complete heart block following the procedure but converted to sinus rhythm with left anterior hemiblock. The authors stated that these conduction abnormalities are comparable to those seen with surgery, but long-term follow-up studies are needed to determine late arrhythmia disturbances. The authors also recommended prospective studies of patients after surgery and transcatheter treatment of VSD.

Thanopoulos and Rigby (2005) evaluated the Amplatzer VSD Occluder in the treatment of muscular ventricular septal defects in a series of 30 patients aged four months to 16 years. The stretched diameter of the defects ranged from 6–14 mm. The communication was completely occluded in 28 of 30 patients (93% closure rate). One four-month-old patient with sustained complete left bundle branch block after the procedure went on to develop complete heart block one year later. No other complications were observed during a mean follow-up of 2.2 years (range 0.25–4.5 years). The authors concluded that the Amplatzer VSD Occluder is an efficient prosthesis that can be safely used in the majority of patients with a single muscular VSD.

Arora, et al. (2004) reported results of a series of 149 patients, age three to 28 years, who underwent transcatheter closure of congenital VSD using various devices. Device deployment was achieved in all 50 of the patients with trabecular muscular defects. The Rashkind umbrella device was deployed in two patients and the Amplatzer VSD Occluder was used in 48 patients. No patients had residual shunt, new aortic regurgitation, or tricuspid regurgitation. Transient complete heart block after 24 hours was seen in one patient. On follow-up at two to 90 months, the device was in position in all patients. The authors concluded that transcatheter closure of muscular VSD is safe and efficacious, and should be considered as a procedure of choice as an alternative to surgery that avoids cardiopulmonary bypass.

Professional Societies/Organizations: ACC/AHA Guidelines for the Management of Adults with Congenital Heart Disease (Warnes et al., 2008) include the following recommendations for device closure of a ventricuular septal defect:

Surgical Ventricular Septal Defect Closure
Class I

- Closure of a VSD is indicated when there is a Qp/Qs (pulmonary–to–systemic blood flow ratio) of 2.0 or more and clinical evidence of LV volume overload. (*Level of Evidence: B*)
- Closure of a VSD is indicated when the patient has a history of IE. (*Level of Evidence: C*)

Class IIa

- Closure of a VSD is reasonable when net left-to-rightshunting is present at a Qp/Qs greater than 1.5 with pulmonary artery pressure less than two thirds of systemic pressure and PVR less than two thirds of systemic vascular resistance. (*Level of Evidence: B*)
- Closure of a VSD is reasonable when net left-to-right shunting is present at a Qp/Qs greater than 1.5 in the presence of LV systolic or diastolic failure. (*Level of Evidence: B*)

Class III

- VSD closure is not recommended in patients with severe irreversible PAH. (*Level of Evidence: B*)

Recommendation for Interventional Catheterization
Class IIb

- Device closure of a muscular VSD may be considered, especially if the VSD is remote from the tricuspid valve and the aorta, if the VSD is associated with severe left-sided heart chamber enlargement, or if there is PAH. (*Level of Evidence: C*)

Perventricular/Transmyocardial Closure of Ventricular Septal Defects: The use of a perventricular approach, also referred to as a transmyocardial approach, has been explored as an alternative to the transcatheter approach for ventricular septal defect (VSD) closure. This hybrid approach has been investigated in the treatment of patients for whom transcatheter closure is challenging, including small infants and patients with poor vascular access. A perventricular approach was reported in five of 55 patients included in the first report of the multicenter CardioSEAL VSD registry. The registry was created following FDA approval of the CardioSEAL VSD Occluder in order to track the device's safety in closing high-risk, complex, muscular VSD The five patients who were treated with perventricular implantation all weighed ≤ seven kg. Four of these procedures were reported to be successful by the implanting center. One perventricular implant failed because the right ventricular arms of the device protruded the right ventricular free wall (Lim, et al., 2007).

Bacha at al. (2007) described a perventricular hybrid approach, combining surgical and interventional techniques, utilized in a series 12 patients with muscular VSD. Using a sternotomy or subxyphoid approach, the right ventricle free wall was punctured under transesophageal echocardiography guidance. A guide wire was introduced across the largest defect, and a short delivery sheath was positioned in the left ventricle cavity. An Amplatzer muscular VSD occluder was deployed across the VSD. Cardiopulmonary bypass was required only for repair of concomitant lesions. At a median follow-up of 12 months, all patients were asymptomatic, and two patients had mild residual ventricular level shunts.

Several case studies have demonstrated successful short- and mid-term outcomes of transcatheter closure of ventricular septal defects. Given the complexity, potential for clinically significant complications, and lack of long-term outcomes, however, this technique should only be considered in carefully selected patients. Transcatheter closure of VSD may be a reasonable alternative to surgical closure with cardiopulmonary bypass in patients with a VSD of significant size to warrant closure and who are considered to be at high risk for standard transatrial or transarterial surgical closure. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of perventricular (transmyocardial) closure of VSD. In addition, no devices have received FDA approval for this application.

Summary—Ventricular Septal Defects (VSD): Congenital VSD can occur in isolation or as one of a combination of cardiac anomalies. Management of VSD is largely dependent on the size and pathophysiology of the defect. Acquired VSD can occur post-myocardial infarction (MI), as well as following multiple trauma. Surgical closure of congenital and acquired VSD is a well established procedure with low perioperative mortality and a high closure rate. Transcatheter closure has evolved as a less invasive alternative to surgical closure of VSD, with high closure rates, low procedural mortality, and positive immediate and short-term results in patients with suitable anatomy. Since long-term data are not yet available, transcatheter VSD closure should be reserved for patients with VSD of significant size to warrant closure who are considered to be at high risk for standard surgical closure.

The use of a perventricular approach, also referred to as a transmyocardial approach, has been explored as an alternative to the transcatheter approach for VSD closure. This hybrid approach has been investigated in the treatment of patients for whom transcatheter closure is challenging, including small infants and patients with poor vascular access. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of perventricular closure of VSD. In addition, no devices have received FDA approval for this application.

Use Outside of the U.S.

The CE Mark was awarded to the CardioSEAL® Septal Occlusion System (Nitinol Medical Technologies, Inc., Boston, MA) and the Amplatzer® PFO Occluder (AGA Medical Corporation, Golden Valley, MN) for PFO closure. An additional device, the Figulla ASD-PFO occluder (Occlutech International AB, Helsingborg, Sweden) also received the CE mark for use outside the U.S.

Recommendations for surgical and device closure of atrial septal defects contained in the European Society of Cardiology Guidelines, Management fo Grown-Up Congenital Heart Disease are similar to recommendations contained in ACC/AHA guidelines for congenital heart disease described above. The ESC guideline does not include recommendations for PFO closure.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom): Interventional Procedure Guidance issued by the National Institute for Clinical Excellence (United Kingdom) in 2004 states that current evidence on the safety and efficacy of endovascular closure of atrial septal defects appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance. The guidance also states that the procedure should be performed in units where there are arrangements for cardiac surgical support in the event of complications.

NICE Interventional Procedure Guidance (United Kingdom) issued in 2010 states that current evidence on the safety and efficacy of percutaneous closure of PFO for recurrent migraine is inadequate in quality and quantity. The evidence on safety shows a small incidence of well-recognized, but sometimes serious adverse events, including device embolization and device prolapse (each reported in less than 1% of patients). Therefore, this procedure should only be used with special governance, consent, and audit or research.

Interventional Procedure Guidance issued in 2004 states that current evidence suggests that there are no major safety concerns and that percutaneous closure of PFO for the prevention of cerebral embolic stroke is efficacious in achieving closure of the foramen. However, its efficacy in preventing future strokes has not been clearly shown. This guidance is currently under review. Publication of revised guidance was delayed pending review of additional published trials.

Interventional Procedure Guidance published in 2004 states that current evidence on the safety and efficacy of endovascular closure of PDA appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. The guidance also states that the procedure should be performed in units where there are arrangements for cardiac surgical support in the event of complications.

Interventional Procedure Guidance issued in 2004, updated in 2010, states that current evidence on the safety and efficacy of endovascular closure of perimembranous VSD appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance. The NICE guidance also states that patient selection is important, especially in children and asymptomatic patients, and that for children, the procedure should only be undertaken in specialized pediatric cardiology units. For all patients, the procedure should only be undertaken by cardiologists training in the technique, with access to emergency cardiac surgery by a surgeon experienced in the treatment of congenital heart disease.

Summary

Moderate or large atrial septal defects (ASD) in secundum position may be associated with significant left-to-right shunting, right heart dilation, or volume overload. Transcatheter closure of these defects has been shown to be a safe and effective alternative to surgical intervention in selected patients when the defect shows no signs of spontaneous closure. There is insufficient evidence in the published medical literature, however, to demonstrate the safety and efficacy of transcatheter closure for ostium primum or sinus venosus ASD.

Transcatheter closure has also been shown to be an effective alternative for closure of patent ductus arteriosus (PDA), and for patients who require fenestration closure following the Fontan procedure. There is also sufficient evidence to demonstrate that this technique is a reasonable alternative for carefully selected patients with a ventricular septal defect (VSD) of significant size to warrant closure and who are considered to be at high risk for standard transatrial or transarterial surgical closure. Long-term outcome data for transcatheter closure of ventricular septal defects is needed, however, prior to broader application of this technique. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of perventricular (transmyocardial) VSD closure.

A paradoxical embolism that passes through a patent foramen ovale (PFO) has been associated with cryptogenic stroke, although a direct causal relationship has not been established between PFO and cryptogenic stroke. A high rate of recurrence of cerebrovascular events has not been demonstrated in patients with PFO who have experienced a cryptogenic stroke or TIA. This is likely due to the fact that a coordinated series of events is necessary for a paradoxical embolism to occur. Randomized controlled trials are needed to definitively determine whether PFO closure prevents recurrent stroke. It has also been proposed that PFOs may be involved in the pathophysiologic mechanism of several other clinical conditions, including migraine headaches, decompression sickness (arterial gas embolism from the venous side), and platypnoea-orthodeoxia syndrome (dyspnea and arterial desaturation in the upright position, which improves on lying down) There is insufficient evidence in the medical literature to determine whether the presence of a PFO is implicated in these conditions or to determine the safety and efficacy of transcatheter PFO closure for these conditions. In addition, there are currently no closure devices with FDA approval to market. Devices for PFO closure are available only through an Investigational Device Exemption (IDE) for investigational use in the context of a clinical trial or through an FDA compassionate use provision for patients who do not meet the criteria for inclusion in a clinical trial.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

<u>Transcatheter closure of patent ductus arteriosus, fenestration following Fontan procedure, or secundum atrial septal defect (excludes patent foramen ovale [PFO])</u>

Covered when medically necessary:

CPT®* Codes	Description
93580†	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant
93582	Percutaneous transcatheter closure of patent ductus arteriosus (Code effective 01/01/2014)

† **<u>NOTE:</u> Experimental/investigational/unproven/not covered when used to report transcatheter closure of patent foramen ovale [PFO]**

<u>Transcatheter closure of ventricular septal defect</u>

Covered when medically necessary:

CPT®* Codes	Description
93581	Percutaneous transcatheter closure of a congenital ventricular septal defect with implant

<u>Perventricular (transmyocardial) closure of ventricular septal defect</u>

Experimental/Investigational/Unproven/Not Covered when used to report perventricular (transmyocardial) closure of ventricular septal defect:

CPT®* Codes	Description
33999	Unlisted procedure, cardiac surgery
93799	Unlisted cardiovascular service or procedure

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