



**Transcatheter Closure of PDA, PFO, ASD/VSD, Fenestrated Fontan and Transmyocardial/Periventricular Device Closure of VSD**

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Transmyocardial/periventricular device closure of ventricular septal defects is considered **investigational/not medically necessary**.

**Rationale**

The evidence from the peer-reviewed literature supports the efficacy of transcatheter closure of a wide variety of anatomical defects of the heart. In comparison to open surgery, transcatheter closure, in general, leads to shorter hospital stays, fewer major complications, and comparable success rates, in terms of defect closure.

For transcatheter closure of a patent ductus arteriosus (PDA), studies suggest a success rate of 90% to 99%, with the higher success rates being associated with newer devices. Serious adverse events tended to be uncommon (occurring in about 1 in 80 procedures). The evidence supporting the net benefit of transcatheter PDA closure rises to include large well-designed case series. Interventional Procedures Guidance issued by the National Institute for Clinical Excellence (NICE) in 2004 stated that current evidence regarding the safety and efficacy of endovascular closure of PDA appears adequate to support the use of this procedure (NICE, 2004).

Transcatheter closure of ventricular septal defects (VSD) is a newer but important application of the procedure. Although open surgical closure has minimal operative mortality, it is associated with significant post-operative patient discomfort and morbidity. Several small, well-designed case series have shown transcatheter closure of VSDs to be effective in carefully selected patients (Thanopoulos, 2003; Thanopoulos, 2005; Arora, 2004; Masura, 2005). Interventional Procedures Guidance issued by NICE stated that current evidence on the safety and efficacy of endovascular closure of perimembranous VSDs appears adequate to support the use of this procedure. The NICE guidance document emphasized that careful patient selection is important and that the procedure should only be undertaken in specialist pediatric cardiology units with on-site surgical facilities (NICE, 2006).

The evidence supporting the net benefit of transcatheter closure of a patent foramen ovale (PFO), in patients with a history of cryptogenic stroke who have failed, or are not candidates for, medical anticoagulation therapy includes well-designed case series. These studies reported that the risk of an embolic event after transcatheter closure was comparable to open surgical closure, with minimal complications.

The evidence supporting the use of transcatheter closure for secundum atrial septal defects (ASD) includes large, non-randomized, controlled trials. Both the open surgery group and the transcatheter closure group had high success rates, in terms of closure of the defect, with significantly fewer complications and shorter hospital stays in the transcatheter closure group. Transcatheter devices are also useful for the safe and effective closure of the fenestration, resulting from a Fontan procedure, and devices have been FDA approved for that indication.

There is no evidence that supports the efficacy and safety of transcatheter closure of other defects not mentioned above, (e.g., for ostium primum ASDs).

FDA approval has been granted to a few devices for specific indications, through the Humanitarian Device Exemption (HDE) process. The HDE approval process is applicable to devices intended to benefit patients in the treatment or diagnosis of conditions or diseases that affect fewer than 4,000 individuals in the U.S. per year. An HDE application is not required to submit the results of scientifically valid clinical investigations demonstrating the effectiveness of the device for its intended use. However, the application must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury and that the probable health benefit outweighs the risks from its use. In August 2006, the FDA notified two manufacturers

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of its intent to formally propose withdrawal of its HDE marketing approvals for two PFO occluders that had been previously approved for the treatment of patients with recurrent cryptogenic stroke, due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy, (i.e., patients who have had at least one additional stroke despite treatment with appropriate medications). The affected devices were the NMT Medical CardioSEAL® STARFlex™ Septal Occlusion System and the AGA Medical AMPLATZER® PFO Occluder. This decision on the part of the FDA was proposed because these devices no longer meet the criteria for an HDE, since the number of patients treated annually with these devices exceeds 4,000 patients. However, on August 14, 2006 both manufacturers agreed to voluntarily withdraw their HDEs, effective October 31, 2006. The FDA informed further that, although these devices will no longer be available for marketing in the U.S., patients who meet the approved HDE indication will continue to have access to these devices in the U.S., through an FDA-approved Investigational Device Exemption (IDE). An IDE allows an investigational device to be used in clinical studies, in order to collect safety and effectiveness data required to support a full premarket approval (PMA) from the FDA.

Transmyocardial/periventricular closure of VSDs involves deployment of an occlusive device via a right ventricular puncture and is being investigated as an alternative to a percutaneous transcatheter approach, particularly in infants or other patients with poor vascular access. It has generally been reported, when performed in combination with cardiac surgery for coexisting abnormalities, in a so called “hybrid” procedure, which normally involves standard cardiac surgery performed in tandem with interventional transcatheter techniques for closure of a coexisting defect. It is reported that the periventricular approach may be performed, in some cases, without the need for cardiopulmonary bypass. Currently, these procedures are performed using the AMPLATZER® VSD occluder, which is not FDA approved for this purpose.

The available literature on the transmyocardial/periventricular technique is very limited. Very small numbers of cases were reported upon (6-8 per report, total of 20 cases), mostly by the same group of investigators and involving a single institution (Bacha 2003, 2005; Holzer 2004; Patel 2005). These case reports were also limited by short follow up periods and lack of randomization. The published scientific evidence currently available is insufficient to demonstrate the safety and efficacy of transmyocardial/periventricular approaches to closure of VSDs, as compared to conventional treatment options.

**Background/Overview****Patent Ductus Arteriosus (PDA)**

A patent ductus arteriosus is the vascular remnant of the left sixth aortic arch, connecting the main pulmonary artery to the aorta. Ordinarily, the channel closes naturally, during the first few days of life. A patent ductus can cause cardiac failure or endarteritis. A patent ductus that persists after two years of age should be closed. Closure may be accomplished by open surgical method or by transcatheter technique, using the Gianturco coil, also known as the Cook embolization coil. The coil is introduced by catheter and guidewire via the femoral artery and vein, in conjunction with cardiac catheterization and/or aortogram. The device is positioned in the ductus. The coil is intended to clot and embolize the ductus. The procedure is usually done on an outpatient basis, although an overnight stay may be required for infants or young children who may require general anesthesia. The Gianturco coil was marketed prior to 1976, when the U.S. Food and Drug Administration (FDA) formally acquired regulatory authority over devices. As such, this device has never undergone formal FDA approval, but it has been investigated for PDA closure and is available for clinical use. In May 2003, the FDA approved the Amplatzer® Duct Occluder (AGA Medical Corp., Golden Valley, MN) for the closure of PDA. This self-expanding device utilizes a nitinol (an alloy of tungsten and nickel) wire mesh. A retention skirt securely positions the device in the opening of the

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ductus. Upon implantation of the device, the occluder expands outward, and the wire mesh pushes against the ductus wall. Polyester fabric is then sewn into the occluder. This highly thrombogenic fabric induces clot formation which closes the ductus.

**Patent Foramen Ovale (PFO)**

PFO describes the persistence of a component of the fetal circulation between the right and left atrium. Although PFOs are found in 10-15% of adult patients, they are typically clinically insignificant. However, they may be associated with paradoxical embolus, in which an embolus arising in the venous circulation gains access to the arterial circulation through the PFO. It is estimated that patients with a history of PFO and paradoxical embolism have a 3.4% and 3.8% yearly risk of recurrent stroke or transient ischemic attack. Therefore, there has been interest in either open surgery or transcatheter approaches to close the PFO, in patients with a history of embolic stroke of unknown cause. Treatment alternatives include chronic coumadin therapy, based, in part, on the theory that clotting disorders may be present in patients with embolic stroke. To date, the FDA has granted a Humanitarian Device Exemption to the CardioSEAL<sup>®</sup> Septal Occlusion System (Nitinol Medical Technologies, Inc., Boston, MA) and the Amplatzer<sup>®</sup> PFO Occluder (AGA Medical Corp., Golden Valley, MN) for closure of a PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through the PFO and who have failed conventional drug therapy with anticoagulants.

**Atrial Septal Defect (ASD)**

Atrial Septal Defects (ASD) are congenital heart defects that may be classified as ostium secundum, (located in the upper portion of the atrial septum), ostium primum (located in the lower portion of the atrial septum), sinus venosus (located at the junction of the atrial septum and the superior vena cava) and ASD of the inferior vena cava, (located at the junction of the atrial septum and the inferior vena cava). Severe defects may require repair immediately after birth. Other forms may go undetected 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 and will require either medical or surgical intervention.

Despite the success of open surgical repair, there has been interest in developing a catheter-based approach to ASD repair, in order to avoid the risks and morbidity of open-heart surgery. To date, the FDA has approved use of the Amplatzer<sup>®</sup> Septal Occluder Device for use in repair of ASDs in the secundum position. The device consists of a self-expanding and repositionable double disc device, constructed of a nitinol wire mesh. A 3 to 4 mm long cylindrical waist connects the two discs. The intent of the device is to stretch and stent the ASD. Polyester fibers are then sewn into the device, which leads to clot formation and defect occlusion. Additional devices are currently under investigation for the transcatheter repair of ASD, as well as other septal defects. The technical challenges include minimizing the size of devices, 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.

**Ventricular Septal Defect (VSD)**

Ventricular Septal Defects (VSD) may be congenital or an uncommon complication, following a myocardial infarction. When there is a large opening between the ventricles, a large amount of oxygen-rich (red) blood from the heart's left side is forced through the defect into the right side. Then it is pumped back to the lungs, even though it has already been refreshed with oxygen. This is inefficient, because oxygenated blood displaces blood that needs oxygen. This means the heart, which must pump more blood, may enlarge from the added work. High blood pressure may occur in the blood vessels of the lungs, because more blood is present. Over time, this increased pulmonary hypertension may permanently damage the blood vessel walls.

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If the opening between the ventricles is small, it does not strain the heart. In that case, the only abnormal finding is a loud murmur. Closing small ventricular septal defects may not be needed. They often close on their own in childhood or adolescence. However, if the opening is large, even in patients with few symptoms, closing the hole in the first two years of life is recommended to prevent serious problems later. Repairing a VSD restores the blood circulation to normal. To date, the FDA has approved use of the CardioSEAL<sup>®</sup> Septal Occlusion System with QuikLoad<sup>™</sup> for patients with a complex ventricular septal defect of significant size to warrant closure who are considered to be at high risk for standard transatrial or transarterial surgical closure, based on anatomical conditions and/or overall medical condition. High-risk anatomical factors for transatrial or transarterial surgical closure include:

- requiring a 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. (FDA, 2002)

**Fontan Procedure**

Infants born with single-ventricle defects often need multiple operations. These include shunts, such as Blalock-Taussig (B-T) or Glenn, placing a band on the pulmonary artery, or the Fontan operation. The Fontan operation largely separates the heart into two circulations. This lets oxygen-poor blood go to the lungs and oxygen-rich blood go to the body. The Fontan operation substantially reduces the mixing of oxygen-poor and oxygen-rich blood and produces a normal or near-normal oxygen supply to the body. It also reduces the risk of a stroke or other complications and decreases the workload on the single ventricle. A fenestrated Fontan leaves a hole or opening in the band/shunt to allow some mixing of oxygen-poor and oxygen-rich blood. This is done for patients when it is thought that they cannot tolerate the change in venous pressure. To date, the FDA has approved the use of the CardioSEAL<sup>®</sup> Septal Occlusion System for patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and the Amplatzer<sup>®</sup> Septal Occluder for patients who need closure of a previously fenestrated Fontan procedure.

Transcatheter procedures are generally well tolerated. Serious complications are uncommon and include device embolization, (i.e., the device breaks free whereby surgical device retrieval may be required) and cardiac arrhythmias (usually transient). Since the Amplatzer<sup>®</sup> occluders contain a nickel alloy, care must be taken when using this instrument in patients with nickel sensitivity.

**Definitions**

**Cryptogenic stroke:** a stroke or transient ischemic attack, due to an embolus, generally felt to reach the brain through a patent foramen ovale; the original source of the embolus may not be known

**Fontan procedure:** a procedure used for certain congenital heart defects that creates a surgical passageway that divides the heart into essentially two circulations; the procedure creates a fenestration (wall with multiple holes)

**Patent ductus arteriosus (PDA):** a communication between the main pulmonary artery (artery bringing blood to the lungs for oxygenation) and the aorta (large artery bringing oxygenated blood to the rest of the body); in this condition, this channel, which generally closes during the first few days of life, remains open and causes mixing of oxygenated and deoxygenated blood, resulting in clinical illness

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**Patent foramen ovale (PFO):** a component of the fetal circulation that consists of a communication between the left and right atria that generally closes after birth; if an opening remains after birth, the possibility of an embolus (blood clot that breaks free in the blood) getting to the brain exists, resulting in a stroke or transient ischemic attack

**Secundum atrial septal defect (ASD):** an atrial septal defect located in the upper portion of the wall (septum) between the right and left atrium

**Ventricular septal defect (VSD):** an opening in the wall between the right and left ventricles

**Coding**

*The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

**When services are Medically Necessary:****CPT**

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

**ICD-9 Procedure**

35.52	Repair of atrial septal defect with prosthesis, closed technique
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**ICD-9 Diagnosis**

429.71	Acquired cardiac septal defect
745.2	Tetralogy of Fallot (includes ventricular septal defect)
745.3	Common ventricle (single ventricle)
745.4	Ventricular septal defect
745.5	Ostium secundum type atrial septal defect (includes patent foramen ovale)
745.69	Endocardial cushion defects; other (ventricular septal defect)
747.0	Patent ductus arteriosus

**When services are Investigational/Not Medically Necessary:**

For the procedure codes listed above, for all other diagnoses, or when the code describes a procedure indicated in the Policy section as investigational/not medically necessary.

**When services are also Medically Necessary:****CPT**

37204	Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis,
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75894	to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck Transcatheter therapy, embolization, any method, radiological supervision and interpretation
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**ICD-9 Diagnosis**

429.71	Acquired cardiac septal defect
745.2	Anomalies of cardiac septal closure
745.3	Common ventricle
745.4	Ventricular septal defect
745.5	Ostium secundum type atrial septal defect
745.69	Endocardial cushion defects; other
747.0	Patent ductus arteriosus

**When services are Investigational/Not Medically Necessary:**

For the procedure codes listed above, for the following diagnoses, or when the code describes a procedure indicated in the Policy section as investigational/not medically necessary.

**ICD-9 Diagnosis**

745.61	Ostium primum defect
745.8	Other anomalies

**When services are also Investigational/Not Medically Necessary:**

For the procedure codes listed below for all applications, or when the code describes a procedure indicated in the Policy section as investigational/not medically necessary.

**CPT**

0166T	Transmyocardial transcatheter closure of ventricular septal defect, with implant; without cardiopulmonary bypass
0167T	Transmyocardial transcatheter closure of ventricular septal defect, with implant; with cardiopulmonary bypass

**ICD-9 Diagnosis**

All diagnoses

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Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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**Transcatheter Closure of PDA, PFO, ASD/VSD, Fenestrated Fontan and Transmyocardial/Periventricular Device Closure of VSD**

**Web Sites for Additional Information**

1. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Humanitarian Use Devices. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm#2>. Accessed on February 3, 2007.
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**Index**

Amplatz® Device	Patent Foramen Ovale
Atrial Septal Defect	PDA
CardioSeal® Device	PFO
Cook Coil	Sinus Venosus
Gianturco Coil	Starflex
Helex	Ventricular Septal Defect
Ostium Primum, Secundum	VSD
Patent Ductus Arteriosus	

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

**Policy History**

<b>Status</b>	<b>Date</b>	<b>Action</b>
Revised	03/08/2007	Medical Policy & Technology Assessment Committee (MPTAC) review. A policy statement was added to state that transmyocardial/periventricular device closure of VSDs is considered investigational/not medically necessary. Rationale section was also updated to include the FDA withdrawal of HDE marketing approval for the CardioSEAL® STARFlex™ and AMPLATZER® PFO occluders. Coding was also updated to add the new CPT Category III codes (0166T, 0167T) effective 01/01/2007. Published on web 05/18/2007.
Reviewed	06/08/2006	MPTAC review. No change to policy criteria. References were updated, including information regarding current FDA-approved devices.
Revised	7/14/2005	MPTAC review. Revision based on Policy Harmonization: Pre-merger Anthem and Pre-merger WellPoint.

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
Anthem, Inc.	01/28/2004	SURG.00032	Transcatheter Closure of Patent Ductus Arteriosus, Foramen Ovale, Closure of a Fenestrated Fontan Procedure, and

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## Medical Policy

SURG.00032

### Transcatheter Closure of PDA, PFO, ASD/VSD, Fenestrated Fontan and Transmyocardial/Periventricular Device Closure of VSD

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WellPoint Health Networks, Inc.	09/23/2004	3.04.04	Atrial and Ventricular Septal Defects
	06/24/2004	3.04.25	Catheter Closure for Atrial Septal Defect and Patent Foramen Ovale Transcatheter Closure for Patent Ductus Arteriosus

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