Transcatheter Closure of Septal Defects

Policy Number: 2015M0035A                     Effective Date: July 1, 2015

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
### POLICY DESCRIPTION:

This policy describes the use of transcatheter septal occlusion devices for the repair of septal wall defects, a hole defect in the wall that separates the chambers in the heart. Septal wall defects are one of the most common congenital heart defects (meaning that a baby is born with it). In adults, septal defects are a rare, but serious complication of heart attacks and are not the result of a birth defect. Septal occlusion devices are implantable devices intended as an alternative to surgical closure of a persistent atrial or ventricular septal defect in the heart. Small septal defects will often close spontaneously and require no intervention. Larger septal defects may require closure, either in the cardiac catheterization laboratory or with traditional heart surgery. In the cardiac catheterization laboratory, a septal occluder device is inserted into the damaged area through a catheter. The device is then opened to effectively close the hole. The device remains in the heart permanently. If left untreated, large septal defects can have a number of adverse consequences.

### COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Transcatheter closure of a septal defect with an U.S. Food and Drug Administration (FDA) approved device, used according to FDA labeling, may be considered **MEDICALLY NECESSARY** for patients who meet 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) of significant size to warrant closure who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical and/or overall medical condition.

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

- 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"); or
- With posterior apical VSD covered by trabeculae.

The use of transcatheter closure of septal defect for any indication not listed above is considered **EXPERIMENTAL OR INVESTIGATIONAL**.

Transmyocardial (perventricular) transcatheter closure of ventricular septal defects with implants is considered **EXPERIMENTAL OR INVESTIGATIONAL**. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of transmyocardial (perventricular) closure of VSD as compared to conventional treatment options. The available literature on this technique is very limited. Very small numbers of cases were reported, mostly by the same group of investigators and involved a single institution. These case reports were also limited by short follow-up periods and lack of randomization. In addition, no devices have received FDA approval for this application.
Clinical Considerations:

Possible Complications: Placement of the CardioSEAL and Amplatzer devices involves using standard interventional cardiac catheterization techniques. Complications associated with cardiac catheterization procedures include, but are not limited to: air embolus; allergic dye reaction; anesthesia reaction; apnea; arrhythmia; death; fever; headache/migraines; hematoma and/or pseudoaneurysm, including blood loss requiring transfusion, hypertension, and hypotension; infection, including endocarditis; perforation of vessel or myocardium; stroke; transient ischemic attack; thromboembolic events; and valvular regurgitation (NMT Medical, 2002). Complications reported in the reviewed studies with either the CardioSEAL or the Amplatzer include transient neurological symptoms and transient ECG changes, malpositioning of the device, thromboembolism, embolization of device, fracture of device arm, hemolysis, and significant blood loss. In the only study comparing transcatheter occlusion with standard surgical repair, the complication rate for the transcatheter device (Amplatzer) was 7.2%, while the complication rate for surgery was 24% (FDA, 2001b). None of the available studies addressed the question of whether the presence of these occlusion devices in the cardiac septum over a number of years could cause long-term complications.

Exclusion criteria include:

- Multiple defects that cannot be adequately covered by the device
- Associated congenital cardiac anomalies that require cardiac surgery (i.e., VSDs, PDAs, etc.)
- Ostium primum ASDs
- Sinus venosus ASDs
- Partial anomalous pulmonary venous drainage
- Pulmonary hypertension
- Congestive heart failure
- Active endocarditis or other infections producing bacteremia or sepsis
- Coagulation disorders in patients who are unable to take antiplatelet or anticoagulant therapy

BACKGROUND:

Defects in the septal wall of the heart can have a number of adverse consequences, including abnormal ventricular volume load, ventricular pressure load, and atrial emptying, mixing of unoxygenated and oxygenated blood, and inadequate systemic cardiac output. These abnormalities can lead to cardiac enlargement, pulmonary hypertension, rhythm disturbance, and stroke. There are several types of atrial and ventricular septal wall defects; these can be congenital or can occur as the result of increased intrathoracic pressure or following a myocardial infarction (MI). Conventional open-heart surgical repair of septal defects carries some risk, especially in patients in whom heart or pulmonary function may be compromised. In addition, there is considerable morbidity associated with open-heart surgery. Moreover, some types of ventricular septal defects (VSDs) are difficult to repair surgically due to their location or orientation. Consequently, there has been considerable interest in the development of a transcatheter method of repairing septal lesions. Access to the defect is achieved through the venous system via the internal jugular or groin.
### Ventricular Septal Defects (VSD):

VSDs are holes in the ventricular septum between the left and right ventricles of the heart. These defects occur in approximately 1 to 2 of every 1000 live births, making them the most common cardiac defect. In rare cases, VSDs occur as a complication of myocardial infarction. Although VSDs often close spontaneously, substantial single or multiple defects allow reverse shunting of blood from the left to right ventricle, which may have serious consequences including congestive heart failure and infective endocarditis. VSDs are classified by their location in the septum; approximately 75% are perimembranous, occurring just below the aortic valve in the membranous or fibrous portion of the septum. Other VSD types include muscular defects, which have entirely muscular rims, and defects situated in the inlet and outlet regions of the septum. Children and adults can present with symptoms due to VSDs, which have traditionally been repaired with open heart surgery, using sutures to close small defects and artificial or biologic patches to close larger defects.

Transcatheter closure involves introducing a guidewire into the femoral artery. A delivery sheath is advanced over the wire across the defect, usually through the right heart system. Under fluoroscopic guidance, an occluder device is placed and expanded like an umbrella to close the defect. Potential advantages of the transcatheter closure over conventional surgery include a smaller incision, shorter hospital stay and fewer complications, particularly those associated with cardiopulmonary bypass. Transmyocardial (perventricular) device closure of a VSD approaches the defect by puncturing the wall of the right ventricle, rather than via a percutaneous approach. It is generally performed as part of a combination "hybrid" procedure, which involves standard cardiac surgical techniques for correction of coexisting abnormalities, combined with a perventricular intervention for VSD closure. The technique has been investigated as an alternative to percutaneous Transcatheter techniques combined with cardiac surgery, for use in the repair of complex congenital cardiac defects that are not readily amenable to more established approaches.

### Atrial Septal Defects (ASD):

ASDs constitute approximately 6% to 10% of congenital heart defects are twice as common in females as males and are characterized by structural deficiency of the atrial septum. Although most cases of ASD are sporadic, ASD is also associated with certain genetic syndromes, such as trisomy 21 (i.e., Down syndrome). The three types of ASDs, secundum, primum, and sinus venosus, are named in relation to their position in the atrial septum. However, all ASDs result in right-to-left shunting of blood. While 20% of ASDs close spontaneously by the time the child is 2 years old, natural closure is rare beyond 2 years. Unrepaired ASDs are associated with a risk of mortality due to pulmonary vascular obstructive disease, right atrial and ventricular enlargement, tricuspid regurgitation, pulmonary hypertension, rhythm disturbances, and stroke. The occurrence of cryptogenic stroke in patients with patent foramen ovale (PFO) is of particular concern due to the high incidence of such events in this patient population. While the cause of cryptogenic strokes is unclear, patients with PFOs are at increased risk of paradoxical embolism resulting from right-to-left shunting, which can be a contributing factor in cryptogenic stroke (Allen et al., 1998; Berkow and Fletcher, 2000).

The most frequent type of ASD is in the ostium secundum (fossa ovalis) location. A PFO is a very small variant of this type of ASD that results from a persistent, flap-like opening between the atrial septum primum and secundum at the location of the fossa ovalis. In utero, the foramen ovale serves as a physiologic conduit for right-to-left shunting. After birth, following the establishment of pulmonary
circulation, the increased left atrial blood flow and pressure results in functional and then anatomical closure of the foramen ovale. The presence of a PFO has no therapeutic consequence in otherwise healthy adults and is typically not treated unless other conditions exist, such as pulmonary hypertension, chronic obstructive pulmonary disease, or pulmonary embolism. In patients with these conditions, the right atrial pressure may be chronically elevated, resulting in the potential for right-to-left shunting through the PFO. In this situation, a thrombus in the right atrium could be carried directly into the left atrium, with the potential for embolism to the brain or coronary arteries. For this reason, patients with PFO who have had a stroke or transient ischemic attack without another cause of cerebral ischemia are considered candidates for prophylactic anticoagulant therapy. Transcatheter occlusion has been proposed as an alternative to long-term anticoagulant therapy for treatment of PFOs associated with cryptogenic stroke (Allen et al., 1998; Hung et al., 2000).

**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.

**CardioSEAL:**
The CardioSEAL system consists of two self-expanding umbrellas that clasp the septal wall by spring tension. Four metal arms radiate from the center of the device, supporting each umbrella. Sewn square Dacron patches cover the arms. Each arm is hinged or jointed in two places to relieve the stresses placed upon the implant during the cardiac cycle. The device comes in five sizes that correspond to the diagonal length of each umbrella: 17, 23, 28, 33, and 40 mm. A specially designed delivery catheter, made of coaxial polyurethane, facilitates attachment, loading, delivery, and deployment of the CardioSEAL (Allen et al., 1998; Hellenbrand et al., 1990; Kaulitz et al., 1998; Pedra et al., 2000; NMT Medical, 2002).

**Amplatzer:**
The Amplatzer device is a self-expandable, double-disc device made from a Nitinol wire mesh (NMT Medical). The two discs are linked together by a short connecting waist corresponding to the size of the ASD. In order to increase its closing ability, the discs and the waist are filled with polyester patches. The polyester patches are securely sewn to each disc by a polyester thread. The Amplatzer is available in 34 sizes ranging from 4 mm to 38 mm (AGA Medical Corporation, 2002).

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   **Amplatzer:**
The Amplatzer (AGA Medical Corporation) and the Amplatzer exchange system were approved on September 7, 2007 (PMA #P040040 assigned). The Amplatzer is indicated for the occlusion of ASDs in secundum position and in patients who have undergone a fenestrated Fontan procedure and now 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 (i.e., 1.5:1 degree of left-to-right shunt or right ventricular enlargement). The Amplatzer exchange system is intended for
the removal of an Amplatzer delivery sheath and subsequent exchange for an Amplatzer delivery sheath of equal or larger diameter (FDA, 2002a).

**CardioSeal:**
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 CardioSEAL was previously approved for limited marketing as a Humanitarian Use Device (HUD) for each of the following indications individually on September 8, 1999; September 28, 1999; and February 1, 2000, respectively:

- Treatment of patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and require closure of the fenestration (FDA, 1999a).
- Treatment of patients with complex VSDs of a significant size to warrant closure but that, based on location, cannot be closed with standard surgical transatrial or transarterial approaches (FDA, 1999b).
- Treatment of patients with a PFO with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy (FDA, 2000).

The new approval allows for more widespread marketing. The approval was conditional on the manufacturer performing a small post approval study to follow certain patient groups for a period of 5 years.

**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.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):** CMS has not issued a national coverage policy on the use of septal occlusion devices.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

Minnesota DHS does not have a policy statement regarding transcatheter closure of septal defects in its Provider Manual or other specific provider references.
# CLINICAL EVIDENCE:

Evidence evaluated for this report was obtained primarily from a search in the MEDLINE and EMBASE databases spanning the years 1985 to August 2013. Search terms included *CardioSEAL, Amplatzer, or occlusion device* as keywords, subject words, and title words, combined with *septal defect, septal occlusion or fenestrated Fontan*. Additional information was obtained from the FDA, NMT Medical, and AGA Medical Corporation.

# 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.
**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. This list of codes may not be all-inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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REFERENCES:


56. National Institute for Health and Clinical Excellence (NICE) [website]. Endovascular closure of perimembranous


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| 07/01/2015 | Policy Update:  
  • Added applicable ICD-10 codes to the Coding Section. The list of codes may not be all-inclusive and does not denote coverage.  
  • Policy identification number updated to 2015M0036A.                                      |