Name of Policy:
Transcatheter Closure of Septal Defects

Policy #: 039
Category: Medical
Latest Review Date: November 2008
Policy Grade: Active Policy for dates of service prior to April 12, 2011 but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:
1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

Description of Procedure or Service:
The AMPLATZER Septal Occluder is a percutaneous, transcatheter, atrial septal defect (ASD) closure device intended for the occlusion of ASD in secundum position or patients who have undergone a fenestrated Fontan procedure and subsequently require closure of the fenestration.

The AMPLATZER Septal Occluder is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the ASD. When expanded, the device forms two disks joined by a center stalk; the stalk occludes the defect, and the disks adhere to the residual septum. In order to increase its closing ability, the discs and the waist are filled with polyester fabric. The polyester fabric is sewn to each disc by a polyester thread.

The AMPLATZER Delivery System was designed specifically to facilitate attachment, loading, delivery, and deployment of AMPLATZER Septal Occluder and is comprised of a delivery sheath, dilator, loading device, plastic vise, and delivery cable. The device is designed to be easily retrievable until it is released from the delivery cable, thereby allowing removal in the event of malpositioning or embolization.

The AMPLATZER Transcatheter Atrial Septal Occlusion Device is inserted in the catheterization lab using transesophageal echocardiography (TEE) monitoring. Aspirin is started at least 24 hours prior to the procedure. Patients take endocarditis prophylaxis for at least six months following device implantation. Further prophylaxis is at the physician’s discretion. Patients are also treated with antiplatelet/anticoagulation therapy (such as aspirin) for at least six months post implant.

The CardioSEAL Septal Occlusion System with QwikLoad™ has an FDA premarket application for use in patients with complex ventricular defects (VSD) of significant size to warrant closure that 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 Amplatzer Muscular VSD Occluder received FDA approval through the PMA process 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 HDE designation has been removed. Please refer to the Approved by Governing Bodies section of this policy for further explanation.

**Policy:**

**Effective for dates of service on or after April 12, 2011**

Refer to Policy #218-Transcatheter Closure Devices for Septal Defects

**Effective for dates of service prior to April 12, 2011:**

Transcatheter closure of secundum atrial septal defects in pediatric patients meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used for the occlusion of atrial septal defects (ASD) in secundum position or to close the fenestration in pediatric patients who have undergone a fenestrated Fontan procedure.

Patients must have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (i.e., 1.5:1.0 degrees of left to right shunt or RV enlargement).

Transcatheter closure of atrial septal defects is contraindicated in the above patient population when:

- Patient is known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of open cardiac surgery
- Patient is known to have sepsis within one month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement
- Patient is known to have a bleeding disorder, untreated ulcer or any other contraindications to aspirin therapy, unless another anti-platelet agent can be administered for 6 months
- Patient is known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi)
- Patient’s size (i.e., too small for transesophageal echocardiography (TEE) probe, catheter size, etc.) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization
- The margins of the patient’s defect are <5mm to the coronary sinus, AV valves or right upper lobe pulmonary vein

Consideration for coverage in adult patients will be done on a case-by-case basis with clinical records. Above contraindications would also apply to adult patients. Pre-determination reviews will be done if requested by the physician. Pre-determination reviews can be requested at:

Blue Cross and Blue Shield of Alabama
Attention: Predetermination Department
P.O. Box 36025
Birmingham, AL 35236
Or
FAX: (205) 220-9560
Transcatheter closure of ventricular septal defects meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for use in patients with complex ventricular septal defects 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 based on 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 VSDs covered by trabeculae

See Policy #68 for Transcatheter Closure Devices for Patent Foramen Ovale (PFO) Defects and effective date.

Refer to Policy #218-Transcatheter Closure Devices for Septal Defects

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

Key Points:
An ASD is an abnormal opening in the atrial septum that allows communication of blood between the left and right atria. ASD is the most common congenital cardiac anomaly and usually is asymptomatic until adulthood. The secundum ASD accounts for approximately 90% of all ASDs and comprises a defect located at and results from a deficient or fenestrated oval fossa near the mid-septum. Most secundum ASDs are not associated with any other anomalies.

ASDs result in a left-to-right shunt, largely because pulmonary vascular resistance is considerably less than systemic vascular resistance and because the compliance of the right ventricle is much greater that that of the left ventricle. Pulmonary blood flow may be two to four times normal. Some neonates may be in congestive heart failure, but most isolated ASDs are well tolerated and usually do not become symptomatic before 30 years of age. Eventually, volume hypertrophy of the right atrium and right ventricle may develop. Irreversible pulmonary hypertension develops in fewer that 10% of patients with an isolated unoperated ASD.

An ASD differs from a patent foramen ovale in that blood flow does not occur in a patent foramen ovale defect unless right atrial pressures are elevated.
The objectives of surgical closure of an ASD are the reversal of hemodynamic abnormalities and the prevention of complications, including heart failure, paradoxical embolization, and irreversible pulmonary vascular disease. Conventional surgical closure through midline sternotomy is considered the gold standard in the treatment of children with secundum type ASD due to very low mortality and morbidity rates. Advances in the use of minimally invasive surgical techniques and interventional percutaneous device applications are changing the role of conventional surgical procedures, especially in patients with small to medium size defects. Advantages of the new approaches include a more cosmetic skin incision, less postoperative pain, shorter hospital stay and earlier return to physical activity.

Ventricular septal defects (VSDs) are usually present at birth but may also occur following myocardial infarction. Small VSDs may never be detected. A large VSD can allow blood to flow from the left to the right ventricle which increases load on the heart and lungs. Septal defects may also be created during surgical repair of certain types of congenital heart defects, such as hypoplastic left ventricle syndrome. A hole is made in the septum of the repaired section of the heart (Fontan fenestration) to improve recovery from the surgery. The fenestration is intended to be closed at a later time.

**Key Words:**
Septal occluder, septal occlusion device, AMPLATZER, atrial septal defect, transesophageal echocardiography, AMPLATZER device, Amplatzer device, AMPLATZER delivery system, CardioSEAL, ventricular septal defect, VSD.

**Approved by Governing Bodies:**
AMPLATZER Septal Occluder was FDA approved via PMA process December 6, 2001

Transcatheter Septal Occluder (Gore Helex) for Closure of Atrial Septal Defects—On September 21, 2007 the FDA approved a premarket application (PMA) for a transcatheter septal occluder with modified catheter delivery system (Gore Helex, W. L. Gore and Associates, Inc).

CardioSEAL® Septal Occlusion System with QwikLoad™ received FDA approval via premarket application (PMA) on December 5, 2001 for complex ventricular septal defects

Amplatzer Muscular VSD Occluder received PMA from the FDA on September 7, 2007.

CardioSEAL® Septal Occlusion System was granted FDA Humanitarian Device Exemption (HDE), February 1, 2000, withdrawn August 16, 2006 effective October 31, 2006

AMPLATZER® PFO Occluder was granted FDA Humanitarian Device Exemption, April 5, 2002, withdrawn August 16, 2006 effective October 31, 2006

The Humanitarian Device Exemption is a category of FDA approval that is applicable to devices that are designed to treat a small patient population of less than 4,000 patients. This approval process requires the manufacturer to submit data on the safety and probable clinical benefit. Clinical trials validating the device effectiveness are not required.
The FDA requested that the manufacturers of the CardioSEAL® STARFlex™ Septal Occlusion System and the AMPLATZER® PFO Occluder be withdrawn from HDE marketing approval. On August 14, 2006 both manufacturers agreed to withdraw their HDEs, effective October 31, 2006. The request for withdrawal came about after the FDA concluded that the population described by the proposed approved indication was in significant excess of 4,000 patients in the U.S. per year. One of the HDE designation criteria is that the target population for use of the devices be 4,000 or fewer individuals annually. Therefore, the FDA is authorized to withdraw the HDE approval as the device no longer meets the eligibility requirements. The FDA believed that the devices should be subject to the same requirement that applies to all class III devices that do not meet the narrow criteria for HDE, i.e. a demonstration of reasonable assurance of both safety and effectiveness, not just safety and probable benefit (FDA Information Sheet, Center for Devices and radiological Health, August 16, 2006). These devices are available to physicians and patients who currently meet the approved HDE indication via an FDA-approved Investigational Device Exemption (IDE) at health care facilities across the United States. Institutional review Boards at these facilities are encouraged by the FDA to consider the proposed IDE protocols in an expedited manner.

According to the FDA, there are several ongoing clinical trials to evaluate the safety and effectiveness of PFO occluders in patients who have had a single cryptogenic stroke and have a PFO. These studies are comparing implantation of a PFO closure device to drug therapy. When one or more of these trials is complete, the FDA would expect to review an associated Pre-Market Application (PMA) under expedited timelines in order to allow device or devices that have been shown to be safe and effective to be widely available for patients for whom the device is indicated.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
BellSouth/AT&T contracts: No special consideration
FEP contracts: No special consideration
Wal-Mart: Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification: Group specific requirements for inpatient hospitalization
Pre-determination requirements: Will be done at physician’s request to determine individual case by case coverage for adult patients.

**CURRENT Coding:**
CPT codes:
**Effective for dates of service on or after January 1, 2003 and prior to April 12, 2011:**

- **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
93799  Unlisted cardiovascular service or procedure
93533  Combined right heart catheterization and transseptal left heart catheterization through existing septal opening, with or without retrograde left heart catheterization, for congenital cardiac anomalies
93315  Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
*99354  Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service; 30-74 minutes
*99355  ;each additional 30 minutes
*99356  Prolonged physician service in the inpatient setting, requiring direct (face-to-face) patient contact beyond the usual service; first hour
*99357  ;each additional 30 minutes

Effective for dates of service on or after January 1, 2009 and prior to April 12, 2011:
*99354  Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service; first hour (list separately in addition to code for office or other outpatient evaluation and management service)
*99355  Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged physician service)
*99356  Prolonged physician service in the inpatient setting, requiring unit/floor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service)
*99357  Prolonged physician service in the inpatient setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged physician service)

* May be used in addition to 93315 to reflect the extended time spent on TEE (beyond the usual 30 minutes) during insertion of AMPLATZER Transcatheter Atrial Septal Occlusion Device. For example, for a 90-minute procedure in the inpatient setting, the TEE should be billed using 93315 and 99356, not 93315, 99356, and 99357.

Effective for dates of service on or after January 1, 2011 and prior to April 12, 2011:
93452  Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.
93453 Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.

93462 Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (List separately in addition to code for primary procedure).

93563 Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (list separately in addition to code for primary procedure).

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

HCPCS codes:

0166T Transmyocardial transcatheter closure of ventricular septal defect, with implant; without cardiopulmonary bypass (CPT category III code)

0167T Transmyocardial transcatheter closure of ventricular septal defect, with implant; with cardiopulmonary bypass (CPT category III code)

Previous Coding:

93542 Injection procedure during cardiac catheterization; for selective right ventricular or right atrial angiography (Deleted effective January 1, 2011)

93543 Injection procedure during cardiac catheterization; for selective left ventricular or left atrial angiography (Deleted effective January 1, 2011)

References:

1. The AMPLATZER® septal occluder and delivery system, AGA Medical Corporation, Golden Valley, Minnesota.


Policy History:
Medical Review Committee, May 2000
Medical Policy Group, April 2001
TEC, November 2001
Medical Policy Group, February 2002
Medical Review Committee, February 2002
Medical Review Committee, March 2002
Available for Comment April 5-May 20, 2002
Medical Policy Group, November 2005 (1)
Medical Policy Group, October 2008 (1)
Medical Policy Administration Committee, November 2008
Available for comment November 5-December 19, 2008
Medical Policy Group, December 2010: 2011 Coding update
Medical Policy Group, February 2010, 2011 Coding update
Medical Policy Group, September 2011(2); Combined with Policy #218. This Policy ends effective April 11, 2011.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.