Effective April 12, 2011

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

BlueCross BlueShield of Alabama

Name of Policy:

Transcatheter Closure Devices for Patent Foramen Ovale (PFO) Defects

Policy #: 068
Category: Medical

Latest Review Date: November 2010
Policy Grade: **Active policy for dates of service prior to April 12, 2011 but no longer scheduled for regular literature reviews and update.**

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:

Transcatheter closure devices are permanent cardiac implants designed to close defects between the chambers of the heart. These self-expandable, self-centering, umbrella-like devices vary in design, shape and method of deployment. They are implanted in a cardiac catheterization laboratory through catheters inserted into the femoral vein. These devices are used as an alternative to open heart surgery to correct PFO defects.

Two devices had received Humanitarian Device Exemption (HDE) status from the U.S. Food and Drug Administration (FDA). The CardioSEAL® Septal occlusion system consist of two primary components: the CardioSEAL®, which is constructed of a metal (MP35N) framework to which polyester fabric is attached, and the Delivery Catheter, a coaxial polyurethane catheter designed specifically to facilitate attachment, loading, delivery and deployment of the CardioSEAL® to the defect.

The AMPLATZER® PFO Occluder is a percutaneous, transcatheter occlusion device. It is a self-expandable, double disc device made from a Nitinol wire mesh. The two discs are linked together by a short connecting waist allowing free motion of each disc. In order to increase its closing ability, the discs contain thin polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread. Like CardioSEAL®, there is also a separate delivery system for the AMPLATZER® PFO Occluder device.

The HDE designation has been removed. Please refer to the Approved by Governing Bodies section of this policy for further explanation.

Policy:

Effective April 12, 2011 refer to Policy #218- Transcatheter Closure Devices for Patent Foramen Ovale (PFO) Defects

Effective for dates of service on or after August 28, 2002 and prior to April 12, 2011:
Transcatheter closure of a patent foramen ovale using a transcatheter approach with an FDA approved device meets Blue Cross and Blue Shield of Alabama's medical criterial for coverage in patients with a history of **cryptogenic** (occurring in the absence of potential cardiac, pulmonary, vascular, or neurological sources) **stroke or TIA *and*** who have **failed or cannot tolerate antiplatelet or anticoagulant therapy** or are **not candidates for antiplatelet or anticoagulant therapy** due to **medical or occupational contraindications.**

At present, no PFO closure devices are FDA approved for patients with cryptogenic stroke. All uses of these PFO closure devices are currently off-label.

Use of transcatheter closure devices for PFO defects is contraindicated in the above patient population when:

- Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained.
- Active endocarditis or other infections producing bacteremia.
- Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.
- Anatomy in which the PFO device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.
- Patients with coagulation disorders who are unable to take antiplatelet or anticoagulant therapy.
- Patients with known hypercoagulable states.
- Patients with intra-cardiac mass or vegetation.

Transcatheter closure of a patent foramen ovale using a transcatheter approach with an FDA approved device in patients that **have not had a TIA or stroke,** but have a PFO **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

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:

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the un-inflated lungs. Prior to birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over a course of months after birth, an increase in left arterial pressure and a decrease in right atrial pressure result in the permanent closure of the foramen ovale in most patients. However, a patent foramen ovale may be detected in 10%-15% of adult patients. Although common, PFOs are typically clinically insignificant and are not associated with right-to-left shunting of blood. 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, resulting in a 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 on the theory that clotting disorders may be present in patients with embolic stroke.

Handke, et al (2007), reported on a prospective study that looked at the association of patent foramen ovale (PFO) and cryptogenic stroke in both older and younger patients. A total of 503 patients admitted with stroke had routine diagnostic tests, including CT and/or MRI of the brain, carotid ultrasound, transthoracic echocardiography, and EKG. The cause of stroke was identified in 276 patients (55%). The stroke was classified as cryptogenic in the remaining 227

patients (45%). All patients then had transesophageal echocardiography to determine the presence of PFO. The results showed the prevalence of PFO was significantly greater among patients with cryptogenic stroke than among those with stroke of known cause, for both younger patients (44% vs. 14%) and older patients (28% vs. 12%). There was an even stronger association between the presence of PFO with atrial septal aneurysm and cryptogenic stroke, as compared to stroke of known cause, among both younger patients (13% vs. 2%) and older patients (15% vs. 4%). The authors noted that PFO plus atrial septal aneurysm may be a "high risk characteristic", although there are no guidelines for therapy in affected patients. The authors concluded that there is an association between PFO and cryptogenic stroke in both older and younger patients and that paradoxical embolism may be the cause of stroke in both age groups.

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Conventional therapy for cryptogenic stroke consists of either antiplatelet therapy (aspirin, clopidogrel, or dipyridamole given alone or in combination) or oral anticoagulation with warfarin. In general, patients with a known clotting disorder or evidence of pre-existing thromboembolism are treated with warfarin, and patients without these risk factors are treated with antiplatelet agents.

Evidence on the efficacy of PFO closure devices consists of a small number of nonrandomized, comparative studies, numerous case series, and meta-analyses of the published studies. Two nonrandomized comparative studies were identified for this policy review. Windecker et al compared 150 patients who underwent PFO closure between 1994 and 2000 with 158 medically treated patients over the same time period. The choice of therapy was based on clinician and/or patient preference. The patients who received closure differed from the medically treated patients on key clinical variables, including the percentage with more than one cerebrovascular event and the size of the PFO. At 4 years' follow-up, there was a trend toward lower recurrence of stroke or TIA in the PFO group that did not reach statistical significance (7.8% vs. 22.2%, p=0.08). Harrer et al reported on 124 patients with cryptogenic stroke and PFO treated over a 10-year period. Eighty-three patients were treated with medical therapy, 34 were treated with percutaneous PFO closure, and 7 were treated with surgical closure. After a mean follow-up of 52 +/- 32 months, annual recurrence rates of stroke were not different between medical therapy and PFO closure (2.1% vs. 2.9%, p=NS).

Many case series report on outcomes of PFO closure in an uncontrolled fashion; some examples of these series are as follows. Onorato et al reported on 256 patients with paradoxical embolism who received transcatheter closure of PFO. The authors reported a 98.1% full closure rate of the PFO and no neurological events at a mean follow-up of 19 months. Martin and colleagues also reported on a study of 110 patients with paradoxical embolism who received transcatheter closure of PFO. While the full closure rate of PFO was 71% at 2 years, only 2 patients had experienced a recurrent neurological event. Windecker et al reported on a case series of 80 patients with a history of at least 1 paradoxical embolic event and who underwent closure of a PFO with a variety of transcatheter devices. Patients were followed up for a mean of 1.6 years. During 5 years of follow-up, the risk of an embolic event (either transient ischemic attack [TIA], stroke, or peripheral embolism) was 3.4%, considered comparable to either medical therapy with anticoagulation or open surgical approaches. The presence of a postprocedural shunt was a predictor of recurrent thromboembolic events, emphasizing the importance of complete closure.

Two systematic reviews of the observational studies have compared outcomes of PFO closure with medical therapy. Worhle compared the results of 12 series of PFO closure (n=2,016) with 8 series (n=998 patients) of medical therapy. At 2 years of follow-up, the range of recurrent stroke was 0–1.6% for PFO closure and 1.8–9.0% for medical therapy. The combined annual incidence of stroke or TIA was 1.3% (95% CI: 1.0–1.8%) following PFO closure compared with 5.2% (95% CI: 4.4–6.2) for medical therapy. In an earlier review, Khairy et al. analyzed 6 series of medical therapy (n=895 patients) and 10 series of PFO closure (n=1,355 patients). These authors noted differences in key clinical characteristics among patients in the two treatment groups. Patients treated with medical therapy were older, had a greater proportion of men, and higher rates of smoking and diabetes. Patients treated with PFO closure were more likely to have had more than one cerebrovascular event. The recurrence rate at 1 year ranged from 0–4.9% with PFO closure, compared with 3.8–12.0% with medical therapy. There was a estimated major complication rate (death, hemorrhage requiring transfusion, tamponade, need for surgical intervention, and pulmonary embolus) for PFO closure of 1.5%, and a minor complication rate of 7.9%.

Guidelines for treatment of patients with PFO and cryptogenic stroke have been published by 3 major medical societies. Guidelines from the American College of Chest Physicians (10) and the American Academy of Neurology, both published in 2004, state that the evidence is inconclusive regarding the comparative efficacy of PFO closure devices and medical therapy. Neither of these guidelines offers specific recommendations as to when PFO closure devices should be used. The American College of Chest Physicians published newer guidelines on antiplatelet and antithrombotic therapy in 2008. These guidelines state, "In patients with cryptogenic ischemic stroke and a PFO, we recommend antiplatelet therapy over no therapy (Grade 1A) and suggest antiplatelet therapy over warfarin (Grade 2A). For patients with evidence of a DVT, we recommend anticoagulation." These 2008 guidelines do not specifically make recommendations on the use of PFO closure devices. The American Heart Association (AHA)/American Stroke Association guidelines published in 2006 offer somewhat more specific recommendations. These guidelines do not recommend PFO closure as initial therapy for patients with a first ischemic stroke and PFO, stating that, “Insufficient data exist to make a recommendation about PFO closure in patients with a first stroke and a PFO.” They also state that “…aspirin (50-325mg/d), aspirin and extended-release dipyridamole in combination, and clopidrogel are all acceptable options for initial therapy (class IIa, level of evidence A),” and that “Warfarin is reasonable for high-risk patients who have other indications for oral anticoagulation, such as underlying hypercoagulable state or evidence of venous thrombosis (class IIa, level of evidence C).” For patients with stroke or TIA while on medical therapy, they state that, “PFO closure may be considered for patients with recurrent cryptogenic stroke despite optimal medical therapy (class IIB, level of evidence C).”

There are at least 5 ongoing randomized, controlled trials comparing PFO closure with medical therapy. These trials have been hampered by slow enrollment and one of the trials is no longer recruiting participants. Two of the trials, the “PC” trial (NCT 00166257) and the “RESPECT PFO” trial (NCT 00465270) have enrolled a majority of patients and should be completed successfully, although the publication date for both remains uncertain.

No clinical trials focus specifically on patients who have failed medical therapy, as defined by recurrent stroke or TIA while on therapy. Many of the published studies include both patients with first cryptogenic stroke, as well as patients with recurrent stroke or TIA, and generally do

not analyze these patient populations separately. As a result, it is not possible to determine from the evidence whether PFO closure in patients who have failed medical therapy reduces the risk of subsequent recurrences.

A sham-controlled randomized clinical trial of PFO closure for the indication of refractory migraine headache was published in 2008. Migraine headache is another condition that has been associated with PFO in epidemiologic studies. In this study, there was no significant difference observed in the primary end point of migraine headache cessation (3 of 74 in the implant group, 3 of 73 in the sham group, p=0.051). The results of this study cast some doubt on the causal relationship between PFO and migraine.

In summary, the evidence does not permit conclusions as to whether PFO closure improves outcomes for patients with cryptogenic stroke and PFO. The causal link between cryptogenic stroke and PFO is not strong enough that success in closure of the PFO alone can be considered a clinical outcome. Two nonrandomized comparative studies do not show significant differences in recurrence rate of stroke or TIA between PFO closure and medical therapy. While the observational data suggest that recurrence of stroke or TIA may be lower following PFO closure, these data are prone to bias and are not definitive. Ongoing randomized, controlled trials, which have been slow in accruing patients, will provide higher quality evidence on this question when they are completed. Some expert groups recommend that PFO closure should be considered for patients who have failed medical therapy. However, since closure devices do not have FDA approval, other options may be explored, including surgical repair.

Key Words:

CardioSEAL® PFO device, transcatheter PFO device, PFO occlusion device, AMPLATZER® PFO device, PFO device, transseptal occlusion device, septal occlusion system, PFO occluder, transcatheter occlusion device, patent foramen ovale (PFO), cryptogenic stroke, atrial septal aneurysm

Approved by Governing Bodies:

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
FEP contracts: No special coverage consideration. Pre-determination reviews are not done for FEP contracts.
Pre-certification requirements: Group specific requirements for inpatient hospitalization

CURRENT Coding:

CPT code:	**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
	93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., fontan fenestration, atrial septal defect) with implant
	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)

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 catherization 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)

* May be used in addition to 93315 to reflect the extended time spent on TEE (beyond the usual 30 minutes) during insertion of **transcatheter closure device for treatment of patent foramen ovale (PFO) defects.** 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.

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)**

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Policy History:

Blue Cross and Blue Shield Association, May 2002
Medical Policy Group, August 2002
Medical Policy Review Committee, August 2002
Medical Policy Administration Committee, September 2002
Available for comment November 19, 2002-January 3, 2002
Medical Policy Group, November 2005 **(1)**
Medical Policy Group, December 2007 **(2)**
Medical Policy Group, November 2008 **(1)**
Medical Policy Group, November 2010 **(1)** Key Points added, References added
Medical Policy Administration Committee, November 2010
Available for comment November 4 – December 20, 2010
Medical Policy Group, February 2011, Code updates
Effective April 12, 2011 refer to Policy #218- Transcatheter Closure Devices for Patent Foramen Ovale (PFO) Defects