Effective November 7, 2011

Please Refer to Policy #218- Transcatheter Closure Devices for Septal Defects for dates of service prior to November 7, 2011

BlueCross BlueShield of Alabama

Name of Policy:

Transcatheter Closure of Patent Ductus Arteriosus

Policy #: 107
Category: Surgery

Latest Review Date: January 2012
Policy Grade: **Active policy for dates of service prior to November 7, 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:

The ductus arteriosus connects the descending aorta to the main pulmonary trunk near the origin of the left subclavian artery. A patent ductus arteriosus (PDA) is the persistent opening of the channel beyond its expected time of closure during the first few days of life. The physiologic consequences are determined by the size and length of the opening; a large non-restrictive ductus with a left to right shunt can cause cardiac failure, while small restrictive PDAs are associated with an increased risk of infective endarteritis. Because of the threat of heart failure or endarteritis, it is recommended that all PDAs, regardless of size, which persist after the age of two years be surgically closed with ligation or division of the PDA.

Recommendations have included that the PDA can be closed surgically or via transcatheter methods. Open surgical treatment of the PDA is a low risk procedure if performed electively. Transcatheter or coil occlusion has become an accepted technique for closure of PDA. This may eliminate the need for general anesthesia, a thoracotomy, and an extended hospital stay and convalescence. However, those very young patients may require general anesthesia and possibly overnight hospitalization.

Two devices have been researched in the past. The Rashkind PDA Occluder System has not received nor is seeking FDA approval. The Gianturco coil, also referred to as the Cook embolization coil, is a device that was marketed prior to the FDA formally acquiring regulatory authority over devices. The Gianturco device has never undergone formal FDA approval but is available for clinical use. Studies have been completed using the Amplatzer duct occluder. Amplatzer also makes a transcatheter closure device for other defects such as atrial septal defects (ASD), ventricular septal defects (VSD) and patent ductus arteriosus (PDA).

Policy:

Effective for dates of service on or after November 7, 2011
Refer to Policy #218-Transcatheter Closure Devices for Septal Defects

Effective for dates of service on or after January 1, 2001 and prior to November 7, 2011:
Transcatheter closure of a patent ductus arteriosus (ICD-9 747.0) using an FDA-approved device **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

According to the labeled indications of the Amplatzer Duct Occluder, the following are **contraindications** for the use of this device:

- Patients weighing less than 6 kg
- Patients less than 6 months of age

- 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
- Patients with pulmonary hypertension with pulmonary vascular resistance of >8 Woods units or Rp/Rs of >0.4.

Effective November 7, 2011 **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:

Statistics from the American Heart Association for the year 2000 state that 40,000 babies are born each year with cardiovascular defects. Of these, 6-11% have patent ductus arteriosus. Pflieger states that morbidity and mortality rates are directly related to the flow volume through the ductus arteriosus. It is estimated that left untreated, the mortality rate is 20% by age 20 years, 42% by age 45 years, and 60% mortality rate by age 60 years. Females are 2-3 times more likely than males to develop PDA and more common in premature infants.

Gianturco coils have been adapted for use in closure of PDAs. Janorkar et al (1999) in a study of 123 patients undergoing transcatheter PDA closure had 122 patients with complete closure at last follow-up (mean of 44.11 +/- of 23.77 months). One had failed coil occlusion and was sent for surgery, complications occurred in 10 patients. 19 patients underwent a second procedure and 1 a third procedure. Transcatheter closure of PDA with the use of different techniques demonstrates that this approach is generally safe in all age groups. The use of transcatheter closure of PDA with the coils was technically much simpler than with the Rashkind device. Wang et al (2002) reported on a study of 55 patients that underwent transcatheter closure of PDA with the Gianturco coils during a 5-year period. 51 patients had successful coil deployment, immediate complete closure in 20 (39%), while trivial to mild leak was present in 31 (61%). No significant complications were encountered. After a follow-up period ranging from 5-42 months, four had a small residual shunt and three underwent a second intervention with complete occlusion. Transcatheter closure of PDA with the Gianturco coils is safe and feasible in the majority of children, adolescents and adults.

A large case series of 1,291 attempted PDA coil occlusions was reported from the European Pediatric Cardiology Registry. Immediate occlusion was demonstrated in 59% of patients, and this increased to 95% 1 year after the procedure. A suboptimal outcome occurred in 10% of patients, defined as failure to implant, coil embolization, residual leak, hemolysis, duct recanalization and flow impairment to adjacent structures. Increasing size of the PDA greater than 2 mm and PDAs that were tubular in shape were associated with an increased likelihood of unfavorable outcome.

In a report by Sandhu et al (2001) using the Amplatzer duct occluder for closure of PDA in 23 patients, immediate closure rate was 86% with a closure rate of 100% at 6 months, 1 year and 2 years following placement device. Amplatzer is safe and effective in the closure of a PDA up to 7.2mm in diameter. Ruiz et al (2002) reported on a study using the Amplatzer duct occluder for PDA in 30 children. 28 patients (93.3%) immediately achieved complete occlusion, and 100% within 24 hours of implantation. PDA can be occluded with the Amplatzer Duct Occluder, which is effective and useful in infants and children with relatively large PDA. This device recently received FDA approval for PDA in May 2003.

In 2003, the Amplatzer Duct Occluder device received FDA approval for closure of PDA. Per the FDA approval letter, this percutaneous transcatheter occlusion device is indicated for the non-surgical closure of patent ductus arteriosus (PDA). The clinical data submitted to the FDA as part of the FDA approval process consisted of results from a multi-center non-randomized pivotal study that enrolled 441 patients. The primary efficacy measure was complete closure and was achieved in greater than 98.6% of patients at 12 months. A total of 1.3% of patients was reported to have serious or major adverse events, and 4.8% was reported to have a minor adverse event.

The Multicenter USA Amplatzer patent ductus arteriosus device trial, conducted by Pass, et al (2004), reported periprocedural and 1-year outcomes in 484 patients from 25 U.S. centers. Of the 484 patients enrolled, the Amplatzer device implantation was not attempted in 45; due to the size of the PDA or the morphology of the PDA was more suited for treatment with a coil. Of the 439 patients in whom implantation was attempted, the device was successfully implanted in 435 patients (99%). Immediate postprocedure occlusion was reported in 76% of patients, which increased to 89% on postprocedure day 1 and to 99% at 1 year. At last evaluation, PDA occlusion was documented in 98% of patients. At 1-year follow-up 359/360 (99.7%) evaluable patients have no evidence of a left to right shunt on echocardiography. Complications were uncommon, with one periprocedural death and major events reported in 2.3% (10/439) of patients. Examples major events include device embolization (n=2), partial obstruction of the pulmonary artery (n=2), and bleeding requiring transfusion (n=2). Minor events occurred in 7.1% (31/439) of patients.

April 2007 Update
No new peer-reviewed published literature has been located that would alter the coverage statement on this policy.

April 2009 Update
No new peer-reviewed published literature has been located that would alter the coverage statement on this policy. No other FDA approved occluding device has been identified for use in performing this procedure.

January 2012 Update
There are several case series of both the Amplatzer device and the Gianturco coils that report good outcomes (Butera 2004, Ghasemi 2010, Masura 2006, Saliba 2009, Wang 2007, Yang 2010). These series vary in terms of patient selection, types of device, and outcomes reported. However, the case series are consistent in reporting a high rate of procedural success, a high rate of successful closure of the PDA, and a low rate of serious complications.
A small number of nonrandomized comparative trials have been published, comparing percutaneous closure to open surgery, or comparing the outcomes of different percutaneous closure devices. In a study from China, Chen et al (2009) compared 72 patients treated with percutaneous closure with 183 patients treated with open surgery. The choice of procedures was made at the discretion of the patient and/or treating physician. There were more procedure-related events in the open surgery group compared to the percutaneous group (13.7% vs.1.4%, $p=0.004$), and recovery time was longer for the open surgery group (8.7 days vs. 1.3 days, $p<0.001$). Freedom from persistent residual shunt was higher in the percutaneous group (98.6% vs. 91.3%, $p=0.04$). Other clinical outcomes such as pulmonary arterial hypertension and left ventricular size were similar between groups.

Wang et al (2006) compared outcomes among 214 patients undergoing percutaneous closure with coils and 134 patients undergoing closure by an occluder device. Patients were selected for either group by the size of the PDA, with coils utilized for small to moderate PDAs and the occluder device utilized for larger PDAs. The procedural success rate was high for both the coils (96.7%) and the occluder (98.5%), with no significant difference between groups. There were higher complication rates reported for the coil group. Distal embolization occurred in 8.9% (19/214) of patients in the coil group compared with 1.5% (2/136) patients in the occluder group ($p<0.01$). Pulmonary artery stenosis occurred in 4.2% (9/214) patients in the coil group compared with zero in the occluder group ($p<0.05$).

Summary
The use of percutaneous closure devices has become the procedure of choice for closure of patent ductus arteriosus in suitable patients. The evidence base for percutaneous closure of PDAs consists of a large number of case series that report high success rates with low rates of adverse events. A few non-randomized comparative trials compare outcomes of different devices, but these are not adequately rigorous to form conclusions. Because percutaneous closure achieves high success rates and avoids the morbidity of open surgery, this technique may be considered medically necessary.

Practice Guidelines and Position Statements
In 2008 the American College of Cardiology/American Hospital Association (ACC/AHA) published guidelines on the management of adults with congenital heart disease. Class I indications for closure of a PDA were listed as:

- Left atrial enlargement, left ventricular enlargement, pulmonary arterial hypertension, or left-to-right shunt (Level of evidence C)
- Prior endarteritis (Level of evidence C)

Class IIa indications for closure of a PDA were:
- It is reasonable to close an asymptomatic small PDA by catheter device (Level of evidence C)
- PDA closure is reasonable for patients with pulmonary arterial hypertension with a net left-to-right shunt (Level of evidence C)

Key Words:

Patent ductus arteriosus, PDA, transcatheter closure device, Gianturco coils, Cook embolization coils, Amplatzer duct occluder, Amplatzer

Approved by Governing Bodies:

Amplatzer Duct Occluder and 180° Delivery System approved by FDA on May 14, 2003
In 2003, the Amplatzer Duct Occluder received FDA approval, with the specific indication for non-surgical closure of patent ductus arteriosus. This device is a self-expandable device made from a Nitinol wire mesh and polyester fabric. As the occluder is implanted, it expands outward, and the wires push against the wall of the ductus. The polyester fabric induces thrombosis, which closes the communication.

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: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: Not applicable

CURRENT Coding:

CPT codes: **93799** Unlisted cardiovascular service or procedure
93531 Combined right heart catheterization and retrograde left heart catheterization, for congenital cardiac anomalies

Effective for dates of service on or after January 1, 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)

PREVIOUS Coding:

93510 Left heart catheterization, retrograde, from the brachial artery, axillary artery or femoral artery; percutaneous **(Deleted effective January 1, 2011)**

93541 Injection procedure during cardiac catheterization; for pulmonary angiography **(Deleted effective January 1, 2011)**

93544 Injection procedure during cardiac catheterization; for aortography **(Deleted effective January 1, 2011)**

93556 Imaging supervision, interpretation and report for injection procedure(s) during cardiac catheterization; pulmonary angiography, aortography, and/or selective coronary angiography including venous bypass grafts and arterial conduits (whether native or used in bypass) **(Deleted effective January 1, 2011)**

References:

1. American Heart Association. *Congenital cardiovascular defects statistics*, http://www.americanheart.org/presenter.jhtml?identifier=4576.
2. Amplatzer Duct Occluder: FDA Summary of Safety and Effectiveness.
3. Butera G, De Rosa G, Chessa M et al. *Transcatheter closure of persistent ductus arteriosus with the Amplatzer duct occluder in very young symptomatic children*. Heart 2004; 90(12):1467-70.
4. Chen ZY, Wu LM, Luo YK et al. *Comparison of long-term clinical outcome between transcatheter Amplatzer occlusion and surgical closure of isolated patent ductus arteriosus.* Chin Med J (Engl) 2009; 122(10):1123-7.
5. Fernandez, Ruiz, del Cerro, Marin, M.J., et al. *Transcatheter closure of patient ductus arteriosus using the Amplatzer duct occluder: Initial results and mid-term follow-up*, Rev Esp Cardiol, October 2002; 55(10): 1057-62.
6. Ghasemi A, Pandya S, Reddy SV et al. *Trans-catheter closure of patent ductus arteriosus-What is the best device?* Catheter Cardiovasc Interv 2010; 76(5):687-95.

7. Goldman, Lee and Bennett, J. Claude. Cecil Textbook of Medicine 21st Edition, Vol. 1, pp. 284-285.
8. Hijazi ZM, Geggel RL. *Results of anterograde transcatheter closure of patent ductus arteriosus using single or multiple Gianturco coils*. Am J Cardiol 1994; 74(9):925-9.
9. Janorkar, Satej, Goh, Tiow, et al. *Transcatheter closure of patient ductus arteriosus with the use of Rashkind occluders and/or Gianturco coils: Long-term follow-up in 123 patients and special reference to comparison, residual shunts, complications, and technique*, Am Heart Journal, 1999; 138(6): 1176-1183.
10. Latson LA. *Residual shunts after transcatheter closure of patent ductus arteriosus. A major concern or benign "techno-malady"?* Circulation 1991; 84(6):2591-3.
11. Magee AG, Huggon IC, Seed PT et al. *Transcatheter coil occlusion of the arterial duct; results of the European Registry*. Eur Heart J 2001; 22(19):1817-21.
12. Masura J, Tittel P, Gavora P et al. *Long-term outcome of transcatheter patent ductus arteriosus closure using Amplatzer duct occluders.* Am Heart J 2006; 151(3):755 e7-55 e10.
13. Pass RH, Hijazi Z, Hsu DT et al. *Multicenter USA Amplatzer patent ductus arteriosus occlusion device trial: initial and one-year results*. J Am Coll Cardiol 2004; 44(3):513-9.
14. Pflieger, Kurt. *Patent ductus arteriosus*, http://www.emedicine.com/emerg/topic358.htm.
15. Rothman A, Lucas VW, Sklansky MS et al. *Percutaneous coil occlusion of patent ductus arteriosus*. J Pediatr 1997; 130(3):447-54.
16. Saliba Z, El-rassi I, Helou D et al. *Development of catheter-based treatment of patent ductus arteriosus: a medium-sized centre experience*. Arch Cardiovasc Dis 2009; 102(2):111-8.
17. Sandhu, S.K., King, T.D., Troutman, W.B., et al. *Transcatheter closure of patent ductus arteriosus with the Amplatzer duct occluder: Short-term follow-up*, J Invasive Cardiol, April 2001; 13(4): 298-302.
18. Wang JK, Hwang JJ, Chiang FT et al. *A strategic approach to transcatheter closure of patent ductus: Gianturco coils for small-to-moderate ductus and Amplatzer duct occluder for large ductus*. Int J Cardiol 2006; 106(1):10-5.
19. Wang JK, Wu MH, Hwang JJ et al. *Transcatheter closure of moderate to large patent ductus arteriosus with the Amplatzer duct occluder*. Catheter Cardiovasc Interv 2007; 69(4):572-8.
20. Wang, J.K., Liau, C.S., Huang, J.J., et al. *Transcatheter closure of patent ductus arteriosus using Gianturco coils in adolescents and adults*, Catheter Cardiovasc Interv, April 2002; 55(4): 513-8.
21. Warnes CA, Williams RG, Bashore TM et al. *ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines on the management of adults with congenital heart disease)*. Circulation 2008; 118(23):e714-833.
22. Yang SW, Zhou YJ, Hu DY et al. *Feasibility and safety of transcatheter intervention for complex patent ductus arteriosus*. Angiology 2010; 61(4):372-6.

Policy History:

Medical Policy Group, April 2003 **(1)**
Medical Policy Administration Committee, May 2003
Available for comment July 1-August 14, 2003
Medical Policy Group, April 2005 **(3)**
Medical Policy Group, April 2007 **(1)**
Medical Policy Group, April 2009 **(1)**
Medical Policy Group, December 2010; 2011 Code update
Medical Policy Group, September 2011 **(2)**: Combined with Policy 218
Medical Policy Administration Committee February 2012
Medical Policy Group, September 2011(2); Combined with Policy #218. This Policy ends effective November 7, 2011.
