

## Corporate Medical Policy

### Congenital Heart Defect, Repair Devices

**File Name:** congenital\_heart\_defect\_repair\_devices  
**Origination:** 10/2000  
**Last CAP Review:** 6/2011  
**Next CAP Review:** 6/2012  
**Last Review:** 6/2011

#### Description of Procedure or Service

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##### Patent Foramen Ovale

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 uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation consisting of a connection between the pulmonary artery and the distal aorta. 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 atrial 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 (PFO) may be detected in up to 25% of adults. Although common, PFOs are typically clinically insignificant and are not associated with right to left shunting with 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 (TIA). 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, also known as cryptogenic stroke.

Cryptogenic stroke is defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurological sources. An ischemic stroke is classified as cryptogenic in up to 40% of cases, and may be even higher in younger populations. Conventional medical therapy consists of either antiplatelet therapy (aspirin, clopidrogel, or dipyramidole 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.

Two transcatheter devices received approval for marketing from the U.S. Food and Drug Administration (FDA) in 2002 as a treatment for patients with cryptogenic stroke and patent foramen ovale: the CardioSeal Septal Occlusion System and the Amplatzer Patent Foramen Ovale occluder. Both received approval by the U.S. Food and Drug Administration (FDA) through a Humanitarian Device Exemption (HDE), a category of FDA approval that is applicable to devices that are designed to treat a patient population of fewer than 4,000 patients per year. This approval process requires the manufacturer to submit data on the safety and the probable clinical benefit. Clinical trials validating the device effectiveness are not required. The labeled indications of both limits the use of these devices to closure of PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a patent foramen ovale and who have failed conventional drug therapy.

Following this limited FDA approval, the use of PFO closure devices increased by over 50-fold, well in excess of the 4,000 per year threshold intended under the HDE. As a result, in 2006, the

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FDA withdrew the HDE approval for these devices. At this time, the FDA also reiterated the importance of randomized, controlled trials of PFO closure devices versus medical therapy, and noted that ongoing trials were hampered by slow enrollment. Withdrawal of the HDE approval was, in part, intended to spur greater enrollment in ongoing randomized, controlled trials of these devices. Currently, all uses of closure devices to treat PFO are off-label uses.

## Atrial Septal Defect

In contrast to patent foramen ovale, which represents the persistence of normal fetal cardiovascular physiology, atrial septal defects (ASDs) represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized according to their anatomy. For example, ostium secundum atrial septal defects are the third most common form of congenital heart disorder and one of the most common congenital cardiac malformations in adults, accounting for 30%–40% of these in patients over the age of 40. Ostium secundum describes defects that are located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and occur commonly in patients with Down's syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins. The ASD often goes unnoticed 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; less than 50% of patients survive beyond 40 to 50 years due to heart failure or pulmonary hypertension related to the left-to-right shunt. Patients with ASDs are also at risk for paradoxical emboli.

Repair of ASDs is recommended for those with pulmonary systemic flows exceeding 1.5:1.0. Despite the success of operative repair, there has been interest in developing a catheter-based approach to ASD repair to avoid the risks and morbidity of open heart surgery. A variety of devices have been researched over the past 20 years; technical challenges include minimizing the size of device 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. Late failures due to mechanical fatigue have also been a concern. Early devices such as the Rashkind hook device and the Lock Clamshell device were limited by their large size and technical malfunctions. At present, 2 devices are FDA approved for ASD closure: the AMPLATZER™ Septal Occluder, and the GORE HELEX™ Septal Occluder.

## Patent Ductus Arteriosus

The ductus arteriosus is the vascular remnant of the left sixth aortic arch, connecting the main pulmonary artery to the aorta. 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. Symptoms are related to the size of the ductus; 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 twin threats of heart failure or endarteritis, it is recommended that all PDAs persisting after the age of 2 years be surgically closed with ligation or division of the PDA.

Open surgical treatment of the PDA is a low-risk procedure if performed electively. However, over the past several decades there has been interest in developing a catheter-based technique to close PDAs, thus eliminating the need for general anesthesia, a thoracotomy, and an extended hospital stay and convalescence. The Gianturco coil, also referred to as the Cook embolization coil, is an arterial and venous occlusive device that was marketed prior to 1976, when the U.S. Food and Drug Administration (FDA) formally acquired regulatory authority over devices. (Please note that the Gianturco coil is entirely different than the Gianturco stent, which is used in coronary arteries.) Therefore, the Gianturco device has never undergone formal FDA approval but is available for clinical use. However, the Gianturco coil has been investigated for PDA closure. Transcatheter insertion of the coil is typically an outpatient procedure performed in the catheterization lab. General anesthesia may only be required in those very young patients who cannot reliably hold still during the procedure. General anesthesia in a child less than 1 year old may require overnight

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hospitalization.

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.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will provide coverage for Congenital Heart Defect Repair Devices when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

**Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Congenital Heart Defect Repair Devices are covered

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Transcatheter closure of patent foramen ovale, secundum atrial septal defects, or patent ductus arteriosus may be considered medically necessary when using a device that has been FDA approved for that purpose and used according to the labeled indications.

## When Congenital Heart Defect Repair Devices are not covered

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Use of congenital heart defect repair devices are not covered if the criteria listed above has not been met.

## Policy Guidelines

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### Patent Foramen Ovale

The evidence does not permit conclusions as to whether PFO closure improves outcomes for patients with cryptogenic stroke and PFO. Two nonrandomized comparative studies do not show significant differences in recurrence rate of stroke or TIA between PFO closure and medical therapy. At present, the majority of experts recommend that PFO closure devices should be considered for patients who have failed medical therapy, as evidenced by recurrent stroke or TIA while on medical treatment. However, since these devices do not have FDA approval, other options may be explored, including surgical repair.

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## Atrial Septal Defect

In December 2001, the Amplatzer Septal Occluder device received FDA approval for the occlusion of atrial septal defects in secundum position. At the present time, it is the only device that has received FDA approval specifically for the transcatheter treatment of Atrial Septal Defects (ASD).

The labeled indications for the Amplatzer device are as follows:

- Those with echocardiographic evidence of ostium secundum atrial septal defect; AND
- Clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left to right shunt or right ventricular enlargement.)

The other FDA-approved device for ASD closure is the GORE HELEX™ Septal Occluder. The labeled indications for this device are similar.

## Patent Ductus Arteriosus

In May 2003, the Amplatzer Duct Occluder device received FDA approval for the nonsurgical closure of patent ductus arteriosus.

Contraindications for the Amplatzer device are as follows:

- 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.

## **Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 37204, 93580*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all

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specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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### **For policy titled: Congenital Heart Defect, Atrial Repair Devices**

BCBSA Medical Policy Reference Manual, 2.02.09, 7/16/99

Specialty Matched Consultant Advisory Group - 9/00

Medical Policy Advisory Group - 10/00

BCBSA Medical Policy Reference manual, 2.02.09, 12/15/00

BCBSA Medical Policy Reference Manual, 2.02.09, 11/20/01

BCBSA Medical Policy Reference Manual, 2.02.09, 5/15/02

Specialty Matched Consultant Advisory Group - 8/2002

BCBSA Medical Policy Reference Manual, 2.02.09, 7/12/02

BCBSA Medical Policy Reference Manual, 7.01.61, 7/17/03

Specialty Matched Consultant Advisory Group - 11/2003

Specialty Matched Consultant Advisory Panel - 11/2005

BCBSA Medical Policy Reference Manual, 2.02.09, 10/9/03

BCBSA Medical Policy Reference Manual, 7.01.61, 2/25/04

Canadian Coordinating Office for Health Technology Assessment (CCOHTA). Transcatheter Closure of Atrial Septal Defects. Issues in Emerging Health Technologies. Issue 47, May 2003. Retrieved 7/19/07 from [http://www.cadth.ca/media/pdf/228\\_transcatheterclosure\\_cetap\\_e.pdf](http://www.cadth.ca/media/pdf/228_transcatheterclosure_cetap_e.pdf)

National Institute for Clinical Excellence (NICE). Guidance on Endovascular closure of atrial septal defect. Interventional Procedure Guidance 96. London, UK: NICE; October 2004. Retrieved 7/19/07 from <http://guidance.nice.org.uk/IPG96/guidance/pdf/English/download.dsp>

National Institute for Clinical Excellence (NICE). Guidance on Percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke. Interventional Procedure Guidance 109. London, UK: NICE; January 2005. Retrieved 7/19/07 from <http://guidance.nice.org.uk/IPG109/guidance/pdf/English/download.dsp>

U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Information for Physicians and Patients on the Withdrawal of Two Humanitarian Device Exemptions (HDEs) for Patent Foramen Oval (PFO) Occluders. Retrieved 8/1/07 from <http://www.fda.gov/cdrh/ode/h000007-h990011withdraw.html>

### **For Policy renamed: Congenital Heart Defect, Repair Devices**

BCBSA Medical Policy Reference Manual, 2.02.09, 12/11/08

BCBSA Medical Policy Reference Manual [Electronic Version] 2.02.09 4/08/10.

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Specialty Matched Consultant Advisory Panel 6/2010

Specialty Matched Consultant Advisory Panel 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version] 2.02.09, 9/1/11

## **Policy Implementation/Update Information**

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### **For policy titled: Congenital Heart Defect, Atrial Repair Devices**

9/00 Specialty Matched Consultant Advisory Group

10/00 Original policy issued. Medical Policy Advisory Group - Approved.

3/01 Revised. Policy renamed. Criteria added for patent foramen ovale.

11/01 Coding format change.

2/02 Policy revised under when it is covered to include patients who have failed or are not candidates for a course of anticoagulant therapy.

8/02 Description revised to include additional information regarding Patent Foramen Ovale and Atrial Septal Defect. Policy revised to include covered indications for transcatheter repair of Atrial Septal Defect.

9/02 Specialty Matched Consultant Advisory Group review. Policy number changed from MED1094 to SUR6166. Amplatzer Patent Foramen Ovale occluder added as a covered device. New source added.

1/03 Removed code 93799 from policy. Added code 93580 to the policy. Policy name changed from Congenital Heart Defect Repair Devices to Congenital Heart Defect, Atrial Repair Devices. System coding changes.

9/03 Added information related to patent ductus arteriosus. Source added to policy. Code 37204 added to the policy.

11/03 Biannual policy review. Specialty Matched Consultant Advisory Panel review. No change to policy criteria. Policy format changed for consistency.

11/17/05 Biennial policy review. Specialty Matched Consultant Advisory Panel review

11/07/05. Revised the statement regarding FDA approval of HUDs in the Policy Guidelines section. No change to policy coverage.

11/19/07 Information added to Description section for clarity. The following statement was deleted from the When It IS Covered section: "Closure of patent foramen ovale using a transcatheter approach with an FDA approved device may be considered medically necessary in patients with a history of stroke of unknown etiology (cryptogenic) and who have failed or are not candidates for a course of anticoagulant therapy." References updated. Specialty Matched Consultant Advisory Panel review meeting 10/29/07. No change in policy statement. (adn)

3/10/08 Deleted CPT Code 37204 from Billing/Coding section. (adn)

### **For Policy renamed: Congenital Heart Defect, Repair Devices**

12/7/09 Policy name changed to Congenital Heart Defect, Repair Devices. Description section

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extensively revised. The following was added to the Policy Statement: "Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions." Updated policy rationale in Policy Guidelines section to include FDA information. Added CPT Code 37204 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 10/30/09. (adn)

8/17/2010 Specialty Matched Consultant Advisory Panel review 6/2010. Removed Medical Policy number. Updated references. (mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy statements. (mco)

11/08/11 References updated. No changes to policy statements. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.