



## Corporate Medical Policy

# Congenital Heart Defect, Atrial Repair Devices

**File Name:** congenital\_heart\_defect\_atrial\_repair\_devices  
**Policy Number:** SUR6166  
**Origination:** 10/2000  
**Last Review:** 10/2007  
**Next Review:** 10/2009

### Description of Procedure or Service

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Transcatheter closure devices are permanent implants designed to close defects between chambers of the heart. These self-expandable, self-centering umbrella-like devices are implanted in the heart defect through catheters inserted into an artery or vein. Most of these heart defects are [congenital](#), but can occur after a myocardial infarction or as the result of a surgical repair of other congenital heart defects.

#### **Patent Foramen Ovale**

The foramen ovale is a normal opening in the septum, the wall between the two atria of the heart in the fetus. This allows the blood to bypass the uninflated fetal lungs. The opening usually closes shortly after birth in most cases. A patent or open foramen ovale (PFO) may be detected in about 10% - 15% of adult patients. Although common, PFOs are typically clinically insignificant and are not associated with right-to-left shunting of blood. However, PFOs may be associated with a risk for embolic events, including pulmonary embolisms, transient ischemic attacks, or recurrent strokes. 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 in part on the theory that clotting disorders may be present in patients with embolic stroke.

#### **Atrial Septal Defect**

Atrial septal defects (ASDs) represent an abnormality in the development of the heart that results in blood flow between the two atria of the heart. ASDs are categorized according to their anatomy. The ostium secundum ASDs 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 patients over the age of 40. Ostium secundum describes defects that are located in the middle of the septum and are typically near the fossa ovalis. Ostium primum defects lie right next to the atrioventricular valves and occur commonly in patients with Down's syndrome. Sinus venus 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 symptoms 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 or embolic events.

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 in order to avoid the risks and morbidity of heart surgery. 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.

#### **Patent Ductus Arteriosus**

The ductus arteriosus is a bypass of the lungs in fetal circulation. The lungs are deflated and nonfunctioning

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as the fetus grows in utero. The ductus arteriosus allows the blood to bypass the lungs and go straight from the pulmonary trunk to the aorta and out to the body. At or shortly after birth, this shunt closes, completing the separation between the right and left sides of the heart. Patent ductus arteriosus (PDA) is a [congenital](#) anomaly where the ductus arteriosus does not close at the time of birth. The blood flows from the aorta to the pulmonary artery, resulting in a recirculation of arterial blood through the lungs.

### 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.**

### Benefits Application

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Please refer to certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the 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**

In 1996, the FDA created a new category of approval for humanitarian use devices (HUDs). As defined by the FDA, a HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions affecting fewer than 4,000 individuals per year in the United States. A Humanitarian Device Exemption (HDE) is an application similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. An approved HDE authorizes marketing of a HUD. One of the criteria that must be satisfied in order for a device to receive marketing approval under this regulation, is that no comparable device, other than another HUD approved under the HDE regulation or a device being studied under an approved IDE, is available to treat or diagnose the disease or condition.

The FDA notified two manufacturers of its intent to formally propose to withdraw the HDE marketing approvals for two patent foramen ovale occluders previously approved for the treatment of patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy. The devices affected are the NMT Medical CardioSEAL® STARFlex™ Septal

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Occlusion system and the AGA Medical AMPLATZER® PFO Occluder. Both manufacturers agreed to voluntarily withdraw their HDEs effective October 31, 2006.

### **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.)

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

## **Policy Key Words**

Key Words: Devices, Atrial Septal Defects, ASD, Atrium, Septum, Patent Foramen Ovale, PFO, Heart, Cardiac, Congenital, Patent Ductus Arteriosus, PDA, SUR6166

## Medical Term Definitions

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### **Congenital**

existing at, and usually before birth; referring to conditions that are present at birth, regardless of their causation.

## Scientific Background and Reference Sources

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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>

## Policy Implementation/Update Information

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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.

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- 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.
- 3/10/08 Deleted CPT Code 37204 from Billing/Coding section.

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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.