

**Policy terminated because Medicaid covers codes in the same manner as  
Health Choice.**

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## **1.0 Description of the Procedure, Product, or Service**

### **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 recipients. 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 recipients 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, clopidogrel, or dipyridole given alone or in combination) or oral anticoagulation with warfarin. In general, recipients with a known clotting disorder or evidence of pre-existing thromboembolism are treated with warfarin, and recipients 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 recipients 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 recipient population of fewer than 4,000 recipients 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 recipients 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 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. 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 recipients with Down's syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins.

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, two (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 that persist after the age of two (2) years be surgically closed with ligation or division of the PDA.

When performed electively, open surgical treatment of the PDA is a low-risk procedure. 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.

In 2003, the AMPLATZER™ Duct Occluder received FDA approval with the specific indication for nonsurgical 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.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NCHC recipients must be enrolled on the date of service.

## **3.0 When the Procedure, Product, or Service Is Covered**

### **3.1 General Criteria**

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### **3.2 Specific Criteria**

Congenital heart defect repair devices may be covered under the NC Health Choice Program. 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.

### **3.3 Other Policy Guidelines**

#### **a. 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.

#### **b. 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:

1. Those with echocardiographic evidence of ostium secundum atrial septal defect; **AND**
2. 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.

c. 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:

1. Recipients weighing less than 6 kg.
2. Recipients less than 6 months of age.
3. 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.
4. Active endocarditis or other infections producing bacteremia.
5. Recipients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.
6. Recipients with pulmonary hypertension with pulmonary vascular resistance of > 8 Woods units or Rp/Rs of > 0.4.

#### **4.0 When the Procedure, Product, or Service Is Not Covered**

##### **4.1 General Criteria**

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

##### **4.2 Specific Criteria**

Use of congenital heart defect repair devices is not covered if the criteria in **Subsection 3.2** have not been met.

#### **5.0 Requirements for and Limitations on Coverage**

##### **5.1 Prior Approval**

Prior approval is not required for congenital heart defect repair devices.

#### **6.0 Providers Eligible to Bill for the Procedure, Product, or Service**

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**

- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## **7.0 Additional Requirements**

### **7.1 Compliance**

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## **8.0 Policy Implementation/Revision Information**

**Original Effective Date:** July 1, 2010

**Revision Information:**

<b>Date</b>	<b>Section Revised</b>	<b>Change</b>
<b>July 1, 2010</b>		Policy Conversion: Implementation of Session Law 2009-451, <b>Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”</b>
February 29, 2012	Throughout	Policy Termination

### **Attachment A: Claims-Related Information**

Reimbursement requires compliance with all NCHC guidelines.

#### **A. Claim Type**

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

#### **B. Diagnosis Codes**

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

#### **C. Procedure Code(s)**

<b>CPT Codes</b>
37204
93580

#### **D. Modifiers**

Providers are required to follow applicable modifier guidelines.

#### **E. Billing Units**

The appropriate procedure code(s) used determines the billing unit(s).

#### **F. Place of Service**

Inpatient Hospital and Outpatient Hospital

#### **G. Co-payments**

Co-payment(s) may apply to covered prescriptions and services.

#### **H. Reimbursement**

Providers must bill their usual and customary charges.