Title

Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

Description

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.(See reference 1) 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.(See reference 2) 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. (See reference 3) 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. (See reference 3)

Atrial Septal Defect

In contrast to patent foramen ovale, which represents the persistence of normal fetal cardiovascular physiology, atrial septal defects 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 (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.(See references 4 and 5) 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.

The FDA approved ASD closure devices are the following:

- AMPLATZER™ Septal Occluder, and
- GORE HELEX™ Septal Occluder.

When services are covered for commercial products and for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx

We cover **transcatheter closure of secundum atrial septal defects** when using a device that has been FDA approved for that purpose and used according to the labeled indications.[1]

When services are not covered for commercial products or for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx

We do not cover **closure of a patent foramen ovale using a transcatheter approach** since it is considered investigational [1] and does not meet the Blue Cross Blue Shield of Massachusetts Medical Technology assessment Guidelines, #350.

Note: There are currently no transcatheter devices with FDA approval or clearance for closure of a patent foramen ovale.

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed	Prior to performance of service
Blue Cross Blue Shield of Massachusetts Provider Appeals PO Box 986065 Boston, MA 02298	Blue Cross Blue Shield of Massachusetts Case Creation/Medical Policy One Enterprise Drive Quincy, MA 02171 Tel: 1-800-327-6716 Fax: 1-888-641-5330

Authorization Information:

For Managed Care members:

- No authorization is required for this service; see ***Managed Care Guidelines*** *for additional requirements.*

For Indemnity and PPO members:

- No authorization is required for this service; *see* ***Indemnity and PPO Guidelines*** *for additional requirements.*

Managed Care Guidelines:

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members**: The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.

- **For Medicare HMO Blue members**: Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO Guidelines:

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Other information

For our Medical Technology Assessment Guidelines, see document #350.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

CPT code:

- **93580**: percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant

Facility coding
ICD-9-CM procedure codes:

- **35.52**: repair of atrial septal defect with prosthesis, closed technique
- **35.71**: other and unspecified repair of atrial septal defect (i.e., patent foramen ovale)

Policy update history

New medical policy, effective 9/1/2009.

References

References for footnote 1:

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Footnotes

[1] Based on the BCBSA national policy 2.02.09, Closure Devices for Patent Foramen Ovale and Atrial Septal Defects, issued 12/2008.