TRANSCATHETER CLOSURE DEVICES FOR PATENT FORAMEN OVALE (PFO) AND ATRIAL SEPTAL DEFECTS (ASD)
SUR707.024

COVERAGE:

**Patent Foramen Ovale (PFO)**

Closure of PFO using a transcatheter approach with a FDA-approved device may be considered medically necessary in patients with a history of cryptogenic stroke who have failed or are not candidates for a course of anticoagulant therapy.

At the present time two transcatheter devices have received approval (through a Humanitarian Device Exemption), from the U.S. Food and Drug Administration (FDA) as a treatment of PFO. The approved devices are the CardioSEAL Septal Occlusion System (approved 2/2000) and the Amplatzer PFO Occluder (approved 4/5/2002).

**Atrial Septal Defect (ASD)**

Closure of ASD’s using an Amplatzer Septal Occluder device transcatheter may be considered medically necessary consistent with the FDA labeled indications in the following patients:

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

All other transcatheter closure devices for the treatment of PFO or ASD (other than those listed above) are considered investigational.

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. 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 PFO may be detected in 10% to 15% of adult patients. PFO 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.

**ATRIAL SEPTAL DEFECT**
In contrast to PFO, which represents the persistence of normal fetal cardiovascular physiology, ASD represents an abnormality in the development of the heart that results in free communication between the atria. 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 ASD’s are also at risk for paradoxical emboli.

Repair of ASD 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 open-heart surgery. Current devices under investigation include the Sideris buttoned device, Angel Wing device, Atrial Septal Defect Occluding System (ASDOS), Amplatz device, and the CardioSEAL device. While most devices attempt to patch the ASD, the Amplatz device is unique in that it consists in part of an atherogenic stent designed to promote thrombosis of the ASD. In December of 2001 the Amplatzer Septal Occluder device received FDA approval for the occlusion of atrial septal defects in secundum position.

RATIONALE:

PATENT FORAMEN OVALE

Treatment options for patients with paradoxical embolism and PFO have included chronic anticoagulation therapy or closure of the PFO. Although the relationship between PFO and paradoxical embolus has been controversial for some time, evidence is accumulating that supports a causal relationship between the two. It is estimated that patients with PFO and a history of paradoxical embolism have a 3.4% and 3.8% yearly risk of recurrent stroke or transient ischemic attack (TIA), respectively. In addition, there is accumulating evidence that closure of the PFO may decrease the incidence of recurrent paradoxical emboli.

Despite lingering uncertainty regarding the causal relationship between PFO and paradoxical embolism, the data are thought strong enough to consider prophylactic closure of PFO, hence, the interest in minimally invasive transcatheter approaches.

ATRIAL SEPTAL DEFECTS

At the present time, only one transcatheter device (the Amplatzer septal occluder) has received FDA approval for the closure of ASD’s. However, the CardioSEAL device, (which has received FDAapproval for the treatment of PFO), is also under investigation for atrial septal defects and has been used for ASD as an off-label indication.

The FDA approval of the Amplatzer Septal Occluder was based on the results of a multi-center; non-randomized study comparing the device to surgical closure of ASD. Effectiveness was measured in terms of technical and procedural success, measured at 5, 12, and 24 months.
The results for the septal occluder group, although lower than the surgical group, were roughly comparable.

OTHER TRANSCATHETER DEVICE FOR ASD CLOSURE

A multi-institutional trial was conducted on the Sideris buttoned device with a total of 46 patients followed up for a mean of 60 months. 98% of the patients had effective closure of the ASD. Report on the experience with the ASDOS (atrial septal defect occluding system) device in a multi-institutional European trial showed that after one year a moderate/large shunt was present in 2% of patients and a small shunt was apparent in 26% of patients. An asymptomatic device frame fracture was found in 14% and frame deformation in 4% of all patients. The Angel Wings device, consisting of two square frames of nitinol wire covered with polyester fabric, was studied in 50 patients with an ASD and 25 patients with a patent foramen ovale. A minor shunt was observed in only 3 (4%) patients during a follow-up of 1 to 17 months. Serious complication requiring surgical removal developed in 3 patients, prompting the authors to suggest that design modifications were warranted.

A case series was conducted of 26 patients who received the Sideris buttoned device, Angel Wings device, or the Amplatzer device. Successful closure was reported in all but one patient, who had a significant shunt associated with the buttoned device after 12 months. The authors preferred the Amplatzer device due to its ease of use.

The Sideris buttoned device was compared with the Amplatzer device in 33 and 39 patients, respectively. The complete occlusion rate at 12 months was 37% for the Sideris buttoned device and 89% for the Amplatzer device, although most of the residual shunts were small or trivial. The authors preferred the Amplatzer device due to its ease of use and the ability to retrieve and reposition the device.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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