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Medical Benefit		Effective Date: 10/01/09	Next Review Date: 05/15
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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

"Closure" devices are intended as less invasive, catheter-based approaches of repairing patent foramen ovale (PFO) or atrial septal defects. These devices are alternatives to treatment with anti-platelet and/or anticoagulant medications in patients with cryptogenic stroke and a PFO.

Background

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 individuals. However, a patent foramen ovale (PFO) is a common finding in normal adults, detected in up to 25% of adults. (1) In some epidemiologic studies, PFO has been associated with cryptogenic stroke, a type of stroke defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources. Studies also show an association of PFO and migraine headache. There has been interest in either open surgery or transcatheter approaches to close the PFO in patients with a history of cryptogenic stroke in order to prevent recurrent stroke.

In 2002, two transcatheter devices received approval for marketing from the U.S. Food and Drug Administration (FDA) as a treatment for patients with cryptogenic stroke and patent foramen ovale: the CardioSEAL® Septal Occlusion System (no longer commercially available) and the Amplatzer® PFO Occluder. Both received approval by the 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 limited the use of these devices to closure of PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy.

Following this limited FDA approval, the use of PFO closure devices increased by more than 50-fold, well in excess of the 4,000 per year threshold intended under the HDE. (2) 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 (RCTs) of PFO closure devices versus medical therapy but noted that ongoing trials were hampered by slow

enrollment. Withdrawal of the HDE approval was, in part, intended to spur greater enrollment in ongoing RCTs of these devices. (2) Currently, all uses of closure devices to treat PFO are off-label uses.

Atrial Septal Defect

In contrast to PFO, 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 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 older than age 40 years. 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; fewer than 50% of patients survive beyond age 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. At present, two devices are FDA approved for ASD closure: the AMPLATZER™ Septal Occluder, and the GORE HELEX™ Septal Occluder.

Related Protocol

Transcatheter Closure of Patent Ductus Arteriosus

Policy (Formerly Corporate Medical Guideline)

Closure of patent foramen ovale using a transcatheter approach is considered **investigational**. (There are currently no transcatheter devices with FDA approval or clearance for this indication.)

Transcatheter closure of secundum atrial septal defects may be considered **medically necessary** when using a device that has been FDA approved for that purpose and used according to the labeled indications.

Policy Guideline

At present, no PFO closure devices are FDA approved for patients with cryptogenic stroke. All uses of these PFO closure devices are currently off-label.

There are two FDA-approved devices for ASD closure: the AMPLATZER™ Septal Occluder, and the GORE HELEX™ Septal Occluder.

The labeled indications for these devices are similar and include:

- 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).

Generally recognized indications for closure include a pulmonary-to-systemic flow ratio of greater than 1.5, right atrial and right ventricular enlargement, and paradoxical embolism.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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