POLICY STATEMENT:

Based upon our criteria and assessment of the peer-reviewed literature:

I. Transcatheter closure of secundum atrial septal defects (ASD) is considered medically appropriate when using a device that has been FDA approved for that purpose and used according to the labeled indications.

II. Percutaneous closure of patent ductus arteriosus (PDA) is considered medically appropriate when using a device that has been FDA approved for that purpose and used according to the labeled indications.

III. Transcatheter closure of complex ventricular septal defects (VSD) is considered medically appropriate when using a device that has been FDA approved for that purpose and used according to the labeled indications.

IV. Perventricular (transmyocardial) closure of ventricular septal defects (VSDs) has not been medically proven to be effective and is considered investigational.

V. Closure of patent foramen ovale (PFO) using a transcatheter approach is considered investigational due to the current absence of any FDA approved device.

POLICY GUIDELINES:

I. Devices for transcatheter PFO closure are currently only available through an Investigational Device Exemption for use in the context of a clinical trial.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Transcatheter closure devices are permanent implants designed to close defects between chambers of the heart or a patent ductus arteriosus. These are self-expandable, self-centering umbrella-like devices. The design and shape of the devices vary, as does their exact mode of deployment. They are implanted in the defect in a cardiac catheterization laboratory, through catheters inserted into either a vein or an artery (transcatheter or percutaneous approach). There are several types of defects, which include atrial septal defect (ASD), persistent patent ductus arteriosus (PDA), ventricular septal defect (VSD) and patent Foramen ovale (PFO). Most of these defects are congenital, but can occur after a myocardial infarction or can be the result of a surgical repair of other congenital heart defects (e.g. fenestrated Fontans).

The standard for managing clinically significant defects mentioned above has been surgical closure, which except for complex ventricular septal defects is associated with very low mortality. Conventional surgical closure is done through a midline sternotomy. More recently developed approaches, such as transcatheter or percutaneous route, utilizing these closure devices, offer repair of the defect without major thoracic surgery, less post-operative pain, and decreased hospital stay without compromising outcomes in many situations.
RATIONALE:

Despite the success of standard open-heart surgery to repair cardiac defects, the risks and morbidity of open-heart surgery remain. Over the last two decades, interventional cardiac catheterization techniques have advanced to a point where percutaneous transcatheter devices can be offered as an alternative for carefully selected patients. The clinical data derived from case series investigating closure devices for FDA approval indicate that the use of these devices does not expose patients to unreasonable or significant risk of illness or injury and the probable health benefit derived from the use of these devices outweighs their risks.

Atrial Septal Defects

Both the Amplatzer® Septal Occluder’s and the HELEX Septal Occluder are approved by the FDA Circulatory System Devices Committee for use in patients who have an ostium secundum ASD that needs to be closed.

The three major types of ASDs, ostium secundum, ostium primum and sinus venosus, are named for their position in the atrial septum. Ostium secundum ASDs constitute 75–80% of all atrial septal defects and are located in the central portion of the septum. Transcatheter closure is not an option for ostium primum and sinus venosus ASDs. These defects are located at the very lower and upper edges of the atrial septum, respectively.

Transcatheter closure of ostium secundum ASDs has been evaluated in several case series. The consensus in these studies was that transcatheter closure is safe and effective with complication and complete closure rates were comparable to those seen with surgical closure, and transcatheter closure offered the advantages of less morbidity and shorter hospitalizations.

Patent Ductus Arteriosus

The Amplatzer® Duct Occluder (ADO) is the only FDA approved device (May 2003) specifically designed for non-surgical closure of a PDA. Previously, the Gianturco coil or Cook embolization coil (arterial and venous occlusive devices) was used in the closure of patent ductus arteriosus, as an off-label use. Use of the Amplatzer® Duct Occluder for closure of PDAs has been demonstrated to be safe and effective for transcatheter closure of a PDA.

Complex Ventricular Septal Defects

The CardioSEAL® Septal Occlusion System received FDA approval through the Premarket Approval process on December 5, 2001, for use in patients with complex ventricular septal defects (VSDs) of significant size to warrant closure and who are considered at high risk for standard surgical closure based on anatomical conditions and/or overall medical condition. The Amplatzer Muscular VSD Occluder received FDA approval through the PMA process on September 7, 2007. The device is indicated for use in patients with a complex VSD of significant size to warrant closure (large volume, left to right shunt, pulmonary hypertension and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. The approval letter lists the same high-risk anatomical factors included in the approval letter for the CardioSEAL Septal Occlusion System. A modified version of the CardioSEAL device, the STARFlex® Septal Occlusion System, received approval through the Premarket Approval process on March 5, 2009. The STARFlex device is indicated for use in patients with a complex ventricular septal defect that warrants closure, but cannot be closed with standard approaches due to the defects location.

The National Institute for Health and Clinical Excellence (NICE) 2006 systematic review of endovascular closure of perimembranous ventricular septal defect concluded that current evidence on the safety and efficacy of endovascular closure of perimembranous ventricular septal defect (VSD) appears adequate to support the use of this procedure. Careful patient selection is important, especially in children and asymptomatic patients. Current evidence on the safety and efficacy of endovascular closure of complex perimembranous ventricular septal defects appears adequate to support the use of this procedure in carefully selected patients.

The use of a perventricular approach, also referred to as a transmyocardial approach, has been explored as an alternative to the transcatheter approach for VSD closure. This hybrid approach has been investigated in the treatment of patients...
for whom transcatheter is challenging, including small infants and patients with poor vascular access. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of perventricular (transmyocardial) closure of VSD. In addition, no devices have received FDA approval for this application.

**Patent Foramen Ovale**

Two transcatheter devices, the CardioSeal Septal Occlusion System and the Amplatzer Patent Foramen Ovale occluder were developed as a treatment of patent foramen ovale. Both received FDA approval through a Humanitarian Device Exemption, a category of FDA approval that is applicable to devices that are designed to treat a patient population of less than 4,000 patients. 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. On October 31, 2006, both of these devices were voluntarily withdrawn from the market by the manufacturers in an arrangement with the FDA. According to the FDA, the patient population described by the approved indication (patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy) is significantly in excess of 4,000 patients in the U.S. per year. This finding means that these devices are no longer eligible for marketing under an HDE. Given the larger number of patients eligible for the device, FDA believes that the devices should be subject to the same requirement that applies to all class III (highest risk) devices that do not meet the narrow criteria for the HDE, namely, a demonstration of reasonable assurance of both safety and effectiveness, not just safety and probable benefit. These devices are currently only available through an Investigational Device Exemption for use in the context of a clinical trial.

Although the relationship between patent foramen ovale (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. To date, there have been no randomized trials to verify that closure of a PFO will result in a decreased incidence of recurrent paradoxical emboli. It is likely that PFO is not the only risk factor for recurrent paradoxical embolus.

Guidelines for prevention of stroke in patients with ischemic stroke or transient ischemic attack: a statement for healthcare professionals from the American Heart Association/American Stroke Association Council on Stroke: co-sponsored by the Council on Cardiovascular Radiology and Intervention: the American Academy of Neurology affirms the value of this guideline (2006) concluded that insufficient data exist to make a recommendation about PFO closure in patients with a first stroke and a PFO. PFO closure may be considered for patients with recurrent cryptogenic stroke despite optimal medical therapy.

Literature investigating PFO closure as a treatment of migraine headache consists mainly of small studies that lack long-term data on effectiveness and safety. Publication of the MIST trial (Dowson, et al. 2008), a prospective, multicenter, randomized, double-blind, sham-controlled trial to investigate the effects of PFO closure for migraine, reported failure to meet either the primary or secondary end points of the study. The authors reported no difference in the primary end point of number of patients with no migraine attacks between 91 and 180 days postprocedure. Results were the same in the per-protocol analysis and in the intention-to-treat analysis (PFOs could not be found or crossed in five of 74 patients). They also saw no differences in the secondary end points, including severity of migraine, change in frequency of migraines, or total headache days. In an "exploratory analysis" that excluded two outliers (two patients in the intervention arm seemed to account for more than one-third of all headache days) the number of headache days was significantly - if modestly - reduced in the implant group (2.2 days per month vs. 1.3 days per month; p=0.027.) In the device arm, there was one case each of cardiac tamponade, pericardial effusion, and retroperitoneal bleed and two cases of atrial fibrillation. In the sham-treated patients, authors reported adverse events mostly related to study medications, including antiplatelet drugs. In an accompanying editorial, Carroll highlighted the high frequency of patients not found to have a PFO during their procedure, calling into question the quality of the echocardiographic screening process; the
higher-than-expected rate of serious adverse events in the device-treated patients, raising concerns about the quality of the procedures; and the "unclear number" of residual shunts, raising a red flag about the efficacy of the device itself.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

CPT:
- 93580 Percutaneous transcatheter closure of congenital interatrial communication (ie fontan fenestration, atrial septal defect) with implant (includes right heart catheterization)
- 93581 Percutaneous transcatheter closure of congenital ventricular septal defect with implant
- 93582 Percutaneous transcatheter closure of patent ductus arteriosis

HCPCS:
- C1760 Closure device, vascular (implantable/insertable)
- C1817 Septal defect implant system, intracardiac

ICD9:
- 745.4 Ventricular septal defect
- 745.5 Ostium secundum type atrial septal defect, patent or persistent foramen ovale
- 745.61 Ostium primum type defect
- 747.0 Patent ductus arteriosus

ICD10:
- Q21.0-Q21.2 Atrial and ventricular septal defect (code range)
- Q25.0 Patent ductus arteriosus

REFERENCES:


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 ovale (PFO) occluders. [http://www.fda.gov/cdrh/ode/h000007-h990011withdraw.html] accessed 1/7/15..


Proprietary Information of YourCare Health Plan


*Key article

**KEY WORDS:**


---

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, transcatheter closure devices for cardiac defects and patent ductus arteriosus are not addressed in National or Regional Medicare coverage determinations or policies.