MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Transcatheter Closure Devices for Cardiac Defects and Patent Ductus Arteriosus**
Policy Number	**7.01.34**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

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 approved by the U.S. Food and Drug Administration (FDA) 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 approved by the FDA 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 approved by the FDA for that purpose and used according to the labeled indications.

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

V. Closure of patent foramen ovale (PFO) using a transcatheter approach to decrease or eliminate the occurrence of cryptogenic stroke is considered **medically appropriate** when using an FDA-approved device in accordance with device-specific, FDA-approved indications and contraindications.

VI. Closure of patent foramen ovale (PFO) using a transcatheter approach to decrease or eliminate the occurrence of migraines is considered **investigational** due to insufficient evidence that this technology improves long-term health outcomes in migraine patients.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

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 the 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 length of 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 (ASDs)
Both the Amplatzer Septal Occluder and the Gore Cardioform 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 Gore HELEX Septal Occluder has been discontinued.

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. Those 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 comparable to those seen with surgical closure; in addition, transcatheter closure offered the advantages of less morbidity and shorter hospitalizations.

Patent Ductus Arteriosus (PDA)
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 (VSDs)
The CardioSEAL Septal Occlusion System received FDA approval through the pre-market approval (PMA) process on December 5, 2001, for use in patients who have complex VSDs of sufficient 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 who have complex VSDs of sufficient size to warrant closure (large volume, left to right shunt, pulmonary hypertension and/or clinical symptoms of congestive heart failure) and who are considered to be at high

risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or 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 PMA process on March 5, 2009. The STARFlex device is indicated for use in patients with complex VSDs that warrant closure but cannot be closed with standard approaches due to the location of the defects.

The National Institute for Health and Clinical Excellence (NICE) 2010 systematic review of endovascular closure of perimembranous ventricular septal defect concluded that current evidence on the safety and efficacy of endovascular closure of perimembranous VSDs appear 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 VSDs 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 (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.

In late October 2016, the FDA granted approval through the PMA process for the AMPLATZER PFO Occluder. The device is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. FDA approval was based on results of the RESPECT trial.

The RESPECT trial was a prospective, multi-center, randomized (1:1), event-driven, unblinded clinical study designed to evaluate whether PFO closure with the AMPLATZER PFO Occluder is superior to standard of care medical management (MM) in reducing the risk of recurrent embolic stroke. Patients were enrolled at 69 investigational sites between August 23, 2003 and December 28, 2011. A total of 980 subjects between 18 and 60 years of age were randomized to PFO Closure (N=499) or MM (N=481). The newest study results further extended follow-up, analyzing data from August 2003 through May 2016 for outcomes of recurrent ischemic strokes and recurrent ischemic strokes of unknown mechanism. The mean follow-up was 6.3 years for the PFO group and 5.5 years for the MM group [total patient years: 3,141 (PFO) and 2,669 (MM)]. Key findings showed that in the intention-to-treat cohort, there was a 45% relative risk reduction [HR 0.55 (95% CI: 0.305, 0.999) Log-rank 2-sided P-value: 0.046] in recurrent ischemic stroke for the PFO group and a 62% risk reduction [HR 0.38 (95% CI: 0.18, 0.79) Log-rank 2-sided P-value: 0.007] from recurrent ischemic stroke of unknown mechanism. An additional sensitivity analysis of all-cause stroke in patients under age 60 showed a 58% relative risk reduction [HR 0.42 (95% CI: 0.21, 0.83) Log-rank 2-sided P-value=0.010).

Although the difference in the rate of recurrent ischemic stroke was lower in the PFO group versus the MM group in the ITT population (the pre-specified primary analysis cohort), the difference did not achieve statistical significance. The safety evaluation performed during the RESPECT study showed an acceptable rate of adverse events. The risk of device- or implantation procedure-related serious adverse events (SAEs) in patients undergoing an AMPLATZER PFO Occluder implantation procedure was 4.2% in the PFO group in the RESPECT trial. There was no device- or implantation procedure-related deaths. However, it should be noted that the PFO group experienced a numerically higher rate of atrial fibrillation, deep venous thrombosis, and pulmonary embolism, compared to the MM group.

An updated practice parameter from the American Academy of Neurology for patients with stroke and patent foramen ovale, based on a systematic review of the current literature, was published in August 2016 by Messe, *et al*. They found that percutaneous PFO closure with the STARFlex device possibly does not provide a benefit in preventing stroke versus medical therapy alone (risk difference [RD] 0.13%, 95% confidence interval [CI] -2.2% to 2.0%). Percutaneous PFO closure with the AMPLATZER PFO Occluder possibly decreases the risk of recurrent stroke (RD -1.68%, 95% CI -3.18% to -0.19%), possibly increases the risk of new-onset atrial fibrillation (AF) (RD 1.64%, 95% CI 0.07%-3.2%), and is highly likely to be associated with a procedural complication risk of 3.4% (95% CI 2.3%-5%). The investigators concluded that there is insufficient evidence to determine the efficacy of anticoagulation compared with antiplatelet therapy in preventing recurrent stroke (RD 2%, 95% CI -21% to 25%). Their recommendation is as follows: Clinicians should not routinely offer percutaneous PFO closure to patients with cryptogenic ischemic stroke outside of a research setting (Level R). In rare circumstances, such as recurrent strokes despite adequate medical therapy with no other mechanism identified, clinicians may offer the AMPLATZER PFO Occluder if it is available (Level C). In the absence of another indication for anticoagulation, clinicians may routinely offer antiplatelet medications instead of anticoagulation to patients with cryptogenic stroke and PFO (Level C).

Updated recommendations were offered in the Guidelines for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association in 2014. The update includes the following changes: For patients with a cryptogenic ischemic stroke or TIA and a PFO without evidence for DVT, available data do not support a benefit for PFO closure (Class III; Level of Evidence A). In the setting of PFO and DVT, PFO closure by a transcatheter device might be considered, depending on the risk of recurrent DVT (Class IIb; Level of Evidence C).

Literature investigating PFO closure as a treatment of migraine headache consists mainly of small studies that lack long-term data on effectiveness and safety. The authors of the publication of the MIST trial (Dowson, *et al*. 2008), a prospective, multi-center, 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. They also reported no difference in the primary end point of the number of patients with no migraine attacks between 91- and 180-days post-procedure. 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.

In 2018, U.S. Food and Drug Administration (FDA) approved an expanded indication for the Gore Cardioform Septal Occluder. The expanded FDA indication was supported by the REDUCE Study, the first and only study to demonstrate that closure of PFO can significantly prevent recurrent ischemic strokes, regardless of PFO anatomy. The REDUCE Study is the only PFO U.S. IDE study to meet its primary endpoint in the primary intent-to-treat analysis. Results showed a statistically significant, 77 percent, reduction in recurrent ischemic stroke in patients who underwent PFO closure with a Gore device in conjunction with antiplatelet therapy, versus those who underwent antiplatelet therapy alone, after an average of 3.4 years of follow-up. The study also met its other primary endpoint of reduction of new brain infarct, inclusive of clinically evident and clinically silent brain infarct, through PFO closure, yielding a 49 percent relative risk reduction.

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 Codes

Code	Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant
93581	Percutaneous transcatheter closure of a congenital ventricular septal defect with implant
93582	Percutaneous transcatheter closure of patent ductus arteriosus

HCPCS Codes

Code	Description
C1760	Closure device, vascular (implantable/insertable)
C1817	Septal defect implant system, intracardiac

ICD10 Codes

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

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*Key Article

KEY WORDS

Atrial Septal Defect, Congenital Septal Defect, Patent Foramen Ovale, Patent Ductus Arteriosus, Ventricular Septal Defect.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, transcatheter closure devices for atrial or ventricular septal defects, patent ductus arteriosus, or patent foramen ovale are not addressed in National or Regional Medicare coverage determinations or policies.