

# 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	11/16/00
Committee Approval Date	12/21/00, 02/21/02, 05/21/03, 07/15/04, 06/16/05, 08/17/06, 07/19/07, 10/23/08, 08/20/09, 10/28/10, 10/20/11, 10/18/12, 01/16/14, 01/22/15, 07/15/21, 07/21/22, 07/20/23
Current Effective Date	07/20/23
Archived Date	07/20/23
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• 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.</li> <li>• 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.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## 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.

## **Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS**

**Policy Number: 7.01.34**

**Page: 2 of 10**

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

## **Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS**

**Policy Number: 7.01.34**

**Page: 3 of 10**

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-

## **Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS**

**Policy Number: 7.01.34**

**Page: 4 of 10**

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,

## Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS

Policy Number: 7.01.34

Page: 5 of 10

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

Copyright © 2023 American Medical Association, Chicago, IL

#### 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

### REFERENCES

\*Abaci A, et al. Short and long term complications of device closure of atrial septal defect and patent foramen ovale: meta-analysis of 28,142 patients from 203 studies. Catheter Cardiovasc Interv 2013 Dec 1;82(7):1123-38.

\*Agarwal S, et al. Meta-analysis of transcatheter closure versus medical therapy for patent foramen ovale in prevention of recurrent neurological events after presumed paradoxical embolism. JACC Cardiovasc Interv 2012 Jul;5(7):777-89.

Agasthi P, et al. Are we there yet with patent foramen ovale closure for secondary prevention in cryptogenic stroke? A systematic review and meta-analysis of randomized trials. SAGE Open Medicine 2019 Jan;7:1-15.

\*Bartakian S, et al. Device closure of secundum atrial septal defects in children < 15 kg: complication rates and indications for referral. JACC Cardiovasc Interv 2012 Nov;5(11):1178-84.

Ben-Assa E, et al. Effect of residual interatrial shunt on migraine burden after transcatheter closure of patent foramen ovale. JACC Cardiovasc Interv 2020 Feb 10;13(3):293-302.

\*Bhindi R, et al. Acute worsening in migraine symptoms following PFO closure: a matter of fact? Int J Cardiol 2010 Oct 8;144(2):299-300.

\*Bialkowski J, et al. Closure of atrial septal defects in children: surgery versus Amplatzer device implantation. Tex Heart Inst J 2004;31(3):220-3.

## **Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS**

**Policy Number: 7.01.34**

**Page: 6 of 10**

- \*Biasco L, et al. Impact of transcatheter closure of patent foramen ovale in the evolution of migraine and role of residual shunt. J Cardiol 2014 Nov;64(5):390-4.
- Bradley EA, Zaidi AN. Atrial Septal Defect. Cardiol Clin 2020 Aug;38(3):317-324.
- \*Butera G, et al. CardioSEAL/STARflex versus Amplatzer devices for percutaneous closure of small to moderate (up to 18 mm) atrial septal defects. Am Heart J 2004 Sep;148(3):507-10.
- \*Butera G, et al. Percutaneous versus surgical closure of secundum atrial septal defects: a systematic review and meta-analysis of currently available clinical evidence. Eurointervention 2011 Jul;7(3):377-85.
- \*Capodanno D, et al. Updating the evidence on patent foramen ovale closure versus medical therapy in patients with cryptogenic stroke: a systematic review and comprehensive meta-analysis of 2,303 patients from three randomized trials and 2,231 patients from 11 observational studies. Eurointervention 2014 Mar 20;9(11):1342-9.
- \*Carroll JD, et al. Closure of patent foramen ovale versus medical therapy after cryptogenic stroke. New Engl J Med 2013;368(12):1092-100.
- \*Chen H, et al. Comparison of long-term clinical outcomes and costs between video-assisted thoracoscopic surgery and transcatheter amplatzer occlusion of the patent ductus arteriosus. Pediatr Cardiol 2012 Feb;33(2):316-21.
- \*Chen L, et al. A systematic review of closure versus medical therapy for preventing recurrent stroke in patients with patent foramen ovale and cryptogenic stroke or transient ischemic attack. J Neurol Sci 2014 Feb 15;337(1-2):3-7.
- Dahal K, et al. Who benefits from percutaneous closure of patent foramen ovale vs medical therapy for stroke prevention? In-depth and updated meta-analysis of randomized trials. World J Cardiol 2019 April 26; 11(4): 126-136.
- \*Darsaklis K, et al. A novel system for transcatheter closure of patent foramen ovale: clinical and echocardiographic outcome comparison with other contemporary devices. Can J Cardiol 2014 Jun;30(6):639-46.
- \*Diveka A, et al. Cardiac perforation after device closure of atrial septal defects with the Amplatzer septal occluder. J Am Coll Cardiol 2005 Apr 19;45(8):1213-8.
- \*Dua JS, et al. Transcatheter closure of postsurgical residual ventricular septal defects: Early and mid-term results. Catheter Cardiovasc Interv 2010 Feb 1;75(2):246-55.
- Fleming GR, et al. Comparison of residual shunt rate and complications across 6 different closure devices for patent foramen ovale. Catheter Cardiovasc Interv 2020 Feb 15;95(3):365-372.
- \*Food and Drug Administration. Safety and effectiveness data Amplatzer PFO Occluder. [[https://www.accessdata.fda.gov/cdrh\\_docs/pdf12/P120021b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120021b.pdf)]. accessed 06/27/23.
- \*Ford MA, et al. Percutaneous device closure of patent foramen ovale in patients with presumed cryptogenic stroke or transient ischemic attack: the Mayo Clinic experience. JACC Cardiovasc Interv 2009 May;2(5):404-11.
- \*Furlan AJ, et al. Study design of the CLOSURE I Trial: a prospective, multicenter, randomized, controlled trial to evaluate the safety and efficacy of the STARFlex septal closure system versus best medical therapy in patients with stroke or transient ischemic attack due to presumed paradoxical embolism through a patent foramen ovale. Stroke 2010 Dec;41(12):2872-83.
- \*Furlan AJ, et al. Closure or medical therapy for cryptogenic stroke with patent foramen ovale. N Engl J Med 2012 Mar 15;366(11):991-9.
- \*Guo JJ, et al. Long-term outcomes of device closure of very large secundum atrial septal defects: a comparison of transcatheter vs intraoperative approaches. Clin Cardiol 2012 Oct;36(10):626-31.
- \*Hakeem A, et al. safety and efficacy of device closure for patent foramen ovale for secondary prevention of neurological events: Comprehensive systematic review and meta-analysis of randomized controlled trials. Cardiovasc Revasc Med 2013 Nov-Dec;14(6):349-55.

## **Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS**

**Policy Number: 7.01.34**

**Page: 7 of 10**

He YD, et al. Transcatheter patent foramen ovale closure is effective in alleviating migraine in a 5-year follow-up. Front Neurol 2019 Nov;10:1224.

\*Hongxin L, et al. New minimally invasive technique of peripulmonary device closure of patent ductus arteriosus through a parasternal approach. Ann Thorac Surg 2012 Mar;93(3):862-8.

\*Inglessis I, et al. Long-term experience and outcomes with transcatheter closure of patent foramen ovale. JACC Cardiovasc Interv 2013 Nov;6(11):1176-83.

\*Jarral OA, et al. Does patent foramen ovale closure have an antiarrhythmic effect? A meta-analysis. Int J Cardiol 2011 Nov 17;153(1):4-9.

\*Javois AJ, et al. Results of the U.S. Food and Drug Administration continued access clinical trial of the GORE HELEX septal occluder for secundum atrial septal defect. JACC Cardiovasc Interv 2014 Aug;7(8):905-12.

\*Kaya MG, et al. Intermediate-term effects of transcatheter secundum atrial septal defect closure on cardiac remodeling in children and adults. Pediatr Cardiol 2010 May;31(4):474-82.

\*Khan AR, et al. Device closure of patent foramen ovale versus medical therapy in cryptogenic stroke: a systematic review and meta-analysis. JACC Cardiovasc Interv 2014 Dec;6(12):1316-23.

\*Kitsios GD, et al. Patent foramen ovale closure and medical treatments for secondary stroke prevention: a systematic review of observational and randomized evidence. Stroke 2012 Feb;43(2):422-31.

\*Kitsios GD, et al. Potentially large yet uncertain benefits: A meta-analysis of patent foramen ovale closure trials. Stroke 2013;44(9):2640-3.

Kleindorfer DO, et al. 2021 Guideline for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack A Guideline from the American Heart Association/American Stroke Association

\*Knepp MD, et al. Long-term follow-up of secundum atrial defect closure with the Amplatzer septal occluder. Congenit Heart Dis 2010 Jan;5(1):32-7.

\*Kretschmar O, et al. Interventional closure of atrial septal defects with the Solysafe Septal Occluder—preliminary results in children. Int J Cardiol 2010 Sep 3;143(3):373-7.

\*Kwong JS, et al. Percutaneous closure of patent foramen ovale for cryptogenic stroke: a meta-analysis of randomized controlled trials. Int J Cardiol 2013 Oct 9;168(4):4132-8.

Lee P, et al. Cryptogenic Stroke and High-Risk Patent Foramen Ovale. JACC Cardiovasc Interv 2018 May;71(20):2335-42.

Li D, et al. Comparisons of perventricular device closure, conventional surgical repair, and transcatheter device closure in patients with perimembranous ventricular septal defects: a network meta-analysis. BMC Surgery 2020;20:115.

Liao ZM, et al. Long-term outcomes after conventional surgical repair versus perventricular device occlusion for doubly committed subarterial ventricular septal defects: a propensity score matched study. Eur J CardioThorac Surg 2020;57:929–936.

\*Mas JL, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. N Engl J Med 2017 Sep 14;377(11):1011-1021.

\*Meier B, et al. Percutaneous closure of patent foramen ovale in cryptogenic embolism. New Eng J Med 2013;368(12):1083-91.

Merkler AE, et al. Safety outcomes after percutaneous transcatheter closure of patent foramen ovale. Stroke 2017 Nov;48(11):3073-3077.

\*Messe SR, et al. Practice parameter: recurrent stroke with patent foramen ovale and atrial septal aneurysm: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurol 2004 Apr 13;62(7):1042-50.

## Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS

Policy Number: 7.01.34

Page: 8 of 10

Mojadidi MK, et al. Pooled analysis of PFO occluder device trials in patients with PFO and migraine. J of Amer Col of Cardiol 2021;77(6):667-676.

\*Nagaraja V, et al. Is transcatheter closure better than medical therapy for cryptogenic stroke with patent foramen ovale? A meta-analysis of randomized trials. Heart Lung Circ 2013 Nov;22(11):903-9.

\*National Institute for Clinical Excellence (NICE). Endovascular closure of atrial septal defect. Interventional Procedure Consultation Document. London, UK: NICE; 2004 Jun [<http://www.nice.org.uk/guidance/IPG96>] accessed 06/27/23.

\*National Institute for Clinical Excellence (NICE). Percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke. London, UK. NICE: 2013 Dec [<https://www.nice.org.uk/Guidance/ipg472>] accessed 06/27/23.

\*National Institute for Health and Clinical Excellence (NICE). Transcatheter endovascular closure of perimembranous ventricular septal defect. London, UK. NICE: 2010 Mar [<https://www.nice.org.uk/guidance/ipg336>] accessed 06/27/23.

\*National Institute for Clinical Excellence (NICE). Percutaneous closure of patent foramen ovale for recurrent migraine. London, UK. NICE: 2010 Dec [<https://www.nice.org.uk/guidance/ipg370>] accessed 06/27/23.

Ng LY., et al. Hybrid subxiphoid periventricular approach as an alternative access in neonates and small children undergoing complex congenital heart interventions. Pediatr Cardiol 2021 42, 526–532.

\*Ntaios G, et al. PFO closure vs medical therapy in cryptogenic stroke or transient ischemic attack: a systematic review and meta-analysis. Int J Cardiol 2013 Oct 30;169(2):101-5.

\*Paciaroni M, et al. Risk of recurrent cerebrovascular events in patients with cryptogenic stroke or transient ischemic attack and patent foramen ovale: the FORI (Foramen Ovale Registro Italiano) study. Cerebrovasc Dis 2011;31(2):109-16.

\*Pandit A, et al. Amplatzer PFO occluder device may prevent recurrent stroke in patients with patent foramen ovale and cryptogenic stroke: a meta-analysis of randomized trials. Heart Lung Circ 2014 Apr;23(4):303-8.

\*Pickett CC, et al. percutaneous closure versus medical therapy alone for cryptogenic stroke patients with a patent foramen ovale: meta-analysis of randomized controlled trials. Tex Heart Inst J 2014 Aug 1;41(4):357-67.

\*Pineda AM, et al. A meta-analysis of transcatheter closure of patent foramen ovale versus medical therapy for prevention of recurrent thromboembolic events in patients with cryptogenic cerebrovascular events. Catheter Cardiovasc Interv 2013 Nov 15;82(6):968-75.

Price MJ. Transcatheter closure of patent foramen ovale: devices and technique. Interv Cardiol Clin 2017 Oct;6(4):555-567.

\*Rengifo-Moreno P, et al. Patent foramen ovale transcatheter closure vs. medical therapy on recurrent vascular events: a systematic review and meta-analysis of randomized controlled trials. Eur Heart J 2013 Nov;34(43):3342-3352.

\*Rhodes JF Jr, et al. Combined prospective United States clinical study data for the GORE® HELEX® septal occlude device. Catheter Cardiovasc Interv 2014 May 1;83(6):944-52.

\*Rigatelli G, et al. Transcatheter patent foramen ovale closure is effective in reducing migraine independently from specific interatrial septum anatomy and closure devices design. Cardiovasc Revasc Med 2010 Jan-Mar;11(1):29-33.

\*Rigatelli G, et al. Five-year follow-up of intracardiac echocardiography-assisted transcatheter closure of complex ostium secundum atrial septal defect. Congenit Heart Dis 2012 Mar-Apr;7(2):103-10.

Rigatelli G, et al. Clinically apparent long-term electric disturbances in the acute and very long-term of patent foramen ovale device-based closure. Cardiovasc Revasc Med 2017 Mar;18(2):118-122.

\*Saliba Z, et al. The Amplatzer duct occluder II: a new device for percutaneous ductus arteriosus closure. J Interv Cardiol 2009 Dec;22(6):446-502.

\*Saver JL, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. N Engl J Med 2017 Sep 14;377(11):1022-1032.



## Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS

Policy Number: 7.01.34

Page: 9 of 10

- \*Smith B, et al. UK multicenter experience using the Gore septal occluder (GSO™) for atrial septal defect closure in children and adults. Catheter Cardiovasc Interv 2014 Mar 1;83(4):581-6.
- \*Snijder RJ, et al. Percutaneous closure of secundum type atrial septal defects: More than 5-year follow-up. World J Cardiol 2015 Mar 26;7(3):150-6.
- \*Sondergaard L, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. N Engl J Med 2017 Sep 14;377(11):1033-1042.
- \*Staubach S, et al. New onset atrial fibrillation after patent foramen ovale closure. Catheter Cardiovasc Interv 2009 Nov 15;74(6):889-95.
- \*Suchon E, et al. Transcatheter closure as an alternative and equivalent method to the surgical treatment of atrial septal defect in adults: comparison of early and late results. Med Sci Monit 2009 Dec;15(12):CR612-7.
- \*Thomson JD, et al. Patent foramen ovale closure with the Gore septal occlude: initial UK experience. Catheter Cardiovasc Interv 2014 Feb 15;83(3):467-73.
- \*Trabattoni D, et al. Sustained long-term benefit of patent foramen ovale closure on migraine. Catheter Cardiovasc Interv 2011 Mar 1;77(4):570-4.
- \*Turc G, et al. Closure, anticoagulation, or antiplatelet therapy for cryptogenic stroke with patent foramen ovale: systematic review of randomized trials, sequential meta-analysis, and new insights from the CLOSE study. J Am Heart Assoc 2018;7:e008356.
- \*Udell JA, et al. Patent foramen ovale closure vs medical therapy for stroke prevention: meta-analysis of randomized trials and review of heterogeneity in meta-analyses. Can J Cardiol 2014 Oct;30(10):1216-24.
- 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. [<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/ucm135747.htm>] accessed 06/27/23.
- \*U. S. Food and Drug Administration (FDA) Center for Devices and Radiological Health Information on Premarket Approval Applications Gore HELEX® Septal Occluder - P050006 August 11, 2006 HELEX [[https://www.accessdata.fda.gov/cdrh\\_docs/pdf5/p050006b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf5/p050006b.pdf)] accessed 06/27/23.
- \*Van den Branden BJ, et al. Patent foramen ovale closure using a bioabsorbable closure device: safety and efficacy at 6-month follow-up. JACC Cardiovasc Interv 2010 Sep;3(9):968-73.
- \*Van den Branden BJ, et al. The BioSTAR® device versus CardioSEAL® device in patent foramen ovale closure: comparison of mid-term efficacy and safety. Eurointervention 2010 Sep;6(4):498-504.
- \*Van Den Branden BJ, et al. percutaneous atrial shunt closure using novel Occlutech Figulla device: 6-month efficacy and safety. J Interv Cardiol 2011 Jun;24(3):264-70.
- \*Vecht JA, et al. Atrial septal defect closure is associated with a reduced prevalence of atrial tachyarrhythmia in the short to medium term: a systematic review and meta-analysis. Heart 2010 Nov;96(22):1789-97.
- \*Vijarnsorn C, et al. Transcatheter closure of atrial septal defects in children, middle-aged adults, and older adults: failure rates, early complications; and balloon sizing effects. Cardiol Res Pract 2012;2012:584236.
- Vishwanath V, et al. Comparative effectiveness of devices for transcatheter closure of atrial septal defects: Systematic review and network meta-analysis. Arch Cardiovasc Dis 2022 Dec;115(12):664-674.
- \*Von Bardleben RS, et al. Long term follow-up after percutaneous closure of PFO in 357 patients in paradoxical embolism: Difference in occlusion systems and influence of atrial septum aneurysm. Int J Cardiol 2009 May 1;134(1):33-41.

## **Medical Policy: TRANSCATHETER CLOSURE DEVICES FOR CARDIAC DEFECTS AND PATENT DUCTUS ARTERIOSUS**

**Policy Number: 7.01.34**

**Page: 10 of 10**

\*Wahl A, et al. Percutaneous closure of patent foramen ovale for migraine headaches refractory to medical treatment. Catheter Cardiovasc Interv 2009 Jul 1;74(1):124-9.

\*Wahl A, et al. Long-term propensity score-matched comparison of percutaneous closure of patent foramen ovale with medical treatment after paradoxical embolism. Circulation 2012 Feb 14;125(6):803-12.

\*Wallenborn J, et al. Recurrent events after percutaneous closure of patent foramen ovale. Catheter Cardiovasc Interv 2013 Oct 1;84(4):541-6.

\*Walters DL, et al. Percutaneous ASD closure in a large Australian series: short- and long-term outcomes. Heart Lung Circ 2012 Sep;21(9):572-5.

\*Wang JK, et al. Transcatheter closure of moderate-to-large patent ductus arteriosus in infants using Amplatzer duct occluder. Circ J 2010 Feb;74(2):361-4.

\*Warnes CA, et al. ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease: Executive Summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines for the management of adults with congenital heart disease). Circulation 2008 Dec 2;118(23):2395-451.

Zhang Y, et al. Patent foramen ovale closure for treating migraine: a meta-analysis. J Interv Cardiol 2022 Feb;2022.

\*Zhu D, et al. Periventricular device closure of residual muscular ventricular septal defects after repair of complex congenital heart defects in pediatric patients. Tex Heart Inst J 2013;40(5):534-40.

\*Zuo J, et al. Results of transcatheter closure of perimembranous ventricular septal defect. Am J Cardiol 2010 Oct 1;106(7):1034-7.

\*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.