# Protocol

# Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

(20209)

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| **Medical Benefit** | | **Effective Date**: 10/01/19 | **Next Review Date**: 07/23 |
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***Preauthorization is not required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.*

## RELATED PROTOCOL

None

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals:<br>• With patent foramen ovale and cryptogenic stroke | Interventions of interest are:<br>• Patent foramen ovale closure with a trans-catheter device | Comparators of interest are:<br>• Medical management | Relevant outcomes include:<br>• Overall survival<br>• Morbid events<br>• Treatment-related mortality<br>• Treatment-related morbidity |
| Individuals:<br>• With patent foramen ovale and migraine | Interventions of interest are:<br>• Patent foramen ovale closure with a trans-catheter device | Comparators of interest are:<br>• Medical management | Relevant outcomes include:<br>• Symptoms<br>• Quality of life<br>• Medication use<br>• Treatment-related mortality<br>• Treatment-related morbidity |
| Individuals:<br>• With patent foramen ovale and conditions associated with patent foramen ovale other than cryptogenic stroke or migraine | Interventions of interest are:<br>• Patent foramen ovale closure with a trans-catheter device | Comparators of interest are:<br>• Usual care | Relevant outcomes include:<br>• Symptoms<br>• Change in disease status<br>• Morbid events<br>• Treatment-related mortality<br>• Treatment-related morbidity |
| Individuals:<br>• With atrial septal defect and evidence of left-to-right shunt or right ventricular overload | Interventions of interest are:<br>• Atrial septal defect closure with a trans-catheter device | Comparators of interest are:<br>• Surgical atrial septal defect repair | Relevant outcomes include:<br>• Symptoms<br>• Change in disease status<br>• Treatment-related mortality<br>• Treatment-related morbidity |

## DESCRIPTION

Patent foramen ovale (PFO) and atrial septal defects (ASDs) are relatively common congenital heart defects that can be associated with a range of symptoms. PFOs may be asymptomatic but have been associated with higher

rates of cryptogenic stroke. PFOs have also been investigated for a variety of other conditions, such as a migraine. Depending on their size, ASDs may lead to left-to-right shunting and signs and symptoms of pulmonary overload. Repair of ASDs is indicated for patients with a significant degree of left-to-right shunting. Transcatheter closure devices have been developed to repair PFO and ASDs. These devices are alternatives to open surgical repair for ASDs or treatment with antiplatelet and/or anticoagulant medications in patients with cryptogenic stroke and PFO.

**SUMMARY OF EVIDENCE**

For individuals who have PFO and cryptogenic stroke who receive PFO closure with a transcatheter device, the evidence includes multiple randomized controlled trials (RCTs) comparing device-based PFO closure with medical therapy, systematic reviews, meta-analyses, and observational studies. Relevant outcomes are symptoms, change in disease status, overall survival, morbid events, and treatment-related morbidity and mortality. The RCTs comparing PFO closure with medical management have suggested that PFO closure is more effective than medical therapy in reducing event rates. Although these results were not statistically significant by intention-to-treat analyses in earlier trials [i.e., Amplatzer PFO Occluder with Medical Treatment in Patients with Cryptogenic Embolism (PC-Trial) and Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment (RESPECT; initial study)], they were statistically significant in later trials [i.e., RESPECT (extended follow-up), Reduction in the Use of Corticosteroids in Exacerbated COPD (REDUCE), and Patent Foramen Ovale Closure or Anticoagulants versus Antiplatelet Therapy to Prevent Stroke Recurrence (CLOSE)]. Use of appropriate patient selection criteria to eliminate other causes of cryptogenic stroke in RESPECT, REDUCE, and CLOSE trials contributed to findings of the superiority of PFO closure compared with medical management. Of note, higher rates of atrial fibrillation were reported in a few of the individual trials and in the meta-analysis that incorporated evidence from RESPECT, REDUCE, and CLOSE trials. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have PFO and migraine who receive PFO closure with a transcatheter device, the evidence includes RCTs of PFO closure and multiple observational studies reporting on the association between PFO and migraine. Relevant outcomes are symptoms, quality of life, medication use, and treatment-related morbidity and mortality. The available sham-controlled randomized trial did not demonstrate significant improvements in migraine symptoms after PFO closure. A second RCT with blinded endpoint evaluation did not demonstrate reductions in migraine days after PFO closure but likely was underpowered. Nonrandomized studies have shown highly variable rates of migraine reduction after PFO closure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have PFO and conditions associated with PFO other than cryptogenic stroke or migraine (e.g., platypnea-orthodeoxia syndrome, myocardial infarction with normal coronary arteries, decompression illness, high-altitude pulmonary edema, obstructive sleep apnea) who receive PFO closure with a transcatheter device, the evidence includes small case series and case reports. Relevant outcomes are symptoms, change in disease status, morbid events, and treatment-related morbidity and mortality. The body of evidence only consists of small case series and case reports. Comparative studies are needed to evaluate outcomes in similar patient groups treated with and without PFO closure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have ASD and evidence of left-to-right shunt or right ventricular overload who receive ASD closure with a transcatheter device, the evidence includes nonrandomized comparative studies and single-arm studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity and mortality. The available nonrandomized comparative studies and single-arm case series have shown rates of closure using transcatheter-based devices approaching the high success rates of surgery, which are supported by meta-analyses of these studies. The percutaneous approach has a low complication rate and avoids the morbidity and

complications of open surgery. If the percutaneous approach is unsuccessful, ASD closure can be achieved using surgery. Because of the benefits of percutaneous closure over open surgery, it can be determined that transcatheter ASD closure improves outcomes in patients with an indication for ASD closure. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

**POLICY**

The percutaneous transcatheter closure of a patent foramen ovale using a device that has been approved by the U.S. Food and Drug Administration for that purpose may be considered **medically necessar**y to reduce the risk of recurrent ischemic stroke if the patient meets all of the following:

- Between 18 and 60 years of age
- Diagnosed with patent foramen ovale with a right-to-left interatrial shunt confirmed by echocardiography with at least one of the following characteristics:
    - PFO with large shunt, defined as >30 microbubbles in the left atrium within three cardiac cycles, after opacification of the right atrium
    - PFO associated with atrial septal aneurysm on transesophageal examination: septum primum excursion >10 mm
- Documented history of cryptogenic ischemic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude any other identifiable cause of stroke, including large vessel atherosclerotic disease and small vessel occlusive disease

AND none of the following are present:

- Uncontrolled vascular risk factors, including uncontrolled diabetes or uncontrolled hypertension
- Other sources of right-to-left shunts, including an atrial septal defect and/or fenestrated septum
- Active endocarditis or other untreated infections
- Inferior vena cava filter.

Transcatheter closure of secundum atrial septal defects may be considered **medically necessary** when using a device that has been approved by the U.S. Food and Drug Administration for that purpose and used according to the labeled indications including:

- Patients with echocardiographic evidence of ostium secundum atrial septal defect;

AND either of the following

- Clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left-to-right shunt or right ventricular enlargement); OR
- Clinical evidence of paradoxical embolism.

Transcatheter closure of secundum atrial septal defects is considered **investigational** for all other indications not meeting criteria outlined above.

**POLICY GUIDELINES**

Two devices approved by the U.S. Food and Drug Administration (FDA) for patent foramen ovale closure and

ASD closure are currently marketed: the Amplatzer™ Septal Occluder and the GORE CARDIOFORM Septal Occluder. The GORE HELEX Septal Occluder has been discontinued.

**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. Before birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over the course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale (PFO) is a common finding in 25% of asymptomatic adults.[1] In some epidemiologic studies, PFO has been associated with cryptogenic stroke, defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources. Studies have also shown an association between PFO and migraine headache.

ATRIAL SEPTAL DEFECTS

Unlike PFO, which represents the postnatal 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 by their anatomy. Ostium secundum describes defects located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and are within the spectrum of atrioventricular septal defects. Primum defects occur commonly in patients with Down syndrome. Sinus venous defects occur high in the atrial septum and are frequently associated with anomalies of the pulmonary veins.

Ostium secundum ASDs are the third most common form of congenital heart disorder and among the most common congenital cardiac malformations in adults, accounting for 30% to 40% of these patients older than age 40 years. 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. Symptoms related to ASD depend on the size of the defect and the relative diastolic filling properties of the left and right ventricles. Reduced left ventricular compliance, and mitral stenosis will increase left-to-right shunting across the defect. Conditions that reduce right ventricular compliance and tricuspid stenosis will reduce left-to-right shunting or cause a right-to-left shunt. Symptoms of an ASD include exercise intolerance and dyspnea, atrial fibrillation, and less commonly, signs of right heart failure. Patients with ASDs are also at risk for paradoxical emboli.

Treatment of Atrial Septal Defects

Repair of ASDs is recommended for those with a pulmonary-to-systemic flow ratio ($Q_p$:$Q_s$) exceeding 1.5:1.0. Despite the success of surgical repair, there has been interest in developing a transcatheter-based approach to ASD repair to avoid the risks and morbidity of open heart surgery. A variety of devices have been researched. Technical challenges include minimizing the size of the device so that smaller catheters can be used, developing techniques to center the device properly across the ASD, and ensuring that the device can be easily retrieved or repositioned, if necessary.

Individuals with ASDs and a history of cryptogenic stroke are typically treated with antiplatelet agents, given an absence of evidence that systemic anticoagulation is associated with outcome improvements.

Transcatheter Closure Devices

Transcatheter PFO and ASD occluders consist of a single or paired wire mesh discs covered or filled with polyester or polymer fabric that are placed over the septal defect. Over time, the occlusion system is epithelialized. ASD occluder devices consist of flexible mesh discs delivered via catheter to cover the ASD.

## REGULATORY STATUS

PATENT FORAMEN OVALE CLOSURE DEVICES

The U.S. Food and Drug Administration (FDA) has approved 2 devices for PFO closure through the premarket approval process or a premarket approval supplement: the Amplatzer PFO Occluder and the GORE CARDIOFORM Septal Occluder (see Table 1). FDA product code: MLV.

In 2002, 2 transcatheter devices were cleared for marketing by the FDA through a humanitarian device exemption as treatment for patients with cryptogenic stroke and PFO: the CardioSEAL® Septal Occlusion System (NMT Medical; device no longer commercially available) and the Amplatzer PFO Occluder (Amplatzer, now St. Jude Medical). Following the limited FDA approval, use of PFO closure devices increased by more than 50-fold, well in excess of the 4000 per year threshold intended under the humanitarian device exemption,[2] prompting the FDA to withdraw the humanitarian device exemption approval for these devices in 2007. The Amplatzer PFO Occluder was approved through the premarket approval process in 2016.

In March 2018, the FDA granted an expanded indication to the Gore Cardioform Septal Occluder to include closure of PFO to reduce the risk of recurrent stroke (see Table 1). The new indication was based on results of the REDUCE pivotal clinical trial.[3]

Table 1. Patent Foramen Ovale Closure Devices Approved by the U.S. Food and Drug Administration

| Device | Manufacturer | PMA Approval Date | Indications |
|---|---|---|---|
| Amplatzer™ PFO Occluder | St. Jude Medical | Nov 2016 | 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.[4] |
| GORE HELEX Septal Occluder | W.L. Gore & Associates | Aug 2006 (discontinued) | Percutaneous, transcatheter closure of ostium secundum ASDs |
| GORE CARDIOFORM Septal Occluder | W.L. Gore & Associates | Mar 2018 (supplement) | PFO closure 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 |

PFO: patent foramen ovale; PMA: premarket approval. FDA product code: MLV.

ATRIAL SEPTAL DEFECT CLOSURE DEVICES

The FDA has approved 4 devices for ASD closure through the premarket approval process or a premarket approval supplement: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), GORE CARDIOFORM ASD Occluder, and the GORE CARDIOFORM Septal Occluder (see Table 2).

FDA product code: MLV.

Table 2. Atrial Septal Defect Closure Devices Approved by the U.S. Food and Drug Administration

| Device | Manufacturer | PMA Approval Date | Indications |
|---|---|---|---|
| Amplatzer™ Septal Occluder | St. Jude Medical (Abbot Medical) | Dec 2001 | • Occlusion of ASDs in the secundum position<br>• Use in patients who have had a fenestrated Fontan procedure who require closure of the fenestration<br>• Patients indicated for ASD closure have echocardiographic evidence of ostium secundum ASD and clinical evidence of right ventricular volume overload. |
| GORE HELEX Septal Occluder | W.L. Gore & Associates | Aug 2006 (discontinued) | • Percutaneous, transcatheter closure of ostium secundum ASDs |
| GORE CARDIOFORM ASD Occluder (formerly GORE CARDIOFORM Septal Occluder) | W.L. Gore & Associates | May 2019 (supplement; name change) Oct 2016 (supplement) | • Percutaneous, transcatheter closure of ostium secundum ASDs |

ASD: atrial septal defect; PMA: premarket approval. FDA product code: MLV.

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

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