Introduction

The heart’s two upper chambers are called atria. The septum is the thin wall of tissue that separates the atria. Sometimes there may be a congenital heart defect in which there is a hole in the septum between the two atria. This is called an atrial septal defect. Atrial septal defects may not cause any problems and might not even be diagnosed until adulthood. Larger atrial septal defects may cause problems and may need to be closed.

One way to treat an atrial septal defect is to use a catheter. A catheter is a long, thin tube which is threaded through a blood vessel in the groin to the heart. Once the catheter is in the correct location, a small device is put in place to seal the opening between the atria. This policy discusses when a catheter may be considered medically necessary to treat atrial septal defects.

The foramen ovale is an opening in the septum between the two atria that is normally found in a baby before it is born. This opening usually closes soon after birth. If a foramen ovale doesn’t automatically close after the baby is born, it is called a patent foramen ovale (PFO). For most people a patent foramen ovale does not cause problems. In the small subset of people who have had a stroke where the cause is uncertain, using a new device to close the PFO may decrease the risk of a second stroke.
**Policy Coverage Criteria**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcatheter closure of secundum atrial septal defects (ASD)</td>
<td>Transcatheter closure of secundum atrial septal defects may be considered medically necessary in the following setting:</td>
</tr>
<tr>
<td></td>
<td>1. One of the following devices is used:</td>
</tr>
<tr>
<td></td>
<td>o The Amplatzer™ Septal Occluder</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>o The GORE CARDIOFORM Septal Occluder</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>2. Medical records document <strong>BOTH</strong> of the following:</td>
</tr>
<tr>
<td></td>
<td>o An echocardiogram shows evidence of ostium secundum atrial septal defect</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>o There is documentation of right ventricular volume overload (ie, 1.5:1 degree of left-to-right shunt or right ventricular enlargement)</td>
</tr>
<tr>
<td>Closure of patent foramen ovale</td>
<td><strong>Closure of patent foramen ovale using a transcatheter approach is considered medically necessary when:</strong></td>
</tr>
<tr>
<td></td>
<td>1. The Amplatzer PFO Occluder is used</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>2. The patient is between the ages of 18 and 60</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>3. There is a documented history of a cryptogenic stroke, determined by the following:</td>
</tr>
<tr>
<td></td>
<td>o A neurologist and cardiologist agree the stroke is cryptogenic</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>o Evaluation has ruled out other sources of stroke</td>
</tr>
</tbody>
</table>
## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 93580</td>
<td>Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Definition of Terms

**Cryptogenic stroke:** A stroke that happens for an unknown reason after other causes such as cardiac, pulmonary, vascular or neurologic sources have been ruled out.

**Ischemic stroke:** A stroke that happens when a blood vessel that carries blood to the brain is blocked either due to arteries narrowed by atherosclerosis or a blood clot (thrombus).

**Paradoxical embolism (PDE):** This happens when a clot (thrombus) passes through the patent foramen ovale (PFO) in the heart, bypassing the lungs that act as a clot filter.

## Evidence Review

### 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. 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. PFOs may be asymptomatic but have been associated with higher rates of cryptogenic stroke. PFOs have also been investigated in association with a variety of other conditions, such as migraine. Compared to open procedures, transcatheter “closure” devices are less invasive, catheter-based approaches
of repairing PFO or ASDs. These closure devices are also alternatives to treatment with antiplatelet 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, is an opening between the right and left atrium that functions as a vascular bypass of the uninflated lungs. Before birth, the foramen ovale is held open by the relatively higher pressure in the right atrium. 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 PFO is a common finding in up to 25% of normal adults.\(^1\) In some epidemiologic studies, PFOs have been associated with cryptogenic strokes. These strokes are a type of ischemic stroke that occur in the absence of known cardiac, pulmonary, vascular, or neurologic sources. Studies also show an association between PFO and migraine headache. There has been an interest in closing PFOs in patients with a history of cryptogenic stroke to prevent recurrent stroke. This closure could be done either by open surgery or by using a transcatheter approach.

* Atrial Septal Defects

Unlike a PFO that represents the postnatal persistence of normal fetal cardiovascular physiology, ASDs represent an abnormality in the development of the heart that results in open and persistent communication between the atria. There are different types of ASDs depending upon their specific embryologic cause and their location within the septum.

ASDs often go unnoticed for decades because the physical signs are subtle and the clinical sequelae are mild. However, fewer than 50% of patients survive beyond age 40 to 50, and virtually all patients who survive into their sixth decade become symptomatic. Symptoms related to ASD depend on the size of the defect and include exercise intolerance, dyspnea, atrial fibrillation, and, less commonly, signs of right heart failure. Patients with ASDs typically develop heart failure or pulmonary hypertension related to their left-to-right shunt, and they are also at risk for paradoxical emboli.
Treatment

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, but there have been technical challenges. These include minimizing the size of the 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.

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

Several devices have been developed to treat PFO and ASDs via a transcatheter approach, including the CardioSEAL® STARFlex™ Septal Occlusion System, the Amplatzer® PFO Occluder, the Figulla® ASD Occluder (Occlutech GmbH, Jena, Germany), and the CeraFlex™ ASD Occluder (Lifetech Scientific, Shenzhen, China).

Transcatheter PFO and ASD occluders typically consist of single or paired wire mesh, polyester-filled disc that is placed over the septal defect. Over time, the occlusion system is epithelialized. In October of 2016, the FDA approved the Amplatzer® Patent Foramen Ovale Occluder for treatment of patent foramen ovale (PFO). The device is intended to reduce the risk of recurrent ischemic stroke in patients who had previously had a cryptogenic stroke, presumably because of a paradoxical embolism.

FDA approval continues for 2 closure devices for ASD that include the AMPLATZER® Septal Occluder, and the GORE HELEX® Septal Occluder.

Summary of Evidence

For individuals who have atrial septal defect (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 a meaningful improvement in the net health outcome.

For individuals who have patent foramen ovale (PFO) and cryptogenic stroke who undergo PFO closure with a transcatheter device, the evidence includes 3 randomized controlled trials (RCTs) comparing device-based PFO closure with medical therapy, multiple nonrandomized comparative studies, and multiple systematic reviews and meta-analyses of these studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. None of the 3 trials reported statistically significant improvements on their main outcomes using intention-to-treat analysis. In all 3 trials, low numbers of outcome events in both groups limited the power to detect differences between groups. One trial showed a significant benefit for the closure group on per protocol analysis and another showed significant benefit on secondary outcomes. Meta-analyses of these trials have also come to different conclusions, with some reporting statistically significant reductions in recurrent events on pooled analysis and others reporting a trend for benefit that was not statistically significant. A high-quality meta-analysis reported a significantly lower risk of recurrent ischemic stroke with device therapy, but a higher risk of atrial fibrillation. While these results suggest that a benefit might be present, the evidence is not definitive and the risk-benefit ratio of transcatheter PFO closure as an alternative to medical therapy is not well-defined. In general the FDA approved device is considered safe and effective in the population specifically studied, which included only individuals with documented cryptogenic stroke. The FDA has required a post approval follow-up trial to include at least 1200 patients to provide additional evidence to regarding the device in this population.

For individuals who have PFO and migraines who receive PFO closure with a transcatheter device, the evidence includes 2 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 end point evaluation did not demonstrate improvements in migraine days after PFO closure, but likely it was underpowered. Nonrandomized studies have shown highly variable rates of migraine improvement after PFO closure. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have PFO and conditions associated with PFO other than cryptogenic stroke or migraine (eg, 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 the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Clinical Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00738894</td>
<td>GORE® HELEX® Septal Occluder / GORE® Septal Occluder and Antiplatelet Medical Management for Reduction of Recurrent Stroke or Imaging-Confirmed TIA in Patients With Patent Foramen Ovale (PFO)</td>
<td>664</td>
<td>May 2017</td>
</tr>
<tr>
<td>NCT01960491</td>
<td>Prospective Single Center Pilot Clinical Study to Evaluate the Safety and Effectiveness of an Intracardiac Septal Closure Device With Biodegradable Framework in Patients With Clinically Significant Atrial Septum Defect (ASD) or Patent Foramen Ovale (PFO)</td>
<td>15</td>
<td>June 2018</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00355056</td>
<td>Prospective, Randomized Investigation to Evaluate Incidence of Headache Reduction in Subjects With Migraine and PFO Using the AMPLATZER PFO Occluder to Medical Management.</td>
<td>230</td>
<td>Dec 2015 (completed)</td>
</tr>
<tr>
<td>NCT00562289</td>
<td>Closure of Patent Foramen Ovale or Anticoagulants Versus Antiplatelet Therapy to Prevent Stroke Recurrence</td>
<td>664</td>
<td>Dec 2016 (completed)</td>
</tr>
</tbody>
</table>
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 academic medical centers (1 of which provided 2 responses) and no specialty societies while this policy was under review in 2016. Input was mixed about the medical necessity of closure devices for patent foramen ovale (PFO) in patients with cryptogenic stroke or transient ischemic attack due to presumed paradoxical embolism through the PFO. There was consensus that closure devices for PFO in patients with other conditions (eg, migraine, platypnea-orthodeoxia syndrome) are not medically necessary.

Practice Guidelines and Position Statements

The American College of Chest Physicians (ACCP)

In 2012, the American College of Chest Physicians updated its guidelines on antithrombotic therapy and the prevention of thrombosis, which made the following recommendations related to patent foramen ovale (PFO) and cryptogenic stroke:

We suggest that patients with stroke and PFO are treated with antiplatelet therapy following the recommendations for patients with noncardioembolic stroke.... In patients with a history of noncardioembolic ischemic stroke or TIA, we recommend long-term treatment with aspirin (75-100 mg once daily), clopidogrel (75 mg once daily), aspirin/extended release dipyridamole (25 mg/200 mg bid), or cilostazol (100 mg bid) over...
no antiplatelet therapy (Grade 1A), oral anticoagulants (Grade 1B), the combination of clopidogrel plus aspirin (Grade 1B), or triflus (Grade 2B).

The American Academy of Neurology (AAN)

In 2016, the American Academy of Neurology (AAN) updated its evidence-based guidelines on the management of patients with stroke and PFO to address whether percutaneous closure of PFO is superior to medical therapy alone. Following a systematic review of the literature and structured formulation of recommendations, AAN developed separate conclusions for the STARFlex and Amplatzer PFO Occluder devices. The conclusions of the systematic review were as follows:

For patients with cryptogenic stroke and PFO, percutaneous PFO closure with the STARFlex device:

- “Possibly does not provide a large benefit in preventing stroke in place of medical therapy alone—RD [risk difference] 0.13%, 95% CI -2.2-2.0%; possibly increases the risk of new-onset AF [atrial fibrillation]—RD 5%, 95% CI 2%-8% (1 Class I study, confidence downgraded to low for risk of bias relative to magnitude of effect);”
- “Probably is associated with a serious periprocedural complication risk of 3.2%, 95% CI 1.9%-5.2% (1 Class I study).”

For patients with cryptogenic stroke and PFO, 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 AF—RD 1.64%, 95% CI 0.07%-3.2% (2 Class I studies; confidence downgraded to low for risk of bias relative to magnitude of effect and imprecision);”
- “Is highly likely to be associated with a procedural complication risk of 3.4%, 95% CI 2.3%-5% (2 Class I studies).”

The guidelines concluded:

“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).”
**American Heart Association (AHA) and American Stroke Association (ASA)**

In 2014, the American Heart Association (AHA) and American Stroke Association updated its guidelines on the prevention of stroke in patients with ischemic stroke or transient ischemic attack (TIA). The guidelines listed the following recommendations for device-based closure for PFO:

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 recommendation; 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).

**American College of Cardiology (ACC) and American Heart Association (AHA)**

Guidelines issued by the American College of Cardiology and AHA in 2008 on the management of congenital heart disease recommended closure of an atrial septal defect (ASD) by percutaneous or surgical methods for several indications. For sinus venosus, coronary sinus, or primum ASD, however, surgery rather than percutaneous closure was recommended.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

**Patent Foramen Ovale (PFO) Closure Devices**

In 2002, 2 transcatheter devices were cleared for marketing by the U.S. Food and Drug Administration (FDA) through a humanitarian device exemption (HDE) as treatment for patients with cryptogenic stroke and patent foramen ovale (PFO): the CardioSEAL® Septal Occlusion
System (NMT Medical; device no longer commercially available) and the Amplatzer® PFO Occluder (Amplatzer, now St. Jude Medical, St. Paul, MN). HDE approval is applicable to devices designed to treat a patient population of fewer than 4000 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 devices limited their use 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, use of PFO closure devices increased by more than 50-fold, well in excess of the 4000 per year threshold intended under the HDE. As a result, in 2006, FDA withdrew the HDE approval for these devices.

In November 2016, the Amplatzer® PFO Occluder was approved by the FDA through the premarket approval (PMA) process for the following indication:

- 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 product code: MLV.

**Atrial Septal Defect Closure Devices (ASD) Closure Devices**

Three devices have been approved by the FDA through the PMA process or a PMA supplement for transcatheter atrial septal defect closure (see Table 2).

**Table 2. ASD Closure Devices Approved by the Food and Drug Administration**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>PMA Approval Date</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplatzer™ Septal Occluder</td>
<td>St. Jude Medical (Plymouth, MN)</td>
<td>Dec 2001</td>
<td>Occlusion of ASDs in the secundum position Use in patients who have had a fenestrated Fontan procedure who</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>PMA Approval Date</td>
<td>Indications</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------------------</td>
<td>------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>GORE HELEX Septal Occluder</td>
<td>W.L. Gore &amp; Associates (Flagstaff, AZ)</td>
<td>Aug 2006</td>
<td>Percutaneous, transcatheter closure of ostium secundum ASDs require closure of the fenestration (Patients indicated for ASD closure have echocardiographic evidence of ostium secundum ASD and clinical evidence of right ventricular volume overload.)</td>
</tr>
<tr>
<td>GORE CARDIOFORM Septal Occluder</td>
<td>W.L. Gore &amp; Associates (Flagstaff, AZ)</td>
<td>Oct 2016 (supp.)</td>
<td>Percutaneous, transcatheter closure of ostium secundum ASDs</td>
</tr>
</tbody>
</table>

ASD: atrial septal defect; PMA: premarket approval.

* Discontinued.

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### References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/07/99</td>
<td>Add to Medicine Section - New Policy</td>
</tr>
<tr>
<td>01/18/01</td>
<td>Replace policy - New information on patent foramen ovale; rest unchanged.</td>
</tr>
<tr>
<td>03/12/02</td>
<td>Replace policy - Revised; added requirements to policy statement patients with PFO must fail trial of oral anticoagulants. Noted FDA approval of Amplatzer device. Policy replaces 2.02.09.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>08/13/02</td>
<td>Replace policy - Policy statement revised to indicate transcatheter treatment of ASD may be considered medically necessary. Replaces P2.02.100.</td>
</tr>
<tr>
<td>05/13/03</td>
<td>Replace policy - Policy reviewed; no change to policy statement; CPT codes updated.</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>03/11/08</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>10/14/08</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>03/10/09</td>
<td>Replace policy - Policy updated with literature search; policy rationale extensively revised. Policy statement for PFO changed to investigational due to the FDA’s withdrawal of the humanitarian device exemption approval. References added.</td>
</tr>
<tr>
<td>06/08/10</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>10/11/11</td>
<td>Replace policy – Policy updated with literature search. Policy statements unchanged. References 5, 8, 15 and 25 added. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>11/27/12</td>
<td>Replace policy - Policy updated with literature search. References 3, 6, 7, and 30 added. No change to policy statement.</td>
</tr>
<tr>
<td>11/20/14</td>
<td>Annual Review. Policy updated with literature review through August 1, 2014. References 8-17, 21, 26, 33-37, 40, 48, 53-55, 58-59 added. Policy statement unchanged. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in adjudication of the policy.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Coding update: Correct ICD-10-PCS codes to support remediation efforts.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy statements unchanged. Clinical input received from physician specialty societies and academic medical centers added. No new literature added.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Interim review, approved December 13, 2016. Changed policy statement from investigational to medically necessary for closure of PFO in the presence of cryptogenic stroke due to paradoxical embolism using a PFO occluder device (Amplatzer PFO) when criteria are met. Updated Regulatory Status with information about the Amplatzer device for PFO. Policy updated with literature review through October 2016.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 22, 2017. Policy moved into new format. Policy updated with literature review through March 23, 2017; references 3, 6-7, 9-10, 48-49, 51-52, 64, and 78 added. Statement, “There are currently no transcatheter devices with the</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>U.S. Food and Drug Administration [FDA] approval or clearance for this indication,* removed from investigational statement for PFO closure devices; policy statements otherwise unchanged.</td>
</tr>
</tbody>
</table>
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  - Qualified interpreters
  - Information written in other languages

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https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

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語得到本訊息和幫助。請拔電話 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):
Beeksinsi kuu oddeefannoobarachaasiga qaba. Beeksisti kun sagantaa
yooan karaa Premera Blue Cross tiin tajajila keessan ilaaichise
odeefannoobarachaasiga qabaachuu danda’a. Guyyaawwaa murteesaa
ta’an beeksisa kana keessatti ilaaalaa. Tarii kaffalidhaan deggarammu
yooan tajajila fayyaa keessanif guyyaaw dhumaaw irrittti wanti rawawatana
jiraachuu danda’a. Kaffaliti irraa bilisaa haala ta’een afaan keessanii
odeefannoobarachuu fiideegarsa arzagarhuf miga ni qabaattu.
Lakkoofts bilbilib 800-722-1471 (TTY: 800-842-5357) tii bilbilib.

Français (French):
Cet avis a d’importantes informations. Cet avis peut avoir d’importantes
informations sur votre demande ou la couverture par l’intermédiaire de
Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous
devrez peut-être prendre des mesures par certains délais pour maintenir
votre couverture de santé ou d’aide avec les coûts. Vous avez le droit
d’obtenir cette information et de l’aide dans votre langue à aucun coût.
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan lodan. Avi sila a kapab genyen
enfòmasyon enpòtan konsènan aplikasyon w l wan oswa konsejan
kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan
avi sila a. Ou ka gen pou pran kék aksyon avan seten dat limit pou ka
kenbe kouvèti asirans sante w la oswa pou yo ka ede w akèk depans yo.
Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou paile a,
san ou pa gen pou peye pou sa. Rate nan 800-722-1471
(TTY: 800-842-5357).

Deutsche (German):
Diese Benachrichtigung enthält wichtige Informationen. Diese
Benachrichtigung enthält unter Umständen wichtige Informationen
bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera
Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser
Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln
müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten
zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen
in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471
(TTY: 800-842-5357).

Hmoob (Hmong):
Tsab ntawv tshaj xo no muaj cov ntsiab lus tseem cebp. Tæj taum
tsab ntawv tshaj xo no muaj cov ntsiab lus tseem cebp boog koy dain
ntawv thov kev pab los yog koy chov kev pab caum los ntsawv Premera Blue
Cross. Tæj taum cov hnbv tseem cebp caum rau hauv daim dain
ntawv no. Tæj taum koy koy juaw tau uu qee yam uu peb kom koy uu taip pub
dhau cov caj nyong uus teev tseg rau hauv daim ntsawv no mas koy tshaj
tawv taub bas kev pab caum kho bhee los yog kev pab them tæj nqi kho
ktroaw. Koy muaj cai kom laww muab cov ntsiab lus no uas tau muab
sa uu koy hom lus pub dawb rau koy. Hu rau 800-722-1471
(TTY: 800-842-5357).

Iloko (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a
pakdaar mabalain nga adda ket naglaon iti napateg nga impormasion
maipangepp iti aplikasyonowo ynu covergae babaen iti Premera Blue
Cross. Daytoy ket mabalain dagiti importante a pelsa iti daytoy a pakdaar.
Mabalain nga adda rumbeng nga aramendid nga adda sabilay dagiti
partikular a naituding nga adda aldaw tapno mapagatinalayendo ti
coverage ti salun-atyo wexo tuglun kadagiti gastos. Adda karbenganyo a mangala iti
daytoy nga impormasion ken tuglun iti bukdoyo a pagasasao nga awan ti

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere
informazioni importanti sulla tua domanda o copertura attraverso Premera
Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe
essere necessario un tuo intervento entro una scadenza determinata per
consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto
di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamata 800-722-1471 (TTY: 800-842-5357).
Polski (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Polskie (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

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