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MEDICAL POLICY – 2.02.09

Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

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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.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Medical Necessity
Transcatheter closure of secundum atrial septal defects (ASD)	**Transcatheter closure of secundum atrial septal defects may be considered medically necessary in the following setting:** 1. One of the following FDA approved devices is used: ○ The Amplatzer™ Septal Occluder **OR** ○ The GORE CARDIOFORM Septal Occluder **AND** 2. Medical records document **BOTH** of the following: ○ An echocardiogram shows evidence of an ostium secundum atrial septal defect **AND** ○ There is documentation of right ventricular volume overload (ie, 1.5:1 degree of left-to-right shunt or right ventricular enlargement)
Closure of patent foramen ovale	**Closure of patent foramen ovale using a percutaneous transcatheter approach may be considered medically necessary when ALL of the following criteria are met:** 1. The Amplatzer PFO Occluder is used **AND** 2. The patient is between the ages of 18 and 60 **AND** 3. 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 3 cardiac cycles, after opacification of the right atrium) **OR**

Procedure	Medical Necessity
	○ PFO associated with atrial septal aneurysm on transesophageal examination (septum primum excursion >10 mm) **AND** 4. There is a documented history of a cryptogenic stroke due to a presumed paradoxical embolism, determined by the following: ○ A neurologist and cardiologist agree the stroke is cryptogenic **AND** ○ Evaluation has ruled out other sources of stroke, including large vessel atherosclerotic disease and small vessel occlusive disease **AND** 5. 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

Note: Generally recognized indications for closure include a pulmonary-to-systemic flow ratio of greater than 1.5, right atrial and right ventricular enlargement, and paradoxical embolism.

Documentation Requirements

The patient's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Results and/or reports from prior imaging or testing completed
- Any prior procedures
- Name of device to be used for closure

Coding

Code	Description
CPT	
93580	Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant

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

Diagnosing the Presence of Right-To-Left Shunt on Transthoracic Echocardiogram

The timing of bubble appearance in the left heart is important in making a correct shunt diagnosis (intracardiac vs. intrapulmonary). If shunting is occurring at the cardiac level, then contrast appears in the left heart usually within 3 cardiac cycles of the contrast entering the right heart. There is no widely accepted grading scheme for the assessment of the degree of left-to-right shunt from a PFO. Most determinations are made by the number of bubbles seen in a single still frame in the left atrium. One protocol uses 4 grades of shunt grading: grade 1: < 5 bubbles, grade 2: 5 to 25 bubbles, grade 3: > 25 bubbles, and grade 4: opacification of the chamber. Another study defined the degree of shunting of a PFO as: small as 3-9 contrast bubbles, moderate was 10-30 contrast bubbles and large if more than 30 contrast bubbles appeared in the left atrium.

Definition of Terms

Atrial septal aneurysm: Is a rare, but well-recognized cardiac abnormality in which there is an overabundant or weakened septal tissue allowing the septum to become very mobile and protrude or bulge into the right or left atrium of at least 10 mm to 15 mm. This can be visualized at echocardiography and the degree of deviation can be measured. Atrial septal aneurysms are often associated with larger PFOs.

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.

Septum primum: A septum in the embryonic heart, dividing the primitive atrium into right and left chambers from Latin, meaning 'first septum'.

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 a migraine. 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.

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 proximal aorta. Before birth, the foramen ovale is held open by the large flow of blood into the right 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 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 also show an association between PFO and migraine headache.

Treatment

Conventional therapy for cryptogenic stroke consists of antiplatelet therapy (aspirin, clopidogrel, or dipyridamole given alone or in combination) or oral anticoagulation with warfarin. In general, patients with a known clotting disorder or evidence of preexisting thromboembolism are treated with warfarin, and patients without these risk factors are treated with antiplatelet agents. Closure devices are nonpharmacologic alternatives to medical therapy for cryptogenic stroke in patients with a PFO.

There has been interest in open surgery and transcatheter approaches to close the PFO in patients with a history of cryptogenic stroke to prevent recurrent stroke.

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

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

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), and the CeraFlex ASD Occluder (Lifetech Scientific).

Transcatheter PFO and ASD occluders typically consist of 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.

Summary of Evidence

For individuals who have patent foramen ovale (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, and meta-analyses of these studies. Relevant outcomes are 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. While these results were not statistically significant by intention-to-treat analyses in the first 3 trials (ie, CLOSURE I, PC, and RESPECT [initial study]), they were statistically significant in later trials (ie, RESPECT [extended follow-up], REDUCE, and 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 a meaningful improvement in the net health outcome.

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 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 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.

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.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT00738894[a]	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)	664	Feb 2020
NCT01960491	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)	15	June 2018
NCT01550588	Device Closure Versus Medical Therapy for Secondary Prevention in Cryptogenic Stroke Patients With High-Risk Patent Foramen Ovale : DEFENSE-PFO	210	Feb 2020
NCT03309332	AMPLATZER PFO Occluder Post Approval Study (PFO PAS)	1214	Dec 2025

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, 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 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 use of closure devices for PFO in patients with other conditions (eg, migraine, platypnea-orthodeoxia syndrome) is not medically necessary.

Practice Guidelines and Position Statements

The American College of Chest Physicians

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[41]:

> 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 triflusal (Grade 2B).

The American Academy of Neurology

In 2016, the American Academy of Neurology 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.[42] Following a systematic review of the literature and structured formulation of recommendations, the Academy developed conclusions for the

Amplatzer PFO Occluder devices. For patients with cryptogenic stroke and PFO, percutaneous PFO closure with the Amplatzer PFO Occluder:

- "Possibly decreases the risk of recurrent stroke—RD [risk difference] -1.68%, 95% CI [confidence interval]-3.18% to -0.19%;"
- "Possibly increases the risk of new-onset AF [atrial fibrillation] —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 and American Stroke Association

In 2014, the American Heart Association and American Stroke Association updated its guidelines on the prevention of stroke in patients with ischemic stroke or transient ischemic attack. The guidelines made the following recommendations for device-based closure for PFO[43]:

- For patients with a cryptogenic ischemic stroke or TIA [transient ischemic attack] and a PFO without evidence for DVT [deep vein thrombosis], 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).

American College of Cardiology and American Heart Association

Guidelines issued by the American College of Cardiology and American Heart Association in 2008 on the management of congenital heart disease recommended closure of an atrial septal defect by percutaneous or surgical methods for several indications.[44] For sinus venosus,

coronary sinus, or primum atrial septal defect, however, surgery rather than percutaneous closure was recommended.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, 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 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 FDA to withdraw the humanitarian device exemption approval for these devices in 2007.

In November 2016, the Amplatzer® PFO Occluder was approved by the FDA through the premarket approval process for the following indication[3]:

> 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 premarket approval process or a premarket approval supplement for transcatheter atrial septal defect closure (see **Table 2**) (FDA product code: MLV).

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

Device	Manufacturer	PMA Approval Date	Indications
Amplatzer™ Septal Occluder	St. Jude Medical	Dec 2001	Occlusion of ASDs in the secundum position Use in patients who have had a fenestrated Fontan procedure who 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
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	Oct 2016 (supp.)	Percutaneous, transcatheter closure of ostium secundum ASDs

ASD: atrial septal defect; PMA: premarket approval.

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History

Date	Comments
09/07/99	Add to Medicine Section - New Policy
01/18/01	Replace policy - New information on patent foramen ovale; rest unchanged.
03/12/02	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.
08/13/02	Replace policy - Policy statement revised to indicate transcatheter treatment of ASD may be considered medically necessary. Replaces P2.02.100.
05/13/03	Replace policy - Policy reviewed; no change to policy statement; CPT codes updated.
05/26/06	Update Scope and Disclaimer - No other changes.
03/11/08	Cross Reference Update - No other changes.
10/14/08	Cross Reference Update - No other changes.
03/10/09	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.
06/08/10	Replace policy - Policy updated with literature search; no change to the policy statement. References added.
10/11/11	Replace policy – Policy updated with literature search. Policy statements unchanged. References 5, 8, 15 and 25 added. ICD-10 codes added to policy.
11/27/12	Replace policy - Policy updated with literature search. References 3, 6, 7, and 30 added. No change to policy statement.
12/04/13	Replace Policy. Policy guidelines reformatted for usability. Updated Regulatory Status with information about the FDA medical device alert issued 10/17/13 for the Amplatzer ASO. Rationale updated with literature search through July 31, 2013.

Date	Comments
	References 4-7, 25 added; others renumbered/removed. Policy statement unchanged.
11/20/14	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.
06/09/15	Coding update: Correct ICD-10-PCS codes to support remediation efforts.
12/08/15	Annual Review. Policy updated with literature review through July, 2015; references 16-19, 48, 55-56, and 67 added. Policy statements unchanged.
07/01/16	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.
01/01/17	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.
07/01/17	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 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.
08/01/18	Annual Review, approved July 10, 2018. Policy updated with literature review through March 2018; references 9-11, 14-15, and 17 added. Policy statement changed to: The percutaneous transcatheter closure of a patent foramen ovale using AMPLATZER PFO Occluder may be considered medically necessary to reduce the risk of recurrent ischemic stroke if patient meets all of the specified criteria.
08/10/18	Corrected errors in the description of the heart anatomy discussed under Background, Patent Foramen Ovale on page 5.
04/01/19	Minor update, added Documentation Requirements section.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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ភាសាខ្មែរ (Khmer):
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ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਜਿਸ ਜਵਚ ਖਾਸ ਤਾਰੀਖਾ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀ ਜਸਹਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ਼ ਤੋਂ ਪਹਿਲਾਂ ਕੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫ਼ਤ ਵਿੱਚ ਤੇ ਆਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):
این اعلامیه حاوی اطلاعات مهم میباشد .این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید .شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید .شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کاربران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócic uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

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 ou 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).

Română (Romanian):
Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastre de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența privitoare la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):
Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'amatalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).