

Corporate Medical Policy

Congenital Heart Defect, Repair Devices

File Name: congenital_heart_defect_repair_devices
Origination: 10/2000
Last CAP Review: 6/2020
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Description of Procedure or Service

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. Prior to 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 the permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale (PFO) may be detected in up to 25% of asymptomatic adults. In some epidemiologic studies, PFO has been associated with cryptogenic stroke, a type of stroke defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurological sources. Studies also show an association between PFO and migraine headache.

Atrial Septal Defect

In contrast to patent foramen ovale, 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 according to their anatomy. Ostium secundum describes defects that are 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 atrial septal defects are the third most common form of congenital heart disorder and one of the most common congenital cardiac malformations in adults, accounting for 30%–40% of these in patients over the age of 40. 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; less than 50% of patients survive beyond 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.

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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 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

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 occlude devices consist of flexible mesh discs delivered via catheter to cover the ASD.

Regulatory Status

PFO Closure Devices

In 2002, 2 transcatheter devices received approval for marketing by the U.S. Food and Drug Administration 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).

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

ASD Closure Devices

FDA has approved 3 devices for atrial septal defect (ASD) closure through the premarket approval process or a premarket approval supplement: the Amplatzer Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder.

ASD occluder devices consist of flexible mesh disks that are passed via catheter to cover the ASD.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Congenital Heart Defect Repair Devices when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit

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design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Congenital Heart Defect Repair Devices are covered

Transcatheter closure of patent foramen ovale, and secundum atrial septal defects may be considered medically necessary when using a device that has been FDA approved for that purpose and used according to the labeled indications.

Percutaneous transcatheter closure of a patent foramen ovale (PFO), using an FDA approved device, may be considered medically necessary 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.

When Congenital Heart Defect Repair Devices are not covered

Use of congenital heart defect repair devices is not covered if the criteria listed above have not been met.

Policy Guidelines

Patent foramen ovale (PFO) and atrial septal defects (ASD) 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. Transcatheter “closure” devices are intended as less invasive, catheter-based approaches of repairing patent foramen ovale (PFO) or atrial septal defects. These devices are alternatives to open surgical repair for ASDs or treatment with antiplatelet and/or anticoagulant medications in patients with cryptogenic stroke and a PFO.

Patent Foramen Ovale

On October 28, 2016, the FDA issued an approval of Amplatzer’s PMA submission, with reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use (i.e., the AMPLATZER PFO Occluder reduces 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). The conditions of approval describe an OSB Lead PMA Post-Approval Study – AMPLATZER PFO Occluder New Enrollment PAS: The study will evaluate the long-term safety and effectiveness of the AMPLATZER PFO Occluder and the effectiveness of a training program for new operators. This will be a prospective, open-label, multi-center evaluation of the AMPLATZER PFO Occluder consisting of at least 1,214 US participants that receive the device post-approval.

Conclusions drawn from preclinical and clinical studies:

Effectiveness Conclusions

Although the difference in the rate of recurrent ischemic stroke was lower in the Device group vs. the MM (medical management) group in the ITT (intention to treat) population (the pre-specified primary analysis cohort), the difference did not achieve statistical significance. Nonetheless, there was a clinically meaningful 50% relative risk reduction in the rate of new ischemic strokes in favor of the Device group. In the Per Protocol analysis, the rate of recurrent ischemic stroke in the Device group was significantly lower compared to the MM group.

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Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in the RESPECT clinical study/trial (Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment) conducted to support PMA approval as described above. The results from the nonclinical laboratory and animal studies performed on the AMPLATZER PFO Occluder demonstrate that the device is suitable for long-term implantation. The risks associated with the device include pulmonary embolism, thrombus in the right atrium, need for device explantation by open surgery, atrial fibrillation, and residual shunting across the PFO requiring additional closure attempts. Additionally, procedure-related risks include but are not limited to cardiac perforation, access site bleeding, and deep vein thrombus. The safety evaluation performed during the RESPECT study showed an acceptable rate of adverse events. The risk of device- or implantation procedure-related serious adverse events (SAEs) in patients undergoing an AMPLATZER PFO Occluder implantation procedure, was 4.2% in the Device group in the RESPECT trial. There were no device- or implantation procedure-related deaths. However, it should be noted that the Device group experienced a numerically higher rate of atrial fibrillation, deep venous thrombosis, and pulmonary embolism compared to the MM group.

Benefit-Risk Determination

The probable risks of the AMPLATZER PFO Occluder include device- and procedure-related serious adverse events such as cardiac perforation and access site bleeding. There was a small increased risk of atrial fibrillation and venous thromboembolic events (pulmonary embolism and deep venous thrombosis) in patients treated with the Device compared with medical therapy. The probable benefits of the device are also based on data collected in the RESPECT trial. There was a 50% relative risk reduction in the rate of recurrent ischemic stroke PMA P120021: FDA Summary of Safety and Effectiveness Data Page 29 in subjects randomized to the Device vs. MM. Additionally, effective PFO closure with the device at 6 months was observed in 94.2% (323/343) of evaluated patients.

Alternative Practices and Procedures

There are several other alternatives for reducing the risk of recurrent ischemic stroke in patients who have had a cryptogenic stroke due to a presumed paradoxical embolism. The 2014 American Heart Association and American Stroke Association stroke guidelines (affirmed by the American Academy of Neurology) recommend antiplatelet agents for patients with an ischemic stroke or transient ischemic attack (TIA) and a PFO who are not otherwise being treated with anticoagulation therapy (Class I; Level of Evidence B). These guidelines note that there are insufficient data to establish whether anticoagulation is equivalent or superior to aspirin for secondary stroke prevention in patients with a PFO (Class IIb; Level of Evidence B). Open surgery to close a PFO is another treatment option but is rarely performed. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

Contraindications:

The AMPLATZER PFO Occluder is contraindicated for use in:

- Patients with intra-cardiac mass, vegetation, tumor or thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the PFO is gained;
- Patients whose vasculature, through which access to the PFO is gained, is inadequate to accommodate the appropriate sheath size;
- Patients with anatomy in which the AMPLATZER PFO device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins;
- Patients with other source of right-to-left shunts, including an atrial septal defect and/or a fenestrated atrial septum; and/or

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- Patients with active endocarditis or other untreated infections.

Atrial Septal Defect

The evidence for ASD closure with a transcatheter device in individuals who have ASD and evidence of left-to-right shunt or right-ventricular overload 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0613T, 37241, 37242, 37243, 37244, 93580

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For policy titled: Congenital Heart Defect, Atrial Repair Devices

BCBSA Medical Policy Reference Manual, 2.02.09, 7/16/99

Specialty Matched Consultant Advisory Group - 9/00

Medical Policy Advisory Group - 10/00

BCBSA Medical Policy Reference manual, 2.02.09, 12/15/00

BCBSA Medical Policy Reference Manual, 2.02.09, 11/20/01

BCBSA Medical Policy Reference Manual, 2.02.09, 5/15/02

Specialty Matched Consultant Advisory Group - 8/2002

BCBSA Medical Policy Reference Manual, 2.02.09, 7/12/02

BCBSA Medical Policy Reference Manual, 7.01.61, 7/17/03

Specialty Matched Consultant Advisory Group - 11/2003

Specialty Matched Consultant Advisory Panel - 11/2005

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BCBSA Medical Policy Reference Manual, 2.02.09, 10/9/03

BCBSA Medical Policy Reference Manual, 7.01.61, 2/25/04

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National Institute for Clinical Excellence (NICE). Guidance on Percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke. Interventional Procedure Guidance 109. London, UK: NICE; January 2005. Retrieved 7/19/07 from <http://guidance.nice.org.uk/IPG109/guidance/pdf/English/download.dsp>

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 Oval (PFO) Occluders. Retrieved 8/1/07 from <http://www.fda.gov/cdrh/ode/h000007-h990011withdraw.html>

For Policy renamed: Congenital Heart Defect, Repair Devices

BCBSA Medical Policy Reference Manual, 2.02.09, 12/11/08

BCBSA Medical Policy Reference Manual [Electronic Version] 2.02.09 4/08/10.

Specialty Matched Consultant Advisory Panel 6/2010

Specialty Matched Consultant Advisory Panel 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version] 2.02.09, 9/1/11

Specialty Matched Consultant Advisory Panel 6/2012

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Wahl A, Juni P, Mono ML et al. Long-term propensity score-matched comparison of percutaneous closure of patent foramen ovale with medical treatment after paradoxical embolism. Circulation 2012; 125(6):803-12. Retrieved from <http://circ.ahajournals.org/content/125/6/803.long>

BCBSA Medical Policy Reference Manual [Electronic Version] 2.02.09, 9/13/12

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.61, 10/11/12

Medical Director review 11/2012

Warnes CA, Williams RG, Bashore TM et al. ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines on

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the management of adults with congenital heart disease). *Circulation* 2008; 118(23):e714-833. Retrieved from <http://www.guidelines.gov/content.aspx?id=14102>

Kazmouz S, Kenny D, Cao QL, Kavinsky CJ, Hijazi ZM. Transcatheter closure of secundum atrial septal defects. *J Invasive Cardiol.* 2013 May;25(5):257-64. Retrieved from <http://www.invasivecardiology.com/articles/transcatheter-closure-secundum-atrial-septal-defects>

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Rengifo-Moreno P, Palacios IF, Junpaparp 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.

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.09, 9/12/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.61, 10/10/13

Medical Director review 11/2013

Specialty Matched Consultant Advisory Panel review 6/2014

Medical Director review 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.09, 9/11/14

Senior Medical Director review 1/2015

Specialty Matched Consultant Advisory Panel review 6/2015

Medical Director review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.09, 4/19/16

Medical Director review 4/2016

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Pickett CA, Villines TC, Ferguson MA, 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.* Aug 2014;41(4):357-367. PMID 25120387

Stortecky S, da Costa BR, Mattle HP, et al. Percutaneous closure of patent foramen ovale in patients with cryptogenic embolism: a network meta-analysis. *Eur Heart J.* Jan 7 2015;36(2):120-128. PMID 25112661

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Specialty Matched Consultant Advisory Panel review 6/2016

Medical Director review 6/2016

Specialty Matched Consultant Advisory Panel review 11/2016

Medical Director review 11/2016

FDA approves Amplatzer PFO Occluder device to for prevention of recurrent strokes in certain patients [news release]. Silver Spring, MD U.S. Food and Drug Administration October 28, 2016. Accessed on November 10, 2016 from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm527096.htm>.

FDA Summary of Safety and Effectiveness Data (SSED) AMPLATZER PFO Occluder Device, May 24, 2016; PMA P120021. Accessed on December 15, 2016 from: http://www.accessdata.fda.gov/cdrh_docs/pdf12/P120021b.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.09, 5/2017

Medical Director review 5/2017

Specialty Matched Consultant Advisory Panel review 6/2017

Medical Director review 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.09, 5/2018

Specialty Matched Consultant Advisory Panel review 6/2018

Medical Director review 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.09, 6/2019

Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019

Specialty Matched Consultant Advisory Panel review 6/2020

Medical Director review 6/2020

Policy Implementation/Update Information

Congenital Heart Defect, Repair Devices

For policy titled: Congenital Heart Defect, Atrial Repair Devices

- 9/00 Specialty Matched Consultant Advisory Group
- 10/00 Original policy issued. Medical Policy Advisory Group - Approved.
- 3/01 Revised. Policy renamed. Criteria added for patent foramen ovale.
- 11/01 Coding format change.
- 2/02 Policy revised under when it is covered to include patients who have failed or are not candidates for a course of anticoagulant therapy.
- 8/02 Description revised to include additional information regarding Patent Foramen Ovale and Atrial Septal Defect. Policy revised to include covered indications for transcatheter repair of Atrial Septal Defect.
- 9/02 Specialty Matched Consultant Advisory Group review. Policy number changed from MED1094 to SUR6166. Amplatzer Patent Foramen Ovale occluder added as a covered device. New source added.
- 1/03 Removed code 93799 from policy. Added code 93580 to the policy. Policy name changed from Congenital Heart Defect Repair Devices to Congenital Heart Defect, Atrial Repair Devices. System coding changes.
- 9/03 Added information related to patent ductus arteriosus. Source added to policy. Code 37204 added to the policy.
- 11/03 Biannual policy review. Specialty Matched Consultant Advisory Panel review. No change to policy criteria. Policy format changed for consistency.
- 11/17/05 Biennial policy review. Specialty Matched Consultant Advisory Panel review 11/07/05. Revised the statement regarding FDA approval of HUDs in the Policy Guidelines section. No change to policy coverage.
- 11/19/07 Information added to Description section for clarity. The following statement was deleted from the When It IS Covered section: "Closure of patent foramen ovale using a transcatheter approach with an FDA approved device may be considered medically necessary in patients with a history of stroke of unknown etiology (cryptogenic) and who have failed or are not candidates for a course of anticoagulant therapy." References updated. Specialty Matched Consultant Advisory Panel review meeting 10/29/07. No change in policy statement. (adn)
- 3/10/08 Deleted CPT Code 37204 from Billing/Coding section. (adn)

For Policy renamed: Congenital Heart Defect, Repair Devices

- 12/7/09 Policy name changed to Congenital Heart Defect, Repair Devices. Description section extensively revised. The following was added to the Policy Statement: "Some patients may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services for Life-Threatening Conditions." Updated policy rationale in Policy Guidelines section to include FDA information. Added CPT Code 37204 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 10/30/09. (adn)

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- 8/17/10 Specialty Matched Consultant Advisory Panel review 6/2010. Removed Medical Policy number. Updated references. (mco)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy statements. (mco)
- 11/08/11 References updated. No changes to policy statements. (mco)
- 7/10/12 Specialty Matched Consultant Advisory Panel review 6/2012. No changes to Policy Statements. (mco)
- 12/11/12 Description section updated. References updated. Policy Guidelines updated. Medical Director review 11/2012. (mco)
- 7/16/13 Specialty Matched Consultant Advisory Panel review 6/2013. Medical Director review 6/2013. References updated. (mco)
- 10/29/13 Policy Guidelines updated. References updated. No changes to Policy Statements. (mco)
- 12/31/13 Removed all information regarding patent ductus arteriosus (PDA) and PDA closure devices. References updated. Deleted CPT code 37204. Added new CPT codes 37241, 37242, 37243, and 37244 to Billing/Coding section. Medical Director review 11/2013. (mco)
- 7/15/14 Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review. No changes to Policy Statements. (mco)
- 1/27/15 References updated. Description section updated. Policy Guidelines section updated. No changes to Policy Statements. Medical Director review 1/2015. (td)
- 9/1/15 Specialty Matched Consultant Advisory Panel review 6/2015. Medical Director review 6/2015. Policy Statement remains unchanged. (td)
- 5/31/16 Policy guidelines updated. References updated. Medical Director review 4/2016 (jd)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/2016. Medical Director review 6/2016. (jd)
- 12/30/16 Language added to “When Covered” section indicating when percutaneous transcatheter closure of a patent foramen ovale (PFO) is considered medically necessary when using an FDA approved device. Policy Guidelines extensively revised to align with FDA approval, as of October 28, 2016, of the Amplatzer PFO Occluder device. References updated. Specialty Matched Consultant Advisory Panel review 11/2016. Medical Director review 11/2016. (jd)
- 6/30/17 Minor updates to Description and Policy Guidelines sections. References updated. Medical Director review 5/2017. (jd)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/2017. (jd)
- 7/27/18 Policy guidelines and references updated. Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)

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- 7/1/19 Moved Regulatory Status section up under Description of Procedure or Service. References updated. Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)
- 6/30/20 Added code 0613T to Billing/Coding section with effective date of 7/1/2020. Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)

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