Corporate Medical Policy

Congenital Heart Defect, Repair Devices

File Name: congenital_heart_defect_repair_devices
Origination: 10/2000
Last Review: 6/2024

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.

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 disc covered or filled with polyester or polymer fabric that are placed over the septal defect. Over time, the occlusion system is epithelialized. ASD occluder devices consist of flexible mesh discs delivered via catheter to cover the ASD.

Regulatory Status

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 Abbott Cardiovascular). 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, prompting the FDA to withdraw the humanitarian device exemption approval for these devices in 2007. The Amplatzer PFO Occluder was approved through the premarket approval process in 2016.

In March 2018, 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 Reduction in the Use of Corticosteroids in Exacerbated COPD (REDUCE) pivotal clinical trial.

ASD Closure Devices
FDA has approved 5 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), GORE CARDIOFORM ASD Occluder, the GORE CARDIOFORM Septal Occluder and Occlutech® ASD Occluder.

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

Related Policy:
Facility Billing Requirements

******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 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 individuals, 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 PFO.

Patent Foramen Ovale

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, meta-analyses, and observational studies. Relevant outcomes are symptoms, change in disease status, overall survival, morbid events, and treatment-related morbidity and mortality. The RCTs comparing PFO closure with medical management have suggested that PFO closure is more effective than medical therapy in reducing event rates. Although these results were not statistically significant by intention to treat (ITT) analyses in earlier trials (ie, Amplatzer PFO Occluder with Medical Treatment in Patients with Cryptogenic Embolism [PC-Trial] and Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment [RESPECT; initial study]), they were statistically significant in later trials (ie, RESPECT [extended follow-up], Reduction in the Use of Corticosteroids in Exacerbated COPD [REDUCE], and Patent Foramen Ovale Closure or Anticoagulants versus Antiplatelet Therapy to Prevent Stroke Recurrence [CLOSE]). Use of appropriate patient

selection criteria to eliminate other causes of cryptogenic stroke in RESPECT, REDUCE, and CLOSE trials contributed to findings of the superiority of PFO closure compared with medical management. Of note, higher rates of atrial fibrillation were reported in a few of the individual trials and in the meta-analysis that incorporated evidence from RESPECT, REDUCE, and CLOSE trials. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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 systematic reviews, 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. In systematic reviews, the risk of overall mortality was similar with transcatheter device versus surgical closure, whereas in-hospital mortality was significantly reduced with transcatheter device closure. 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.bcbsnc.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

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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For Policy renamed: Congenital Heart Defect, Repair Devices

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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

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Medical Director review 11/2012

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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

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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.

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Senior Medical Director review 1/2015

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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

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Medical Director review 5/2017

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

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Medical Director review 6/2020

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Specialty Matched Consultant Advisory Panel review 6/2024

Medical Director review 6/2024

Policy Implementation/Update Information

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 arteriosis. 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)

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 medicall 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)

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)

7/1/21 Minor revision to regulatory status. References updated. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)

5/31/22 The following reimbursement policy was added to Related Policies section: Facility Billing Requirements. (jd)

7/12/22 Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)

6/30/23 Description section updated. References added. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. (tm)

7/17/24 Description, Policy Guidelines and References updated. Specialty Matched Consultant Advisory Panel review 6/2024. Medical Director review 6/2024. (tm)