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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Description:

Patent foramen ovale (PFO) and atrial septal defects (ASDs) are relatively common congenital heart defects that can be associated with a range of symptoms. PFOs may be asymptomatic but have been associated with higher rates of cryptogenic stroke. PFOs have also been investigated for a variety of other conditions, such as a migraine. Depending on their size, ASDs may lead to left-to-right shunting and signs and symptoms of pulmonary overload. Repair of ASDs is indicated for individuals with a significant degree of left-to-right shunting. Transcatheter closure devices have been developed to repair PFO and ASDs. These devices are alternatives to open surgical repair for ASDs or treatment with antiplatelet and/or anticoagulant medications in individuals with cryptogenic stroke and PFO.

Patent Foramen Ovale

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Before birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over the course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in permanent closure of the foramen ovale in most individuals. However, a patent foramen ovale (PFO) is a common finding in 25% of asymptomatic adults. In some epidemiologic studies, PFO has been associated with cryptogenic stroke, defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurologic sources. Studies have also shown an association between PFO and migraine headache.

Atrial Septal Defects

Unlike PFO, which represents the postnatal persistence of normal fetal cardiovascular physiology, atrial septal defects (ASDs) represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized by their anatomy. Ostium secundum describes defects located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and are within the spectrum of atrioventricular septal defects. Primum defects occur commonly in individuals 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 individuals 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 individuals who survive into their sixth decade are symptomatic; fewer than 50% of individuals 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. Individuals with ASDs are also at risk for paradoxical emboli.

CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Description: (cont.)

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

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

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

Two devices approved by the U.S. Food and Drug Administration for patent foramen ovale closure and atrial septal defect closure are currently marketed: the Amplatzer™ Septal Occluder and the GORE® CARDIOFORM Septal Occluder. The GORE® HELEX Septal Occluder has been discontinued.

CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Criteria:

Closure devices for patent foramen ovale and atrial septal defects will be reviewed by the medical director(s) and/or clinical advisor(s).

- The percutaneous transcatheter closure of a patent foramen ovale using a device that has been approved by the U.S. Food and Drug Administration for that purpose is considered ***medically necessary*** to reduce the risk of recurrent ischemic stroke with documentation of **ALL** of the following:

  1. Between 18 and 60 years of age

  2. 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
     - PFO associated with atrial septal aneurysm on transesophageal examination: septum primum excursion >10 mm

  3. Documented history of cryptogenic ischemic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude any other identifiable cause of stroke, including large vessel atherosclerotic disease and small vessel occlusive disease

  4. Absence of **ALL** of the following:

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

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

  1. Individuals with echocardiographic evidence of ostium secundum atrial septal defect

  2. **ONE** of the following:

     - Clinical evidence of right ventricular volume overload (ie, 1.5:1 degree of left-to-right shunt or right ventricular enlargement)
     - Clinical evidence of paradoxical embolism

CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Criteria: (cont.)

- Transcatheter closure of secundum atrial septal defects for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 08/16/22. We do not include marketing materials, poster boards and non-published literature in our review.

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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Resources: (cont.)

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10. Chambault AL, Olsen K, Brown LJ, et al. Transcatheter versus surgical closure of atrial septal defects: a systematic review and meta-analysis of clinical outcomes. *Cardiol Young*. Jan 2022;32(1):1-9. doi:10.1017/s1047951121004583

11. Chen TH, Hsiao YC, Cheng CC, et al. In-Hospital and 4-Year Clinical Outcomes Following Transcatheter Versus Surgical Closure for Secundum Atrial Septal Defect in Adults: A National Cohort Propensity Score Analysis. *Medicine (Baltimore)*. Sep 2015;94(38):e1524. doi:10.1097/md.0000000000001524

12. De Rosa S, Sievert H, Sabatino J, Polimeni A, Sorrentino S, Indolfi C. Percutaneous Closure Versus Medical Treatment in Stroke Patients With Patent Foramen Ovale: A Systematic Review and Meta-analysis. *Ann Intern Med*. Mar 6 2018;168(5):343-350. doi:10.7326/m17-3033

13. Dowson A, Mullen MJ, Peatfield R, et al. Migraine Intervention With STARFlex Technology (MIST) trial: a prospective, multicenter, double-blind, sham-controlled trial to evaluate the effectiveness of patent foramen ovale closure with STARFlex septal repair implant to resolve refractory migraine headache. *Circulation*. Mar 18 2008;117(11):1397-404. doi:10.1161/circulationaha.107.727271

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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Resources: (cont.)

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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Resources: (cont.)

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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

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36. Nyboe C, Hjortdal VE, Nielsen-Kudsk JE. First experiences with the GORE(®) Septal Occluder in children and adults with atrial septal defects. *Catheter Cardiovasc Interv*. Nov 15 2013;82(6):929-34. doi:10.1002/ccd.24851

37. Oho S, Ishizawa A, Akagi T, Dodo H, Kato H. Transcatheter closure of atrial septal defects with the Amplatzer septal occluder--a Japanese clinical trial. *Circ J*. Sep 2002;66(9):791-4. doi:10.1253/circj.66.791

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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

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CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Coding:

CPT: 33999, 93580, 93799
HCPCS: C1817

History:	Date:	Activity:
Medical Policy Panel	08/16/22	Approved guideline (Effective 9/19/22)

Policy Revisions:

CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

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Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

CLOSURE DEVICES FOR PATENT FORAMEN OVALE AND ATRIAL SEPTAL DEFECTS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
[تماس حاصل نمایید.

Assyrian:

[illegible] Blue Cross Blue Shield of Arizona [illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799