BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 10/13/15**
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CLOSURE DEVICES FOR ATRIAL AND VENTRICULAR SEPTAL DEFECTS AND PATENT FORAMEN OVALE

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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

Description:

Transcatheter occlusion devices are implanted as less-invasive, catheter-based approaches to repair atrial septal defects (ASDs), ventricular septal defects (VSD) and patent foramen ovale (PFO). Transcatheter occlusion devices have also been investigated as alternatives to treatment with anti-platelet and/or anticoagulant medications in individuals with cryptogenic stroke and a PFO.

Three devices are currently FDA-approved for ASD closure: the Amplatzer™ Septal Occluder, the GORE HELEX™ Septal Occluder (discontinued) and the GORE® CARDIOFORM Septal Occluder. The Amplatzer device is intended for the occlusion of ASDs in the secundum position or in individuals who have undergone a fenestrated Fontan procedure who require closure of the fenestration. Individuals indicated for ASD closure have echocardiographic evidence of ostium secundum ASD and clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left to right shunt or rv enlargement). The GORE HELEX Septal Occluder is indicated for the percutaneous, transcatheter closure of ostium secundum ASDs. Other devices that have been investigated to treat ASDs via a transcatheter approach, but are not yet FDA approved, include the CeraFlex™ ASD Occluder and the Figulla® ASD Occluder.

CardioSEAL® Septal Occlusion System with QwikLoad is FDA-approved for closure of complex VSDs of significant size to warrant closure who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. High risk anatomical factors for transatrial or transarterial surgical closure include: individuals requiring a left ventriculotomy or an extensive right ventriculotomy; a failed previous VSD closure; multiple apical and/or anterior muscular VSDs ("swiss cheese septum"); or posterior apical VSDs covered by trabeculae.

One device currently FDA approved for PFO closure is: the Amplatzer® PFO Occluder. The Amplatzer device is indicated for the percutaneous, transcatheter closure of a PFO 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.

The GORE CARDIOFORM Septal Occluder is a device that is permanently implanted in the heart to close a patent foramen ovale (PFO). A PFO occurs when the foramen ovale, a naturally occurring hole located between the two upper chambers of the heart (the right atrium and the left atrium), does not close shortly after birth. If untreated, a PFO can allow a small amount of blood to pass from the right side of the heart to the left side of the heart. In rare cases, a PFO may lead to the occurrence of strokes. The device includes an implant (occluder) and a delivery catheter (a small tube). The GORE CARDIOFORM Septal Occluder is intended to be used for adult patients between the ages of 18-60 years old who have had a previous cryptogenic stroke (a stroke with an unidentified cause), who are also taking blood-thinning medications to prevent another stroke, and should only be used after a neurologist and cardiologist have ruled out other causes of stroke.

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

Criteria:

For transcatheter closure of patent ductus arteriosus, see BCBSAZ Medical Coverage Guideline #O832, *"Transcatheter Closure of Patent Ductus Arteriosus"*.

Closure of ventricular septal defects devices will be reviewed by the medical director(s) and/or clinical advisor(s).

Atrial Septal Defects (ASD):

- Gore Cardioform Septal Occluder and GORE HELEX Septal Occluder for the percutaneous, transcatheter closure of ostium secundum atrial septal defects are considered ***medically necessary***.
- Amplatzer Septal Occluder for the occlusion of atrial septal defects (ASD) in secundum position and in individuals who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration is considered ***medically necessary***.

Ventricular Septal Defects (VSD):

- CardioSEAL Septal Occlusion System with QwikLoad is considered ***medically necessary*** for closure of ventricular septal defects in an individual considered to be at high risk for surgical closure.

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

Criteria: (cont.)

Patent Foramen Ovale (PFO):

- Amplatzer PFO Occluder for the percutaneous, transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual is ≥ 18 years of age to ≤ 60 years of age
  2. Diagnosis of patent foramen ovale (PFO) with a right-to-left interatrial shunt confirmed by echocardiography with a 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. 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

- Gore Cardioform Septal Occluder for the percutaneous, transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual is ≥ 18 years of age to ≤ 60 years of age
  2. 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.

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

Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.02.09 BCBS Association Medical Policy Reference Manual. Closure Devices for Patent Foramen Ovale and Atrial Septal Defects. Re-issue date 05/04/2018, issue date 07/16/1999.

2. InterQual® Care Planning Procedures. Atrial Septal Defect (ASD) Repair.

FDA Premarket Approval Database for GORE CARDIOFORM Septal Occluder:

- FDA approved indication: For the percutaneous, transcatheter closure of a defect of the atrial septum 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 Summary of Safety and Effectiveness Data (SSED) for GORE CARDIOFORM Septal Occluder:

- FDA-approved indication: Patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominately between the ages of 18 and 60 years, who have had a cryptic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

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

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

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 ATRIAL AND VENTRICULAR SEPTAL DEFECTS AND PATENT FORAMEN OVALE (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]
[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