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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

### Description:

Intracranial arterial disease includes thromboembolic events, vascular stenoses and aneurysms. Endovascular techniques have been investigated for treatment of intracranial arterial disease, as an alternative to intravenous tissue plasminogen activator (tPA) and supportive care for acute stenosis and as an alternative to risk factor modification for chronic stenosis. For cerebral aneurysms, stent-assisted coiling has been investigated as an alternative to endovascular coiling in individuals whose anatomy is not amenable to simple coiling.
ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE (cont.)

Description: (cont.)

Angioplasty:
Passage of a catheter through the blood vessel to decrease obstruction and restore blood flow. Percutaneous transluminal angioplasty (PTA) uses a balloon tipped catheter which is inserted to the area of disease and then inflated to compress the plaque against the vessel wall. Other devices that can be attached to the catheter are a laser and rotating shaver to “open” the vessel.

Endovascular Stent Placement:
Placement of a plastic or metal mesh tube into a blood vessel to maintain patency. Stent placement may be done following an angioplasty or as an alternative to an angioplasty. Stent devices that have received FDA approval through the Humanitarian Device Exemption (HDE) for intracranial arterial disease include:

- Enterprise™ Vascular Reconstruction Device and Delivery System
- Low-Profile Visualized Intraluminal Support Device (LVIS™ and LVIS™ Jr)
- Neuroform™ Microdelivery Stent System
- Neurolink System®
- Wingspan™ Stent System

Flow-Diverting Stent Placement:
Flow-diverting devices are deployed in the parent blood vessel to divert blood flow away from the aneurysm (e.g., Pipeline® Embolization Device).

Mechanical Embolectomy:
Mechanical embolectomy has been investigated as a technique to restore blood flow in the neurovasculature by removing thrombus during an ischemic stroke. A balloon guide catheter is used to reach the occlusion, visualize the vessel and target treatment. A micro catheter is then advanced through the balloon catheter and positioned beyond the obstruction. The mechanical embolectomy device is advanced through the micro catheter beyond the occlusion and slowly drawn back allowing the thrombus to be ensnared. Once the clot is ensnared, the balloon catheter is inflated to control blood flow and the micro catheter and mechanical embolectomy device are removed, engaging the thrombus as they are withdrawn. The balloon is then deflated.

Mechanical embolectomy devices include, but are not limited to:

- MERCI® Retriever
- Modified MERCI® Retriever
- Penumbra System™
- Solitaire™ FR Revascularization Device
- Trevo® Retriever
ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE (cont.)

Criteria:

For angioplasty and endovascular stent placement, see BCBSAZ Medical Coverage Guideline #O270, “Angioplasty and Endovascular Stent Placement”.

For carotid artery angioplasty with or without endovascular stent placement, see BCBSAZ Medical Coverage Guideline #O710, “Carotid Artery Angioplasty”.

For endovascular stent grafts for abdominal aortic aneurysms, see BCBSAZ Medical Coverage Guideline #O751, “Endovascular Stent Grafts for Abdominal Aortic Aneurysms”.

For endovascular stent grafts for disorders of the thoracic aorta, see BCBSAZ Medical Coverage Guideline #O821, “Endovascular Stent Grafts for Disorders of the Thoracic Aorta”.

➢ Angioplasty of the cerebral arteries is considered medically necessary for the treatment of vasospasms induced by a subarachnoid hemorrhage.

➢ Endovascular stent placement for the treatment of intracranial saccular aneurysm is considered medically necessary with documentation of ALL of the following:

1. Use in conjunction with coil embolization
2. Wide neck aneurysm (neck of 4 mm or more or a dome-to-neck ratio less than 2:1) arising from a parent vessel with a diameter of greater than or equal to 2mm and less than or equal to 4.5mm
3. Not amenable to treatment with surgical clipping

➢ Intracranial flow-diverting stent placement for the treatment of large or giant wide-necked intracranial aneurysm is considered medically necessary with documentation of ALL of the following:

1. Size greater than or equal to 10 mm, neck diameter greater than or equal to 4 mm, in the internal carotid artery from the petrous to the superior hypophyseal segments
2. Aneurysm is not amenable to surgical treatment or standard endovascular therapy
3. Device is FDA-approved for the treatment of intracranial aneurysm
ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE (cont.)

Criteria: (cont.)

- Endovascular mechanical embolectomy as part of the treatment of acute ischemic stroke is considered *medically necessary* with documentation of ALL of the following:
  1. Device is FDA-approved for the treatment of acute ischemic stroke
  2. Have a demonstrated occlusion within the proximal intracranial anterior circulation (intracranial internal carotid artery, or M1 or M2 segments of the middle cerebral artery, or A1 or A2 segments of the anterior cerebral artery)
  3. Can receive endovascular mechanical embolectomy within 12 hours of symptom onset OR within 24 hours of symptom onset if there is evidence of a mismatch between specific clinical and imaging criteria
  4. Have evidence of substantial and clinically significant neurological deficits
  5. Have evidence of salvageable brain tissue in the affected vascular territory
  6. Have no evidence of intracranial hemorrhage or arterial dissection on CT or MRI imaging

- Endovascular stent placement for the treatment of intracranial aneurysm for all other indications not previously listed or if above criteria not met is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

- Angioplasty with or without stenting for the treatment of intracranial artery atherosclerotic cerebrovascular disease is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE
(cont.)

Criteria: (cont.)

- Angioplasty with or without endovascular stent placement for the treatment of stenosis/occlusion/dissection of the following cranial arteries is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

Arteries include, but are not limited to:

- Basilar artery
- Cerebral arteries (e.g., anterior, posterior, communicating)
- Vertebrobasilar artery

Resources:

Literature reviewed 05/01/18. 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.

Resources prior to 06/11/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE (cont.)

Resources: (cont.)


6. UpToDate. Spontaneous cerebral and cervical artery dissection: Treatment and prognosis. Last updated 01/18/2018, 09/16/2015, 05/18/2015, 08/21/2014.
ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE

(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 kweé atah nilíngiiíí Blue Cross Blue Shield of Arizona haadá yit’éego bíná’ilíkidgó éí doo doh Háida bijníí niíyiígilíí t’áádoó lé’é yina’ilíkidgó beehaz’ááníí hólóó díí t’áá hazaadk’ehjí háká a’doowolgo bee haz’a doo báq’áh ilínígóó. Atá’ halné’éjijí kojí bíjí’ hodiilíinh 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 bạn có vấn đề gì, hãy gọi cho chúng tôi để Blue Cross Blue Shield of Arizona hỗ trợ bạn. Bạn có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một chuyên viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تشاركه أسباب للاستعانة بخدمات Blue Cross Blue Shield of Arizona الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم يصلب ب 877-475-4799.
ENDOVASCULAR PROCEDURES FOR INTRACRANIAL ARTERIAL DISEASE
(cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, 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 Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 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 Diomscher 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 آن کمک می‌کنید، سوال در مورد اطلاعاتی که با یابندرا در طول رایگان دریافت نمایید 877-475-4799 کمک حاصل نمایید.

Assyrian: Blue Cross Blue Shield of Arizona، ئینی کەوە دەستبەرەیەکان وەکو شەمانەوە، مەنمەوە جەنە وەکو نەمە. 877-475-4799 کەوە دەستبەرەیەکان وەکو شەمانەوە، مەنمەوە جەنە وەکو نەمە.

Serbo-Croatian: Ukoiko Vi ili neko kome Vi pomaže imaj pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณช่วยเหลืออยู่มีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถจะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่มีค่าใช้จ่าย ที่หมายเลข โทร 877-475-4799