CAROTID ARTERY ANGIOPLASTY

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.

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CAROTID ARTERY ANGIOPLASTY (cont.)

Description:

Carotid artery angioplasty with or without stenting is a treatment for carotid stenosis that is intended to prevent future stroke. It is an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy (CEA). Symptomatic carotid stenosis includes symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in the previous 120 days, with symptom duration less than 24 hours or non-disabling stroke. Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices through the femoral artery and into the carotid artery. The procedure is most often performed through the femoral artery, but a transcervical approach can also be used to avoid traversing the aortic arch. The procedure generally takes 20–40 minutes. Interventionalists almost uniformly use an embolic protection device (EPD) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Embolic protection devices can be deployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty is usually performed with stent placement.

Criteria:

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

For endovascular procedures for intracranial arterial disease, see BCBSAZ Medical Coverage Guideline #O754, “Endovascular Procedures for Intracranial Arterial Disease”.

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”.


CAROTID ARTERY ANGIOPLASTY (cont.)

Criteria: (cont.)

Carotid artery angioplasty (common, internal and external) with or without endovascular stent placement¹ will be reviewed by the medical director(s) and/or clinical advisor(s).

- Carotid artery angioplasty with or without endovascular stent placement¹ is considered medically necessary for individuals symptomatic with a ≥ 50% carotid stenosis confirmed by duplex ultrasound OR asymptomatic with a ≥ 70% carotid stenosis confirmed by duplex ultrasound.

- Carotid artery angioplasty with or without endovascular stent placement¹ 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.

These indications include, but are not limited to:

- Individual with carotid stenosis who is a suitable candidate for carotid endarterectomy (CEA)
- Individual with carotid artery dissection

¹ Procedure may include insertion of an embolic protection device.

Resources:

Literature reviewed 06/06/17. 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 published prior to 04/02/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.68. Extracranial Carotid Artery Stenting. Re-issue date 05/08/2017, issue date 07/10/1998.


CAROTID ARTERY ANGIOPLASTY (cont.)

Resources: (cont.)

4. California Technology Assessment Forum. Percutaneous Coronary Intervention as an Alternative to Coronary Artery Bypass Grafting in Patients with Diabetes Mellitus and Multi-vessel Disease. 03/06/2013.


FDA Summary Statements for carotid stent. Device names include, but are not limited to:

Acculink® Carotid Stent System
RX Acculink® Carotid Stent System

- FDA-approved indication: Used in conjunction with Guidant carotid embolic protection systems for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below: 1) Patients with neurological symptoms and >=50% stenosis of the common or internal carotid artery by ultrasound or angiogram or patients without neurological symptoms and >=80% stenosis of the common or internal carotid artery by ultrasound or angiogram, and 2) patients must have a reference vessel diameter.

FDA Summary Statements for carotid stent. Device names include, but are not limited to:

Endotex Nexstent® Carotid Stent and Delivery System
Endotex Carotid Stent and Monorail® Delivery System

- FDA-approved indication: For treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below: 1) patients with neurological symptoms and >=50% stenosis of the common or internal carotid artery by duplex ultrasound or angiogram or patients without neurological symptoms and >=80% stenosis of the common or internal carotid artery by ultrasound or angiogram, and 2) patients must have a vessel diameter of 4mm and 9mm at the target lesion and a stenosis less than 30mm in length.
CAROTID ARTERY ANGIOPLASTY (cont.)

Resources: (cont.)

FDA Summary Statements for carotid stent. Device names include, but are not limited to:

Protégé® GPS™ Carotid Stent System
Protégé® Rx Carotid Stent System

- FDA-approved indication: Used in conjunction with ev3 embolic protection devices for the treatment of patients at high risk for adverse events from carotid endarterectomy who require percutaneous carotid revascularization and meet the following criteria: 1) patients with carotid artery stenosis (>=50% for symptomatic patients by ultrasound or angiography or >=80% for asymptomatic patients by ultrasound or angiography) of the common or internal carotid artery, and 2) patients must have a reference vessel diameter within the range of 4.5 mm and 9.5 mm at the target lesion.

FDA Premarket Approval Database for Cordis Precise® Nitinol Stent System:

- FDA-approved indication: Use in conjunction with the ANGIOGUARD® XP Emboli Capture Guidewire for patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below: 1) patients with neurological symptoms and >=50% stenosis of the common or internal carotid artery by ultrasound or angiomram or patients without neurological symptoms and >=80% stenosis of the common or internal carotid artery by ultrasound or angiography, and 2) patients must have a vessel diameter of 4-9mm at the target lesion. The vessel distal to the target lesion must be within the range of 3mm and 7.5mm to allow for placement of the ANGIOGUARD XP Emboli Capture Guidewire.

FDA Premarket Approval Database for Xact® Carotid Stent System:

- FDA-approved indication: Used in conjunction with the abbott vascular devices embolic protection system for the improvement of the lumen diameter of carotid arteries in patients considered at high risk for adverse events from carotid endarterectomy who require percutaneous carotid angioplasty and stenting for occlusive artery disease and meet the criteria outlined as follows: 1) patients with carotid artery stenosis (>=50% for symptomatic patients by ultrasound or angiography or >=80% for asymptomatic patients by ultrasound or angiography), located between the origin of the common carotid artery and the intra-cranial segment of the internal carotid artery; and 2) patients must have a reference vessel diameter ranging between 4.8 mm and 9.1 mm at the target lesion.
CAROTID ARTERY ANGIOPLASTY (cont.)

Resources: (cont.)

FDA 510K Summary for FilterWire EZ™ Embolic Protection System:

- FDA-approved indication: For use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts and carotid arteries. The diameter of the vessel at the site of filter loop placement should be between 2.25 mm and 5.5 mm for coronary saphenous vein bypass graft procedures and between 3.5 mm and 5.5 mm for carotid procedures. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature, peripheral vessels other than carotid arteries, or in treating native coronaries, including acute myocardial infarction.

FDA Premarket Approval Database for Carotid WALLSTENT® Monorail® Endoprosthesis:

- FDA-approved indication: Used in conjunction with the boston scientific embolic protection system, is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy due to either anatomic or comorbid conditions who require carotid revascularization in the treatment of ipsilateral or bilateral carotid artery disease and meet the criteria outlined below: 1) patients with neurological symptoms and > 50% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram, or patients without neurological symptoms and > 80% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram, and; 2) patients with a reference vessel diameter within the range of 4.0 mm and 9.0 mm at the target lesion.

FDA Premarket Approval Database for Enroute® Transcarotid Stent system:

- FDA-approved indication: Used in conjunction with the enroute transcarotid neuroprotection system (NPS) for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meeting the criteria outlined below. 1) patients with neurological symptoms and > = 50% stenosis of the common or internal carotid artery by ultrasound or angiogram, or patients without neurological symptoms and > = 80% stenosis of the common or internal carotid artery by ultrasound or angiogram, and; 2) patients must have a vessel diameter of 4-9 mm at the target lesion and 3) carotid bifurcation is located at minimum 5 cm above the clavicle to allow for placement for the enroute transcarotid NPS.
CAROTID ARTERY ANGIOPLASTY (cont.)

**Resources:** (cont.)

FDA 510K Summary for MO.MA® ULTRA Proximal Cerebral Protection Device:

- FDA-approved indication: The MO.MA ULTRA Proximal Cerebral Protection Device is indicated as an embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures involving lesions of the internal carotid artery and or the carotid bifurcation. The reference diameter of the external carotid artery should be between 3-6 mm and the reference diameter of the common carotid artery should be between 5-13 mm.

FDA 510K Summary for SpideRX™ Embolic Protection Device:

- FDA-approved indication: For use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

FDA 510K Summary for SpideRX™ Embolic Protection Device:

- FDA-approved indication: For use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral or peripheral vasculature.

FDA 510K Summary for SpiderFX® Embolic Protection Device:

- FDA-approved indication: For use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.
CAROTID ARTERY ANGIOPLASTY (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 nílînígíí Blue Cross Blue Shield of Arizona haada yit’éeego bíná’dí́líkídgo éí doodo Háída bijá aniyeedígíí t’aadoo le’é yina’dílíkídgo bee haza’ániin hóló díí t’aá hazaadk’ehí háká a’doooolgo bee haza’á doo baą́h ilínígóó. Ata’ halne’ígíí kojí bích’í́ hodilinh 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 vỉ đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vỉ sẽ có quyền được giúp vỉ và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viển, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أسلحة بخصوص معلومات Blue Cross Blue Shield of Arizona，则您可以使用此服务来获取帮助和信息。您有权使用自己的语言免费拨打877-475-4799。
CAROTID ARTERY ANGIOPLASTY (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuanan, 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 makuasap 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 귀하의 권리와 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사이며 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。通訳をお話される場合、877-475-4799 までお電話ください。

Farsi:

انگلیسی: اگر شما یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعات بازی که با طور رایگان دروازه تماشایی 877-475-4799 877-475-4799 می‌کنید، مطمئن شوید.

Assyrian:

Serbo-Croatian: Ukoliko Vi ćete neko neko 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: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ที่จะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่เสียเงิน โทร 877-475-4799.