BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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CAROTID ARTERY ANGIOPLASTY

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.

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.

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.

CAROTID ARTERY ANGIOPLASTY (cont.)

Criteria:

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

- Carotid artery angioplasty with or without endovascular stent placement* 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.

* Procedure may include insertion of an embolic protection device.

- Carotid artery angioplasty with or without endovascular stent placement* 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

Resources:

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 Angioplast/Stenting. Re-issue date 03/13/2014, issue date 07/10/1998.

2. Brott TG, Hobson RW, 2nd, Howard G, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med.* Jul 1 2010;363(1):11-23.

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

CAROTID ARTERY ANGIOPLASTY (cont.)

Resources: (cont.)

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 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 4-9mm 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 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.

CAROTID ARTERY ANGIOPLASTY (cont.)

Resources: (cont.)

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.