

Corporate Medical Policy

Carotid Artery Angioplasty/Stenting (CAS)

File Name: carotid_artery_angioplasty_stenting_cas
Origination: 4/2004
Last CAP Review: 6/2019
Next CAP Review: 6/2020
Last Review: 6/2019

Description of Procedure or Service

Carotid artery angioplasty with stenting (CAS) 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).

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (CEA). Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices. 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 typically 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 rarely is performed without stent placement.

Proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local/regional anesthesia)
- Cranial nerve palsies are infrequent sequelae (although almost all following CEA resolve over time)
- Simultaneous procedures may be performed on the coronary and carotid arteries

The U.S. Food and Drug Administration (FDA) has approved carotid artery stents and EPDs from various manufacturers through the premarket approval process:

Acculink™ and RX Acculink™ carotid stents and Accunet™ and RX Accunet™ cerebral protection filters, Guidant Corp., now Abbot Vascular (approved August 2004);

Xact® RX carotid stent system and Emboshield® embolic protection system, Abbott Vascular (approved September 2005);

Precise® nitinol carotid stent system and AngioGuard™ XP and RX emboli capture guidewire systems, Cordis Corp. (approved September 2006);

NexStent® carotid stent over-the-wire and monorail delivery systems, EndoTex Interventional Systems; and FilterWire EZ™ embolic protection system, Boston Scientific Corp. (approved October 2006);

ProtégéRx® and SpideRx®, ev3 Inc, Arterial Evolution Technology. (approved January 2007);

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Carotid Wallstent®, Boston Scientific Corp. (approved October 2008);

GORE® Flow Reversal System (clearance February 2009); GORE® Embolic Filter (clearance May 2011);

Mo.Ma® Ultra Proximal Cerebral Protection Device, Medtronic/Invatec (approved October 2009);

ENROUTE™ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System, Silk Road Medical (approved May 2015).

Each FDA-approved carotid stent system is indicated for combined use with an EPD. This combined use is to reduce the risk of stroke in patients considered to be at increased risk for periprocedural complications from CEA, who are symptomatic with >50% stenosis, or asymptomatic with >80% stenosis-with degree of stenosis assessed by ultrasound or angiogram with computed tomography (CT) angiography. Patients are considered at increased risk for CEA complications if affected by any item from a list of anatomic features and comorbid conditions included in each stent system's Information for Prescribers.

The RX Acculink™ Carotid Stent System is also approved for use in conventional risk patients (not considered at increased risk for complications during CEA) with symptoms and 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram, and asymptomatic patients with 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram.

FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the RX (rapid exchange) devices designed for more rapid stent and filter expansion. FDA has mandated postmarketing studies for EPDs, including longer follow-up for patients already reported to the FDA and additional registry studies, primarily to compare outcomes as a function of clinician training and facility experience. Each manufacturer's system is available in various configurations (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In 2015, FDA cleared for marketing the ENROUTE™ Transcarotid Neuroprotection System through the 510(k) process. ENROUTE™ is a flow-reversal device designed to be placed via direct carotid access.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for carotid angioplasty with associated stenting and embolic protection when it is considered to be medically necessary because the medical criteria and guidelines listed below are met.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

When Carotid Angioplasty/Stenting is covered

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Carotid angioplasty with associated stenting and embolic protection may be considered medically necessary in patients with:

1. 50-99% stenosis (NASCET measurement); AND
2. Symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days with symptom duration less than 24 hours, or nondisabling stroke; AND
3. Anatomic contraindications for carotid endarterectomy such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy; OR
4. One or more of the following comorbid conditions that places the patient at high risk for surgery:
 - clinically significant cardiac disease (CHF, abnormal stress test, or need for open-heart surgery);
 - severe pulmonary disease, i.e. COPD;
 - contralateral carotid occlusion;
 - contralateral laryngeal-nerve palsy;
 - age >80 years

When Carotid Angioplasty/Stenting is not covered

Carotid angioplasty with associated stenting and embolic protection is considered investigational for all other indications, including but not limited to, patients with carotid stenosis who are suitable candidates for CEA and patients with carotid artery dissection.

Carotid angioplasty without associated stenting and embolic protection is considered investigational for all indications, including but not limited to, patients with carotid stenosis who are suitable candidates for carotid endarterectomy and patients with carotid artery dissections.

Policy Guidelines

A substantial body of RCT evidence compares outcomes of CAS with CEA for symptomatic and asymptomatic patients with carotid stenosis. The evidence does not support use of CAS in carotid artery disease for the average risk patient, since early adverse events are higher with CAS and long-term outcomes are not better. Data from RCTs and large database studies establish that the risk of death or stroke with CAS exceeds the threshold set to indicate overall benefit from the procedure. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS does not improve health outcomes.

However, based on limited data, clinical input, an indirect chain of evidence, and unmet medical need, CAS may be considered a reasonable treatment option in recently symptomatic patients when CEA cannot be performed due to anatomic reasons, as well as, in patients when surgery poses an increased risk. For this population, CAS may be considered medically necessary. It is considered investigational for all other indications, including carotid dissection.

There are ongoing randomized trials comparing CEA and CAS (ACT I, enrolling asymptomatic patients at average risk for complications from CEA was terminated).

- SPACE 2: Stent-protected angioplasty in asymptomatic carotid artery stenosis versus endarterectomy: two 2-arm clinical trials comparing CAS, CEA, and best medical therapy in asymptomatic patients with carotid stenosis (ISRCTN78592017), estimated completion date 2020;

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- ACST-2: Carotid Endarterectomy Versus Carotid Artery Stenting in Asymptomatic Patients (NCT00883402), estimated completion date December 2019.
- CREST-2: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis trial (NCT02089217), estimated completion date December 2020.
- ECST-2: European Carotid Surgery Trial 2: a randomized controlled trial, estimated completion date March 2022.

There are no ongoing or direct comparisons of CAS versus CEA in patients at increased risk for CEA complications. Particularly problematic is the lack of adequate data, from either randomized or non-randomized studies, to separately compare outcomes of the alternatives (CAS vs. CEA vs. current optimal medical management) in symptomatic and asymptomatic increased-risk subgroups.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0075T, 0076T, 37215, 37216, 37217, 37218

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.68, 12/17/2003.

Specialty Matched Consultant Advisory Panel - 6/2004

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Brown MM. Editorial. Carotid artery stenting-evolution of a technique to rival carotid endarterectomy. *American Journal of Medicine*. 2004; 116(4):273-275.

ECRI Target Report #870 (2004, October) Carotid stenting with embolic protection for carotid artery stenosis.

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Centers for Medicare and Medicaid Services (CMS). Decision Memo for Carotid Artery Stenting (CAG-00085R). National Coverage Analysis. Medicare Coverage Database. Baltimore, MD: CMS; March 17, 2005. Retrieved 1/29/08 from <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=157&>

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SAPPHIRE Worldwide: Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy. Retrieved on 04/29/10 from <http://clinicaltrials.gov/ct2/show/NCT00403078>

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Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). Retrieved 7/5/10 from <http://clinicaltrials.gov/show/NCT00004732>

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Carotid Stenting vs. Surgery of Severe Carotid Artery Disease and Stroke Prevention in Asymptomatic Patients (ACT I). Retrieved on May 11, 2011 from <http://clinicaltrials.gov/ct2/show/NCT00106938>

Carotid Endarterectomy Versus Carotid Artery Stenting in Asymptomatic Patients (ACST-2). Retrieved on May 11, 2011 from <http://clinicaltrials.gov/ct2/results?term=NCT00883402>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.68, 3/10/11

Specialty Matched Consultant Advisory Panel review 6/2011

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Brott TG, Halperin JL, Abbara S et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. Vasc Med. 2011 Feb; 16(1):35-77. Retrieved on April 11, 2012 from <http://vmj.sagepub.com/content/16/1/35.long>

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Specialty Matched Consultant Advisory Panel review 6/2019

Medical Director review 6/2019

Policy Implementation/Update Information

- 7/29/04 New policy implemented. Carotid Artery Angioplasty/Stenting is considered investigational. Reviewed by Specialty Matched Consultant Advisory Panel 6/22/04. Notification given 7/29/04. Effective date 10/14/04.
- 1/6/05 Codes 0075T, 0076T, 37215, 37216 added to Billing/Coding section of policy.
- 8/7/06 Specialty Matched Consultant Advisory Panel review 5/3/06. Expanded description for clarification. Addition to Policy statement: Carotid artery angioplasty/stenting **may** be eligible for coverage in the context of an approved clinical trial on an individual consideration basis for those members whose certificates include clinical trial benefits. Rationale added to Policy Guidelines to support continued investigational status. Policy number added to Key Words. CPT codes and References updated. (adn)
- 7/16/07 Added the following statement to the When Carotid Artery Angioplasty/Stenting is Covered section: "Currently, the only approved clinical trial is the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) sponsored by the National Institute of Neurological Disorders and Stroke (NINDS)." (adn)
- 6/30/08 Policy Guidelines section updated with the following statement: "In a report of the SAPPHIRE trial, investigators could not demonstrate a significant difference between protected carotid artery stenting and carotid endarterectomy with respect to the risk of stroke or other major adverse events in high-risk patients at 3 years. They also found no evidence of an increased risk of repeat revascularization within 3 years after treatment. This data are specific to patients who are at high surgical risk, and provide no insight into outcomes of treatment of a carotid artery stenosis in patients at low-to-moderate risk. Further randomized trials that are specifically designed and have adequate statistical power to address the use of CAS in lower-risk patients are needed." References updated. Specialty Matched Consultant Advisory Panel review 5/15/08. No change to policy statement.(adn)
- 3/02/10 Description section extensively revised. Policy statement changed to read: BCBSNC will provide coverage for carotid angioplasty with associated stenting and embolic protection when it is considered to be medically necessary because the medical criteria and guidelines listed below are met. Information in the **When CAS Is Covered section revised to read:** "Carotid angioplasty with associated stenting and embolic protection may be considered medically necessary in patients with 50-99% stenosis (NASCET measurement); AND, Symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days, symptom duration less than 24 hours or nondisabling stroke; AND Anatomic contraindications for carotid endarterectomy (such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy." When CAS Is Not Covered Section revised to read: "Carotid angioplasty with or without associated stenting and embolic protection is considered investigational for all other indications." Policy Guidelines rationale for coverage updated. Reference added. (adn)
- 4/13/10 Added statement regarding the ACT-1 clinical trial to the Policy section (mco)
- 8/03/10 Specialty Matched Consultant Advisory Panel review 6/2010. Medical Policy number removed. Policy Guidelines updated. References updated. (mco)

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- 5/24/11 References updated. Added new clinical trials information. Added two new FDA approved carotid stents. No changes in policy statements. (mco)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy statement. (mco)
- 5/1/12 “When not Covered” section revised to state: “Carotid angioplasty with or without associated stenting and embolic protection is considered investigational for all other indications, including but not limited to, patients with carotid stenosis who are suitable candidates for CEA and patients with carotid artery dissection.” Description section updated. Policy Guidelines updated. References updated. Medical Director review 4/2012. (mco)
- 7/10/12 Specialty Matched Consultant Advisory Panel review 6/2012. No changes to Policy Statements.(mco)
- 7/16/13 Description section updated. References updated. Specialty Matched Consultant Advisory Panel review 6/2013. Medical Director review 6/2013. (mco)
- 7/15/14 Description section updated. The statement regarding the ACT-1 clinical trial removed from the Policy Statements section, as that study is listed as terminated. Policy Guidelines updated. References updated. Added CPT code 37217 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review 6/2014. (mco)
- 12/30/14 Added CPT code 37218 to Billing/Coding section effective 1/1/15. (td)
- 4/28/15 Description section updated. Policy Guidelines section updated. References updated. Policy Statement unchanged. (td)
- 9/1/15 Specialty Matched Consultant Advisory Panel review 6/2015. Medical Director review 6/2015. Policy Statement unchanged. (td)
- 7/26/16 Description section updated. Policy Guidelines and references updated. Specialty Matched Consultant Advisory Panel review 6/2016. Medical Director review 6/2016. (jd)
- 7/28/17 Minor update to Description section. Revised When Not Covered section with separation of “Carotid angioplasty with or without associated stenting...” into two paragraphs. No change to policy intent. Policy guidelines with minor updates and added ECST-2: European Carotid Surgery Trial: a randomized controlled trial, estimated completion date March 2022.” References updated. Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6/3017. (jd)
- 7/27/18 Added item 4 to the “When Covered” section: **“One or more of the following comorbid conditions that places the patient at high risk for surgery”**, along with noted bulleted indications. Added “OR” to item 3 under the same section. No change to policy intent. Minor update to policy guidelines. References updated. Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)
- 7/1/19 Minor revisions to Regulatory Status and Policy Guidelines. Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.