

Corporate Medical Policy

Carotid Artery Angioplasty/Stenting (CAS)

File Name: carotid_artery_angioplasty_stenting_cas
Origination: 4/2004
Last CAP Review: 6/2011
Next CAP Review: 6/2012
Last Review: 4/2012

Description of Procedure or Service

The success of coronary artery angioplasty and stenting has prompted interest in applications of catheter-based endovascular intervention in carotid artery disease. Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (CEA), currently considered the standard treatment for patients with significantly obstructing carotid atherosclerosis (stenosis). 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 typically takes from 20 to 40 minutes. Interventionalists almost uniformly use a distally placed embolic protection device (EPD) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. 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:

ACCULINK™ and RX ACCULINK™ carotid stents and ACCUNET™ and RX ACCUNET™ cerebral protection filters, Guidant Corp. (approved August 2004);

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

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

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

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GORE® Flow Reversal System (clearance February 2009);

Mo.Ma® Ultra Proximal Cerebral Protection Device, Invatec S.P.A. (approved October 2009).

Each FDA-approved carotid stent system is indicated for combined use with an EPD to reduce 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. 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. CAS with these devices for patients outside those indications is an off-label use.

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. The Precise® and AngioGuard™ devices were studied in a randomized, controlled trial (the SAPPHERE trial). Other devices were approved based on uncontrolled, single-arm trials or registries, and comparison to historical controls. The FDA has mandated postmarketing studies for these devices, 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.

*****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.

The ACT-1 clinical trial is considered a covered clinical trial for patients who meet trial eligibility.

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

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.

When Carotid Angioplasty/Stenting is not covered

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.

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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 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 is considered investigational.

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. For this population, CAS may be considered medically necessary. It is considered investigational for all other indications, including carotid dissection. There are major ongoing randomized trials comparing CAS versus CEA:

- ACT I, enrolling asymptomatic patients at average risk for complications from CEA (NCT00106938), estimated completion date 12/2017;
- SPACE 2, comparing CAS, CEA, and medical therapy in asymptomatic patients (ISRCTN78592017), estimated completion date 1/2015;
- ACST-2, Carotid Endarterectomy Versus Carotid Artery Stenting in Asymptomatic Patients (NCT00883402), estimated completion date 1/2018.

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.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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

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

National Institute for Clinical Excellence (NICE) 2004, July. Interventional procedures overview of carotid artery stent placement for carotid stenosis. Retrieved March 2, 2006 from <http://www.nice.org.uk/page.aspx?o=218165>

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. Retrieved on March 2, 2006 from <http://www.target.ecri.org/summary/>

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[detail.aspx?doc_id=7939&q=carotid+artery+stenosis&anm](http://www.ta.ecri.org/Forecast/Prod/summary/detail.aspx?doc_id=7939&q=carotid+artery+stenosis&anm)

ECRI Health Technology Forecast (2005, September) Carotid stenting with embolic protection for carotid artery stenosis. Retrieved on March 2, 2006 from http://www.ta.ecri.org/Forecast/Prod/summary/detail.aspx?doc_id=8427&q=carotid+artery+angioplasty&anm

BCBSA TEC Assessment [Electronic Version]. February 2005.

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=viewdecision-memo.asp&id=157&>

Institute for Clinical Systems Improvement (ICSI). Technology Assessment Report: Carotid, Vertebral and Intracranial Artery Angioplasty and Stenting. TA #93. June 2006. Retrieved 1/30/08 from http://www.icsi.org/technology_assessment_reports_-_active/carotid__vertebral_and_intracranial_artery_angioplasty_and_stenting_2.html

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.68, 4/17/07

BCBSA TEC Assessment [Electronic Version]. June 2007

Gurm HS, Yadav JS, Fayad P, et al. Long-term results of carotid stenting versus endarterectomy in high-risk patients. *J Engl J Med*. 2008 Apr 10; 358(15): 1572-9.

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.68, 12/10/09

Senior Medical Director Review 2/2010

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>

California Technology Assessment Forum Carotid Artery Stenting.(2009, June 17). Retrieved 04/27/10 from <http://www.ctaf.org/content/assessment/detail/1026>

BCBSA TEC Assessment [Electronic Version]. January 2010

Brott TG, Hobson RW, Howard G, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med* 2010. Retrieved on 7/5/10 from <http://content.nejm.org/cgi/content/abstract/363/1/11>

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

Specialty Matched Consultant Advisory Panel 6/2010

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

Bangalore S, Kumar S, Wetterslev J et al. Carotid Artery Stenting vs Carotid Endarterectomy: metaanalysis and diversity-adjusted trial sequential analysis of randomized trials. *Arch Neurol* 2011; 68(2):172-84. Retrieved on April 11, 2012 from <http://archneur.ama-assn.org/cgi/content/full/68/2/172>

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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>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.68, 3/8/12

Medical Director review 4/2012

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 SAPHIRE 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

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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)
- 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)

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.