Corporate Medical Policy

Carotid Artery Angioplasty/Stenting (CAS)

File Name: carotid_artery_angioplasty_stenting_cas
Origination: 4/2004
Last Review: 6/2023

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:

Table 1. FDA Premarket Approvals for Carotid Artery Stents and Embolic Protection Devices

Manufacturer	Device	PMA Date
Cordis Corp.	Cordis Precise Nitinol Stent System	Sept 2006
Abbott Vascular	Acculink Carotid Stent System and Rx Acculink Carotid Stent System	Aug 2004
Abbott Vascular	XACT Carotid Stent System	Sep 2005
Boston Scientific Corp.	Carotid Wallstent Monorail Endoprosthesis	Oct 2008

Boston Scientific Corp.	Endotex Nexstent Carotid Stent and Delivery System and Endotex Carotid Stent and Monorail Delivery System	Oct 2006
Medtronic Vascular	jProtege GPS and Protege Rx Carotid Stent Systems	Jan 2007
Medtronic Vascular	Exponent Self-Expanding Carotid Stent System with Over-the-Wire or Rapid-Exchange Delivery System	Oct 2007
Silk Road Medical, Inc.	Enroute Transcarotid Stent System	May 2015
	Enroute Transcarotid Stent System	Apr 2022
W. L Gore & Associates, Inc Gore Carotid Stent	Gore Carotid Stent	Nov 2018

Table 2. FDA 510(k) Carotid Artery Stents and Embolic Protection Devices

Manufacturer	**Stents and Devices**	**PMA/510(k) Date**
Guidant, now Abbott Vascular	Accunet and RX AccunetEmbolic protection system	Aug 2004
Guidant, now Abbott Vascular	Rx Accunet 2 Embolic Protection System	Nov 2004
Guidant, now Abbott Vascular	Rx Accunet Embolic Protection System	Aug 2005
Abbott Vascular	Emboshield® embolic protection system	Sep 2005
Cordis Corp.	AngioGuardä XP and RX emboli capture guidewire systems	Sep 2006
Boston Scientific	FilterWire EZ™ embolic protection system	Dec 2006
EV3 Inc	Spiderx	Feb 2007
EV3 Inc	Spidefx	Nov 2007
GORE	GORE® Flow Reversal System	Feb 2009
GORE	GORE® Embolic Filter	May 2011
Medtronic/Invatec	Mo.Ma® Ultra Proximal Cerebral Protection Device	Oct 2009
Silk Road Medical	ENROUTE™ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System	Feb 2015
Gardia Medical	Wirion	Jun 2015
Abbott Vascular	Rx Accunet Embolic Protection System	Nov 2015
Silk Road Medical, Inc.	Enroute Transcarotid Neuroprotection System	Mar 2016
Gardia Medical Ltd.	Wirion	Mar 2018
Contego Medical, LLC	Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection (Paladin System)	Sep 2018

Contego Medical, LLC	Vanguard lep Peripheral Balloon Angioplasty System With Integrated Embolic Protection	Dec 2018
Abbott Vascular	Emboshield Nav6 Embolic Protection System, Barewire Filter Delivery Wires	Jul 2019
Cardiovascular Systems	Wirion	Mar 2020
Cardiovascular Systems	Wirion Embolic Protection Device	Mar 2021
Cordis Corporation	Angioguard Xp Emboli Capture Guidewire, Angioguard Rx Emboli Capture Guidewire	Apr 2022
Contego Medical Inc.	Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection	Jun 2022
Silk Road Medical	Enroute® Transcarotid Neuroprotection System	Apr 2023

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 the 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. The 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. In April 2022, the ENROUTE® Transcarotid Stent System received expanded approval for use in the treatment of individuals at standard risk of complications from CEA. For those with neurological symptoms, criteria include 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram. For asymptomatic individuals, criteria include 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram. The carotid bifurcation location must be a minimum of 5 cm above the clavicle to allow for the placement of the ENROUTE Transcarotid Neuroprotection System.

******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

Carotid Artery Angioplasty/Stenting (CAS)

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

Carotid angioplasty with associated stenting and embolic protection may be considered medically necessary in individuals 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 individual 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, individuals with carotid stenosis who are suitable candidates for CEA and individuals with carotid artery dissection.

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

Policy Guidelines

Evidence for individuals who have carotid artery stenosis who receive carotid artery stenting (CAS), include RCTs and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. 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 because early adverse events are higher with CAS and long-term outcomes are similar between the 2 procedures. 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).

- CREST-2: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis trial (NCT02089217), estimated completion date February 2026.
- ECST-2: European Carotid Surgery Trial 2: a randomized controlled trial, estimated completion date March 2025.

The Asymtpomatic Carotid Trial 2 (ACST-2) was a multicenter RCT comparing CAS and CEA in 3625 asymptomatic patients with severe carotid stenosis. There was no significant difference between groups in the composite of death, MI, or stroke with CAS or CEA (3.9% vs. 3.2%; p=.26) within 30 days of the procedure. Five-year non-procedure related stroke was also similar between groups (5.3% with CAS vs. 4.5% with CEA; RR, 1.6; 95% CI, 0.86 to 1.57; p=.33). The authors considered the long-term outcomes of these procedures to be similar with uncommon serious complications.

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, 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.

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Institute for Clinical Systems Improvement (ICSI).Technology Assessment Report: Carotid, Vertebral and Intracranial Artery Angioplasty and Stenting. TA #93. June 2006.

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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

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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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Yadav J, Wholey M, et al. Protected Carotid-Artery Stenting versus Endarterectomy in High-Risk Patients. N Engl J Med. Oct 7 2004;351(15): 1493-1501.

Specialty Matched Consultant Advisory Panel review 6/2019

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Specialty Matched Consultant Advisory Panel review 6/2020

Medical Director review 6/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.68, 6/2020

Specialty Matched Consultant Advisory Panel review 6/2021

Medical Director review 6/2021

Specialty Matched Consultant Advisory Panel review 6/2022

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Halliday A, Bulbulia R, Bonati LH, et al. Second asymptomatic carotid surgery trial (ACST-2): a randomised comparison of carotid artery stenting versus carotid endarterectomy. Lancet. Sep 18 2021; 398(10305): 1065-1073. PMID 34469763

Specialty Matched Consultant Advisory Panel review 6/2023

Medical Director review 6/2023

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)

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)

6/30/20 References updated. Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)

7/1/21 Description section revised; replaced listed approved carotid artery stents and EPDs with Table 1 and Table 2 for updated listing of approved devices for clarity. Updated policy guidelines and references. No change to policy intent. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)

7/12/22 Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)

6/30/23 Description, Policy Guidelines and References sections updated. When Covered and Not Covered sections edited for clarity, no changes to policy statement. Specialty

Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. (tm)