

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS
Policy Number	7.01.60
Category	Technology Assessment
Effective Date	08/21/03
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

- I. Based on our criteria and assessment of the peer-reviewed literature, carotid artery angioplasty with or without stenting and distal embolic protection is considered **medically appropriate** for *symptomatic* patients with greater than 50% stenosis, who are considered at high risk for adverse outcomes (morbidity and mortality) during carotid endarterectomy surgery.
- II. Based on our criteria and assessment of the peer-reviewed literature, carotid artery angioplasty with or without stenting is considered **not medically appropriate** for *asymptomatic* patients unless the patient is enrolled in a clinical trial.
- III. Based on our criteria and assessment of the peer-reviewed literature, all other indications for carotid artery angioplasty, with or without stenting, have not been medically proven to be effective and are considered **investigational**.
- IV. Based on our criteria and assessment of the peer-reviewed literature, vertebral artery angioplasty with or without stenting has not been medically proven to be effective and is considered **investigational**.

Refer to Corporate Medical Policy # 7.01.70 regarding Angioplasty of Intracranial Atherosclerotic Stenosis with or without Stenting.

Refer to Corporate Medical Policy # 7.01.81 regarding Endovascular Repair of Intracranial Aneurysms.

Refer to Corporate Medical Policy # 7.01.82 regarding Endovascular Treatment of Acute Ischemic Stroke.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

POLICY GUIDELINES

- I. Patients at high risk for carotid endarterectomy (CEA) are defined as having significant comorbidities and/or anatomic risk factors (e.g., recurrent stenosis and/or previous neck dissection), and would be poor candidates for CEA in the opinion of a surgeon. Significant comorbid conditions include, but are not limited to:
 - A. congestive heart failure (CHF) class III/IV;
 - B. left ventricular ejection fraction (LVEF) less than 30%;
 - C. unstable angina;
 - D. contralateral carotid occlusion;
 - E. recent myocardial infarction (MI);
 - F. previous CEA with recurrent stenosis; and

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- G. an anatomic contraindication to carotid endarterectomy (e.g., prior radiation or neck surgery, spinal immobility, tracheostomy).
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Carotid angioplasty with or without associated stenting has been investigated as a less invasive alternative to open CEA for treatment of carotid stenosis. Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, stents and other devices through the femoral artery and into the carotid artery. The procedure typically takes 20 - 40 minutes and is performed with the patient completely awake. Carotid angioplasty may be performed alone, but the current trend is toward placement of a stent to decrease plaque embolization and residual stenosis. At present, most practitioners also use a distally placed embolic protection (DEP) device that is designed to reduce the risk of peri-procedural stroke caused by thromboembolic material dislodged during CAS.

CAS may have some advantages over carotid endarterectomy, the current gold standard of treatment for carotid stenosis. Carotid endarterectomy is an open surgical procedure, and as such is accompanied by the usual surgical risks – infection, bleeding, adverse reaction to anesthesia, etc. In addition, cranial nerve palsies are seen more often with carotid endarterectomy than with CAS.

Atherosclerosis of the vertebral artery is thought to be an etiologic factor in approximately 20% of posterior circulation strokes, either alone or in combination with other factors. Vertebral artery stenosis occurs most frequently at the vessel origin as it arises from the subclavian artery. The safety and efficacy of invasive treatment is uncertain and until recently, patients with vertebral artery stenosis have been treated with medical treatment alone. Extracranial vertebral artery endarterectomy and vessel reconstruction have shown to be feasible and can have favorable outcomes, however, surgery at this site is technically challenging and complications are frequent. Similar to CAS, endovascular treatment has been proposed as an alternative, less invasive approach to treat atherosclerotic vertebral artery stenosis when medical management is not successful in alleviating symptoms.

RATIONALE

The FDA has approved a variety of stents and distally placed embolic protection (DEP) devices for endoluminal treatment of carotid artery stenosis, including, but not limited to:

- I. ACCULINK™ and RX ACCULINK™ carotid stents and ACCUNET™ and RX ACCUNET™ cerebral protection filters, Guidant Corp. (Aug 2004); 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 greater than 70% stenosis by ultrasound or greater than 50% stenosis by angiogram, and asymptomatic patients with greater than 70% stenosis by ultrasound or greater than 60% stenosis by angiogram (May 2011).
- II. Xact® RX carotid stent system and Emboshield® embolic protection system, Abbott Vascular Devices (Sep 2005);
- III. SpideRX™ embolic protection device, ev3 Inc. (Feb 2006);
- IV. Precise® nitinol carotid stent system and AngioGuard™ XP and RX embolic capture guidewire systems, Cordis Corp. (Sept 2006);
- V. NexStent® carotid stent over-the-wire and monorail delivery systems, Endotex Interventional Systems and FilterWireEZ™ embolic protection system, Boston Scientific Corp. (Oct 2006).

These carotid stent systems are indicated for combined use with a DEP device to reduce stroke risk in patients at high risk for surgical complications from CEA who are symptomatic with greater than or equal to 50% stenosis or asymptomatic with greater than or equal to 80% stenosis. CAS with these devices for patients outside these indications is considered an unlabeled use.

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Carotid artery

A Cochrane systematic review (10 trials involving 3178 patients) by Ederle et al. (2009) found the following: Endovascular treatment was significantly better than surgery in avoiding cranial neuropathy (OR 0.15) and myocardial infarction (OR 0.34). There was no significant difference between endovascular treatment and surgery in the following comparisons: 30-day stroke, MI, or death (OR 1.12); 30-day disabling stroke or death (OR 1.19); 30-day death (OR 0.99); 24-month death or stroke (OR 1.26); and 30-day death or stroke in endovascular patients treated with or without protection devices (OR 0.75). The results do not support a change in clinical practice away from recommending carotid endarterectomy as the treatment of choice for suitable carotid artery stenosis but support continued recruitment in the large ongoing trials.

In August 2010, the BCBSA TEC Assessment was updated including publication of two trials enrolling “conventional” or “average-risk” patients—the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST) and the International Carotid Stenting Study (ICSS).

Between May 2001 and October 2008, ICSS enrolled 1,713 symptomatic patients at 50 academic medical centers across Europe, Australia, New Zealand, and Canada. EPDs were recommended but not required (utilized in 72% of procedures), and a number of different stents and EPD types were used. Based on plausible event rates, a target study sample size of 1,500 was estimated able to define a between-group difference less than 3.3% in disabling stroke or death, but also a 3.0% difference in 30-day stroke, death, or MI. Only interim 30- and 120-day results were included in the initial report. Although from a per-protocol analysis, the 7.1% periprocedural death/stroke death rates accompanying CAS both exceed rates established to provide a net clinical benefit and was more than twice the rate following CEA (3.4%). In a substudy of 231 ICSS participants, new ischemic brain lesions were approximately 3-fold more frequent following CAS - protection devices did not appear to mitigate their occurrence. (48) While follow-up of the sample for the primary endpoint is ongoing, interim results are consistent with the accompanying editorialist’s conclusion that “routine stenting in symptomatic patients must now be difficult to justify....”

CREST was conducted between December 2000 and July 2008, enrolling 2,522 patients at 108 centers across the U.S. and Canada. Of 427 interventionalists who applied to participate in CREST, only 224 (52%) were ultimately approved. Inclusion was initially restricted to recently symptomatic patients; due to slow enrollment, the protocol subsequently amended to include asymptomatic patients. A March 2004 protocol amendment excluded further enrollment of patients 80 years and older due to poor outcomes. Of the 1,271 patients randomized to CAS, 65 underwent CEA and 54 neither procedure; of the 1,251 patients randomized to CEA, 13 underwent CAS and 44 neither procedure. There were 20 patients excluded from one site due to reported data fabrication. A sample size of 2,500 was targeted to detect a 46% reduction in the hazard ratio for the primary endpoint of any stroke, MI, or death during the periprocedural period or ipsilateral stroke within 4 years after randomization. In the entire sample (symptomatic and asymptomatic patients), investigators reported no difference between CAS and CEA for the primary outcome of any periprocedural stroke, MI, or death or postprocedural ipsilateral stroke. Stroke was more frequent following CAS, MI after CEA. The periprocedural MI rate after CEA (2.3%) was considerably higher in CREST than any comparable trial (e.g., in EVA-3S 0.8%, SPACE 0%, ICSS 0.6%). While this may be attributable to a somewhat higher prevalence of coronary artery disease among participants, the relative difference was large. Periprocedural CAS death/stroke rates were the lowest reported in any trial. Although participating interventionalists performing CAS were highly selected, periprocedural death/stroke rates following CAS exceeded those for CEA: in symptomatic patients 5.6% versus 2.4%, respectively; in asymptomatic patients 2.6% versus 1.5%, respectively. (51) The RR for periprocedural death/stroke in the symptomatic group was 1.89 (95% CI: 1.11 to 3.21) in the asymptomatic group 1.88 (95% CI: 0.79 to 4.42). The trial had limited power in the asymptomatic group—21% power to detect a RR of 1.88. Finally, commenting on CREST, the principle investigator of North American Symptomatic Carotid Endarterectomy Trial (NASCET), Barnett et al. expressed a view that combining dissimilar patient groups (symptomatic and asymptomatic) flawed the trial.

Following completion of the current BCBSA TEC Assessment, while numerous meta-analyses have been published, the most notable was an individual patient data meta-analysis (n=3,433) of SPACE, EVA-3S and ICSS. In these symptomatic patients the 30-day death/stroke risk (per-protocol analyses) with CAS was 7.7% versus 4.4% following CEA (RR 1.74; 95% CI: 1.32 to 2.30). However, in the subgroup younger than 70 years of age, comparative 30-day death/stroke rates were 5.1% (CAS) and 4.5% (CEA) (RR: 1.11; 95% CI: 0.73 to 1.71); for patients 70 years or older 10.5% (CAS) and 4.4% (CEA) (RR: 2.41; 95% CI: 1.65 to 3.51).

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Finally, trials have found restenosis more common following CAS than CEA. In a meta-analysis of 13 trials, among those reporting restenosis rates, Bangalore et al. reported pooled relative odds for restenosis following CAS compared to CEA of 2.8 (95% CI: 2.0 to 4.0; $I^2=0\%$).

In average risk symptomatic patients there is a body of evidence demonstrating worse outcomes with CAS compared to CEA. While data show secular improvement in periprocedural outcomes following CAS (30, 51) there is evidence of a net harm compared to CEA. The individual patient data meta-analysis of SPACE, EVA-3S, and ICSS indicates some uncertainty in comparative periprocedural death/stroke rates for younger symptomatic patients. Still, that subgroup result must be considered carefully given the larger body of evidence, as well as the evidence on restenosis.

Only CREST enrolled asymptomatic average risk patients and found a relative risk for periprocedural death/stroke identical to that for symptomatic ones - the failure to reject similarity of CEA to CAS (the null hypothesis) would be suspected due to lack of power. At the same time, there have been marked improvements in medical therapy and declining stroke rates in asymptomatic patients over the 2 decades since completion of landmark trials. There is considerable evidence that medical therapy in asymptomatic patients is preferred to intervention. For example, Naylor and Bell (2008) noted that between 1985 and 2008, a steady decline occurred in ipsilateral stroke rates in medically treated asymptomatic patients with greater than 50% carotid stenosis. Most recently, Marquardt et al. (2009) described a contemporary annual ipsilateral stroke or transient ischemic attack (TIA) rate of 0.34% among asymptomatic patients with asymptomatic carotid stenosis equal to or greater than 50%; a rate less than the 0.51% estimated by Arazi et al. needed justify the periprocedural risk of death and stroke. In comparison, in 1993 the Asymptomatic Carotid Artery Stenosis trial completed randomization of asymptomatic patients with equal to or greater than 60% stenosis; the annual ipsilateral stroke rate was approximately 2.0% with medical therapy.

Vertebral artery

There is limited evidence concerning the net benefit of angioplasty and stenting for extracranial vertebral arteries. A 2009 update of a Cochrane review focused on randomized trials of angioplasty of vertebral artery stenosis compared with best medical therapy alone. The review noted that only one completed randomized trial was available. This trial, known as the CAVATAS trial (Carotid and Vertebral Artery Transluminal Angioplasty Study) included a small group of 16 patients with symptomatic severe vertebral artery stenosis who were randomized to either endovascular treatment (n=8) or medical treatment alone (n=8). There were no strokes in any arterial territory or deaths from any cause in either group within 30 days of treatment (endovascular group) or 30 days of randomization (medical group). In the endovascular group, two patients had a posterior circulation transient ischemic attack at the time of the procedure. In the endovascular group, the mean vessel stenosis at follow up was 47% (range 0% to 80%). Patients were followed up for a mean of 4.5 years in the endovascular group and 4.9 years in the medical group. There were no further vertebrobasilar territory strokes in either group for the duration of follow up. Morbidity and mortality was related to carotid and coronary artery disease in this study. The authors concluded the following: There is currently insufficient evidence to assess the effects of percutaneous transluminal angioplasty with or without stenting or primary stenting for vertebral artery stenosis.

AN Stayman, et al. (2011) conducted a systematic review of the literature to determine the risk of endovascular treatment of extracranial vertebral artery stenosis (ECVAS). A total of 27 articles were identified with a total of 980/993 patients treated with stents. The technical success rate was very high, with 973 of 980 (99.3%) stenting cases demonstrating less than 20% residual stenosis at the conclusion of the procedure. The use of drug-eluting stents was reported in 305 (31%) patients. A total of 11 vertebrobasilar strokes were reported during the first 30 days after the procedure, yielding a 1.2% procedural risk of stroke, whereas an additional 8 (0.9%) vertebrobasilar TIA were reported. A small number of deaths were reported during the 30 days after the procedure, but none was directly related to posterior ischemia provoked by vertebral artery stenting. During a follow-up period spanning an average of 21 months, 13 of 980 (1.3%) patients had a vertebrobasilar territory infarction and 64 of 980 (6.5%) had recurrent vertebrobasilar TIA symptoms. Of 993 patients, 498 (50%) were reported to have undergone follow-up angiography. The majority of studies did not have a set protocol for follow-up angiography and such procedures were largely performed on an as-needed basis for patients exhibiting recurrent symptoms. The authors concluded the following: "Heterogeneity in patient selection, clinical/angiographic follow-up, and outcome measures comprises a limitation in analysis of the data. Nonetheless, even a conservative appraisal of cumulative outcomes leads to a favorable conclusion regarding the safety and feasibility of stent placement for vertebral artery origin stenosis. The question remains as to how long-term

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outcomes (ie, vertebrobasilar stroke, recurrent vertebrobasilar TIA) differ between patients undergoing stenting and those receiving optimal medical management.”

In a systematic review by Antoniou and colleagues (2011) of percutaneous transluminal angioplasty and stenting in patients with proximal vertebral artery stenosis, the authors concluded that there is limited comparative evidence on the safety and efficacy of medical, surgical, and endovascular treatment of proximal vertebral artery disease. PTA and stenting has evolved as a safe minimally invasive therapeutic method, associated with low periprocedural neurologic adverse events and death. There seems to be a significant restenosis rate associated with angioplasty and primary stenting, which has, however, an asymptomatic course and leads to a lower reintervention rate. Further randomized trials comparing stenting with medical therapy are required, and the role of novel therapeutic modalities with the use of drug-eluting stents in the long-term efficacy of the endovascular treatment needs to be separately evaluated.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT Codes

Code	Description
0075T (E/I)	Transcatheter placement of extracranial vertebral artery stents(s), including radiologic supervision & interpretation, percutaneous; initial vessel
0076T (E/I)	each additional vessel (List separately in addition to code for primary procedure)
37215	Transcatheter placement of intravascular stents(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection
37216	without distal embolic protection
37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation

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HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

Code	Description
I63.031-I63.039	Cerebral infarction due to thrombosis of carotid artery (code range)
I63.131-I63.139	Cerebral infarction due to embolism of carotid artery (code range)
I63.231-I63.239	Cerebral infarction due to unspecified occlusion or stenosis of carotid arteries
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I65.21-I65.29	Occlusion and stenosis of carotid artery (code range)

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Code	Description
I65.8	Occlusion and stenosis of other precerebral arteries

REFERENCES

- ACST-2 Collaborative Group, et al. Status update and interim results from the asymptomatic carotid surgery trial-2 (ASCT-2). Eur J Vasc Endovasc Surg 2013 Nov;46(5):510-8.
- Altinbas A, et al. Effects of carotid endarterectomy or stenting on hemodynamic complications in the International Carotid Stenting Study: a randomized comparison. Int J Stroke 2014 Apr;9(3):284-90.
- Antoniou GA, et al. Meta-analysis and meta-regression analysis of outcomes of carotid endarterectomy and stenting in the elderly. JAMA Surg 2013 Dec 1;148(12):1140-52.
- Antonopoulos CN, et al. The impact of carotid artery stenting on cognitive function in patients with extracranial cranial artery stenosis. Ann Vasc Surg 2015 Apr;29(3):457-69.
- *Arquiza C, et al. Restenosis is more frequent after carotid stenting than after endarterectomy: the EVA-3S study. Stroke 2011 Apr;42(4):1015-20.
- *Arya S, et al. Carotid endarterectomy is superior to carotid angioplasty and stenting for perioperative and long-term results. Vasc Endovascular Surg 2011 Aug;45(6):490-8.
- *Baldi S, et al. Carotid artery stenting without angioplasty and cerebral protection: a single-center experience with up to 7 years' follow-up. AJNR Am J Neuroradiol 2011 Apr;32(4):759-63.
- *Bangalore S, et al. Carotid artery stenting vs carotid endarterectomy: meta-analysis and diversity-adjusted trial sequential analysis of randomized trials. Arch Neurol 2011 Feb;68(2):172-84.
- Baron EL, et al. Surgical versus percutaneous therapy of carotid artery disease: an evidence-based outcomes analysis. J Cardiothorac Vasc Anesth 2017 Apr 18;31(2):755-767.
- *Blackshear JL, et al. Myocardial infarction after carotid stenting and endarterectomy: results from the carotid revascularization endarterectomy versus stenting trial. Circulation 2011 Jun 7;123(22):2571-8.
- BlueCross BlueShield Association. Extracranial carotid angioplasty/stenting. Medical Policy Reference Manual Policy #7.01.68. 2018 May 4.
- BlueCross BlueShield Association. Endovascular therapies for extracranial vertebral artery disease. Medical Policy Reference Manual Policy #7.01.148. 2018 May 4.
- *BlueCross BlueShield Association. Technology Evaluation Center (TEC). Angioplasty and stenting of the cervical carotid artery with distal embolic protection of the cerebral circulation. 2007 Jun;22(1).
- *BlueCross BlueShield Association. Technology Evaluation Center (TEC). Angioplasty and stenting of the cervical carotid artery with distal embolic protection of the cerebral circulation. 2010 Aug;24(12).
- *Bonati LH, et al. Long-term risk of carotid restenosis in patients randomly assigned to endovascular treatment or endarterectomy in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): long-term follow-up of a randomized trial. Lancet Neurol 2009 Oct;8(10):908-17.
- *Bonati LH, et al. New ischemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of International Carotid Stenting Study (ICSS). Lancet Neurol 2010 Apr;9(4):353-62.
- *Bonati LH, et al. Percutaneous transluminal balloon angioplasty and stenting for carotid artery stenosis. Cochrane Database Syst Rev 2012 Sep 12;CD000515.
- Bonati LH, et al. Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomized trial. Lancet 2015 Feb 7;385(9967):529-38.
- *Bowser AN, et al. Outcome of carotid stent-assisted angioplasty versus open surgical repair of recurrent carotid stenosis. J Vasc Surg 2003 Sep;38(3):432-8.

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Brasiliense LB, et al. Advances and innovations in revascularization of extracranial vertebral artery. Neurosurgery 2014 Feb;74 Suppl:S102-15.

*Brott TG, et al. ASA/ACCF/AAN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the management of patients with extracranial carotid and vertebral artery disease: executive summary. Stroke 2011 Aug;42(8):e420-63.

Brott TG, et al. Long-term results of stenting versus endarterectomy for carotid-artery stenosis. N Engl J Med 2016 March 17;374(11):1021-1031.

Calvet D, et al. Symptomatic carotid stenosis: is stenting as safe and effectiveness as carotid endarterectomy? Curr Opin Neurol 2017 Feb;30(1):22-27.

*Carotid Stenting Guidelines Committee. Guidelines for patient selection and performance of carotid artery stenting. J Med Imaging Radiat Oncol 2009 Dec;53(6):538-45.

*Carotid Stenting Trialists' Collaboration, et al. Short-term outcome after stenting versus endarterectomy for symptomatic carotid stenosis: a preplanned meta-analysis of individual patient data. Lancet 2010 Sep 25;376(9746):1062-73.

*Carotid Stenting Trialists' Collaboration. The risk of carotid artery stenting compared with carotid endarterectomy is greatest in patients treated within 7 days of symptoms. J Vasc Surg 2013 Mar;57(3):619-626.

Chang JY, et al. Restenosis after stenting in symptomatic vertebral arterial orifice disease and considerations for better outcome. Interv Neuroradiol 2017 April;23(2):180-185.

*Chaturvedi S, et al. Carotid artery stenting in octogenarians: periprocedural stroke risk predictor analysis from the multicenter Carotid ACCULINK/ACCUNET Post Approval Trial to Uncover Rare Events (CAPTURE 2) clinical trial. Stroke 2010 Apr;41(4):757-64.

*Chen X, et al. Drug-eluting stent for the treatment of symptomatic vertebral origin stenosis: Long-term results. J Clin Neurosci 2011 Jan;18(1):47-51.

Cho SM, et al. Radiographic and symptomatic brain ischemia in CEA and CAS: A systematic review and meta-analysis. Neurology 2017 Nov 7;89(19):1877-1984.

Clinical practice guidelines. Management of atherosclerotic carotid artery disease. Society for Vascular Surgery [<https://www.jvascsurg.org/article/S0741-5214%2808%2900816-1/fulltext>] accessed 2/4/19.

Cohen JE, et al. Ischemic complications after tailored carotid artery stenting in different subpopulations with high-grade stenosis: feared but rare. J Clin Neurosci 2015 Jan;22(1):189-94.

Compter A, et al. Stenting versus medical treatment in patients with symptomatic vertebral artery stenosis: a randomized open-label phase 2 trial. Lancet Neurology 2015 Jun;14(6):606-14.

*Coward LJ, et al. Percutaneous transluminal angioplasty for vertebral artery stenosis. Cochrane Database Syst Rev 2009 Jan 21;(1):CD000516.

*Coward LJ, et al. Long-term outcome after angioplasty and stenting for symptomatic vertebral artery stenosis compared with medical treatment in the carotid and vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomized trial. Stroke 2007 May;38(5):1526-30.

De Haro J, et al. Carotid stenting in patients with high risk versus standard risk for open carotid endarterectomy (REAL-1 Trial). Am J Cardiol 2017 July 15;120(2):322-326.

De Rango P, et al. Management of carotid stenosis in women: consensus document. Neurology 2013 Jun 11;80(24):2258-68.

Diao Z, et al. Carotid endarterectomy versus carotid angioplasty for stroke prevention: a systematic review and meta-analysis. J Cardiothorac Surg 2016 Sept 8;11:142.

*Eckstein HH, et al. Results of the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) study to treat symptomatic stenosis at 2 years: a multinational, prospective, randomised trial. Lancet Neurol 2008 Oct;7(10):893-902.

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- *Ecoonomopoulos KP, et al. Carotid artery stenting versus carotid endarterectomy: a comprehensive meta-analysis of short-term and long-term outcomes. Stroke 2011 Mar;42(3):687-92.
- *Ederle J, et al. Percutaneous transluminal angioplasty and stenting for carotid artery stenosis. Cochrane Database Rev 2007 Oct 17;(4):CD000515.
- *Ederle J, et al. Randomized controlled trials comparing endarterectomy and endovascular treatment for carotid artery stenosis: a Cochrane systematic review. Stroke 2009 Apr;40(4):1373-80.
- Featherstone RL, et al. Carotid artery stenting compared with endarterectomy in patients with symptomatic carotid stenosis (International Carotid Stenting Study): a randomized controlled trial with cost effectiveness analysis. Health Technol Assess 2016 March;20(20):1-94.
- Feng H, et al. Endovascular vs. medical therapy in symptomatic vertebral artery stenosis: a meta-analysis. J Neurol 2017 May;264(5):829-838.
- Fokkema M, et al. Carotid stenting versus endarterectomy in patients undergoing reintervention after prior carotid endarterectomy. J Vasc Surg 2014 Jan;59(1):8-15.
- *Garg N, et al. Cerebral protection devices reduce periprocedural strokes during carotid angioplasty and stenting: a systematic review of the current literature. J Endovasc Ther 2009 Aug;16(4):412-27.
- Geraghty PJ, et al. preoperative symptom type influences the 30-day perioperative outcomes of carotid endarterectomy and carotid stenting in the Society for Vascular Surgery Vascular Registry. J Vasc Surg 2014 Sep;60(3):639-44.
- *Giacovelli JK, et al. Outcomes of carotid stenting compared with endarterectomy are equivalent in asymptomatic patients and inferior in symptomatic patients. J Vasc Surg 2010 Oct;52(4):906-13.
- Gonzales NR, et al. Complication rates and center enrollment volume in the carotid revascularization endarterectomy versus stenting trial. Stroke 2014 Nov;45(11):3320-24.
- Gross BA, et al. Stenting versus aggressive medical management for symptomatic vertebral artery stenosis. World Neurosurg 2015 Sep;84(3):613-5.
- *Guay J, et al. Endovascular stenting or carotid endarterectomy for treatment of carotid stenosis: a meta-analysis. J Cardiothorac Vasc Anesth 2011 Dec;25(6):1024-9.
- *Hassoun HT, et al. Secondary stroke prevention in the era of carotid stenting: update on recent trials. Arch Surg 2010 Oct;145(10):928-35.
- *Hill MD, et al. Stroke after carotid stenting and endarterectomy in the carotid revascularization endarterectomy versus stenting trial (CREST). Circulation 2012 Dec 18;126(25):3054-61.
- Hong CS, et al. Endovascular stenting versus carotid endarterectomy for treatment of severe carotid stenosis: recent results from ACT I and the updated CREST studies. World Neurosurg 2016 Aug;92:473-375.
- *Howard VJ, et al. Does sex matter? Thirty-day stroke and death rates after carotid artery stenting in women versus men: results from the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) lead-in phase. Stroke 2009 Apr;40(4):1140-7.
- Hussain MA, et al. Impact of clinical trial results on the temporal trends of carotid endarterectomy and stenting from 2002-2014. Stroke 2016 Dec;47(12):2923-2930.
- Hussain MA, et al. Long-term outcomes of carotid endarterectomy versus stenting in a multicenter population-based Canadian study. Ann Surg 2018 Aug;268(2):364-373.
- Hynes BG, et al. Carotid artery stenting for recurrent artery restenosis after previous ipsilateral carotid artery endarterectomy or stenting: a report from the National Cardiovascular Data Registry. JACC Cardiovasc Interv 2014 Feb;7(2):180-6.
- *Ielasi A, et al. Clinical outcomes following protected carotid artery stenting in symptomatic and asymptomatic patients. J Endovasc Ther 2010 Jun;17(3):298-307.

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Jalbert JJ, et al. Outcomes after carotid artery stenting in Medicare beneficiaries, 2005-2009. JAMA Neurol 2015 Mar;72(3):276-86.

Jonas DE, et al. Screening for asymptomatic carotid artery stenosis: A systematic review and meta-analysis for U.S. Preventative Services Task Force. AHRQ No. 111 [<https://www.ncbi.nlm.nih.gov/books/NBK223225/>] accessed 2/4/19.

Jung JM, et al. Long term durability and outcomes of carotid stenting and carotid endarterectomy. J Neurointerv Surg 2017 Aug;9(8):750-755.

Kakkos SK, et al. Endarterectomy achieves lower stroke and death rates compared with stenting in patients with asymptomatic carotid stenosis. J Vasc Surg 2017 Aug;66(2):607-617.

Kuliha M, et al. Randomized clinical trial comparing neurological outcomes after carotid endarterectomy or stenting. Br J Surg 2015 Feb;102(3):194-201.

Kumar R, et al. Restenosis after carotid interventions and its relationship with recurrent ipsilateral stroke: a systematic review and meta-analysis. Eur J Vasc Endovasc Surg 2017 June;53(6):766-775.

Lal BK, et al. Restenosis after carotid artery stenting and endarterectomy: a secondary analysis of CREST, a randomized controlled trial. Lancet Neurol 2012 Sep;11(9):755-63.

Li FM, et al. Therapeutic effect of carotid artery stenting versus endarterectomy for patients with high-risk carotid stenosis. Int J Clin Exp Med 2014 Sep 15;7(9):2895-900.

Li Y, et al. Long-term efficacy and safety of carotid artery stenting versus endarterectomy: a meta-analysis of randomized controlled trials. PLoS One 2017 July 14;12(7):e0180804.

*Liu ZJ, et al. Updated systematic review and meta-analysis of randomized clinical trials comparing carotid artery stenting and carotid endarterectomy in the treatment of carotid stenosis. Ann Vasc Surg 2012 May;26(4):576-90.

Lokuge K, et al. Meta-analysis of the procedural risks of carotid endarterectomy and carotid artery stenting over time. Br J Surg 2018 Jan;105(1):26-36.

Luitse MJ, et al. Residual high-grade stenosis after recanalization of extracranial carotid occlusion in acute ischemic stroke. Stroke 2015 Jan;46(1):12-15.

*Mantese VA, et al. The Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST): stenting versus carotid endarterectomy for carotid disease. Stroke 2010 Oct;41(10 Suppl):S31-4.

Markus HS, et al. Stenting for symptomatic vertebral artery stenosis: the Vertebral Artery Ischaemia Stenting Trial. Neurology 2017 Sept 19;89(12):1229-1236.

Mas JL, et al. Long-term follow-up study of endarterectomy versus angioplasty in patients with symptomatic severe carotid stenosis trial. Stroke 2014 Sep;45(9):2750-6.

*Matsumura JS, et al. Results of carotid artery stenting with distal embolic protection with improved symptoms: protected Carotid Artery Stenting in Patients at High Risk for Carotid Endarterectomy (PROTECT) trial. J Vasc Surg 2012 Apr;55(4):968-76.

McDonald RJ, et al. Comparative effectiveness of carotid revascularization therapies: evidence from a National Hospital Discharge Database. Stroke 2014 Nov;45(11):3311-9.

Mercado N, et al. Carotid artery stenting of a contralateral occlusion and in-hospital outcomes: results from the CARE (Carotid Artery Revascularization and Endarterectomy) Registry. JACC Cardiovasc Interv 2013 Jan;6(1):59-64.

Mo D, et al. Comparative outcomes of carotid artery stenting for asymptomatic and symptomatic carotid artery stenosis: a single-center prospective study. J Neurointerv Surg 2016 Feb;8(2):126-129.

Moresoli P, et al. Carotid stenting versus endarterectomy for asymptomatic carotid artery stenosis: a systematic review and meta-analysis. Stroke 2017 Aug;48(8):2150-2157.

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Müller MD, et al. Immediate and delayed procedural stroke or death in stenting versus endarterectomy for symptomatic carotid stenosis. Stroke 2018;49:2715-2722.

*Murad MH, et al. A systematic review and meta-analysis of randomized trials of carotid endarterectomy vs stenting. J Vasc Surg 2011 Mar;53(3):792-7.

*Naggara O, et al. Anatomical and technical factors associated with stroke or death during carotid angioplasty and stenting: results from the endarterectomy versus angioplasty in patients with symptomatic severe carotid stenosis (EVA-3S) trial and systematic review. Stroke 2011 Feb;42(2):380-8.

National Institute for Health and Clinical Excellence (NICE). Carotid artery stent placement for asymptomatic extracranial stenosis. IPG 388. 2011 Apr [https://www.nice.org.uk/guidance/ipg388] accessed 2/4/19.

National Institute for Health and Clinical Excellence (NICE). Carotid artery stent placement for symptomatic extracranial stenosis. IPG 389. 2011 Apr [https://www.nice.org.uk/guidance/ipg389] accessed 2/4/19.

Nevidomskyye D, et al. Comparison of outcomes in women and men following carotid interventions in the Washington state's Vascular Interventional Surgical Care and Outcomes Assessment Program. J Vasc Surg. 2018 Oct 6 [Epub ahead of print].

Radak D, et al. Endovascular treatment of symptomatic high-grade vertebral artery stenosis. J Vasc Surg 2014 Jul;60(1):92-7.

Radak D, et al. Carotid angioplasty and stenting is safe and effective for treatment of recurrent stenosis after eversion endarterectomy. J Vasc Surg 2014 Sep;60(3):645-51.

Raman G, et al. Management strategies for asymptomatic carotid stenosis: a systematic review and meta-analysis. Ann Intern Med 2013 May 7;158(9):676-85.

Rantner B, et al. The risk of carotid artery stenting compared with carotid endarterectomy is greatest in patients treated within 7 days of symptoms. J Vasc Surg 2013 Mar;57(3):619-26.

*Ricotta JJ, et al. Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease: executive summary. J Vasc Surg 2011 Sep;54(3):832-6.

*Ringleb PA, et al. Safety of endovascular treatment of carotid artery stenosis compared with surgical treatment: a meta-analysis. J Vasc Surg 2008 Feb;47(2):350-5.

Rosenfield K, et al. Randomized trial of stent versus surgery for asymptomatic carotid stenosis. N Engl J Med 2016 March 17;374(11):1011-1020.

*Sacco RL, et al. Guidelines for prevention of stroke in patients with ischemic stroke or transient ischemic attack: a statement for healthcare professionals from the American Heart Association/American Stroke Association Council on Stroke: co-sponsored by the Council on Cardiovascular Radiology and Intervention: the American Academy of Neurology affirms the value of this guideline. Stroke 2006 Feb;37(2):577-617.

Sardar P, et al. Carotid artery stenting versus endarterectomy for stroke prevention: a meta-analysis of clinical trials. J Am Coll Cardiol 2017 May 9;69(18):2266-2275.

Schermerhorn ML, et al. The impact of Centers for Medicare and Medicaid Services high-risk criteria on outcome after carotid endarterectomy and carotid artery stenting in the SVS Vascular registry. J Vasc Surg 2013 May (57(5):1318-24.

Setacci F, et al. Carotid restenosis after endarterectomy and stenting: a critical issue? Ann Vasc Surg 2013 Oct;27(7):888-93.

*Stayman AN, et al. A systematic review of stenting and angioplasty of symptomatic extracranial vertebral artery stenosis. Stroke 2011 Aug;42(8):2212-6.

Sun X, et al. The long term results of vertebral artery ostium stenting in a single center. J Neurointerv Surg 2015 Dec;7(12):888-91.

Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS

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Texakalidis P, et al. Carotid artery endarterectomy versus carotid artery stenting for patients with contralateral carotid occlusion: a systematic review and meta-analysis. World Neurosurg. 2018 Dec;120:563-571.

Timaran CH, et al. Differential outcomes of carotid stenting and endarterectomy performed exclusively by vascular surgeons in the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST). J Vasc Surg 2013 Feb;57(2):303-8.

Touze E, et al. A clinical rule (sex, contralateral occlusion, age, and restenosis) to select patients for stenting versus carotid endarterectomy: systematic review of observational studies and validation in randomized trials. Stroke 2013 Dec;44(12):3394-400.

Ullary BW, et al. Results of carotid angioplasty and stenting are equivalent for critical versus high-grade lesions in patients deemed high risk for carotid endarterectomy. J Surg Res 2013 Nov;185(1):21-6.

*Veselka J, et al. Comparison of carotid artery stenting in patients with single versus bilateral carotid artery disease and factors affecting midterm outcome. Ann Vasc Surg 2011 Aug;25(6):796-804.

Vincent S, et al. Meta-analysis of randomized controlled trials comparing the long-term outcomes of carotid artery stenting versus endarterectomy. Circ Cardiovasc Qual Outcomes 2015 Oct;8(6 Suppl 3):S99-1-8.

Wach MM, et al. Early carotid angioplasty and stenting may offer non-inferior treatment for symptomatic cases of carotid artery stenosis. J Neurointerv Surg 2014 May;6(4):276-80.

*Wang FW, et al. Outcomes after carotid artery stenting and endarterectomy in the Medicare population. Stroke 2011 Jul;42(7):2019-25.

Wimmer NJ, et al. Risk prediction for adverse events after carotid artery stenting in higher surgical risk patients. Stroke 2012 Dec;43(12):3218-24.

*Yavin D, et al. Carotid endarterectomy versus stenting: a meta-analysis of randomized trials. Can J Neurol Sci 2011 Mar;38(2):230-5.

*Key Article

KEY WORDS

Carotid angioplasty, Carotid stenosis, Carotid stents, CEA, CAS, Percutaneous Transluminal Angioplasty (PTA).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting. Please refer to the following NCD websites for Medicare Members:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201&ncdver=10&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAA%3d%3d&>