

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Extracranial Carotid and Vertebral Artery Angioplasty and Stents
Policy Number	7.01.60
Category	Technology Assessment
Original Effective Date	08/21/03
Committee Approval Date	06/17/04, 10/06/04, 04/21/05, 04/20/06, 04/19/07, 03/20/08, 04/16/09, 03/18/10, 02/17/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18, 03/21/19, 03/19/20, 03/18/21, 03/24/22, 03/23/23, 03/21/24
Current Effective Date	03/21/24
Archived Date	N/A
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> <li>• Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, extracranial 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 upon our criteria and assessment of the peer-reviewed literature, extracranial carotid artery angioplasty, with or without stenting, is considered **not medically necessary** for asymptomatic patients, unless the patient is enrolled in a clinical trial.
- III. Based upon our criteria and assessment of the peer-reviewed literature, extracranial carotid artery angioplasty, with or without stenting, has not been medically proven to be effective and, therefore, is considered **investigational** for all other indications.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, extracranial vertebral artery angioplasty, with or without stenting, has not been medically proven to be effective and, therefore, is considered **investigational**.

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

*Refer to Corporate Medical Policy #11.01.03 Investigational or Experimental Services*

*Refer to Corporate Medical Policy #11.01.10 Clinical Trials*

## POLICY GUIDELINE

- 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:

## **Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS**

**Policy Number: 7.01.60**

**Page: 2 of 8**

- A. New York Heart Association (NYHA) Functional Class III/IV congestive heart failure (CHF);
- 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;
- G. an anatomic contraindication to carotid endarterectomy (e.g., prior radiation or neck surgery, spinal immobility, tracheostomy).

### **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 with 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 to 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 which 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 percent 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. Like 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 United States Food and Drug Administration (FDA) has approved a variety of stents and DEP devices for endoluminal treatment of CAS.

Each FDA approved carotid stent is indicated for combined use with an EPD to reduce risk of stroke in patients considered at increased risk for periprocedural complications from CEA who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis with degree of stenosis assessed by ultrasound or angiogram, with computed tomography angiography also used. Patients are considered at increased risk for complications during CEA 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.

The FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the rapid exchange devices designed for more rapid stent and filter expansion. The FDA has mandated post marketing 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.

## Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS

Policy Number: 7.01.60

Page: 3 of 8

### Carotid Artery

The CREST clinical trial 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 approved. Inclusion was initially restricted to recently symptomatic patients; however, due to slow enrollment, the protocol was subsequently amended to include asymptomatic patients. A March 2004 protocol amendment excluded further enrollment of patients aged 80 years and older, due to poor outcomes. Of the 1,271 patients randomized to CAS, 65 underwent CEA, and 54 underwent neither procedure; of the 1,251 patients randomized to CEA, 13 underwent CAS, and 44 underwent 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 percent reduction in the hazard ratio for the primary endpoint of any stroke, MI, or death during the peri-procedural period, or ipsilateral stroke within four 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 peri-procedural stroke, MI, or death, or post-procedural ipsilateral stroke. Stroke was more frequent following CAS, while MI was more frequent after CEA. The peri-procedural 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. Peri-procedural CAS death/stroke rates were the lowest reported in any trial. Although participating interventionalists performing CAS were highly selected, peri-procedural death/stroke rates following CAS exceeded those for CEA: in symptomatic patients, 5.6 percent versus 2.4 percent, respectively; in asymptomatic patients, 2.6 percent versus 1.5 percent, respectively. The relative risk (RR) for peri-procedural death/stroke in the symptomatic group was 1.89 (95% confidence interval (CI): 1.11 to 3.21); in the asymptomatic group, it was 1.88 (95% CI: 0.79 to 4.42). The trial had limited power in the asymptomatic group: 21 percent power to detect an RR of 1.88. Commenting on CREST, Barnett et al., the principal investigators of the North American Symptomatic Carotid Endarterectomy Trial (NASCET), expressed a view that combining dissimilar patient groups (symptomatic and asymptomatic) flawed the trial.

A number of meta-analyses were published, the most notable being 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 percent versus 4.4 percent following CEA (RR: 1.74; 95% CI: 1.32 to 2.30). However, in the subgroup younger than age 70 years, comparative 30-day death/stroke rates were 5.1 percent (CAS) and 4.5 percent (CEA) (RR: 1.11; 95% CI: 0.73 to 1.71); for patients 70 years or older, the rates were 10.5 percent (CAS) and 4.4 percent (CEA) (RR: 2.41; 95% CI: 1.65 to 3.51).

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 peri-procedural outcomes following CAS (~~30, 51~~), there is evidence of a net harm when compared to CEA. The individual patient data meta-analysis of SPACE, EVA-3S, and ICSS indicates some uncertainty in comparative peri-procedural 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 the CREST clinical trial enrolled asymptomatic, average-risk patients and found a relative risk for peri-procedural 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 two 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 percent carotid stenosis. Marquardt et al. (2009) described a contemporary annual ipsilateral stroke or transient ischemic attack (TIA) rate of 0.34 percent among asymptomatic patients, with asymptomatic carotid stenosis equal to or greater than 50 percent (less than Arazi et al.'s estimated rate of 0.51 percent needed to justify the peri-procedural risk of death and stroke. In comparison, in 1993, the Asymptomatic

## Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS

Policy Number: 7.01.60

Page: 4 of 8

Carotid Artery Stenosis trial completed randomization of asymptomatic patients with equal to or greater than 60 percent; the annual ipsilateral stroke rate was approximately 2.0 percent with medical therapy.

Reiff et al. (2022) published 5-year outcomes from Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy 2 (SPACE-2) Randomized Control Trial. The median follow-up was 59.9 months (interquartile range, 46.6 to 60). The cumulative incidence of any stroke (ischemic or hemorrhagic) or death from any cause within 30 days, or any ipsilateral ischemic stroke within five (5) years of follow up was 2.5% (95% CI, 1.0 to 5.8), 4.4% (95% CI, 2.2 to 8.6), and 3.1% (95% CI, 1.0 to 9.4) with carotid endarterectomy (CEA) plus best medical treatment (BMT), carotid angioplasty with stenting (CAS) plus BMT, and BMT alone, respectively. No significant difference in risk for the primary efficacy endpoint was found for CEA plus BMT versus BMT alone (HR, 0.93; 95% CI, 0.22 to 3.91;  $p=.93$ ) or for CAS plus BMT versus BMT alone (HR, 1.55; 95% CI, 0.41 to 5.85;  $p=.52$ ). Since superiority of CEA or CAS to BMT was not demonstrated, noninferiority testing was not conducted. In both the CEA and CAS groups, five (5) strokes and no deaths occurred in the 30-day periprocedural period. During 5-year follow-up, three (3) ipsilateral strokes occurred in both the CAS plus BMT and BMT alone groups compared to none in the CEA plus BMT group.

The Society of Vascular Surgery Clinical Practice Guidelines for Management of Extracranial Cerebrovascular Disease (2022) has a 1A (Strong, High) recommendation: CEA over CAS in low- and standard surgical risk patients with greater than 50% symptomatic carotid artery stenosis.

### 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 Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS), 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 percent (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 were related to carotid and coronary artery disease in this study. The authors concluded that there was insufficient evidence to assess the effects of percutaneous transluminal angioplasty (PTA), with or without stenting, or primary stenting for vertebral artery stenosis.

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 of the 993 patients treated with stents. The technical success rate was very high, with 973 of the 980 (99.3%) stenting cases demonstrating less than 20 percent 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 percent procedural risk of stroke, whereas an additional eight (0.9%) vertebrobasilar TIAs 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. Most 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 outcomes (i.e., vertebrobasilar stroke, recurrent vertebrobasilar TIA) differ between patients undergoing stenting and those receiving optimal medical management.

**Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS**

**Policy Number: 7.01.60**

**Page: 5 of 8**

In a systematic review by Antoniou and colleagues (2011) of PTA and stenting in patients with proximal vertebral artery stenosis, the authors concluded that there was limited comparative evidence on the safety and efficacy of medical, surgical, and endovascular treatment of proximal vertebral artery disease. PTA and stenting have evolved as a safe, minimally invasive therapeutic method, associated with low peri-procedural 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 must 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.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

**CPT Codes**

<b>Code</b>	<b>Description</b>
0075T (E/I)	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or 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**

<b>Code</b>	<b>Description</b>
No specific codes	

**ICD10 Codes**

<b>Code</b>	<b>Description</b>
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 (code range)
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)

## Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS

Policy Number: 7.01.60

Page: 6 of 8

Code	Description
I65.8	Occlusion and stenosis of other precerebral arteries
I65.9	Occlusion and stenosis of unspecified precerebral artery

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## Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS

Policy Number: 7.01.60

Page: 7 of 8

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**Medical Policy: EXTRACRANIAL CAROTID AND VERTEBRAL ARTERY ANGIOPLASTY AND STENTS**

**Policy Number: 7.01.60**

**Page: 8 of 8**

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\*Key Article

**KEY WORDS**

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

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Per our review, there is currently a National Coverage Determination (NCD#20.7) for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting. Please refer to the following NCD websites for Medicare Members: [<https://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=gAAAABAAAAAAA%3d%3d&>] accessed 02/15/24.