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**
Revised 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**
Product Disclaimer	• *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 necessary** 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, therefore, 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, 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 # 7.01.81 Endovascular Repair of Intracranial Aneurysms.

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

Refer to Corporate Medical Policy #11.01.10 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
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) involve 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 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 AngioGuard® 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.

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 to include 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 exceeded rates established to provide a net clinical benefit and were more than twice the rate following CEA (3.4%). In a sub-study of 231 ICSS participants, new ischemic brain lesions were approximately threefold more frequent following CAS; protection devices did not appear to mitigate their occurrence. 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; 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% reduction in the hazard ratio for the primary endpoint of any stroke, MI, or death during the periprocedural 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 periprocedural stroke, MI, or death, or postprocedural ipsilateral stroke. Stroke was more frequent following CAS, while MI was more frequent 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. The RR for periprocedural death/stroke in the symptomatic group was 1.89 (95% 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% 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 age 70 years, 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, the rates were 10.5% (CAS) and 4.4% (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 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 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% carotid stenosis. 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 to 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 were related to carotid and coronary artery disease in this study. The authors concluded that there was currently insufficient evidence to assess the effects of percutaneous transluminal angioplasty, 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 980/993 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 transient ischemic attacks (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. 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 outcomes (i.e., 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 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 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, 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

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
I65.21-165.29	Occlusion and stenosis of carotid artery (code range)
I65.8	Occlusion and stenosis of other precerebral arteries
I65.9	Occlusion and stenosis of unspecified precerebral artery

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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

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&

There is currently a Local Coverage Determination (LCD) for Category III CPT® Codes. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-

details.aspx?LCDId=33392&ver=98&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=1&bc=AAgAAAQBAAAA&

There is currently a Local Coverage Article (LCA) for Category III CPT® Codes. Please refer to the following LCA website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56195&ver=21&LCDId=33392&ContrId=298&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=1&bc=AAgAAAQAgAAA&