

## Medical Policy



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### Title: Extracranial Carotid Angioplasty/Stenting

#### **Professional**

Original Effective Date: July 1, 2007  
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#### **Institutional**

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#### **DESCRIPTION**

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 through the femoral artery and into the carotid artery. 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. Examples include:

- Acculink™ and RX Acculink™ carotid stents and Accunet™ and RX Accunet™ cerebral protection filters, Guidant Corp. (approved August 2004);
- Xact® RX carotid stent system and Emboshield™ embolic protection system, Abbott Vascular Devices (approved September 2005);
- Precise® nitinol carotid stent system and AngioGuard™ XP and RX emboli capture guidewire systems, Cordis Corp. (approved September 2006);
- NexStent® carotid stent over-the-wire and monorail delivery systems, Endotex Interventional Systems; and FilterWire EZ™ embolic protection system, Boston Scientific Corp. (approved October 2006);
- ProtégéRx® and SpideRx®, ev3 Inc, Arterial Evolution Technology. (approved January 2007);
- Carotid Wallstent®, Boston Scientific Corp. (approved October 2008);
- GORE® Flow Reversal System (clearance February 2009); GORE® Embolic Filter (clearance May 2011)
- Mo.Ma® Ultra Proximal Cerebral Protection Device, Invatec S.P.A. (clearance October 2009).

Each FDA-approved carotid stent is indicated for combined use with an EPD to reduce risk of stroke in patients considered to be at increased risk for periprocedural complications from CEA who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis—degree of stenosis being assessed by ultrasound or angiogram with computed tomography (CT) angiography also sometimes 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% stenosis by ultrasound or ≥50% stenosis by angiogram, and asymptomatic patients with ≥70% stenosis by ultrasound or ≥60% 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 Precise® and AngioGuard □ devices were studied in a randomized, controlled trial (RCT) (the SAPHIRE trial; see Rationale section). Other devices were approved based on uncontrolled, single-arm trials or registries and comparison to historical controls. The FDA has mandated postmarketing studies for these devices, including longer follow-up for patients already reported to the FDA and additional registry studies, primarily to compare outcomes as a function of clinician training and facility experience. Each manufacturer's system is available in various configurations (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

**POLICY**

A. Extracranial carotid artery angioplasty and stent placement (CAS) is considered **medically necessary** in patients who meet one or more of the following criteria:

1. Symptomatic stenosis equal to or greater than 50%, or asymptomatic stenosis equal to or > 80% in a patient at a high risk for surgery due to one or more of the following conditions:
  - a. Age > 80 years; or
  - b. Congestive heart failure (NYHA Class III/IV) and/or left ventricular ejection fraction < 30%; or
  - c. Open heart surgery needed within the next 6 weeks; or
  - d. Recent myocardial infarction (> 24 hours and < 4 weeks); or
  - e. Severe chronic obstructive pulmonary disease; or
  - f. Unstable angina (CCS class III/IV);

**OR**

2. Symptomatic stenosis equal to or greater than 50% or asymptomatic stenosis equal to or greater than 80% and one or more of the following conditions:
  - a. Contralateral laryngeal nerve palsy; or
  - b. Existence of lesions distal or proximal to the usual location; or
  - c. Radiation-induced stenosis following previous radiation therapy to the neck or radical neck dissection; or
  - d. Restenosis after carotid endarterectomy (CEA); or
  - e. Severe tandem lesions that may require endovascular therapy; or
  - f. Stenosis secondary to arterial dissection; or
  - g. Stenosis secondary to fibromuscular dysplasia; or
  - h. Stenosis secondary to Takayasu arteritis; or
  - i. Stenosis that is surgically difficult to access (e.g., high bifurcation requiring mandibular dislocation); or
  - j. Stenosis associated with contralateral carotid artery occlusion; or
  - k. Pseudoaneurysm;

**OR**

3. Inability to move the neck to a suitable position for surgery;

**OR**

4. Tracheostomy.

- B. Carotid artery angioplasty and stent placement (CAS) is considered **experimental / investigational** when the above criteria are not met, including but not limited to, the following conditions:
1. Complete occlusion (100% stenosis) of the relevant carotid artery;
  2. Severe symptomatic carotid stenosis in patients not meeting the criteria above;
  3. Symptomatic stenosis < 50% of the relevant carotid artery;
  4. Asymptomatic stenosis < 80% of the relevant carotid artery.
- C. Percutaneous Angioplasty (PTA) with or without associated stenting is considered **experimental / investigational** when used in the treatment of atherosclerotic stenosis of:
1. Extracranial vertebral arteries;
  2. Intracranial arteries.

## **RATIONALE**

### **Risk/benefit ratio of invasive carotid procedures**

Endovascular carotid angioplasty and stenting (CAS) or surgical endarterectomy (CEA) for carotid artery disease trades procedure-related harms of stroke and death for the benefit of reduced stroke risk over subsequent years—the balance determines whether either intervention will result in a net clinical benefit. That balance has been scrutinized for CEA although not for CAS; accordingly results from trials of CEA must be extrapolated to CAS.

A series of landmark clinical trials from the late 1980s through the 1990s compared the benefits and harms of CEA to best medical therapies then available in symptomatic and asymptomatic individuals with carotid artery stenosis. (1-7) Those trial results defined the magnitude of risk reduction for stroke, and periprocedural stroke and death rates that can be traded to achieve a net clinical benefit or benefit outweighing harm—30-day rates less than 3% for asymptomatic (greater than 60% stenosis), and less than 6% for symptomatic patients (50–69% or 70–99% stenosis). Furthermore, because periprocedural harms are immediate but benefit is accrued over time, a net clinical benefit is obtained only in those patients surviving long enough to counterbalance the immediate harms. The necessary life expectancy was defined by the trial duration needed to demonstrate benefit—2 years for symptomatic patients with 70–99% stenosis, 5 years for symptomatic patients with 50–69% stenosis or asymptomatic patients with greater than 60% stenosis (summarized in the following Table).

Symptoms	Stenosis (%)	Acceptable Periprocedural Death / Stroke Rate, %	Anticipated Life Expectancy, yr
No	60-99	<3%	5
Yes	50-69	<6%	5
	70-99	<6%	2

As an example of the fine line between benefit and harm, Arazi et al. (8) performed a decision analysis of benefit for patients with asymptomatic stenosis using a base case derived from the Asymptomatic Carotid Surgery Trial (ACST) (periprocedural death/stroke rate of 1.8%). (7) Over a 5-year time horizon, CEA provided 4 days of stroke-free survival and a net harm when periprocedural death/disabling stroke rates exceeded 2.1%.

Since the landmark trials were performed, there have been considerable improvements in medical care and evidence of substantial decline in stroke rates with medical care in asymptomatic carotid disease. (9, 10) Current medical therapies including aggressive lipid lowering were inconsistently used in the landmark trials. While indirect, evidence for impact of improved medical care supports a perspective that guidelines for periprocedural death/stroke rates reflect upper limits needed to obtain a net clinical benefit. Surgeons in contemporary clinical trials have also achieved CEA periprocedural death and stroke rates lower than those in pivotal trials. For example, in the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST), (11) the death/stroke rates for symptomatic patients was 3.2% and for asymptomatic patients was 1.4%. Accordingly, benchmarks established decades ago might no longer be appropriate upper bounds.

Excluded from landmark CEA trials were patients with significant comorbidities such as those judged likely to cause death within 5 years that might also increase periprocedural and anesthetic risk for complications. Therefore, CAS has appeal as a treatment option for patients with potentially higher periprocedural risk due to medical or anatomic reasons (e.g., medical factors include severe cardiac dysfunction, requirement for combined coronary and carotid revascularization, severe renal or pulmonary dysfunction, and other characteristics associated with increased surgical risk; anatomic factors include surgically inaccessible stenosis, prior radiation, prior neck surgery, spinal immobility, prior laryngeal nerve palsy, contralateral occlusion, prior ipsilateral CEA, restenosis after CEA).

Although general anesthetic risk is considered a potential reason to use CAS, CEA can typically be safely performed under local or regional anesthesia (12) as confirmed in the 95-center General Anesthesia versus Local Anesthesia (GALA) trial. (13) Investigators randomized 3,526 patients undergoing CEA to general or local anesthesia and found no difference in 30-day death/stroke/myocardial infarction (MI) rates according to anesthetic approach (risk ratio [RR]: 0.94; 95% confidence interval [CI]: 0.70 to 1.3). (13)

### **Randomized controlled trials of CAS versus CEA**

SAPPHIRE. The first major RCT of CAS versus CEA was the Stenting and Angioplasty, with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) (14) trial. The relevant conclusions are summarized as follows:

- SAPPHIRE included few patients with symptomatic stenosis at increased risk for periprocedural complications from CEA (n=96), which resulted in wide confidence intervals; differences between arms in 30-day and 1-year outcomes were not statistically significant.
- For patients with asymptomatic stenosis at increased risk for periprocedural complications from CEA, differences in 30-day outcomes also had wide confidence intervals and were not statistically significant. While there were significant differences in 1-year outcomes favoring CAS with EPD for this indication, the adequacy of 1 year's follow-up duration was questionable, since durability of benefits from CAS with EPD [embolic protection device] was unknown, and since the time to benefit relative to

medical management is long when surgical risks are high. Furthermore, publicly available data reviewed by the FDA but not included in the published trial report suggested more frequent restenosis at 2 years in the CAS with EPD arm.

- Early study closure resulted in fewer study patients than planned, which compromised the evaluation of noninferiority.
- Variance in differential complication rates for the two treatments across sites may have influenced results, since 5 of 34 sites contributed 64% of randomized patients, and data were unavailable for comparison.
- Direct comparative evidence was lacking for optimal medical management alone as an alternative to adding CAS with EPD or CEA for patients with increased risk of surgical complications.

Long-term follow-up of SAPPHERE was reported at 3 years. (15-17) For asymptomatic and symptomatic patients combined, ipsilateral strokes from day 31 to 1,080 days were observed in 4.4% of patients undergoing CAS and 3.6% with CEA (from digitized figure). Cumulative 3-year repeat target vessel revascularization (a proxy for restenosis) was more common after CEA (7.1% vs. 3.0%).(16)

SPACE. In 2006, the Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE) trial was published. This trial randomized 1,200 patients within 180 days of neurologic symptoms, transient ischemic attack, or moderate (non-disabling) stroke, and with  $\geq 50\%$  stenosis of the ipsilateral carotid artery, to CAS (N=605) with or without EPD (73% of procedures performed without), or CEA (N=595). (18) The analysis (N=1,183) failed to conclude that CAS was noninferior to CEA by a margin of 2.5% for the primary outcome of ipsilateral ischemic stroke or death by 30 days after randomization. Periprocedural (30-day) event rates were 6.8% for the CAS group and 6.3% for the CEA group. The absolute between-group difference favored CEA and was 0.5% (90% CI: -1.9% to 2.9%) by intent-to-treat (ITT) analysis and 1.3% (90% CI: -1.1 to 3.8) in per-protocol analysis.

Editorialists (19, 20) pointed to some methodologic issues raised with SPACE, including the high rate of rejection for potential participating collaborators (approximately 25%, based on their prior outcomes records, but review criteria were not reported), and the trial did not require use of an EPD with CAS (although 30-day event rates were 7.3% with vs. 6.7% without EPD).

Long-term follow-up of the SPACE study was reported at 2-years. (15-17) Approximate annual ipsilateral stroke rates from day 31 through longest follow-up for CAS and CEA, respectively, were 0.4% and 0.4%. These results support a conclusion that following the periprocedural period (i.e., 31 days to longest follow-up), stroke risk reduction in symptomatic patients not selected for medical or anatomic comorbidities is similar with either CAS or CEA. Recurrent stenosis greater than 70% was more frequent 2 years following CAS versus CEA (10.7% vs. 4.6%, respectively).

EVA-3S. The Endarterectomy Versus Stenting in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial was a noninferiority comparison of CAS (with EPD in 92%) versus CEA in symptomatic patients at average risk for complications from CEA with  $\geq 60\%$  stenosis of the ipsilateral carotid artery. (21) The trial was terminated prematurely (N=527 enrolled; original target N=872), based on interim analysis of 30-day outcomes. The incidence of any stroke or death through 30 days was 3.9% (95% CI: 2.0% to 7.2%) after CEA and 9.6% (95% CI: 6.4% to 14%) after CAS (RR: 2.5; 95% CI: 1.2% to 5.1%;  $p=0.01$ ).

Over a mean follow-up of 2.1 years restenosis (>50%) was more frequent following CAS than CEA (12.5% versus 5.0%).(22) Long-term follow-up of EVA-3S was reported at 4 years. (15-17) Approximate annual ipsilateral stroke rates from day 31 through longest follow-up for CAS and CEA, respectively, were 1.1% and 0.9%. These results support a conclusion that following the periprocedural period (i.e., 31 days to longest follow-up) stroke risk reduction in symptomatic patients not selected for medical or anatomic comorbidities is similar with either CAS or CEA.

Editorialists (19, 20) criticized EVA-3S for recommending but not requiring, antiplatelet premedication (3 days of aspirin plus either ticlopidine or clopidogrel) and for not requiring interventionalists to be adequately experienced with the specific stent and EPD devices they used to treat trial subjects. Participating interventionalists were required to have successfully completed 12 or more CAS procedures, compared with 25 or more CEAs for vascular surgeons. EVA-3S also permitted use of 5 different stents and 7 different EPDs but required only 2 prior procedures with a new device before an investigator could use that device on a patient randomized to CAS.

ICSS. The International Carotid Stenting Study (23) enrolled 1,713 symptomatic patients at 50 academic medical centers across Europe, Australia, New Zealand, and Canada between May 2001 and October 2008. 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. From a per-protocol analysis, the 7.1% periprocedural death/stroke death rates accompanying CAS both exceed the rate established to provide a net clinical benefit and was more than twice that 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. (24) 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...." (25)

CREST. The Carotid Revascularization Endarterectomy vs. Stenting Trial (11) was conducted between December 2000 and July 2008, enrolling 2,522 patients at 117 centers across the U.S. and Canada. Of 427 interventionalists who applied to participate in CREST, only 224 (52%) were ultimately approved. (26) Inclusion was initially restricted to recently symptomatic patients; due to slow enrollment, the protocol was 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%). This may be attributable to a somewhat higher prevalence of coronary artery disease among participants and routine cardiac

enzyme assays, but 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 (the lowest rate for CAS reported in any trial); in asymptomatic patients 2.6% versus 1.4%, respectively. (27) The RR for periprocedural death/stroke in the symptomatic group was 1.89 (95% CI: 1.11 to 3.21) in the asymptomatic group 1.85 (95% CI: 0.79 to 4.34). The trial had limited power to detect a difference between procedures in the asymptomatic group. In CREST, 2-year restenosis (>70%) or reocclusion rates were similar following either CEA (6.3%) or CAS (6.0%)—2-year restenosis alone 5.8% with either procedure. (28)

Interventionalists in CREST were the most carefully selected in any trial, and the lack of similar careful selection has been a critique expressed concerning the other trials. (29) However, analyses of CAS in Medicare patients between 2005 and 2007 found that few CAS operators had the experience of CREST investigators. (30) Among the 11,846 procedures where operator experience was documented, 68% were performed by operators having performed fewer than 12 procedures.

**Conclusions.** These RCTs enrolled a mix of symptomatic and asymptomatic patients and employed different selection criteria for participating centers. Periprocedural stroke and death rates following CAS exceeded those after CEA. Following the early perioperative period, the subsequent rate of ipsilateral and/or transient ischemic attack (TIA) appears to be similar for the 2 procedures. While some trials found higher restenosis rates after CAS (SAPPHIRE, SPACE, EVA-3S) restenosis in CREST occurred with similar frequency following either procedure. The rates of early complications in these trials exceed the threshold that has been set to denote overall benefit. There is some variability in the results of these trials. For example, results from CREST were more favorable for CAS than those reported from the SPACE, EVA-3S, or ICSS. Periprocedural death/stroke rates with CAS were lower than 6% in symptomatic and 3% in asymptomatic patients. Interventionalists in CREST were the most carefully selected in any trial and the criteria used to credential in other trials has been a focus criticisms along with the inconsistent use of embolic protection devices.(31)

There are no RCTs of CAS versus medical therapy. Since the pivotal CEA versus medical therapy trials, there have been marked improvements in medical therapy and declining stroke rates in asymptomatic patients with carotid stenosis. In 1993 the Asymptomatic Carotid Artery Stenosis trial (32) reported that the annual ipsilateral stroke rate was approximately 2.0% with medical therapy. (10) A recent estimate in 2009 (9) 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. (8) needed justify the periprocedural risk of death and disabling stroke. This evidence can be used to argue that medical therapy in asymptomatic patients is preferable to intervention. (25, 33, 34) Therefore, it is not possible to determine whether CAS is superior to medical therapy.

### **Systematic Reviews and Meta-analysis of RCTs**

Several TEC Assessments and meta-analyses have been published with similar findings. (35) (36-39) In average risk symptomatic patients the body of evidence demonstrates worse periprocedural outcomes with CAS compared to CEA. While data show secular improvement in periprocedural outcomes following CAS (27, 40) 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, lack of stratified randomization, as well as the evidence on restenosis. Meta-analyses have generally found that restenosis is more common following CAS than CEA. In a meta-analysis of 13 trials, among those reporting restenosis rates, Bangalore et al. (41) reported pooled relative odds for restenosis following CAS compared to CEA of 2.8 (95% CI: 2.0 to 4.0; I<sup>2</sup>=0%).

Of note was the individual patient data meta-analysis (n=3,433) of SPACE, EVA-3S and ICSS. (42) 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). However, randomization was not stratified by age in these trials.

**Conclusions.** The systematic reviews corroborate the results of individual RCTs in reporting that early adverse events are higher with CAS compared to CEA, that long-term stroke rates following the perioperative period are similar, and that restenosis is higher with CAS. These data indicate that for the average risk patient with carotid stenosis, CAS is associated with a net harm compared to CEA.

### **Periprocedural death/stroke rates following CAS**

This question was assessed in the October 2009 TEC Assessment. (43) Noting again that CAS (like CEA) trades procedure-related risk of stroke and death for a reduced risk of stroke over subsequent years, and limits for periprocedural stroke and death rates that can be traded to achieve a net clinical benefit outlined in current guidelines are less than 3% for asymptomatic and less than 6% for symptomatic patients, the Assessment sought evidence to address the following questions:

1. Is the periprocedural death/stroke rate with CAS less than 3% for asymptomatic and less than 6% for symptomatic patients?  
Eighteen multicenter prospective registries collectively enrolling 20,194 patients were identified; 11 enrolled patients in accordance with FDA labeling and with 30-day outcomes available for analysis according to symptomatic status (13,783 asymptomatic and 3,353 symptomatic). For 9 registries 30-day death/stroke rates were either reported or obtained from investigators; in the remaining 2, death/stroke rates were estimated from 30-day death/stroke/MI and MI rates. An independent assessment of neurological outcomes was required in all but one registry. For asymptomatic patients, the pooled periprocedural death/stroke rate was 3.9% (95% CI: 3.3% to 4.4%; I<sup>2</sup>=57%); for symptomatic patients 7.4% (95% CI: 6.0% to 9.0%; I<sup>2</sup>=59%).  
  
A subsequent systematic review, without consideration to FDA labeling, reported results consistent with the TEC Assessment (pooled periprocedural death/stroke rates in asymptomatic patients of 3.3% [95% CI: 2.6% to 4.1%; 23 studies; 8,504 patients] and in symptomatic patients of 7.6% [95% CI: 6.3% to 9.1%; 42 studies; 4,910 patients]). (40)
2. For those subgroups defined by a) medical comorbidities or b) unfavorable anatomy, are periprocedural death/stroke rates with CAS less than 3% for asymptomatic and less than 6% for symptomatic patients?

Combined data from 2 registries reported periprocedural death/stroke rates for patients with unfavorable anatomy (44, 45) but included only 371 asymptomatic (30-day death/stroke rate 2.7% [95% CI: 1.5% to 4.9%]) and 60 symptomatic patients (30-day death/stroke rate 1.7% [95% CI: 0.3% to 8.9%]). No other registry reported results by symptomatic status for those subgroups.

### **Carotid Dissection**

Carotid dissection is uncommon (incidence approximately 2 per 100,000/year) and occurs generally in younger individuals. (46) With a frequently favorable prognosis, conservative therapy with anticoagulants to restore blood flow is typically employed while surgical intervention reserved for patients whose symptoms fail to respond to conservative care. Some have described CAS as a potential treatment in those instances (47, 48) however, there are no clinical trials comparing alternative strategies and interventions. Current guidelines (detailed below) rate CAS in for this indication as a class IIb (Level of Evidence: C) recommendation.

### **Ongoing Clinical Trials**

Major ongoing randomized trials comparing CAS versus CEA include:

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

There are no ongoing or direct comparisons of CAS versus CEA in patients at increased risk for CEA complications. (49) 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.

### **Clinical Input Received through Physician Specialty Societies and Academic Medical Centers**

In response to requests, input was received through 4 physician specialty societies (6 reviewers) and 4 academic medical centers while this policy was under review in 2009. (In addition, one unsolicited response from a specialty society was also received.) While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. This clinical input strongly supported use of CAS in recently symptomatic patients where CEA cannot be performed due to anatomic reasons, although acknowledging the limited evidence pertaining to this subgroup. The lack of alternative treatments for recently symptomatic patients and the established increased risk of stroke were factors supporting this opinion.

## Summary

A substantial body of RCT evidence compares outcomes of CAS with CEA for symptomatic and asymptomatic patients with carotid stenosis. The evidence does not support use of CAS in carotid artery disease for the average risk patient, since early adverse events are higher with CAS and long-term outcomes are not better. Data from RCTs and large database studies establish that the risk of CAS exceeds the threshold set to indicate overall benefit from the procedure. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS is considered investigational.

However, based on limited data, clinical input, an indirect chain of evidence, and unmet medical need, CAS may be considered a reasonable treatment option in recently symptomatic patients when CEA cannot be performed due to anatomic reasons. For this population, CAS may be considered medically necessary. It is considered investigational for all other indications, including carotid dissection.

## Practice Guidelines and Position Statements (50-52)

2011 ASA/ACCF/AHA/AANN/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients with Extracranial Carotid and Vertebral Artery Disease. (50-52)

	Level of Evidence
<b>CLASS I Benefit &gt;&gt;&gt; Risk</b>	
CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by more than 70% as documented by noninvasive imaging or more than 50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is less than 6% (360).	B
Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences.	C
<b>CLASS IIa Benefit &gt;&gt; Risk</b>	
It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention.	B
It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery.	B
When revascularization is indicated for patients with TIA or stroke and there are no contraindications to early revascularization, intervention within 2 weeks of the index event is reasonable rather than delaying surgery.	B
<b>CLASS IIb Benefit ≥ Risk</b>	
Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established.	B
In symptomatic or asymptomatic patients at high risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established.	B

Carotid angioplasty and stenting might be considered when ischemic neurological symptoms have not responded to antithrombotic therapy after acute carotid dissection.	C
<b>CLASS III; NO BENEFIT</b>	
Except in extraordinary circumstances, carotid revascularization by either CEA or CAS is not recommended when atherosclerosis narrows the lumen by less than 50%.	A
Carotid revascularization is not recommended for patients with chronic total occlusion of the targeted carotid artery.	C
Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function.	C

Levels of Evidence:

A—Data derived from multiple randomized controlled trials or meta-analyses; multiple populations evaluated.

B—Data derived from a single randomized controlled trial or non-randomized studies; limited populations evaluated.

C—Only consensus opinion of experts, case studies, or standard of care; very limited populations evaluated.

Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease.  
(53)

	Level of Evidence
<b>GRADE I "benefit clearly outweighs risk"</b>	
In most patients with carotid stenosis who are candidates for intervention, CEA is preferred to CAS for reduction of all-cause and periprocedural death	B
<b>GRADE II "benefits and risks are more closely matched and are more dependent on specific clinical scenarios"</b>	
CAS is preferred over CEA in symptomatic patients with >50% stenosis and tracheal stoma, situations where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy, prior cranial nerve injury, and lesions that extend proximal to the clavicle or distal to the C2 vertebral body	B
CAS is preferred over CEA in symptomatic patients with >50% stenosis and severe uncorrectable coronary artery disease, congestive heart failure, or chronic obstructive pulmonary disease	C
There are insufficient data to recommend CAS as primary therapy for neurologically asymptomatic patients with 70% to 99% diameter stenosis. In properly selected asymptomatic patients, CAS is equivalent to CEA in the hands of experienced interventionalists with a combined stroke and death rate <3%	B

Levels of Evidence:

A (high quality)

B (moderate quality)

C (Low quality)

## ESC Guidelines on the diagnosis and treatment of peripheral artery diseases. (54)

	Level of Evidence
Class IIa "Should be considered"	
In symptomatic patients at high surgical risk requiring revascularization, CAS should be considered as an alternative to CEA	B
Class IIb "May be considered"	
In symptomatic patients requiring carotid revascularization, CAS may be considered as an alternative to CEA in high-volume centers with documented death or stroke rate <6%	B

## Levels of Evidence

A (Data derived from a multiple randomized clinical trials or meta-analyses.)

B (Data derived from a single randomized clinical trial or large non-randomized studies.)

C Consensus of opinion of the experts and/or small studies, retrospective studies, registries.)

## NICE (55)

"Current evidence on the safety of CAS placement for asymptomatic extracranial carotid stenosis shows well documented risks, in particular, the risk of stroke. The evidence on efficacy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

## Australasian (56)

"CAS may be considered as a treatment option for patients with symptomatic severe carotid stenosis who are at high risk of stroke, but are surgically unsuitable for CEA, namely postradiation therapy, block dissection of the neck, in situ tracheostomy, recurrent stenosis following previous CEA, severe cervical spine arthritis, surgically inaccessible carotid stenosis (eg, obesity, high carotid bifurcation), contralateral recurrent laryngeal nerve injury, and contralateral internal carotid occlusion."

"The overall results of randomized controlled trials indicate that CAS is not as safe as CEA for treatment of symptomatic carotid stenosis for prevention of ipsilateral stroke."

"There is currently no evidence to support CAS as a treatment for asymptomatic carotid stenosis."

**CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

CPT/HCPCS

37215 Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection

37216 Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection

- 37217 Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation (*New code, effective January 1, 2014*)
- 0075T Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel
- 0076T Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel (List separately in addition to code for primary procedure)

### DIAGNOSIS

**These diagnoses are otherwise subject to medical policy as stated above**

- 433.10 Occlusion and stenosis of carotid artery without mention of cerebral infarction
- 433.11 Occlusion and stenosis of carotid artery with cerebral infarction
- 433.30 Occlusion and stenosis of multiple and bilateral precerebral arteries without mention of cerebral infarction
- 433.31 Occlusion and stenosis of multiple and bilateral precerebral arteries with cerebral infarction

### ICD-10 Diagnosis (*Effective October 1, 2014*)

- I63.031 Cerebral infarction due to thrombosis of right carotid artery
- I63.032 Cerebral infarction due to thrombosis of left carotid artery
- I63.039 Cerebral infarction due to thrombosis of unspecified carotid artery
- I63.131 Cerebral infarction due to embolism of right carotid artery
- I63.132 Cerebral infarction due to embolism of left carotid artery
- I63.139 Cerebral infarction due to embolism of unspecified carotid artery
- I63.231 Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
- I63.232 Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
- I65.21 Occlusion and stenosis of right carotid artery
- I65.22 Occlusion and stenosis of left carotid artery
- I65.23 Occlusion and stenosis of bilateral carotid arteries

### **REVISIONS**

12-09-2011	Updated the Description section.
	Updated the Rationale section.
	In the coding section:
	▪ Diagnosis nomenclature updated.
	Added the Revisions section
	Updated Reference section.

09-05-2013	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Added ICD-10 Diagnosis ( <i>Effective October 1, 2014</i> )
	Updated Reference section.
12-31-2013	In Coding section: ▪ Added CPT code 37217 ( <i>New code, effective January 1, 2014</i> )

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