Regence

Medical Policy Manual Surgery, Policy No. 93

Extracranial Carotid Angioplasty and Stenting and Embolic Protection Devices

Effective: April 1, 2026

Next Review: September 2026
Last Review: March 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Extracranial carotid angioplasty/stenting (CAS) is the insertion of a stent (wire-mesh tube) with or without an embolic protection device into a narrowed carotid artery. CAS is a treatment for carotid stenosis that is intended to prevent future stroke.

MEDICAL POLICY CRITERIA

Note: This policy does not address percutaneous angioplasty and stenting of veins, which is addressed in a separate policy (see Cross References section).

I. Extracranial carotid angioplasty and stenting may be considered **medically necessary** for the treatment of carotid artery dissection.

II. Extracranial carotid angioplasty with associated stenting and embolic protection may be considered **medically necessary** when all of the following criteria (A. – B.) are met:

A. Documented stenosis including either of the following:

1. At least 80% stenosis; or

2. At least 50% stenosis along with symptoms with duration less than 24 hours of focal ischemia (transient ischemic attack or monocular blindness) in

previous 120 days, or nondisabling stroke; and

B. One or more of the following anatomic contraindications for carotid endarterectomy are present:

1. Tissue changes from prior extensive ipsilateral neck radiation
2. Prior ipsilateral radical neck resection
3. Anatomical malformation that prevents collateral circulation to the brain during open carotid endarterectomy
4. Lesions surgically inaccessible (such as high internal carotid lesion that cannot be accessed from the neck)
5. Spinal immobility preventing open carotid endarterectomy
6. Tracheostomy

III. Extracranial carotid angioplasty is considered **investigational** for all indications that do not meet Criteria I or II.

IV. Permanent bilateral common carotid embolic protection devices are considered **investigational** for all indications, including stroke prevention in patients with atrial fibrillation.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Current symptomology
- Documentation of percent of stenosis
- Documentation of focal ischemia, including duration and date of occurrence, or nondisabling stroke, for symptomatic patients
- Contraindications for carotid endarterectomy, including one or more listed in policy

CROSS REFERENCES

1. Percutaneous Angioplasty and Stenting of Veins, Surgery, Policy No. 109

BACKGROUND

The extracranial carotid angioplasty and stenting (CAS) procedure is proposed as an alternative to medical therapy and a less invasive alternative to carotid endarterectomy (CEA). CAS involves the insertion of a stent (wire-mesh tube) into a narrowed carotid artery. A catheter (a long hollow tube) is inserted into a groin or neck artery and guided through the arteries to the narrowing in the carotid artery. A balloon at the end of the catheter is inflated to push open the narrowed area, and a metal stent is inserted to keep this area from narrowing again. The procedure is performed with the patient fully awake and without sedation. At

present, most practitioners also use a distally placed embolic protection device (EPD) that is designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Carotid angioplasty is rarely performed without stent placement.

Permanent bilateral common carotid embolic protection devices are implants placed bilaterally in the common carotid arteries via direct transcutaneous puncture to capture emboli originating from cardiac sources before they reach the brain.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved several carotid artery stents and EDPs from various manufacturers. The FDA has mandated post marketing studies for these devices. Each FDA-approved carotid stent system is indicated for combined use with a EPD.

EVIDENCE SUMMARY

CAROTID ANGIOPLASTY WITH STENT AND EMBOLIC PROTECTION FOR STENOSIS

This evidence review is focused on carotid angioplasty with stenting (CAS) compared with carotid endarterectomy (CEA) for treatment of carotid stenosis, and not on carotid stenting as a treatment for carotid artery dissection. Evidence from well-designed, well-conducted randomized controlled trials (RCTs) is necessary to establish the safety and efficacy of CAS as compared with CEA for stenosis treatment.

Systematic Reviews

Loufopoulos (2024) published as systematic review (SR) with meta-analysis evaluating new ischemic cerebral lesions using postprocedural magnetic resonance imaging in carotid artery stenting versus carotid endarterectomy (CEA).[1] A total of 25 studies reporting on 1827 CEA and 1500 CAS interventions were included. The incidence of new cerebral ischemic lesions was significantly lower after CEA compared to CAS, regardless of the time of MRI assessment (first 24 hours; OR: 0.33, 95% CI: 0.17-0.64, $p < 0.001$), (the first 72 hours, OR: 0.25, 95% CI 0.18-0.36, $p < 0.001$), (generally within a week after the operation; OR: 0.24, 95% CI: 0.17-0.34, $P < 0.001$). Also, the rate of stroke (OR: 0.38, 95% CI: 0.23-0.63, $P < 0.001$) and the presence of contralateral new cerebral ischemic lesions (OR: 0.16, 95% CI 0.08-0.32, $p < 0.001$) were less frequent after CEA. Subgroup analysis based on the study design and the use of embolic protection device during CAS showed consistently lower rates of new lesions after CEA.

Gasior (2023) published a SR with network meta-analysis evaluating the management of asymptomatic carotid artery stenosis (ACAS), including carotid endarterectomy (CEA), carotid artery stenting (CAS), and best medical treatment (BMT).[2] The study assessed peri-operative (within 30 days) and long term (30 days - five years) stroke and mortality risk between ACAS interventions. Seventeen reports (14 310 patients) with > 50% ACAS were included. CEA reduced the odds of a peri-operative stroke event occurring vs. CAS (odds ratio [OR] 1.6, 95% confidence interval [CI] 1.1 - 2.2 [0 - 20 fewer/1 000]). CEA and CAS reduced the long-term odds of minor strokes (OR 0.35, 95% CI 0.21 - 0.59 [20 fewer/1 000]) and ipsilateral strokes (OR 0.27, 95% CI 0.19 - 0.39 [30 fewer/1 000]) vs. all BMT. CEA reduced the odds of major strokes and combined stroke and mortality vs. traditional BMT; however, no difference was found between CEA and modern BMT. CAS reduced the odds of peri-operative MI (OR 0.49, 95% CI 0. 26 - 0.91) and CNI (OR 0.07, 95% CI 0.01 - 0.42) vs. CEA.The authors conclude

that BMT carries the potential to reduce the requirement for surgical intervention in patients with ACAS.

A 2020 Cochrane review found CAS associated with an increased risk of periprocedural death or stroke compared with CAE, based on 10 RCTs that included 5,396 patients (odds ratio [OR] 1.70, 95% confidence interval [CI] 1.31 to 2.19). Risk or periprocedural death or stroke remained higher with CAS in subgroup analysis of patients younger than age 70 years (OR 1.11, 95% CI 0.74 to 1.64) and in those patients aged 70 years and older (OR 2.23, 95% CI 1.61 to 3.08), although this estimate was not statistically significant. The effect was similar in asymptomatic patients based on seven trials of 3,378 individuals (OR 1.72, 95% CI 1.00 to 2.97). The review also found CAS associated with a significantly increased risk of at least moderate (≥50%) restenosis (four RCTs, n=2,115, OR 2.00, 95% CI 1.12 to 3.60) and a nonsignificant risk of severe (≥70%) restenosis (nine RCTs, n=5,744, OR 1.26, 95% CI 0.79 to 2.00) in a pooled group of symptomatic and asymptomatic patients.

A systematic review and meta-analysis of RCTs by Li (2016) assessed the long-term efficacy and safety of CAS compared to CEA.[3] Eight trials, including the large RCTs ACT I, CREST, ICCS, EVA-3S, CAVATAS, and BACASS, with a total of 7,005 patients were included in the analysis. All studies had at least four years of follow-up. Seven of the trials contributed data on stroke risk, which was significantly higher with stenting event rate (9.3% vs 6.8%, OR 1.45, 95% CI 1.22 to 1.73, p<0.0001). Stenting was also associated with an increased risk for the composite endpoint of death, ipsilateral stroke, or periprocedural stroke compared with CEA in eight trials (OR 1.25, 95% CI 1.05 to 1.48, p=0.01).

Vincent (2015) conducted a similar meta-analysis of eight RCTs (total n=7,091 patients).[4] Studies were selected that compared CAS to CEA, enrolled more than 50 patients, and reported periprocedural or long-term outcomes, and included CREST, ICSS, SPACE, EVA-3S, CAVATAS, and SAPPHIRE. CAS was associated with an increased rate of any type of periprocedural stroke (relative risk [RR] 1.49, 95% CI 1.11 to 2.01), a similar risk of a disabling or major stroke, and a decreased risk of periprocedural myocardial infarction (RR 0.47, 95% CI 0.29 to 0.78). However, in follow-up ranging from 2 to 10 years, stenting was associated with an increased risk of stroke (RR 1.36, 95% CI 1.16 to 1.61) and an increased risk of a composite end point of ipsilateral stroke, periprocedural stroke, or periprocedural death (RR 1.45, 95% CI 1.20 to 1.75). This analysis supports the conclusion that CEA remains the treatment of choice for most patients, due to the increase in adverse events with CAS.

Three systematic reviews and meta-analyses compared CEA and CAS outcomes in patients with asymptomatic stenosis. The review by Kakkos (2017) included nine RCTs with a total of 3,709 patients (CEA n=1,479, CAS n=2,230).[5] In this analysis, CAS was associated with a higher rate of stroke or death at 30 days (2.9% vs. 1.9% with CEA, OR 1.57, 95% CI 1.01 to 2.44). Myocardial infarction (MI) at 30 days did not differ significantly between groups, but cranial nerve injury at 30 days was lower in the CAS group (OR 0.13, 95% CI 0.07 to 0.26). The composite outcome of stroke or death at 30 days plus ipsilateral stroke at one year was higher for CAS than CEA (OR 1.51, 95% CI 1.02 to 2.24). A similar review by Moresoli (2017) included 11 reports of five RTCs with 3,019 asymptomatic patients.[6] They found a trend toward higher incidences of periprocedural stroke with CAS, which was not statistically significant (RR 1.95, 95% CI 0.98 to 3.89). A review by Galyfos (2019) included 10 randomized trials (total n=8,771) and concluded that CEA was associated with a lower risk of early stroke in asymptomatic patients compared with CAS, but other outcomes were not significantly different.[7]

Paraskavas (2014) conducted a systematic review of studies comparing cognitive outcomes after CEA with those after CAS.[8] Thirteen studies were included, with heterogeneity in the types of cognitive outcome measures reported. In a qualitative analysis, the authors report that the majority of studies did not report a significant difference between CEA and CAS in terms of cognitive outcomes, but that the heterogeneity in outcomes reported precluded more definitive conclusions.

Galyfos (2014) reported results of a systematic review that included nine trials (n=5,959) with a focus on risk of periprocedural symptomatic or asymptomatic myocardial ischemia or infarction.[9] Four studies did not report their definition used for myocardial ischemia, and other studies varied in their definitions. In pooled analysis, compared with CEA, CAS was associated with decreased risk for cardiac damage (pooled RR 0.37, 95% CI 0.22 to 0.61, p=0.0001). However, the study provides incomplete information about selection of studies for inclusion, which limits conclusions that can be drawn.

A 2012 updated Cochrane Review systematically reviewed all RCTs comparing carotid angioplasty and stenting with carotid endarterectomy or medical care.[10] The Cochrane Review found strong evidence that endovascular treatment in patients with symptomatic carotid stenosis is associated with a higher risk of death or stroke than CEA up to 30 days after the procedure. The evidence was also rated strong for an association between patient age and excess risk with endovascular treatment. There was insufficient evidence to determine whether the comparative risks of endovascular treatment versus CEA depended on the patient's sex, vascular anatomy, or characteristics of atherosclerotic plaque. Little is known on the long-term durability of endovascular treatment beyond four years, especially with respect to restenosis and recurrent stroke rates. The combined results of two large[11, 12] and three small trials showed no significant increase in severe restenosis after primary stenting compared with endarterectomy, but there was a wide confidence interval surrounding the effect measure and evidence of substantial heterogeneity (I^2 = 58%). The available evidence does not rule out the possibility of a small increase in restenosis rates among patients receiving stent treatment compared with endarterectomy, and it is not known if restenosis increases the risk of recurrent stroke. The existing evidence does not allow any firm conclusions on the comparative safety and efficacy of endovascular treatment versus endarterectomy in patients with asymptomatic carotid stenosis.

A 2012 Agency for Healthcare Research and Quality (AHRQ) report evaluated the evidence from 60 eligible studies of treatment strategies for patients with asymptomatic carotid artery stenosis.[13, 14] The report noted that the definitions of "asymptomatic" patients were heterogeneous across the evaluated studies (i.e., patients without symptoms, patients with symptoms present for at least six months before their enrollment in the study but recently [within six months] asymptomatic, or patients with symptoms in a vascular territory other than ipsilateral carotid [e.g., vertebrobasilar territory]). The report focused on evidence for the following treatments:

- Medical therapy alone
- CEA and medical therapy compared with medical therapy alone
- CAS and medical therapy compared with medical therapy alone
- CAS and medical therapy compared with CEA and medical therapy.

For evidence on CAS and medical therapy compared with CEA and medical therapy, the review concluded that "one recent large trial (CREST) reported higher rates of postprocedural

ipsilateral stroke (including any periprocedural stroke) and its composite primary endpoint in the CAS[group], as compared with CEA, but this did not reach statistical significance in patients with asymptomatic carotid stenosis. The CREST and the SAPPHIRE trials randomized patients with symptomatic and asymptomatic carotid stenosis stratified according to symptom status. Therefore, the treatment assignment was randomized among the subgroup of patients with asymptomatic carotid stenosis. However, neither trial was powered to detect a significant difference in the primary composite endpoint among subgroups of patients with asymptomatic carotid stenosis. The failure to find a significant difference does not rule out the possibility that real difference exists between the intervention modalities tested." The authors also stated that "future trials should focus not only on whether CAS is equivalent or superior to CEA, but also on whether an invasive interventional procedure is likely to translate into any significant benefit to the patient treated with current best medical therapy."

The 2007 and 2009 BlueCross BlueShield Association Technology Evaluation Center (TEC) assessments did not identify reliable evidence in support of CAS.[15, 16] Five major randomized trials of CAS vs. CEA were reviewed in the TEC Assessments (SPACE, EVA-3S, SAPPHIRE, ICSS, and CREST) and all had significant limitations, including early termination (SPACE and EVA-3S), small numbers of symptomatic vs. asymptomatic patients (SAPPHIRE), significant loss to follow-up (CREST),[17] and lack of power to reliably detect differences between treatment arms overall as well as in the subanalyses (CREST)[17].

Khan (2014) published a systematic review with meta-analysis of risk factors associated with stroke and/or death in patients undergoing CAS.[18] The following were reported to be independent risk factors for 30-day stroke and death following CAS:

- Symptomatic carotid stenosis compared with asymptomatic stenosis
- Age >80 years for 30-day stroke/death
- Age >70 years for 4-year stroke/death
- Lesion characteristics (e.g., ulceration, irregularity, calcification, length)
- Final residual stenosis >30%

No significantly increased risk of 30-day post-CAS stroke and/or death was found for gender, cardiac disease, or cardiovascular risk factors including hypertension, hyperlipidemia chronic obstructive pulmonary disease, peripheral artery disease, cigarette smoking. Mixed and unclear associations with risk were found for chronic renal failure, diabetes mellitus, high C-reactive protein levels, timing of procedure relative to the index ischemic event. Pre- and postprocedural use of statin medications was reported to be associated with lower periprocedural stroke and/or death.

Many other meta-analyses of the studies that compare carotid angioplasty/stenting (CAS) with endarterectomy (CEA) have been published.[19-33] These analyses reported inconsistent findings, most of which favor CEA over CAS for symptomatic carotid stenosis. The reliability of the conclusions from these meta-analyses is limited by pooling results from unreliable, heterogenous primary studies (different patient samples, endovascular procedures, duration of follow-up and/or completion status of the trials). A review of 17 systematic reviews comparing these procedures found that none fulfilled all items of the AMSTAR-2, an appraisal tool for systematic reviews, and graded the overall confidence in the results of 16 of the reviews as critically low.[34]

Randomized Controlled Trials

The Asymptomatic Carotid Trial (ACT) I was a noninferiority trial of CAS versus CEA in asymptomatic individuals who were not at high risk for surgical complications.[35] Enrollment began in 2005 with a target of 1,658 participants, but because of slow enrollment, the trial was halted in 2013 with 1,453 participants. The primary composite endpoint of death, stroke, MI within 30 days, or ipsilateral stroke within one year was obtained in 3.8% of CAS and 3.4% of CEA patients, while the cumulative five-year rate of stroke-free survival was 93.1% with CAS and 94.7% with CEA (p=0.44). This study does not answer the question of how best to treat asymptomatic patients, since it does not include a medical therapy arm. Patients who are treated with current best medical therapy may have an ipsilateral stroke rate of only 0.5% to 1% per year.[36]

The second asymptomatic carotid surgery trial (ACST-2) was a multicenter RCT comparing CAS and CEA in 3,625 asymptomatic patients with severe carotid stenosis.[37] There was no significant difference between groups in the composite of death, MI, or stroke with CAS or CEA (3.9% vs. 3.2%, p=0.26) within 30 days of the procedure. Five-year non-procedure related stroke was also similar between groups (5.3% with CAS vs. 4.5% with CEA, RR=1.6, 95% CI 0.86 to 1.57, p=0.33). The authors considered the long-term outcomes of these procedures to be similar with uncommon serious complication.

Meschia (2022) published a post hoc analysis of 826 asymptomatic patients enrolled in the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) with no stroke symptoms at baseline and with at least one completed follow-up Questionnaire for Verifying Stroke-free Status (QVSS).[38] The hazards ratio (HR) for adjudicated stroke with CAS compared to CEA in this analysis was nonsignificant at 1.02 (95% CI, 0.57 to 1.85). However, significant treatment differences for CAS versus CEA were detected for the outcome of stroke symptoms (HR, 1.54; 95% CI, 1.15 to 2.08) and the composite outcome of adjudicated stroke or stroke symptoms (HR, 1.38; 95% CI, 1.04 to 1.83). The authors concluded that inclusion of stroke symptoms to broaden the outcome of stroke prevention trials should be considered to permit sufficiently powered analyses in low-risk populations.

Brott (2016) reported long-term follow-up for CREST.[39] There were no significant differences in the primary composite outcome (any periprocedural stroke, MI, death or postprocedural ipsilateral stroke) between the CEA (9.9%) and CAS (11.8%, HR 1.10) groups when measured out to 10 years. The second primary endpoint of post procedural ipsilateral stroke rate was also not significantly different between CEA (5.6%) and CAS (6.9%, HR 0.99).

Several publications have analyzed data from the CREST trial to compare specific outcomes of CAS vs. CEA or investigate the safety of these procedures in different subgroups.[40-42] However, any findings based on the CREST data are unreliable due to the biases introduced by the loss to follow-up and inadequate statistical power. In a follow up analysis of the CREST trial data, Gonzalez (2014) reported no differences in outcomes for subjects treated in high-, medium-, or low-volume centers.[43]

Featherstone (2016) published a health technology assessment (HTA) on the International Carotid Stenting Study (ICSS) funded by the U.K.’s National Institute for Health Research Health Technology Assessment program.[44] The HTA reviewed the all of the data from the study, concluding that “the functional outcome after stenting is similar to endarterectomy, but stenting is associated with a small increase in the risk of non-disabling stroke. The choice between stenting and endarterectomy should take into account the procedural risks related to individual patient characteristics.”

Altinbas (2014) reported that periprocedural rates of hemodynamic instability in ICSS differed between CEA and CAS groups.[45] Hemodynamic depression occurred more commonly in CAS patients (13.8% vs 7.2%, RR 1.9, 95% CI 1.4 to 2.6, p<0.0001), while hypertension requiring treatment occurred less commonly in CAS patients (RR 0.2, 95% CI 0.1 to 0.4, p<0.0001). Hemodynamic instability was not associated with the ICSS study's primary composite outcome.

Reiff (2022) published 5-year outcomes from Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy 2 (SPACE-2) RCT.[46] 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 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 CEA plus Best Medical Treatment (BMT), 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 strokes and no deaths occurred in the 30-day periprocedural period. During 5-year follow-up, three ipsilateral strokes occurred in both the CAS plus BMT and BMT alone groups compared to none in the CEA plus BMT group.

Reiff (2019) published one-year interim results of the Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy 2 (SPACE-2) RCT.[47] The SPACE-2 RCT was originally planned to compare best medical treatment (BMT) to CEA plus BMT or CAS plus BMT in 3,550 patients with high grade asymptomatic extracranial carotid artery stenosis. But, because patient recruitment was slow, the RCT was amended in 2013 to become two parallel randomized studies (BMT alone versus CEA plus BMT, and BMT alone versus CAS plus BMT). After recruitment continued to be slow, SPACE-2 was ultimately stopped early in 2016 after only 513 patients were randomized. Although the interim analysis did not find significant differences between CEA and CAS in one-year rates of stroke or all-cause mortality, SPACE-2 authors noted that it is insufficiently powered to detect such differences.

Additional smaller trials not included in the systematic reviews above have compared CEA with CAS. A study by Li (2014) randomized 130 subjects at high risk of stroke due to angiographically confirmed carotid stenosis (≥50%) to CEA (n=65) or CAS (n=65).[48] The authors reported a three-month post-operative risk of mortality of 1.5% with CAS, compared with 9.2% with CEA. However, "existence of complete follow-up data" is an inclusion criterion, and insufficient details are provided about enrollment and randomization procedures to allow conclusions to be drawn about the study. Kuliha (2015) published results of an RCT which randomized 150 subjects with at least 70% carotic stenosis to CEA (n=73) or CAS (n=77). New infarctions on MRI were found more frequently after CAS (49% vs 25%, p=0.002).[49] A randomized trial comparing CAS to CEA in 136 asymptomatic patients with >70% carotid stenosis was published by Mannheim and Karmeli (2016). After a mean follow-up time of 26 months, they found no difference in short- or long-term outcomes.[50]

Non-randomized Studies

Ishida (2024) published a retrospective review analyzing the early postoperative outcomes of carotid artery stenting and endarterectomy in patients with prior contralateral carotid

revascularization.[51] The study included a review of the Society of Vascular Surgery Vascular Quality Initiative database and included 20,761 patients with prior unilateral carotid revascularization, of which 12,788 underwent contralateral carotid endarterectomy and 7,973 underwent contralateral carotid artery stenting. Patients with prior carotid endarterectomy undergoing contralateral carotid artery stenting had higher rates of postoperative in-hospital stroke (1.8% vs 1%, p = 0.003), new-onset arrhythmia (2% vs 1.2%, p = 0.006), and 30-day mortality (1.3% vs 0.8%, p = 0.04) compared to prior carotid artery stenting followed by contralateral carotid artery stenting.

Columbo (2018) published an analysis of long-term outcomes for registry patients who underwent CEA (n=29,235) or CAS (n=4,415) between 2003 and 2013.[52] Mortality among these patients from the Vascular Quality Initiative registry was tracked through the patients' Medicare claims files. After adjustment for age, sex and comorbidities, CEA was associated with lower five-year mortality compared with CAS (HR 0.75, 95% CI 0.69 to 0.82). Similar results were seen in a propensity-matched analysis (n=4,261 matched pairs).

Hussain (2017) reported on a multi-center, population-based Canadian study comparing long-term outcomes for CAS and CEA for 15,525 patients treated between 2002 and 2014.[53] The incidence of the primary composite outcome, which included 30-day death, stroke, or MI, and any stroke during follow-up, was higher with CAS than CEA (adjusted hazard ratio [HR] 1.57, 95% CI 1.43 to 1.73, p<0.001). This was primarily due to the higher rates of 30-day death, 30-day stroke, and stroke during follow-up seen in patients with stenting. However, CAS was associated with a lower incidence of 30-day MI (adjusted HR 0.70, 95% CI 0.57 to 0.86).

Salzler (2017) conducted a large retrospective analysis of the increased use of CAS since the Centers for Medicare & Medicaid guidelines recommended CAS for high-risk patients needing carotid revascularization.[54] Data from the Nationwide Inpatient Sample were searched for patients undergoing carotid revascularization. From 2005 (when the guidelines were published) to 2011, 20,079 CEAs and 3,447 CASs were performed on high-risk patients. During the study period, CAS utilization increased significantly among all high-risk patients. A subgroup analysis of symptomatic high-risk patients did not show an increase in CAS use, indicating that the increase in CAS was primarily in asymptomatic high-risk patients. The odds of in-hospital mortality (OR 2.6, 95% CI 1.2 to 5.6) and postoperative in-hospital stroke (OR 1.5, 95% CI 1.1 to 3.7) were independently and significantly higher in patients undergoing CAS compared with CEA in the overall sample of high-risk patients.

Additional evidence has been published related to rates of periprocedural stroke/death following CAS, particularly related to subgroups defined by medical comorbidities. Spangler (2014) evaluated patients treated with isolated primary CEA (n=11,336) or primary CAS (n=544) at 29 centers between 2003 and 2013 to assess periprocedural mortality and stroke risks for patients considered medically high risk.[55] A Cox proportional hazards model was used to generate predicted five-year mortality, and patients in the highest risk score quartile were considered high- risk. For asymptomatic patients, there were no significant differences between CEA and CAS for major periprocedural outcomes (major or minor stroke, myocardial infarction, death) for either high- or low-risk patients. Periprocedural death/stroke rates with CAS were 1.1% for low-risk patients and 1.6% for high- risk patients. For symptomatic patients, periprocedural death/stroke rates were higher with CAS than CEA for both low- and high-risk groups. For low-risk symptomatic patients, periprocedural death/stroke rates were 6.0% for CAS, compared with 2.2% for CEA (p<0.01). For high-risk symptomatic patients, periprocedural death/stroke rates were 9.3% for CAS, compared with 2.5% for CEA (p<0.01).

Section Summary

A number of other nonrandomized studies, case series, and registries on carotid angioplasty and stenting (CAS) have been published.[55-73] While these studies contribute to the body of knowledge by providing direction for future research, evidence from these studies does not permit conclusions due to methodological limitations such as nonrandom allocation of treatment and lack of appropriate comparison groups. In addition, registry data may be unreliable due to incomplete reporting. Finally, the technology under investigation may change over time, further limiting the ability to carry out reliable comparisons based on the registry data.

PERMENANT CAROTID EMBOLIC PROTECTION DEVICES

Reddy (2019) published a multicenter, nonrandomized, first-in-human clinical trial evaluating the feasibility and safety of bilateral permanent coil filter placement in both common carotid arteries for stroke prevention in atrial fibrillation patients unsuitable for oral anticoagulation (n = 25).[74] The study achieved 92% procedural success (23 of 25 patients with bilateral deployment), with no device or procedure-related major adverse events at 30 days; however, asymptomatic thrombi were detected in four patients during mean 6-month follow-up (all resolved with subcutaneous heparin), and one patient experienced two device-unrelated minor strokes. Study limitations include the small sample size, nonrandomized design, short follow-up period, and lack of a control group for comparison.

There is not enough research to show that permanent bilateral common carotid embolic protection devices improve health outcomes. This technology differs from temporary embolic protection devices used during carotid artery stenting procedures. The available evidence consists of a single small feasibility study (CAPTURE trial, n = 25) demonstrating technical feasibility and short-term safety, but not clinical efficacy in individuals with atrial fibrillation. No permanent bilateral common carotid embolic protection devices have received FDA approval, and current clinical practice guidelines do not address these devices. Therefore, permanent bilateral common carotid embolic protection devices are considered investigational for all indications, including stroke prevention in patients with atrial fibrillation.

PRACTICE GUIDELINE SUMMARY

AMERICAN HEART ASSOCIATION/AMERICAN STROKE ASSOCIATION (AHA/ASA)

The American Heart Association and the American Stroke Association (2021) issued guidance for the prevention of stroke in patients with stroke and transient ischemic attack (TIA).[75] They recommended that for patients with severe extracranial carotid artery stenosis ipsilateral to a nondisabling stroke or TIA, the choice between CEA and CAS in patients who are candidates for intervention should be patient specific. Specific recommendations for CAS or CEA include the following:

- In patients with a TIA or nondisabling ischemic stroke within the past 6 months and ipsilateral severe (70%-99%) carotid artery stenosis, CEA is recommended to reduce the risk of future stroke, provided that perioperative morbidity and mortality risk is estimated to be <6%. (Class of recommendation [COR]: 1, Level of evidence [LOE]: A)
- In patients with recent TIA or ischemic stroke and ipsilateral moderate (50%-69%) carotid stenosis as documented by catheter-based imaging or noninvasive imaging, CEA is recommended to reduce the risk of future stroke, depending on patient-specific

factors such as age, sex, and comorbidities, if the perioperative morbidity and mortality risk is estimated to be <6%. (COR: 1, LOE: B-R)

- In patients ≥70 years of age with stroke or TIA in whom carotid revascularization is being considered, it is reasonable to select CEA over CAS to reduce the periprocedural stroke rate. (COR: 2a, LOE: B-R)
- In patients in whom revascularization is planned within 1 week of the index stroke, it is reasonable to choose CEA over CAS to reduce the periprocedural stroke rate. (COR: 2a, LOE: B-R)
- In patients with symptomatic severe stenosis (≥70%) in whom anatomic or medical conditions are present that increase the risk for surgery (such as radiation-induced stenosis or restenosis after CEA) it is reasonable to choose CAS to reduce the periprocedural complication rate. (COR: 2a, LOE: C-LD)
- In symptomatic patients at average or low risk of complications associated with endovascular intervention, when the ICA stenosis is ≥70% by noninvasive imaging or >50% by catheter-based imaging and the anticipated rate of periprocedural stroke or death is <6%, CAS may be considered as an alternative to CEA for stroke prevention, particularly in patients with significant cardiovascular comorbidities predisposing to cardiovascular complications with endarterectomy. (COR: 2b, LOE: A)

ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS

The 2011 Guideline on the Management of Patients with Extracranial Carotid and Vertebral Artery Disease[76] specifies the circumstances in which CAS may be indicated as an alternative to CEA, as well as the circumstances when it may be reasonable to choose CAS over CEA. However, the recommendations are based on B level of evidence, the lower level of evidence defined in the guideline as derived from a single randomized trial or non-randomized studies. Further, the specific randomized trials referenced for these determinations are the CREST and SAPPHIRE trials. The findings from these trials are considered unreliable due to significant study limitations as explained above.

SOCIETY FOR VASCULAR SURGERY

The Society for Vascular Surgery published updated guidelines for management of extracranial cerebrovascular disease in 2022.[77] They recommended CEA over CAS in low- and standard-risk patients with more than 50% symptomatic artery stenosis (strong evidence of high quality). The guidelines note that while present data are inadequate to make a recommendation on the role of transcarotid arterial revascularization (TCAR) in low surgical risk patients with symptomatic carotid stenosis, TCAR is superior or preferable to TF-CAS or CEA for patients with high anatomic and/or physiologic surgical risk.

SUMMARY

There is enough research to show that carotid artery stenting (CAS) can improve health outcomes for individuals with carotid artery dissection. Therefore, CAS is considered medically necessary for this indication.

There is enough research to show that carotid artery stenting (CAS) improves health outcomes compared with carotid endarterectomy (CEA) for certain higher-risk individuals with carotid artery stenosis that should not have CEA, and in these individuals, CAS may provide better health outcomes. Therefore, CAS is considered medically necessary for

individuals who meet policy criteria.

There is not enough research to show that carotid artery stenting (CAS) improves health outcomes compared with carotid endarterectomy (CEA) except in a select group of individuals identified in the policy criteria. Therefore, for individuals that do not meet these criteria, CAS is considered investigational.

There is not enough research to show that percutaneous placement of permanent bilateral common carotid embolic protection devices improves health outcomes for any individual. Current evidence based clinical guidelines do not recommend these devices. Therefore, percutaneous placement of permanent bilateral common carotid embolic protection devices is considered investigational for any indication including for stroke prevention in individuals with atrial fibrillation.

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CODES

Codes	Number	Description
CPT	37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection
	37216	;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
	37246	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery
	37247	;each additional artery (List separately in addition to code for primary procedure)
HCPCS	C7532	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), initial

Codes	Number	Description
		artery, open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, with intravascular ultrasound (initial noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation
HCPCS	C7563	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery, initial artery and all additional arteries
	C8010	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral

Date of Origin: *May 2010*