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# Extracranial Carotid Angioplasty or Stenting

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## Disclaimer

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## Coverage

Carotid angioplasty or transcarotid artery revascularization (TCAR) with the placement of a Food and Drug Administration (FDA)-approved carotid stent with an FDA-approved or cleared embolic protection device **may be considered medically necessary** when:

- Individual has symptomatic carotid artery stenosis with 50% to 99% stenosis (NASCET [North American Symptomatic Carotid Endarterectomy Trial] measurement); OR
- Individual has asymptomatic carotid artery stenosis ≥70%.

Carotid angioplasty or transcarotid artery revascularization (TCAR) **is considered experimental, investigational and/or unproven** for all other indications, including but not limited to:

- Individuals with carotid stenosis who are suitable candidates for carotid endarterectomy (CEA); AND
- Individuals with carotid artery dissection.

## Policy Guidelines

None.

## Description

Carotid artery angioplasty with stenting and transcarotid artery revascularization are treatments for carotid stenosis that is intended to prevent future stroke. They are an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy (CEA).

**Background**

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to CEA. Carotid artery stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices. The procedure is most often performed through the femoral artery, but a transcervical approach can also be used to avoid traversing the aortic arch. The procedure typically takes 20 to 40 minutes. Interventionalists almost uniformly use an embolic protection device (EPD) 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 is rarely performed without stent placement.

The proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local or 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.

Transcarotid artery revascularization (TCAR) is another option among individuals with carotid stenosis who were defined as high risk (includes both clinical and anatomic characteristics). (1) The procedure involves a stenting technique that incorporates direct cervical carotid artery exposure and flow-reversal embolic protection.

**Regulatory Status**

A number of CAS and EPDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) or the 510(k) process. Table 1 lists the original PMAs with product code NIM and Table 2 lists 510(k) approvals with product code NTE.

**Table 1. FDA Premarket Approvals for Carotid Artery Stents and Embolic Protection Devices**

| Manufacturer | Device | PMA | PMA Date |
|---|---|---|---|
| Cordis Corp. | Cordis Precise Nitinol Stent System | P030047 | Sep 2006 |
| Abbott Vascular | Acculink Carotid Stent System and Rx Acculink Carotid Stent System | P040012 | Aug 2004 |
| Abbott Vascular | XACT Carotid Stent System | P040038 | Sep 2005 |
| Boston Scientific Corp. | Carotid Wallstent Monorail Endoprosthesis | P050019 | Oct 2008 |

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|---|---|---|---|
| Boston Scientific Corp. | Endotex Nexstent Carotid Stent and Delivery System and Endotex Carotid Stent and Monorail Delivery System | P050025 | Oct 2006 |
| Medtronic Vascular | Protege GPS and Protégé Rx Carotid Stent Systems | P060001 | Jan 2007 |
| Medtronic Vascular | Exponent Self-Expanding Carotid Stent System with Over-the-Wire or Rapid-Exchange Delivery System | P070012 | Oct 2007 |
| Silk Road Medical, Inc. | Enroute Transcarotid Stent System | P140026 | May 2015 |
| | Enroute Transcarotid Stent System | P140026 S016 | Apr 2022 |
| W.L. Gore & Associates, Inc. | Gore Carotid Stent | P180010 | Nov 2018 |
| Contego Medical | Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection | P240009 | Oct 2024 |

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

**Table 2. FDA 510(k) Carotid Artery Stents and Embolic Protection Devices**

| Manufacturer | Device | 510(k) Number | PMA/510(k) Date |
|---|---|---|---|
| Guidant, now Abbott Vascular | Accunet and RX Accunet Embolic Protection System | K042218 | Aug 2004 |
| Guidant, now Abbott Vascular | RX Accunet 2 Embolic Protection System | K042908 | Nov 2004 |
| Guidant, now Abbott Vascular | RX Accunet Embolic Protection System | K052165 | Aug 2005 |
| Abbott Vascular | Emboshield® Embolic Protection System | K052454 | Sep 2005 |
| Cordis Corp. | AngioGuard XP and RX Emboli Capture Guidewire Systems | K062531 | Sep 2006 |
| Boston Scientific | FilterWire EZ™ Embolic Protection System | K063313 | Dec 2006 |
| EV3 Inc. | Spiderx | K052659 | Feb 2007 |
| EV3 Inc. | Spidefx | K063204 | Nov 2007 |
| GORE | GORE® Flow Reversal System | K083300 | Feb 2009 |
| GORE | GORE® Embolic Filter | K103500 | May 2011 |
| Medtronic/Invatec | Mo.MA® Ultra Proximal Cerebral Protection Device | K092177 | Oct 2009 |
| Silk Road Medical | ENROUTE™ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System | K143072 | Feb 2015 |
| Gardia Medical | Wirion | K143570 | Jun 2015 |
| Abbott Vascular | RX Accunet Embolic Protection System | K153086 | Nov 2015 |

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|---|---|---|---|
| Silk Road Medical, Inc. | Enroute Transcarotid Neuroprotection System | K153485 | Mar 2016 |
| Gardia Medical Ltd. | Wirion | K180023 | Mar 2018 |
| Contego Medical, LLC | Paladin Carotid Post-Dilation Balloon System with Integrated Embolic Protection (Paladin System) | K181128 | Sep 2018 |
| Contego Medical, LLC | Vanguard lep Peripheral Balloon Angioplasty System with Integrated Embolic Protection | K181529 | Dec 2018 |
| Abbott Vascular | Emboshield Nav6 Embolic Protection System, Barewire Filter Delivery Wires | K191173 | Jul 2019 |
| Cardiovascular Systems | Wirion | K200198 | Mar 2020 |
| Cardiovascular Systems | Wirion Embolic Protection System | K210282 | Mar 2021 |
| Cordis Corporation | Angioguard Xp Emboli Capture Guidewire, Angioguard Rx Emboli Capture Guidewire | K220654 | Apr 2022 |
| Contego Medical Inc. | Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection | K221339 | Jun 2022 |
| Silk Road Medical | Enroute® Transcarotid Neuroprotection System | K230402 | Apr 2023 |

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

FDA product codes: NIM (stents) and NTE (EPDs).

## Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias

and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Carotid Artery Stenting**

Clinical Context and Therapy Purpose

The purpose of carotid artery stenting (CAS) is to provide a treatment option for carotid artery stenosis that is an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy (CEA).

The following PICO was used to select literature to inform this policy.

*Populations*

The relevant population of interest is individuals with carotid artery stenosis.

*Interventions*

The therapy being considered is CAS. Revascularization with CAS can be accomplished via transfemoral, transradial, or transcarotid endovascular approaches.

*Comparators*

The comparator of interest is CEA.

*Outcomes*

The general outcomes of interest are overall survival, morbid events, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Risk-Benefit Ratio of Invasive Carotid Procedures

Endovascular CAS and surgical CEA for carotid artery disease trade 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 but not for CAS; accordingly, results from trials of CEA must be extrapolated to assess outcomes for CAS.

*Randomized Controlled Trials*

A series of landmark clinical trials from the late 1980s through the 1990s compared the benefits and harms of CEA with best medical therapies then available in symptomatic and asymptomatic individuals with carotid artery stenosis. (2-8) Those trial results defined the magnitude of risk reduction for stroke and the periprocedural stroke and death rates for 30 days, which must be offset to achieve a net clinical benefit (benefit outweighing harm), less than 3% for asymptomatic (>60% stenosis), and less than 6% for symptomatic patients (50%-69% or 70%-99% stenosis). Furthermore, because periprocedural harms are immediate, but benefit accrues over time, a net clinical benefit is obtained only for those patients surviving long enough to counterbalance the immediate harms. The necessary life expectancy defined by the trial duration needed to demonstrate benefit is summarized in Table 3.

**Table 3. Acceptable Periprocedural Death or Stroke Rate in Clinical Trials of CEA**

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

CEA: carotid endarterectomy; y: year(s).

As an example of the fine line between benefit and harm, Arazi et al. (2008) (9) 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, 1.8%). (8) Over a 5-year time horizon, CEA provided 4 days of stroke-free survival and net harm when periprocedural death or disabling stroke rates exceeded 2.1%.

Since the landmark trials were performed, there has been considerable improvement in medical care resulting in a substantial decline in stroke rates among patients with asymptomatic carotid disease. (10, 11) Current medical therapies, such as aggressive lipid-lowering medications, were inconsistently used in the landmark trials. Also, surgeons in contemporary clinical trials have achieved CEA periprocedural death and stroke rates lower than those in the pivotal trials used to establish the benchmarks. For example, in the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), the death or stroke rate for symptomatic patients was 3.2%, and for asymptomatic patients was 1.4%. (12) Accordingly, the benchmarks established decades ago may no longer be appropriate. A recent consensus document by De Rango et al. (2013) has suggested benchmarks of 2.0% for asymptomatic and 4.0% for symptomatic individuals. (13)

Excluded from landmark CEA trials were patients with significant comorbidities 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 (e.g., severe cardiac dysfunction, requirement for combined coronary and carotid revascularization, severe renal or pulmonary dysfunction, and

other characteristics associated with increased surgical risk) or anatomic reasons (e.g., surgically inaccessible stenosis, prior radiation, prior neck surgery, spinal immobility, prior laryngeal nerve palsy, contralateral occlusion, prior ipsilateral CEA, restenosis after CEA).

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, and restenosis after CEA).

Although the general anesthetic risk is considered a potential reason to use CAS, CEA can be safely performed under local or regional anesthesia, (14) as confirmed in the 95-center General Anesthesia versus Local Anesthesia (GALA) trial. (15) The GALA trial investigators randomized 3,526 patients undergoing CEA to general or local anesthesia and found no difference in 30-day death, stroke, or myocardial infarction (MI) rates based on anesthetic approach (relative risk [RR], 0.94; 95% confidence interval [CI], 0.70 to 1.3). (15)

Randomized Controlled Trials of Carotid Artery Stenting Versus Carotid Endarterectomy

*SAPPHIRE Trial*

The first major RCT comparing CAS with CEA was the Stenting and Angioplasty, with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial reported by Yadav et al. (2004). (16) The relevant conclusions are summarized below:

- For patients with symptomatic stenosis at increased risk for periprocedural complications from CEA (n=96), the sample size was small, resulting in wide confidence intervals for estimated effects; 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 (n=238), differences in 30-day outcomes also had wide confidence intervals and were not statistically significant.
- The study closed early due to slow recruitment as nonrandomized stent registries were established, resulting in fewer study patients than planned, which compromised the evaluation of non-inferiority.
- Variance in differential complication rates for the 2 treatments across sites might have influenced results, because 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 an embolic protection device (EPD) or CEA for patients with increased risk of surgical complications.

Long-term follow-up of SAPPHIRE was reported at 3 years. (17, 18) For asymptomatic and symptomatic patients combined, ipsilateral strokes from day 31 to day 1080 were observed in 4.4% of patients undergoing CAS and in 3.6% with CEA (estimated from a digitized figure). Cumulative 3-year repeat target vessel revascularization (a proxy for restenosis) was more

common after CEA, but the difference was not statistically significant (7.1% versus 3.0%; p=0.26).

*SPACE Trial*

Ringleb et al. (2006) published results from the Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE) trial. This trial randomized 1200 patients within 180 days of neurologic symptoms, transient ischemic attack (TIA), or moderate (nondisabling) stroke, and with 50% or more stenosis of the ipsilateral carotid artery to CAS (n=605) with or without EPD (73% of procedures performed without) or to CEA (n=595). (19) The analysis (N=1183) 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 intention-to-treat analysis, and 1.3% (90% CI, -1.1 to 3.8) in the per-protocol analysis.

Editorialists pointed to some methodologic issues raised with the SPACE trial, including the high rate of rejection for potential participating collaborators (≈25%, based on their prior outcomes records, but review criteria were not reported), and the lack of a requirement to use an EPD with CAS (although 30-day event rates were 7.3% with versus 6.7% without EPD). (20, 21)

Long-term follow-up of the SPACE trial was reported at 2 years. (18) Approximate annual ipsilateral stroke rates from day 31 through longest follow-up for CAS and CEA were 0.4% in each group. Following the periprocedural period (i.e., 31 days to longest follow-up), stroke risk reduction in symptomatic patients not selected based on medical or anatomic comorbidities was similar for CAS and CEA. Recurrent stenosis greater than 70% was more frequent 2 years with CAS (10.7%) than with CEA (4.6%; p=0.001).

*EVA-3S Trial*

The Endarterectomy Versus Stenting in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial was a noninferiority comparison of CAS (with EPD in 92% of patients) to CEA in symptomatic patients at average-risk for complications from CEA with 60% or more stenosis of the ipsilateral carotid artery. (22) 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 2.1 years of follow-up, restenosis (≥50%) was more frequent following CAS (12.5%) than CEA (5.0%). (23) Long-term follow-up from the EVA-3S trial was reported at 4 years. (24) 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 supported a conclusion that following the periprocedural period (i.e., 31 days to longest follow-up), stroke risk reduction in symptomatic patients not selected based on medical or anatomic comorbidities was similar for CAS and CEA.

Editorialists criticized the EVA-3S trial for recommending but not requiring antiplatelet premedication (3 days of aspirin plus ticlopidine or clopidogrel) and for not requiring interventionalists to be adequately experienced with the specific stent and EPDs used to treat trial subjects. (20, 21) Participating interventionalists were required to have completed 12 or more CAS procedures compared with 25 or more CEAs for vascular surgeons. The EVA-3S trial also permitted the 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.

Mas et al. (2014) published long-term follow-up results (median, 7.2 years) from the EVA-3S trial. (25) Complete follow-up until death or the final telephone interview was obtained in 493 (94%) of the 527 patients. At the 5-year follow-up, the main composite endpoint (ipsilateral stroke after randomization or procedural stroke or death) occurred in 29 (11%) of 265 subjects in the CAS group and 16 (6.1%) of 262 subjects in the CEA group (5-year absolute risk reduction, 4.7%). The hazard ratio (HR) for CAS versus CEA was 1.85 (95% CI, 1.0 to 3.40; p=0.04). At the 10-year follow-up, the HR for the main composite endpoint for CAS versus CEA was 1.70 (95% CI, 0.95 to 3.06; p=0.07).

*International Carotid Stenting Study*

The International Carotid Stenting Study (ICSS) enrolled 1713 symptomatic patients at 50 academic medical centers across Europe, Australia, New Zealand, and Canada between May 2001 and October 2008. (26) EPDs were recommended but not required (used 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 1500 was estimated to be able to define a between-group difference less than 3.3% in disabling stroke or death and 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 or 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 subgroup analysis of 231 ICSS participants, new ischemic brain lesions were approximately 3-fold more frequent following CAS, and protective devices did not appear to mitigate their occurrence. (27) Interim results were consistent with the accompanying editorialist's conclusion that "routine stenting in symptomatic patients must now be difficult to justify…." (28)

Bonati et al. (2015) published longer-term follow-up results from ICSS. (29) The cumulative 5-year risk of fatal or disabling stroke did not differ significantly between the CAS (6.4%) and the CEA groups (6.5%; HR, 1.06; 95% CI, 0.72 to 1.57; p=0.77). However, the 5-year cumulative risk of any stroke was higher in the CAS group (15.2%) than in the CEA group (9.45%; HR, 1.71; 95% CI, 1.28 to 2.3; p<0.001). The authors noted that the difference between the CEA and CAS groups in stroke risk after the procedural period was mainly attributable to strokes occurring in the contralateral carotid or vertebrobasilar territory in the CAS group. Functional outcomes, measured by modified Rankin Scale scores, did not differ significantly between groups.

Altinbas et al. (2014) reported that periprocedural rates of hemodynamic instability in the ICSS differed between CEA and CAS groups. (30) Hemodynamic depression occurred more commonly in CAS patients (13.8% versus 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.

Featherstone et al. (2016) published a health technology assessment on ICSS funded by the National Institute for Health Research. (31) The assessment reviewed the data presented above, 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."

*CREST Trial*

The Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) was conducted between December 2000 and July 2008 and enrolled 2,522 patients at 117 centers across the United States and Canada. (12) Of 427 interventionalists who applied to participate in CREST, only 224 (52%) were approved. (32) Inclusion was initially restricted to recently symptomatic patients. Due to slow enrollment, the protocol was amended to include asymptomatic patients. A protocol amendment in March 2004 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 underwent neither procedure; of the 1251 patients randomized to CEA, 13 underwent CAS and 44 underwent neither procedure. Twenty patients were excluded from 1 site due to reported data fabrication. A sample size of 2500 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. Stroke was more frequent following CAS; 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%). This might 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 or stroke rates were the lowest reported in any trial. Although participating interventionalists performing CAS were highly selected, periprocedural death or 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); and in asymptomatic patients, 2.6% versus 1.4%, respectively. (33) The relative risk for periprocedural death or stroke in the symptomatic group was 1.89 (95% CI, 1.11 to 3.21) and in the asymptomatic group it was 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 CEA (6.3%) and CAS (6.0%); 2-year restenosis alone was 5.8% with either procedure. (34)

Brott et al. (2016) reported on long-term follow-up from the CREST trial. 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 followed up to 10 years. (35) The second primary endpoint (postprocedural ipsilateral stroke rates) also did not differ significantly between CEA (5.6%) and CAS (6.9%; HR=0.99).

Interventionalists in CREST were the most carefully selected in any trial, and the lack of similar selection criteria has been a critique of the other trials. (36) Analyses of CAS in Medicare patients between 2005 and 2007 found that few CAS operators had the experience of CREST investigators. (37) Among the 11,846 procedures with documented operator experience, 68% were performed by operators having performed fewer than 12 procedures.

In a follow-up analysis of CREST data, Gonzales et al. (2014) reported no differences in efficacy and safety outcomes for subjects based on receiving treatment in high-, medium-, or low-volume centers. (38)

In 2022, Meschia et al. published a post hoc analysis of 826 asymptomatic patients enrolled in CREST with no stroke symptoms at baseline and with at least 1 completed follow-up Questionnaire for Verifying Stroke-free Status (QVSS). (39) The 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.

*Asymptomatic Carotid Trial*

The Asymptomatic Carotid Trial (ACT) was a noninferiority trial reported by Rosenfield et al. (2016) who compared CAS with CEA in asymptomatic individuals not at high-risk for surgical complications. (40) Enrollment began in 2005, with a target of 1658 participants, but the trial was halted in 2013 at 1453 participants because of slow enrollment. The primary composite endpoint (death, stroke, or MI within 30 days or ipsilateral stroke within 1 year) was met by 3.8% of CAS and 3.4% of CEA patients, while the cumulative 5-year rate of stroke-free survival was 93.1% with CAS and 94.7% with CEA (p=0.44). This trial did not answer how best to treat asymptomatic patients because it did not include a medical therapy arm. Patients treated with current best medical therapy might have had an ipsilateral stroke rate of only 0.5% to 1% per year. (41)

*Asymptomatic Carotid Trial 2*

The second asymptomatic carotid surgery trial (ACST-2) was a multicenter RCT comparing CAS and CEA in 3625 asymptomatic patients with severe carotid stenosis. (42) 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=.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=.33). The authors considered the long-term outcomes of these procedures to be similar with uncommon serious complications.

*Additional RCTs*

Several other smaller trials have compared CEA with CAS. Li et al. (2014) published a trial that randomized 130 subjects at high-risk of stroke due to angiographically confirmed carotid stenosis (≥50%) to CEA (n=65) or CAS (n=65). (43) The authors reported a 3-month postoperative risk of mortality of 1.5% with CAS compared with 9.2% with CEA. However, "existence of complete follow-up data" was an inclusion criterion, and insufficient details were provided about enrollment and randomization procedures to permit conclusions about the trial.

Kuliha et al. (2015) published results of an RCT that allocated 150 subjects with at least 70% internal carotid artery stenosis to CEA (n=73) or to CAS (n=77). (44) New infarctions on magnetic resonance imaging (MRI) were found more frequently after CAS (49% vs 25%; p=0.002).

Reiff et al. (2019) published one-year interim results of the Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy 2 (SPACE-2) RCT. (45) The SPACE-2 RCT was originally planned to compare best medical treatment (BMT) to CEA plus BMT or CAS plus BMT in 3550 patients with high-grade asymptomatic extracranial carotid artery stenosis. However, 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. Reiff et al. (2022) published 5-year outcomes from SPACE-2. (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 5 years of follow up was 2.5% (95% CI, 1.0 to 5.8), 4.4% (95% CI, 2.2 to 8.6), and 3.1% (95% CI, 1.0 to 9.4) with CEA plus 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, 5 strokes and no deaths occurred in the 30-day periprocedural period. During 5-year follow-up, 3 ipsilateral strokes occurred in both the CAS plus BMT and BMT alone groups compared to none in the CEA plus BMT group.

Brott et al. (2025) published results of the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2; NCT02089217) to elucidate whether CAE or CAS plus contemporary intensive medical management is superior in preventing stroke beyond medical management alone. (47) CREST-2 consists of 2 parallel clinical trials enrolling patients

with high-grade (≥70%) asymptomatic carotid stenosis. Notably, CAS and CAE were not directly compared. One trial compared intensive medical management alone to medical management plus CAS. The other trial compared intensive medical management alone to medical management plus CEA. The primary outcome consists of the composite of stroke and death within 44 days of randomization and incidence of ipsilateral stroke through 4 years. A total of 1245 patients were randomized in the CAS trial and 1240 in the CEA trial. Demographic and risk factor profiles were similar among the groups in both studies. The primary outcome was significantly reduced with CAS plus medical management compared to medical management alone (6.0% vs 2.8%; absolute risk difference 3.2%; 95% CI, 0.6 to 5.9; p=.02; relative risk, 2.13; 95% CI, 1.15 to 4.39). However, there was no significant difference between CEA plus medical management compared to CEA alone (5.3% vs 3.7%; absolute risk difference, 1.6%; 95% CI, -1.1 to 4.3; p=.24; relative risk, 1.43; 95% CI, 0.7 to 2.8). In the first 44 days of the CAS trial, no strokes or deaths occurred in the medical therapy group, but 7 strokes and 1 death occurred in the CAS group. In the first 44 days of the CEA trial, 3 strokes occurred in the medical therapy group, but 9 strokes occurred in the CEA group. Conclusions regarding the comparative efficacy of CEA and CAS from the CREST-2 trials are difficult given that the treatments were not directly compared.

*Subsection Summary: Randomized Controlled Trials of Carotid Artery Stenting versus Carotid Endarterectomy*

Randomized controlled trials comparing CEA with CAS enrolled a mix of symptomatic and asymptomatic patients and employed different selection criteria for participating centers. Periprocedural stroke and death rates following CAS often exceeded those after CEA. Following the early perioperative period (≥31 days), the rates of ipsilateral stroke and/or TIA appear to be similar for the 2 procedures. While some trials found higher restenosis rates after CAS (SAPPHIRE, SPACE, EVA-3S), restenosis in CREST occurred at a similar frequency following either procedure. The rates of early complications in SPACE, EVA-3S, and ICSS exceeded 6.0%. In CREST, periprocedural death or stroke rates with CAS were less 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 of criticisms, along with the inconsistent use of EPDs. (48) Recent trials comparing CAS with contemporary medical management are conflicting, but the CREST-2 trials indicated improved long-term outcomes in patients managed with CAS plus medical management compared with medical management alone; however, CEA plus medical management did not improve outcomes compared with medical management alone.

Systematic Reviews

Several meta-analyses have been published, all reporting similar findings. (49-53) In average-risk symptomatic patients, the body of evidence has demonstrated worse periprocedural outcomes with CAS than with CEA. For example, a 2020 Cochrane review found CAS associated with an increased risk of periprocedural death or stroke based on 10 RCTs that included 5396 patients (odds ratio [OR]=1.70, 95% CI, 1.31 to 2.19). (49) Risk of 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 7 trials of 3378 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 (4 RCTs; n=2115; OR=2.00, 95% CI, 1.12 to 3.60) and a nonsignificant risk of severe (≥70%) restenosis (9 RCTs; n=5744; OR 1.26, 95% CI, 0.79 to 2.00) in a pooled group of symptomatic and asymptomatic patients.

The Carotid Stenting Trialists' Collaboration (2016) published an individual patient data (IPD) meta-analysis (N=4754 patients) of SPACE, EVA-3S, and ICSS data, plus data from symptomatic patients in CREST to evaluate the association between age and risk of stroke or death with CEA and CAS. (54) The periprocedural period was defined as 120 days, which is considerably longer than the conventional 30-day periprocedural definition. For symptomatic patients assigned to CEA, there was no increase in periprocedural or postprocedural risk of death or stroke for patients older than 65 years compared with those younger than 60 years. In contrast, for patients assigned to CAS, the risk of periprocedural events increased with age, from a 2.1% risk for patients younger than 60 years, to 11% for patients older than 70 years. These analyses found increased periprocedural stroke risk for CAS versus CEA in patients approximately 65 years and older, but not among those younger patients (an age threshold was not defined). Age was not significantly associated with postprocedural stroke risk. The results would suggest that the risk-benefit profile for CAS in symptomatic patients enrolled in these trials could be modified by age, but there was considerable imprecision in the age-specific CAS versus CEA comparisons for periprocedural risk. For example, among patients aged 60 to 64 years, the hazard ratio comparing CAS to CEA for the periprocedural risk of stroke or death was 1.07 (95% CI, 0.56 to 2.01). These results were consistent with those in the 2020 Cochrane review. (49) In 2019, on behalf of the Carotid Stenting Trialists' Collaboration, Brott et al. (2019) published another individual patient data meta-analysis of the same symptomatic patient group (N=4775 patients) from SPACE, EVA-3S, ICSS, and CREST to evaluate long-term outcomes (mean follow-up of 4 years). (55) Periprocedural and postprocedural risks continued to favor CEA.

Paraskevas et al. (2014) conducted a systematic review of studies comparing cognitive outcomes after CEA with those after CAS. (56) Thirteen studies were included, with heterogeneity in the types of cognitive outcome measures reported. In qualitative analysis, reviewers found that most studies did not report a significant difference between CEA and CAS regarding cognitive outcomes and that heterogeneity across outcomes reported precluded more definitive conclusions.

Wang et al. (2022) conducted a meta-analysis of 7 RCTs, including ASCT-2, reporting outcomes for 7118 asymptomatic patients. (57) No significant difference was observed with CAS compared to CEA in the perioperative composite outcome of stroke, death, or any MI (OR, 1.13; 95% CI, 0.87 to 1.47; p=.37). However, CAS had a higher risk of any stroke (OR, 1.62; 95% CI, 1.16 to 2.24; p=.004) and nondisabling stroke (OR, 1.81; 95% CI, 1.23 to 2.65; p=.003). No significant difference in risk of disabling stroke and death was detected between groups (OR, 0.91; 95% CI, 0.50 to 1.65; p=.76).

Chu et al. (2025) conducted a meta-analysis of RCTs comparing CEA and CAS in patients with carotid artery stenosis. (58) For the outcome of all-cause mortality (n=14,669; 14 studies), the risk was similar between groups (risk ratio [RR], 1.267; 95% CI, 0.919 to 1.746; p=.149). The risks of stroke (RR, 1.490; 95% CI, 1.282 to 1.731; p<.001; n=22,005; 20 studies) or restenosis (RR, 1.257; 95% CI, 1.000 to 1.578; p=.05; n=3166; 4 studies) were higher with CAS. However, the risks of MI (RR, 0.476; 95% CI, 0.341 to 0.664; p<.001; n=14,621; 11 studies) or cranial nerve palsy (RR, 0.079; 95% CI, 0.042 to 0.149; p<.001; n=6880; 7 studies) were lower with CAS.

*Subsection Summary: Systematic Reviews*

The systematic reviews comparing CAS with CEA have corroborated the results of individual RCTs that early adverse events are higher with CAS than with CEA, that long-term stroke rates following the perioperative period are similar, and that restenosis rates are higher with CAS. These data would indicate that, for the average-risk patient with carotid stenosis, CAS is associated with a net harm compared with CEA. A recent meta-analysis of RCTs with asymptomatic patients demonstrated a higher risk of any stroke or nondisabling stroke in the periprocedural period.

Periprocedural Death or Stroke Rates Following Carotid Artery Stenting

Touze et al. (2009) reported pooled periprocedural death/stroke rates in asymptomatic patients of 3.3% (95% CI, 2.6 to 4.1; 23 studies; N=8504 patients) and in symptomatic patients of 7.6% (95% CI, 6.3 to 9.1; 42 studies; n=4910 patients). (59)

Additional evidence related to rates of periprocedural stroke and death following CAS, particularly for subgroups defined by medical comorbidities, was published by Spangler et al. in 2014. (60) The study 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 in medically high-risk patients. A Cox proportional hazards model was used to generate predicted 5-year mortality, and patients in the highest risk score quartile were considered high-risk. For asymptomatic patients, there were not significant differences between CEA and CAS for major periprocedural outcomes (major or minor stroke, MI, death) in either normal- or high-risk patients. Periprocedural death or stroke rates with CAS were 1.1% for normal-risk patients and 1.6% for high-risk patients. For symptomatic patients, periprocedural death or stroke rates were higher with CAS than with CEA for both normal- and high-risk groups. For normal-risk symptomatic patients, periprocedural death or stroke rates was 6.0% for CAS and 2.2% for CEA (p<0.01). For high-risk symptomatic patients, periprocedural death or stroke rates was 9.3% for CAS and 2.5% for CEA (p<0.01).

*Observational Study*

Salzler et al. (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. (61) 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 3447 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.

Carotid Artery Stenting for Carotid Dissection

Carotid dissection is uncommon (incidence approximately 2 per 100,000/year) and generally occurs in younger individuals. (62) With a frequently favorable prognosis, conservative therapy with anticoagulants to restore blood flow is typically employed while surgical intervention is reserved for patients whose symptoms fail to respond to conservative care. Some have described CAS as a potential treatment in those instances. (63-65) However, there are no clinical trials comparing alternative strategies and interventions. Current guidelines (detailed below) rate CAS for this indication as a class IIb (level of evidence: C) recommendation.

**Transcarotid Artery Revascularization**

Clinical Context and Therapy Purpose

The purpose of transcarotid artery revascularization (TCAR) is to provide a treatment option for carotid artery stenosis that is an alternative to medical therapy and a less-invasive alternative to CEA.

The following PICO was used to select literature to inform this policy.

*Populations*

The relevant population of interest is individuals with coronary artery stenosis.

*Interventions*

The therapy being considered is TCAR.

*Comparators*

The Comparator of interest is CEA.

*Outcomes*

The general outcomes of interest are overall survival, morbid events, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Naazie et al. (2020) published a systematic review and meta-analysis of 9 nonrandomized studies including 4012 individuals who underwent TCAR and smaller comparative analyses of outcomes between TCAR and transfemoral CAS (TF-CAS; 2 studies) or CEA (4 studies). (66) Periprocedural (30-day) rates of stroke, death, MI, stroke/death/MI, or cranial nerve injury were 1.89% (95% CI, 1.50 to 2.37), 1.34% (95% CI, 1.02 to 1.75), 0.76% (95% CI, 0.56 to 1.08), 0.60% (95% CI, 0.23 to 1.59), 2.20% (95% CI, 1.31 to 3.69), and 0.31% (95% CI, 0.12 to 0.83), respectively. The perioperative risks of stroke (1.33% vs. 2.55%; OR, 0.52; 95% CI, 0.36 to 0.74) and death (0.76% vs. 1.46%; OR, 0.52; 95% CI, 0.32 to 0.84) were significantly lower with TCAR compared to TF-CAS. When compared against CEA, no statistically significant differences were observed for rates of death, stroke, or stroke/death/MI with TCAR. However, the risk of death alone was significantly elevated with TCAR (0.81% vs. 0.41%; OR, 1.92; 95% CI, 1.01 to 3.67). Analysis of data based on symptomatic status was not feasible. The authors note that larger, prospective studies comparing TCAR with TF-CAS and CEA are needed, particularly in high-risk patients.

Gao et al. (2021) published a systematic review and meta-analysis of 6 comparative cohort studies that compared the efficacy of TCAR to CEA. (67) A total of 14,200 patients (TCAR, n=6881; CEA, n=7319) were included. No statistically significant difference was found between groups for reduction in composite incidence of stroke, death, or myocardial infarction (OR, 0.85, 95% CI, 0.67 to 1.07; p=.17). There was also no statistically significant difference in individual outcomes of death (OR, 1.14; 95% CI, 0.67 to 1.94; p=.63) or stroke (OR, 1.03; 95% CI, 0.77 to 1.37; p=.84) between groups however there was a difference detected in the incidence of myocardial infarction (OR, 0.55; 95% CI, 0.36 to 0.83; p=.004). When compared to CEA, TCAR was also associated with a lower incidence of cranial nerve injury and shorter procedural time. When compared to CEA, TCAR was also associated with a lower incidence of cranial nerve injury and shorter procedural time. Overall, the certainty of evidence included in this review was deemed as moderate and low due to the risk of bias; the quality of the evidence in this trial was also low since it included all non-randomized trials.

Nonrandomized Studies

There have been a few key nonrandomized trials that have reported outcomes for the TCAR procedure (as summarized in Table 4 and Table 5), which mainly include evaluation of the Enroute® Transcarotid Neuroprotection System.

**Table 4. Summary of Key Nonrandomized Trial Characteristics**

| Study | Study Type | Country | Dates | Participants | Treatment | Treatment | Follow-Up |
|---|---|---|---|---|---|---|---|
| Kwolek et al. (2015) (68) | Prospective | United States | 2012-2014 | N=141 symptomatic patients with ≥50% stenosis | Enroute® Transcarotid NPS | NA | Up to 6 months |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | and asymptomatic patients with ≥70% stenosis | | | |
| Kashyap et al. (2020) (69) | Prospective | United States and Europe | 2015-2019 | N=692 (ITT population); N=632 (PP population); Symptomatic patients with ≥50% stenosis and asymptomatic patients with ≥80% stenosis | Enroute® Transcarotid NPS | NA | NR |

ITT: intention-to-treat; NA: not applicable; NPS: neuroprotection system; NR: not reported; PP: per-protocol.

**Table 5. Summary of Key Nonrandomized Trials Results**

| Study | Rate of procedural success | Composite of stroke, death, and MI | Incidence of CNI | Incidence of stroke | Incidence of MI | Incidence of death |
|---|---|---|---|---|---|---|
| **Kwolek et al. (2015) (68)** | | | | | | |
| Enroute® Trans-carotid NPS | N (%) | N (%); 95% CI; p value | N (%) | N (%) | N (%) | n (%) |
| | 135 (96%) | 5 (3.5%); 95% CI, 1.16 to 8.08; p=.0047 | 1 (0.7%) | 2 (1.4%) | 1 (0.7%) | 2 (1.4%) |
| **Kashyap et al. (2020) (69)** | | | | | | |
| Enroute® Trans-carotid NPS | N (%) | N (%) | N (%) | N (%) | N (%) | n (%) |
| | ITT population: 690 (96.5%); PP population: | ITT population: 22 (3.2%); PP population: 11 (1.7%) | ITT population: 10 (1.4%); PP population: 8 (1.3%) | ITT population: 13 (1.9%); PP population: 4 (0.6%) | ITT population: 6 (0.9%); PP population: 6 (0.9%) | ITT population: 3 (0.4%); PP population: 1 (0.2%) |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 630 (99.7%) | | | | | |

CI: confidence interval; ITT: intention-to-treat; MI: myocardial infarction; NPS: neuroprotection system; PP: per protocol; CNI: cranial nerve injury.

Observational Studies

Malas et al. (2022) compared real-world outcomes of TCAR to CEA utilizing data from the Vascular Quality Initiative Surveillance Project. (70) Patients who had undergone TCAR and CEA for carotid artery stenosis between 2016 to 2019 were included (CEA, n=53,869; TCAR, n=8104). There were no statistically significant differences between groups for the composite of stroke and death (RR, 1.01; 95% CI, 0.77 to 1.33; p=.945), stroke (RR, 1.02; 95% CI, 0.76 to 1.37; p=.881), or death (RR, 1.14; 95% CI, 0.64 to 2.02; p=.662). The TCAR procedure was associated with a significantly lower incidence of myocardial infarction (RR, 0.53; 95% CI, 0.35 to 0.83; p=.005), cranial nerve injury (RR, 0.14; 95% CI, 0.08 to 0.23; p<.001) and post-procedural hypertension (RR, 0.69; 95% CI, 0.63 to 0.76; p<.001) compared to CEA.

Zhang et al. (2022) performed a retrospective review of Vascular Quality Initiative (VQI) to assess perioperative outcomes in patients who underwent TCAR, TF-CAS, or CEA. (71) The study included 124,531 patients (TCAR, n=15,597; TF-CAS, n=17,247; CEA, n=91,687), and patients were stratified by whether they met CMS CAS criteria (i.e., high-risk). After adjusting for baseline demographic and clinical factors, high-risk patients who had undergone TCAR had statistically significant lower odds of stroke (adjusted OR, 0.82; 95% CI, 0.68 to 0.99), death (adjusted OR, 0.50; 95% CI, 0.34 to 0.73), stroke/death (adjusted OR, 0.73; 95% CI, 0.61 to 0.86), and perioperative myocardial infarction (adjusted OR, 0.46; 95% CI, 0.33 to 0.62) compared to CEA. After adjusting for baseline demographic and clinical characteristics, risks of stroke, mortality, or stroke/death were not significantly different between standard-risk patients receiving TCAR and CEA (all p>.05).

Liang et al. (2023) evaluated the risk of stroke, death and myocardial infarction following TCAR compared to CEA in patients with standard surgical risk. (72) This retrospective registry study utilized data from the Society for Vascular Surgery VQI Carotid Artery Stent and Carotid Endarterectomy registries (N=38,025). The 30-day composite risk of myocardial infarction, stroke, and death or 1-year ipsilateral stroke was 3.0% for TCAR compared to 2.6% for CEA (absolute difference, 0.40%; 95% CI, -0.43% to 1.24%; RR, 1.14; 95% CI, 0.87 to 1.50; p=.34) and was not statistically significant. There was also no statistically significant difference in the individual outcomes of 30-day death of 1-year all-cause mortality. TCAR was associated with a higher risk of 30-day stroke (1.6% vs. 1.1%; absolute difference, 0.42%; 95% CI, −0.06% to 0.93%; RR, 1.38; 95% CI, 0.97 to 1.96; p=.07) and 1-year ipsilateral stroke (1.6% vs 1.1%; absolute difference, 0.52%; 95% CI, 0.03 to 1.08; RR, 1.49; 95% CI, 1.05 to 2.11%; p=.03).

Section Summary: Transcarotid Artery Revascularization

The evidence on the effectiveness and safety of TCAR procedures is limited to nonrandomized and observational studies. A systematic review found no statistically significant difference between TCAR and CEA for reduction in composite incidence of stroke, death, or myocardial

infarction; a reduction in incidence of myocardial infarction and cranial nerve injury was found with TCAR versus CEA. Another systematic review comparing TCAR and CAS found no statistically significant differences for rates of death, stroke, or stroke/death/MI with TCAR; however, the risk of death alone was significantly elevated with TCAR. Key nonrandomized trials also highlighted safety outcomes of the TCAR procedure, and observational comparative studies found similar results to what the systematic reviews reported.

**Summary of Evidence**

For individuals who have carotid artery stenosis who receive carotid artery stenting (CAS), the evidence includes randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. A substantial body of RCT evidence has compared outcomes of CAS with carotid endarterectomy (CEA) for symptomatic and asymptomatic patients with carotid stenosis. The evidence does not support the use of CAS in carotid artery disease for the average-risk patient because early adverse events are higher with CAS and long-term outcomes are similar between the 2 procedures. Data from RCTs and large database studies have established that the risk of death or stroke with CAS exceeds the threshold considered acceptable to indicate overall benefit from the procedure. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS does not improve health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have carotid artery stenosis who receive transcarotid artery revascularization (TCAR), the evidence includes systematic reviews, nonrandomized trials, and observational studies. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. There is a lack of a body of evidence comprised of RCTs. The evidence on the effectiveness and safety of TCAR procedures is limited to nonrandomized and observational studies. A systematic review found no statistically significant difference was found between TCAR and CEA for reduction in composite incidence of stroke, death, or myocardial infarction; a reduction in incidence of myocardial infarction and cranial nerve injury was found with TCAR versus CEA. Another systematic review comparing TCAR and CAS found no statistically significant differences were observed for rates of stroke or death, stroke, or stroke/death/MI with TCAR; however, the risk of death alone was significantly elevated with TCAR. Key nonrandomized trials also highlighted safety outcomes of the TCAR procedure, and observational comparative studies found similar results to what the systematic reviews reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Practice Guidelines and Position Statements**

American Heart Association and American Stroke Association

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). (73) They recommended that, for patients with severe extracranial carotid artery stenosis ipsilateral to a nondisabling stroke or TIA, the choice between carotid endarterectomy (CEA) and CAS in

patients who are candidates for intervention should be patient specific. Specific recommendations for CAS or CEA are summarized in Table 6.

**Table 6. Guidelines for CAS/CEA in Extracranial Carotid Stenosis**

| Recommendation | COR[a] | LOE[b] |
|---|---|---|
| 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%. | I | 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%. | I | 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. | IIa | 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. | IIa | 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. | IIa | 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. | IIb | A |

CAS: carotid artery stenting; CEA: carotid endarterectomy; COR: class of recommendation; LOE: level of evidence; TIA: transient ischemic attack; ICA: internal carotid artery.

[a] *Key to Classification of Recommendations:*

Class I: benefit >>> risk;

Class IIa: benefit >> risk;

Class IIb: benefit ≥ risk;

[b] *Key to Levels of Evidence:*

Level A (data derived from multiple randomized controlled trials, meta-analyses of high-quality RCTs, or RCT corroborated by high-quality registry study);

Level B-R (data derived from ≥1 randomized controlled trial of moderate quality or meta-analysis of such trials);

Level C-LD (randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies in human subjects).

Society for Vascular Surgery

The Society for Vascular Surgery published updated guidelines for management of extracranial cerebrovascular disease in 2022. (74) They recommended CEA over transfemoral CAS (TF-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.

American Stroke Association (ASA)

The ASA (2011), along with 13 other medical societies, issued guidelines on the management of extracranial carotid and vertebral artery diseases, which are summarized in Table 7. (75-77)

**Table 7. Guidelines for Managing Patients with Extracranial Carotid and Vertebral Artery Disease**

| Recommendation | COR[a] | LOE[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 >70%, as documented by noninvasive imaging or >50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is <6% (360). | I | 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. | I | C |
| It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention. | IIa | B |
| It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery. | IIa | B |
| When revascularization is indicated for patients with TIA or stroke and there are no contraindications to early revascularization, intervention within two weeks of the index event is reasonable rather than delaying surgery. | IIa | 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. | IIb | B |
| In symptomatic or asymptomatic patients at high-risk of complications for carotid revascularization by either CEA or CAS because of | IIb | B |

| | | |
|---|---|---|
| comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established. | | |
| Carotid angioplasty and stenting might be considered when ischemic neurological symptoms have not responded to antithrombotic therapy after acute carotid dissection. | IIb | C |
| Except in extraordinary circumstances, carotid revascularization by either CEA or CAS is not recommended when atherosclerosis narrows the lumen by <50%. | III | A |
| Carotid revascularization is not recommended for patients with chronic total occlusion of the targeted carotid artery. | III | C |
| Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function. | III | C |

CAS: carotid artery stenting; CEA: carotid endarterectomy; COR: class of recommendation; LOE: level of evidence; TIA: transient ischemic attack.

[a] *Key to Classification of Recommendations:*

Class I: benefit >>> risk;

Class IIa: benefit >> risk;

Class IIb: benefit ≥ risk;

Class III: no benefit.

[b] *Key to 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.

**United States (U.S.) Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force recommends against screening for asymptomatic carotid artery stenosis in the general adult population (Grade D; reaffirmed in 2021). (78)

**Medicare National Coverage**

The Center for Medicaid & Medicare Services (CMS) updated their national coverage policy in 2023 to state the following (79):

"CMS finds that coverage of percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting is reasonable and necessary with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following conditions:

A. Patients with symptomatic carotid artery stenosis ≥50%; and
B. Patients with asymptomatic carotid artery stenosis ≥70%.

For both A and B above:

1. Neurological assessment by a neurologist or National Institutes of Health (NIH) stroke scale (NIHSS) certified health professional before and after carotid artery stenting (CAS) must be performed.

2. First-line evaluation of carotid artery stenosis must use duplex ultrasound.
3. Computed Tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra- and intracranial circulation.
4. Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.

Prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary. The shared decision-making interaction must include:

- Discussion of all treatment options including carotid endarterectomy (CEA), CAS (which includes transcarotid artery revascularization [TCAR]), and optimal medical therapy (OMT).
- Explanation of risks and benefits for each option specific to the beneficiary's clinical situation.
- Integration of clinical guidelines (e.g., patient comorbidities and concomitant treatments).
- Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must at least include and ensure the following:

- Facilities have a clearly delineated program for granting carotid stent privileges and for monitoring patient outcomes for individual physicians and the program as a whole.
- The oversight committee for this program shall be empowered to identify the minimum case volume for a physician to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from specialty societies and widely-used, published professional society guidelines to determine appropriate physician qualifications.
- Facilities have appropriately trained staff capable of fulfilling roles and responsibilities as delineated under the dedicated carotid stent program.
- Facilities have appropriate supporting personnel and equipment for imaging, emergency management, advanced physiologic monitoring, and other ancillary care.
- Facilities must ensure continuous quality improvement by assessing procedural outcomes and making necessary programmatic adjustments to assure patient safety."

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 8.

**Table 8. Summary of Key Trials**

| NCT Number | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|

| | | | |
|---|---|---|---|
| NCT07054060 | Endarterectomy Versus Stenting in Patients With Symptomatic Severe Carotid Stenosis - 2 | 600 | Mar 2028 |
| NCT07204678 | Post Market Clinical Follow-up Study of the Precise Pro Rx Nitinol Stent System in the Treatment of Carotid Artery Disease (REAL-PRECISE) | 187 | Jan 2026 |
| ISRCTN97744893 | European Carotid Surgery Trial 2 (ECST-2): A Randomized Controlled Trial | 429 | Mar 2025 |
| NCT05623904 | Carotid Revascularization Versus Best Medical Treatment for Asymptomatic Carotid Stenosis: a Multicenter, Open, Randomized Controlled Trial in Chinese Population | 1056 | Dec 2025 |
| NCT05465122 | Long-Term Observational Extension of Participants in CREST-2 (C2LOE) | 2480 | May 2026 |
| NCT02850588 | TransCarotid Revascularization Surveillance Project of the Society for Vascular Surgery Vascular Quality Initiative (VQI-TCAR) | 60000 | Dec 2027 |

ISRCTN: International Standard Randomized Controlled Trial Number; NCT: National Clinical Trial.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

| | |
|---|---|
| **CPT Codes** | 37215, 37216, 37217, 37218 |
| **HCPCS Codes** | C2623 |

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

| Policy History/Revision | |
|---|---|
| **Date** | **Description of Change** |
| 04/01/2026 | Document updated. The following changes were made to Coverage: 1) Removed "with associated stenting and embolic protection" from the conditional coverage statement and the experimental, investigational and or unproven statement. 2) Added to the conditional coverage statement, "with the placement of a Food and Drug Administration (FDA) approved carotid stent with an FDA-approved or cleared embolic protection device"; 3) Removed from Coverage bullets 2 and 3 that stated, "Symptoms of focal cerebral ischemia (transient ischemic attack [TIA] or monocular blindness) within the previous 120 days, symptom duration less than 24 hours, or nondisabling stroke; AND Anatomic contraindication for carotid endarterectomy (CEA) (e.g., prior radiotherapy or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy)"; and 4) Added conditional coverage criteria for asymptomatic individuals. Added references 47 and 58; others removed and some updated. |
| 12/15/2025 | Document updated. Coverage unchanged. Added reference 81; other(s) removed. |
| 02/15/2025 | Document updated with literature review. The following change was made to Coverage: Added transcarotid artery revascularization (TCAR) as conditionally medically necessary, and as experimental, investigational, and/or unproven when those criteria are not met. References 1, 68-73, and 81 added. |
| 03/01/2024 | Document updated with literature review. Coverage unchanged. References 38, 45-46, 58, 62, and 72 added. |
| 01/15/2023 | Document updated with literature review. Minor editorial changes made to coverage with intent unchanged. References 41, 55, and 62-63 added; others removed. |
| 08/01/2021 | Reviewed. No changes. |
| 01/01/2021 | Document updated with literature review. Coverage unchanged. The following references were added: 42, 46 and 55. |
| 01/15/2020 | Document updated with literature review. Coverage unchanged. The following references were added: 60, 69, 71. |

| | |
|---|---|
| 10/15/2018 | Reviewed. No changes. |
| 10/15/2017 | Document updated with literature review. The following indication was added to the experimental, investigational and/or unproven coverage statement, “patients who are not considered high-risk and are asymptomatic.” |
| 10/01/2016 | Reviewed. No changes. |
| 08/15/2015 | Document updated with literature review. Coverage unchanged. |
| 10/15/2014 | Document updated with literature review. Coverage unchanged. CPT/HCPCS code(s) updated. |
| 09/15/2012 | New medical document. Carotid angioplasty with associated stenting and embolic protection may be considered medically necessary when meeting specific criteria; otherwise carotid angioplasty with or without associated stenting and embolic protection is considered experimental, investigational and unproven. (This topic was previously addressed on MED202.032 Angioplasty and Stenting for Vascular Occlusive Disease.) |