

Medical Policy



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***Current Policy Effective Date: 5/1/25**

Title: Extracranial Carotid Artery Stenting

Description/Background

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (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 rarely is performed without stent placement.

The proposed advantages of CAS over CEA include the following:

- 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 carotid artery stents 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	Sept 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
Boston Scientific Corp.	Endotex Nexstent Carotid Stent and Delivery System and Endotex Carotid Stent and Monorail Delivery System	P050025	Oct 2006
Medtronic Vascular	jProtege GPS and Protege 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	Gore Carotid Stent	P180010	Nov 2018

FDA: Food and Drug Administration; PMA: Premarket approval.

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

Manufacturer	Carotid Stents and Devices	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
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 Iep 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	March 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	June 2022
Silk Road Medical	Enroute® Transcarotid Neuroprotection System	K230402	April 2023

Each FDA-approved carotid stent is indicated for combined use with an EPD to reduce risk of stroke in patients considered at increased risk for periprocedural complications from CEA who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis with degree of stenosis assessed by ultrasound or angiogram, with computed tomography angiography also used. Patients are considered at increased risk for complications during CEA if affected by any item from a list of anatomic features and comorbid conditions included in each stent system's Information for Prescribers.

The RX Acculink™ Carotid Stent System is also approved for use in conventional risk patients (not considered at increased risk for complications during CEA) with symptoms and 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram, and asymptomatic patients with 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram.

FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the rapid exchange devices designed for more rapid stent and filter expansion. FDA has mandated postmarketing studies for EPDs, including longer follow-up for patients already reported to the FDA and additional registry studies, primarily to compare outcomes as a function of clinician training and facility experience. Each manufacturer's system is available in various configurations (eg, straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In 2015, the ENROUTE™ Transcarotid Neuroprotection System was cleared for marketing by FDA through the 510(k) process. ENROUTE™ is a flow reversal device designed to be placed via direct carotid access. In April 2022, the ENROUTE® Transcarotid Stent System received expanded approval for use in the treatment of individuals at standard risk of complications from CEA. For those with neurological symptoms, criteria include 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram. For asymptomatic individuals, criteria include 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram. The

carotid bifurcation location must be a minimum of 5 cm above the clavicle to allow for the placement of the ENROUTE Transcarotid Neuroprotection System.

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

Medical Policy Statement

Carotid angioplasty with stenting and embolic protection is established when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions

Carotid angioplasty with associated stenting and embolic protection in individuals with:

- 50% to 99% stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] measurement); **AND**
- symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days, symptom duration less than 24 hours, or nondisabling stroke; **AND**
- anatomic contraindication for carotid endarterectomy (such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).

Exclusions

Carotid angioplasty with or without associated stenting and embolic protection for all other indications, including but not limited to:

- Individuals with carotid stenosis who are suitable candidates for carotid endarterectomy
 - Individuals with carotid artery dissection.
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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

37215

37216

37217

37218

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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 review.

Populations

The relevant population of interest is individuals with (CAS).

Interventions

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

Comparators

The comparator of interest is carotid endarterectomy.

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.

Review of Evidence

Randomized Controlled Trials

A series of landmark clinical trials from the late 1980s through the 1990s compared the benefits and harms of CEA to best medical therapies then available in symptomatic and asymptomatic individuals with carotid artery stenosis.²⁻⁸ Those trial results defined the magnitude of risk reduction for stroke and periprocedural stroke and death rates for 30 days, that must be offset to achieve a net clinical benefit (benefit outweighing harm), less than 3% for asymptomatic patients (>60% stenosis), and less than 6% for symptomatic patients (50% to 69% or 70% to 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/Stroke Rate, %	Anticipated Life Expectancy, y
No	60-99	<3	5
Yes	50-69	<6	5
	70-99	<6	2

CEA: carotid endarterectomy

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 (periprocedural death/stroke rate, 1.8%).⁸ Over a five-year time horizon, CEA provided 4 days of stroke-free survival and net harm when periprocedural death/disabling stroke rates exceeded 2.1%.

Since the landmark trials, 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 (eg, 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 (eg, surgically inaccessible stenosis, prior radiation, prior neck surgery, spinal immobility, prior laryngeal nerve palsy, contralateral occlusion, prior ipsilateral CEA, 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 3526 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 of 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 as follows:

- For patients with symptomatic stenosis at increased risk for periprocedural complications from CEA (n=96), the sample size was small resulting in wide CIs 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 CIs and were not statistically significant.
- The study closure due to slow recruitment as nonrandomized stent registries were established, resulting in fewer study patients than planned, which compromised the evaluation of noninferiority.
- Variance in differential complication rates for the two 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 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 1080 days were observed in 4.4% of patients undergoing CAS and in 3.6% with CEA (estimated from 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% vs. 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, 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 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 SPACE trial, including the high rate of rejection for potential participating collaborators ($\approx 25\%$, 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 vs 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 (ie, 31 days to longest follow-up), stroke risk reduction in symptomatic patients not selected based on medical or anatomic comorbidities was similar for CAS or CEA. Recurrent stenosis greater than 70% was more frequent at 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%; $p=.01$).

Over a mean 2.1 years of follow-up, restenosis ($\geq 50\%$) 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 (ie, 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 EPD 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 (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 subject 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 end point 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 Embolic protection devices 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 exceeded 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; $p<.001$). 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 study differed between CEA and CAS groups.³⁰ Hemodynamic depression occurred more commonly in CAS patients (13.8% vs 7.2%; RR, 1.9 ; 95% CI, 1.4 to 2.6; $p<.000$), while hypertension requiring treatment occurred less commonly in CAS patients (RR, 0.2; 95% CI, 0.1 to 0.4; $p<.000$). 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 (CREST) Trial was conducted between December 2000 and July 2008, and enrolled 2522 patients at 117 centers across the U.S. 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 1271 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 HR for

the primary end point 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 (eg, in EVA-3S 0.8%, in SPACE 0%, and in 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 RR for periprocedural death or stroke in the symptomatic group was 1.89 (95% CI, 1.11 to 3.21) 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 end point (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 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 11846 procedures with documented operator experience, 68% were performed by operators having performed fewer than 12 procedures.

In a follow-up analysis of CREST data, Gonzalez 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 was a noninferiority trial reported by Rosenfield et al (2016) who compared CAS to 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 end point (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 ($p=.44$). 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 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 Randomized Controlled Trials

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 ($\geq 50\%$) 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 CAS ($n=77$).⁴⁴ New infarctions on magnetic resonance imaging were found more frequently after CAS (49% vs 25%; $p=.002$).

Reiff et al (2019) published 1-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 2 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 1-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.

The ongoing Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2; NCT02089217) may elucidate whether CAE or CAS plus contemporary intensive medical management is superior in preventing stroke beyond medical management alone.⁴⁷ The primary outcome consists of the composite of stroke and death within 44 days of randomization and incidence of ipsilateral stroke through 4 years. Change in cognition and differences in major and minor stroke are planned secondary outcomes.

Section 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 exceeded those after CEA. Following the early perioperative period (≥ 31 days), the rates of ipsilateral stroke and/or transient ischemic attack 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 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

No sufficiently powered RCTs have compared CAS with medical therapy. Therefore, it is not possible to determine whether CAS is superior to medical therapy to date, and the CREST-2 trial is ongoing. Since the pivotal CEA versus medical therapy trials, there has been a marked improvement in medical therapy and declining stroke rates in asymptomatic patients with carotid stenosis. In 1993, the Asymptomatic Carotid Surgery Trial reported that the annual ipsilateral stroke rate was approximately 2.0% with medical therapy.⁵ A meta-analysis of studies completing enrollment between 2000 and 2010 found a pooled estimate for annual ipsilateral stroke incidence of 1.13%. This decrease in stroke risk has been used to argue that medical therapy in asymptomatic patients is preferable to surgical intervention.^{28,49,50}

Systematic Reviews

Several TEC Assessments and meta-analyses have been published, all reporting similar findings.⁵¹⁻⁵⁶ 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 5,396 patients (odds ratio [OR], 1.70; 95% CI, 1.31 to 2.19).⁵¹ 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 age 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 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 ($\geq 50\%$) restenosis (4 RCTs; $n=2,115$; OR, 2.00; 95% CI 1.12 to 3.60) and a nonsignificant risk of severe ($\geq 70\%$) restenosis (9 RCTs; $n=5,744$; OR 1.26; 95% CI, 0.79 to 2.00) in a pooled group of symptomatic and asymptomatic patients.

The Carotid Stenosis Trialists' Collaboration (2016) published an individual patient data 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.⁵⁷ 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 the 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 less than 60 years, to 11% for patients over 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 ages 60 to 64 years, the HR comparing CAS with 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.⁵¹ In 2019, on behalf of the Carotid Stenosis 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).⁵⁸ 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.⁵⁹ 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.⁶⁰ 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).

Section 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 are higher with CAS. These data would indicate that, for the average risk patient with carotid stenosis, CAS is associated with 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

Questions of periprocedural death/stroke rates were assessed in a TEC Assessment (2010).⁶¹ Given that CAS (like CEA) trades the procedure-related risks of stroke and death for a reduced risk of stroke over subsequent years, and limits for periprocedural stroke and death rates that can be assumed to achieve a net clinical benefit outlined in current guidelines are less than 3% for asymptomatic and less than 6% for symptomatic patients, the Assessment sought to address two questions: (1) Is the periprocedural rate of death or stroke with CAS less than 3% for asymptomatic and less than 6% for symptomatic patients? And (2) For those subgroups defined by (a) medical comorbidities or (b) unfavorable anatomy, are periprocedural rates of death or stroke with CAS less than 3% for asymptomatic and less than 6% for symptomatic patients?

To address the first question, the Assessment identified 18 multicenter prospective registries collectively enrolling 20194 patients. Eleven of those registries enrolled patients in accordance with the U.S. Food and Drug Administration labeling and with 30-day outcomes available for analysis by symptomatic status (13783 asymptomatic; 3353 symptomatic). In 9 of those registries, 30-day death or stroke rates were either reported or obtained from investigators and in the remaining 2, death or stroke rates were estimated from 30-day death/stroke/MI and MI rates. An independent assessment of neurologic outcomes was required in all but 1 registry. For asymptomatic patients, the pooled periprocedural death or stroke rate was 3.9% (95% CI, 3.3 to 4.4; $I^2=57\%$); for symptomatic patients, it was 7.4% (95% CI, 6.0 to 9.0; $I^2=59\%$).

A subsequent systematic review, without consideration to the Food and Drug Administration labeling, reported results consistent with the TEC Assessment (pooled periprocedural death or 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]).⁶²

To address the second question, the Assessment found that combined data from 2 registries reported periprocedural death or stroke rates for patients with unfavorable anatomy.^{63,64} However, this included only 371 asymptomatic (30-day death or stroke rate, 2.7%; 95% CI, 1.5 to 4.9) and 60 symptomatic patients (30-day death or stroke rate, 1.7%; 95% CI, 0.3 to 8.9). No other registry reported results by symptomatic status for those subgroups.

Since the 2010 TEC Assessment, additional evidence has been published on rates of periprocedural stroke and death following CAS, particularly for subgroups defined by medical comorbidities. Spangler et al (2014) evaluated patients treated with isolated primary CEA (n=11336) or primary CAS (n=544) at 29 centers between 2003 and 2013 to assess periprocedural mortality and stroke risks for those considered medically high-risk.⁶⁵ 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 no significant differences between CEA and CAS for major periprocedural outcomes (major or minor stroke, MI, death) for either the high- or low-risk groups. Periprocedural death or stroke rates with CAS were 1.1% for low-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 the low- and high-risk groups. For low-risk symptomatic patients, periprocedural death or stroke rates were 6.0% for CAS and 2.2% for CEA ($p<0.01$). For high-risk

symptomatic patients, periprocedural death or stroke rates were 9.3% for CAS and 2.5% for CEA ($p < .01$).

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.⁶⁶ Data from the Nationwide Inpatient Sample were searched for patients undergoing carotid revascularization. From 2005 (when the guidelines were published) to 2011, 20079 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 ≈ 2 per 100,000/year) and generally occurs in younger individuals.⁶⁷ 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.^{68,69,70} 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 versus Transfemoral Carotid Artery Stenting

Naazie et al (2020) published a systematic review and meta-analysis of 9 nonrandomized studies including 4012 individuals who underwent transcarotid artery revascularization (TCAR) and smaller comparative analyses of outcomes between TCAR and transfemoral CAS (TF-CAS; 2 studies) or CEA (4 studies).⁷¹ Periprocedural (30-day) rates of stroke or death, 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 stroke or 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.

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 sufficient to determine that the technology is unlikely to improve the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

In response to requests by the Blue Cross Blue Shield Association, input was received from 4 physician specialty societies (6 reviewers) and 4 academic medical centers while their policy was under review in 2009. (Also, an unsolicited response from a specialty society was received.) Input strongly supported the use of carotid artery stenting (CAS) in recently symptomatic patients where surgical carotid endarterectomy cannot be performed due to anatomic reasons, although acknowledging the limited evidence about this subgroup. The lack of alternative treatments for recently symptomatic patients and the established increased risk of stroke were factors supporting this opinion.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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).⁷² 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 4.

Table 4. Guidelines for CAS/CEA in Extracranial Carotid Stenosis

Table 4. Guidelines for Managing Patients with Extracranial Carotid and Vertebral Artery Disease

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%.	1	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%.	1	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.	2a	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.	2a	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.	2a	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.	2b	A

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

a Class I: benefit >>> risk; class IIa benefit >> risk; class IIb benefit ≥ risk; class III: no benefit.

b Level A (data derived from multiple randomized controlled trials or meta-analyses; multiple populations evaluated); level B (data derived from a single randomized controlled trial or nonrandomized studies; limited populations evaluated); level C (only consensus opinion of experts, case studies, or standard of care; very limited populations evaluated).

Society for Vascular Surgery

The Society for Vascular Surgery published updated guidelines for management of extracranial cerebrovascular disease in 2022.⁷³ 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

The American Stroke Association (2011), along with 13 other medical societies, issued guidelines on the management of extracranial carotid and vertebral artery diseases, which are summarized in Table 5 .[74,75,76,77,78](#)

Table 5. 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)	1	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	1	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 2 week 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 comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established	IIb	B
Carotid angioplasty and stenting might be considered when ischemic neurologic 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 angioplasty with stenting; CEA: carotid endarterectomy; COR: class of recommendation; LOE: level of evidence; TIA; transient ischemic attack.

^a Class I: benefit >>> risk; class IIa benefit >> risk; class IIb benefit ≥ risk; class III: no benefit.

^b Level A (data derived from multiple randomized controlled trials or meta-analyses; multiple populations evaluated; level B (data derived from a single randomized controlled trial or nonrandomized studies; limited populations evaluated); level C (only consensus opinion of experts, case studies, or standard of care; very limited populations evaluated).

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). [79](#)

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05416853	Radial Versus Femoral Access For Carotid Artery Stenting In Patients With Carotid-Artery Stenosis: a Prospective, Randomized, Multicenter, Noninferiority Trial (RACE-CAS)	2688	Aug 2024
NCT02089217	Carotid revascularization and medical management for asymptomatic carotid stenosis trial (CREST-2)	2480	Dec 2020
ISRCTN97744893	European Carotid Surgery Trial 2 (ECST-2): a randomized controlled trial	2000	Mar 2023
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.

Government Regulations

National:

NCD 20.7 Percutaneous Transluminal Angioplasty

Effective date of this version 10/11/2023; Implementation date 05/13/2024

[Following is an excerpt from the NCD, with focus on information related to the carotid artery]

Item/Service Description

A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

Indications and Limitations of Coverage

B. Nationally Covered Indications

The PTA is covered when used under the following conditions:

2. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service when provided in the context of such a clinical trial.

3. Concurrent with Carotid Stent Placement in FDA-Approved Post Approval Studies
Effective October 12, 2004, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. The Centers for Medicare & Medicaid Services (CMS) determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

4. Concurrent with Carotid Stent Placement in Patients at High Risk for Carotid Endarterectomy (CEA)

Effective October 11, 2023, CMS covers PTA of the carotid artery concurrent with stenting with the placement of an 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 $\geq 50\%$; and,

B. Patients with asymptomatic carotid artery stenosis $\geq 70\%$.

For both A and B above:

1. Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after 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 intra-cranial 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 transcatheter aortic valve replacement (TAVR), 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.*

5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials

Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis $\geq 50\%$ in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

C. Nationally Non-Covered Indications

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain non-covered.

All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain non-covered.

D. Other

In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at the discretion of the MACs.

Local:

There is no local coverage determination (LCD) on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Endovascular Therapies for Extracranial Vertebral Artery Disease

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/14/25, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/02	7/1/02	7/1/02	Joint policy established
11/18/03	11/18/03	11/18/03	Policy retired
5/1/12	2/21/12	2/21/12	Policy unretired, routine maintenance, HCPCS code S2211 deleted 1/1/02, CPT codes effective 1/1/05, 37215, 37216, 0075T and 0076T added, title changed from Carotid Angioplasty with Stent to Extracranial Carotid Angioplasty/Stenting
7/1/14	4/10/14	4/15/14	Routine maintenance
5/1/16	2/16/16	2/24/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance
5/1/18	2/20/18	2/20/18	Routine maintenance
5/1/19	2/19/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance
5/1/21	2/16/21		Routine maintenance
5/1/22	2/15/22		Routine maintenance
5/1/23	2/21/23		Routine maintenance (jf) added references 40,66, and 67 Vendor Managed: NA
5/1/24	2/20/24		Routine maintenance (jf) Added references 38,45,46,59,66,76 Vendor Managed: NA
5/1/25	2/18/25		Routine maintenance (jf) Vendor Managed: NA Added Ref: 1 Edit to MPS: removed safe and effective

Next Review Date: 1st Qtr, 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: EXTRACRANIAL CAROTID ARTERY STENTING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy criteria apply
BCNA (Medicare Advantage)	See the Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.