MEDICAL POLICY

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MEDICAL POLICY DETAILS	
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POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, extracranial carotid artery angioplasty, with or without stenting and distal embolic protection, via transfemoral or transcarotid artery revascularization (TCAR) is considered **medically necessary** for the treatment of carotid artery stenosis for symptomatic individuals with greater than 50% carotid artery stenosis, who are considered at risk for adverse outcomes (morbidity and mortality) during carotid endarterectomy (CEA) surgery.

II. Based upon our criteria and assessment of the peer-reviewed literature, extracranial carotid artery angioplasty, with or without stenting, via transfemoral or transcarotid artery revascularization (TCAR) is considered **medically necessary** for asymptomatic individuals with greater than 70% carotid artery stenosis of the common or internal artery, who are considered at risk for adverse outcomes (morbidity and mortality) during carotid endarterectomy (CEA) surgery.

III. Based upon our criteria and assessment of the peer-reviewed literature, extracranial carotid artery angioplasty, with or without stenting, has not been medically proven to be effective and, therefore, is considered **investigational** for all other indications.

IV. Based upon our criteria and assessment of the peer-reviewed literature, extracranial vertebral artery angioplasty, with or without stenting, has not been medically proven to be effective and, therefore, is considered **investigational.**

V. Based upon our criteria and assessment of the peer-reviewed literature, intracranial percutaneous transluminal angioplasty, with or without stenting, has not been medically proven to be effective and, therefore, is considered **investigational** for treatment of intracranial atherosclerotic stenosis.

VI. Contraindications for carotid artery stenting (CAS) systems and distal embolic protection devices are included in the United States Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data. These include but are not limited to the following:
   A. Contraindication to anticoagulant and/or antiplatelet therapy;
   B. Severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide, catheter, sheath, embolic protection system, or stent system;

C. Known hypersensitivity to nickel-titanium;
D. Uncorrected bleeding disorders;
E. Lesions in the ostium of the common carotid artery.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

Refer to Corporate Medical Policy #11.01.10 Clinical Trials

POLICY GUIDELINE

I. Individuals at high risk for carotid endarterectomy (CEA) are defined as having significant comorbidities and/or anatomic risk factors (e.g., recurrent stenosis and/or previous neck dissection), and would be poor candidates for CEA in the opinion of a surgeon. Significant comorbid conditions include, but are not limited to:
   A. New York Heart Association (NYHA) Functional Class III/IV congestive heart failure (CHF);
   B. Left ventricular ejection fraction (LVEF) less than 30 percent;
   C. Unstable angina;
   D. Contralateral carotid artery occlusion;
   E. Recent myocardial infarction (MI);
   F. Previous CEA with recurrent stenosis; or
   G. An anatomic contraindication to carotid endarterectomy (e.g., prior radiation or neck surgery, spinal immobility, tracheostomy).

DESCRIPTION

Extracranial Artery

Carotid endarterectomy (CEA) is considered the current gold standard of treatment for symptomatic carotid artery stenosis. Symptomatic is defined as focal neurologic symptoms caused by ischemic stroke in the carotid artery territory or transient ischemic attacks (TIAs), and ipsilateral to significant carotid atherosclerotic pathology. Carotid endarterectomy is an open surgical procedure, and, as such, is accompanied by the usual surgical risks of infection, bleeding, adverse reaction to anesthesia, etc. In addition, cranial nerve palsies are seen more often with CEA than with carotid angioplasty with or without associated stenting (CAS).

Carotid angioplasty, with or without associated stenting, is a less-invasive alternative endovascular procedure to open CEA for treatment of carotid stenosis. Carotid angioplasty with stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, stents, and other devices through various approach sites (e.g., transfemoral, transaxillary, transbrachial, transcervical) and into the carotid artery. The procedure typically takes 20 to 40 minutes and is performed with the patient completely awake. Carotid angioplasty may be performed alone or with placement of a stent to decrease plaque embolization and residual stenosis. At present, most practitioners also use a distally placed embolic protection (DEP) device which is designed to reduce the risk of peri-procedural stroke caused by thromboembolic material dislodged during CAS.

Transcarotid artery revascularization (TCAR) is a specific technique that accesses the carotid artery through a transcervical approach and therefore the aorta is not traversed. The TCAR procedure is performed through a short carotid sheath in conjunction with flow reversal for embolic protection using a proprietary device; thereby providing neuroprotection by reducing the incidence of embolization.

Intracranial Artery

Approximately 795,000 people suffer from stroke in the United States annually, of which 87% are ischemic. A significant number of ischemic strokes are due to intracranial atherosclerosis. Intracranial stenosis may contribute to stroke either by thrombosis or low-flow ischemia (symptomatic stenosis) in the absence of collateral circulation. Medical treatment with either antithrombotic therapy or agents to increase mean arterial blood pressure is considered less than optimal, and surgical options have resulted in only minimal success.

Percutaneous transluminal angioplasty (PTA) has been approached cautiously in the intracranial circulation, due to technical difficulties in catheter and stent design, and the risk of embolism. However, improvement in catheter trackability and the increased use of stents have created ongoing interest in exploring PTA as a minimally invasive treatment for the prevention of stroke in patients with intracranial artery stenosis. Most published studies of intracranial PTA have focused on the vertebrobasilar circulation as treatment for symptomatic stenosis. A few studies have explored the use of stents as a rescue measure in situations of failed thrombolytic therapy or in patients who are not candidates for thrombolytic treatment.

Vertebral Artery

Atherosclerosis of the vertebral or basilar artery accounts for approximately 20 to 25 percent of posterior circulation strokes, either alone or in combination with other factors. Vertebral artery stenosis occurs most frequently at the vessel origin, as it arises from the subclavian artery. The safety and efficacy of invasive treatment is uncertain, and, until recently, patients with vertebral artery stenosis have been treated with medical treatment alone. Extracranial vertebral artery endarterectomy and vessel reconstruction have shown to be feasible and can have favorable outcomes; however, surgery at this site is technically challenging, and complications are frequent. Like CAS, endovascular treatment has been proposed as an alternative, less-invasive approach to treat atherosclerotic vertebral artery stenosis, when medical management is not successful in alleviating symptoms.

Angioplasty and stenting may be recommended for patients who remain symptomatic despite maximal medical management; however, anatomically these arteries are more difficult to access compared to the extracranial arteries. Evidence in the peer-reviewed published scientific literature has demonstrated a high risk of ischemic stroke with intracranial vertebral artery stenting, and treatment is reserved for individuals with stenosis who are hemodynamically unstable and are refractory to maximal medical management (Padalia et al., 2018).

RATIONALE

The United States Food and Drug Administration (FDA) has granted Premarket Approval (PMA) for numerous stents and stent systems for the treatment of carotid stenosis and embolic protection devices (EPDs) from various manufacturers.

Each FDA approved carotid stent or stent system 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.

Contraindications for each CAS system and distal embolic protection device are included in the FDA Summary of Safety and Effectiveness Data. These include but are not limited to 1) contraindication to anticoagulant and/or antiplatelet therapy; 2) severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system, or stent system; 3) known hypersensitivity to nickel-titanium; 4) uncorrected bleeding disorders and 5) lesions in the ostium of the common carotid artery.

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.

The 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. The FDA has mandated post marketing 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 (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

In 2015, the FDA approved transcarotid artery revascularization (TCAR) for high-risk patients with carotid artery stenosis. While TCAR's long-term durability continues to be studied (Malas et al., 2019; Kashyap et al., 2020, 2022; Zhang et al. 2022), in 2022 the FDA granted an expanded indication to TCAR to approving its use among standard-risk patients (Columbo et al., 2023).

Extracranial Carotid Artery

Kashyap et al. (2022) published the one-year outcomes after transcarotid artery revascularization (TCAR) in the ROADSTER 2 trial. All patients were considered high risk for CEA and underwent independent neurological assessments preoperatively, postoperatively, and had long-term clinical follow-up. The primary end point was incidence of ipsilateral stroke after treatment with the ENROUTE Transcarotid Stent System. Secondary end points included individual/composite rates of stroke, death, and perioperative myocardial infarction. Between June 2016 and November 2018, 155 patients at 21 centers in the United States and one in the European Union were enrolled and represented a subset of the overall trial. Asymptomatic (n = 119; 77%) and symptomatic patients (n = 36; 23%) with high-risk anatomic (i.e., high lesion, restenosis, radiation injury; 43%), physiologic (32%), or combined factors (25%) were enrolled. No patient suffered a perioperative myocardial infarction or stroke. Over the one-year follow-up, no patient had an ipsilateral stroke, but four patients died (2.6%), all from non-neurological causes. Additionally, a technical success rate of 98.7% with a low cranial nerve deficit rate of 1.3% was achieved. The authors concluded, in patients with high risk factors, TCAR yields high technical success with a low stroke and death rate at one (1) year. The authors concluded that further comparative studies with CEA are warranted.

Zhang et al. (2022) performed a retrospective review of Vascular Quality Initiative to assess perioperative outcomes in patients who underwent TCAR, transfemoral carotid artery stenting (TFCAS), or CEA. The study included 124,531 patients (TCAR, n=15,597; TFCAS, 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). The authors concluded that the perioperative risks associated with CEA, TFCAS, and TCAR in high-risk patients support the current Centers for Medicare & Medicaid Services criteria, although the risks associated with each revascularization approach in standard-risk patients suggest that distinguishing TCAR from TFCAS may be warranted.

Columbo et al. (2022) performed a retrospective review to measure stroke or death of patients after a TCAR procedure compared with carotid endarterectomy (CEA) and transfemoral carotid artery stenting (TF-CAS) perioperative and 1-year after procedure across 662 centers. Data was collected from the Vascular Quality Initiative registry to study 118,566 patients who underwent TCAR (21,234 patients), CEA (82,737 patients) , or TF-CAS (14,595 patients) from September 2016 to June 2021. The perioperative rate of stroke or death was 2.0% for TCAR, 1.7% for CEA, and 3.7% for TF-CAS (P<0.001). Compared with TCAR, the IV-adjusted odds ratio of perioperative stroke or death for CEA was 0.74 (95% CI, 0.55–0.99) and for TF-CAS was 1.66 (95% CI, 0.99–2.79). Results were similar among both symptomatic and asymptomatic patients. The 1-year rate of stroke or death was 6.4% for TCAR, 5.2% for CEA, and 9.7% for TF-CAS (P<0.001). Compared with TCAR, the IV-adjusted hazard ratio of 1 year stroke or death for CEA was 0.97 (95% CI, 0.80–1.17), and for TF-CAS was 1.45 (95% CI, 1.04–2.02). IV analysis further demonstrated that symptomatic patients with carotid stenosis had the lowest 1-year likelihood of stroke or death with TCAR (compared with TCAR, symptomatic IV-adjusted hazard ratio for CEA: 1.30 [95% CI, 1.04–1.64], and TF-CAS:1.86 [95% CI, 1.27–2.71]). The authors concluded that perioperative stroke or death was greater following TCAR as compared to CEA. However, there was no statistically significant difference in stroke or death between the two procedures at one year. TCAR performed favorably compared with TF-CAS at both time points. The authors stated that TCAR appears to be a safe alternative to CEA and TF-CAS when used selectively and may be useful when treating symptomatic patients.

Society for Vascular Surgery (SVS)

The Society for Vascular Surgery published updated guidelines for management of extracranial cerebrovascular disease in 2022. They recommended CEA over CAS in low- and standard-risk patients with more than 50% symptomatic artery stenosis (Strong Evidence of High Quality: 1A). The guidelines note that while present data are inadequate to make a recommendation on the role of 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.

The CREST clinical trial was conducted between December 2000 and July 2008, enrolling 2,522 patients at 108 centers across the U.S. and Canada. Of 427 interventionalists who applied to participate in CREST, only 224 (52%) were approved. Inclusion was initially restricted to recently symptomatic patients; however, due to slow enrollment, the protocol was subsequently amended to include asymptomatic patients. A March 2004 protocol amendment excluded further enrollment of patients aged 80 years and older, due to poor outcomes. Of the 1,271 patients randomized to CAS, 65 underwent CEA, and 54 underwent neither procedure; of the 1,251 patients randomized to CEA, 13 underwent CAS, and 44 underwent neither procedure. There were 20 patients excluded from one site, due to reported data fabrication. A sample size of 2,500 was targeted to detect a 46 percent reduction in the hazard ratio for the primary endpoint of any stroke, MI, or death during the peri-procedural period, or ipsilateral stroke within four years after randomization. In the entire sample (symptomatic and asymptomatic patients), investigators reported no difference between CAS and CEA for the primary outcome of any peri-procedural stroke, MI, or death, or post-procedural ipsilateral stroke. Stroke was more frequent following CAS, while MI was more frequent after CEA. The peri-procedural MI rate after CEA (2.3%) was considerably higher in CREST than any comparable trial (e.g., in EVA-3S 0.8%, SPACE 0%, ICSS 0.6%). While this may be attributable to a somewhat higher prevalence of coronary artery disease among participants, the relative difference was large. Peri-procedural CAS death/stroke rates were the lowest reported in any trial. Although participating interventionalists performing CAS were highly selected, peri-procedural death/stroke rates following CAS exceeded those for CEA: in symptomatic patients, 5.6 percent versus 2.4 percent, respectively; in asymptomatic patients, 2.6 percent versus 1.5 percent, respectively. The relative risk (RR) for peri-procedural death/stroke in the symptomatic group was 1.89 (95% confidence interval (CI): 1.11 to 3.21); in the asymptomatic group, it was 1.88 (95% CI: 0.79 to 4.42). The trial had limited power in the asymptomatic group: 21 percent power to detect an RR of 1.88. Commenting on CREST, Barnett et al., the principal investigators of the North American Symptomatic Carotid Endarterectomy Trial (NASCET), expressed a view that combining dissimilar patient groups (symptomatic and asymptomatic) flawed the trial. The CREST trial demonstrated that stenting and CEA were similar in regards to the primary outcome of periprocedural stroke, MI, death, or ipsilateral stroke within four (4) years. Secondary analyses revealed more periprocedural strokes with stenting (4.1% versus 2.3%) but fewer periprocedural Mis (1.1% versus 2.3%).

A number of meta-analyses were published, the most notable being an individual patient data meta-analysis (n=3,433) of SPACE, EVA-3S, and ICSS. In these symptomatic patients, the 30-day death/stroke risk (per-protocol analyses) with CAS was 7.7 percent versus 4.4 percent following CEA (RR: 1.74; 95% CI: 1.32 to 2.30). However, in the subgroup younger than age 70 years, comparative 30-day death/stroke rates were 5.1 percent (CAS) and 4.5 percent (CEA) (RR: 1.11; 95% CI: 0.73 to 1.71); for patients 70 years or older, the rates were 10.5 percent (CAS) and 4.4 percent (CEA) (RR: 2.41; 95% CI: 1.65 to 3.51).

Finally, trials have found restenosis more common following CAS than CEA. In a meta-analysis of 13 trials, among those reporting restenosis rates, Bangalore et al. reported pooled relative odds for restenosis following CAS, compared to CEA of 2.8 (95% CI: 2.0 to 4.0; I^2=0%).

In average-risk symptomatic patients, there is a body of evidence demonstrating worse outcomes with CAS, compared to CEA. While data show secular improvement in peri-procedural outcomes following CAS, there is evidence of a net harm when compared to CEA. The individual patient data meta-analysis of SPACE, EVA-3S, and ICSS indicates some uncertainty in comparative peri-procedural death/stroke rates for younger symptomatic patients. Still, that subgroup result must be considered carefully, given the larger body of evidence, as well as the evidence on restenosis.

Only the CREST clinical trial enrolled asymptomatic, average-risk patients and found a relative risk for peri-procedural death/stroke identical to that for symptomatic ones - the failure to reject similarity of CEA to CAS (the null hypothesis)

would be suspected due to lack of power. At the same time, there have been marked improvements in medical therapy and declining stroke rates in asymptomatic patients over the two decades since completion of landmark trials. There is considerable evidence that medical therapy in asymptomatic patients is preferred to intervention. For example, Naylor and Bell (2008) noted that, between 1985 and 2008, a steady decline occurred in ipsilateral stroke rates in medically treated asymptomatic patients with greater than 50 percent carotid stenosis. Marquardt et al. (2009) described a contemporary annual ipsilateral stroke or transient ischemic attack (TIA) rate of 0.34 percent among asymptomatic patients, with asymptomatic carotid stenosis equal to or greater than 50 percent (less than Arazi et al.'s estimated rate of 0.51 percent needed to justify the peri-procedural risk of death and stroke. In comparison, in 1993, the Asymptomatic Carotid Artery Stenosis trial completed randomization of asymptomatic patients with equal to or greater than 60 percent; the annual ipsilateral stroke rate was approximately 2.0 percent with medical therapy.

Reiff et al. (2022) published five-year outcomes from the Stent-supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy 2 (SPACE-2) Randomized Control Trial. The median follow-up was 59.9 months (interquartile range, 46.6 to 60). The cumulative incidence of any stroke (ischemic or hemorrhagic) or death from any cause within 30 days, or any ipsilateral ischemic stroke within five (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 carotid endarterectomy (CEA) plus best medical treatment (BMT), carotid angioplasty with stenting (CAS) plus BMT, and BMT alone, respectively. No significant difference in risk for the primary efficacy endpoint was found for CEA plus BMT versus BMT alone (HR, 0.93; 95% CI, 0.22 to 3.91; p=.93) or for CAS plus BMT versus BMT alone (HR, 1.55; 95% CI, 0.41 to 5.85; p=.52). Since superiority of CEA or CAS to BMT was not demonstrated, noninferiority testing was not conducted. In both the CEA and CAS groups, five (5) strokes and no deaths occurred in the 30-day periprocedural period. During five-year follow-up, three (3) ipsilateral strokes occurred in both the CAS plus BMT and BMT alone groups compared to none in the CEA plus BMT group.

Intracranial Artery

The Wingspan Stent System with Gateway PTA Balloon Catheter (Stryker Neurovascular) is the only Food and Drug Administration (FDA) approved system currently indicated for improving cerebral artery lumen diameter in patients 22-80 years old with recurrent (two or more) strokes refractory to a comprehensive regimen of medical therapy and due to atherosclerotic disease of intracranial vessels with 70-99% stenosis and that are accessible to the stent system. Patients in this subset have a poor prognosis, and treatment options are limited. The system consists of a highly flexible, microcatheter-delivered, self-expanding, nitinol stent, which may be suitable for lesions in the distal internal carotid and middle cerebral arteries. The Wingspan was approved following a prospective, multi-center, single-arm trial of 45 patients enrolled at 12 international centers (Bose, et al 2007). The primary safety endpoint was a composite of stroke and death clinical outcomes at 30 days, which occurred in 4.5% of patients. Clinical follow-up (42 patients) and angiographic follow-up (40 patients) were performed at six months. The type and frequency of observed adverse events, including stroke, were consistent with, or lower than, similar neurovascular procedures. Therefore, the FDA concluded that the probable benefit to health from using the Wingspan Stent System with Gateway PTA Balloon Catheter for treating transcranial stenosis outweighs the risk of illness or injury when used in accordance with the Instructions for Use and when considering the probable risks and benefits of currently available alternative forms of treatment. The system is authorized under a Humanitarian Device Exemption and requires institutional review board approval prior to clinical site use.

The Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial was a randomized, controlled trial (RCT) by Chimowitz et al. (2011) with a follow up study published by C.P. Derdeyn and colleagues (2014) comparing aggressive medical management alone, to aggressive medical management plus stenting in patients with symptomatic cerebrovascular disease and an intracranial stenosis of between 70-99%. That trial used the Wingspan Stent System, implanted by experienced neuro-interventionists who had been credentialed to participate in the trial. The authors had planned for an enrollment of approximately 750 patients, based on power calculations. However, the trial was stopped early for futility, after 451 patients had been randomized. The trial was terminated due to an excess of the primary outcome, stroke or death, at 30 days in the stenting group. In the stenting group, the rate of stroke or death at 30 days was 14.7%, compared to a rate of 5.8% (p=0.002) in the medical management

group. At the time of termination, the mean follow-up was 11.9 months. Kaplan-Meier estimates of the primary outcome of stroke or death at one year was 20.5% in the stenting group, compared to 12.2% (p=0.009) in the medical management group.

The long-term follow up to the SAMMPRIS trial from C.P. Derdeyn and colleagues (2014) discovered that during a median follow-up of 32.4 months, 34 (15%) of 227 patients in the medical group and 52 (23%) of 224 patients in the stenting group had a primary endpoint event. The cumulative probability of the primary endpoints was smaller in the medical group versus the percutaneous transluminal angioplasty and stenting (PTAS) group (p=0.0252).The absolute differences in the primary endpoint rates between the two groups were 7.1% at year one (95% CI 0.2 to 13.8%; p=0.0428), 6.5% at year two (-0.5 to 13.5%; p=0.07), and 9.0% at year three (1.5 to 16.5%; p=0.0193). The occurrence of the following adverse events was higher in the stenting group than in the medical group: any stroke (59 [26%] of 224 patients versus 42 [19%] of 227 patients; p=0.0468) and major hemorrhage (29 [13%] of 224 patients versus 10 [4%] of 227 patients; p=0.0009). The researchers concluded that, for high-risk patients with intracranial stenosis, aggressive medical management is superior to stenting with the Wingspan device, at both early and later phases of follow-up.

The Wingspan post-market surveillance study, the WEAVE trial, was published by Alexander and colleagues in 2019. It was a prospective, single-arm, multicenter, consecutive enrollment study. The primary objective was to evaluate the rate of stroke and death within 72 hours post stenting in patients treated with the Wingspan Stent System, strictly according to the Instructions for Use (n=198). A total of 152 patients met on-label indications and underwent the procedure, and 46 patients did not meet the approved indications for use criteria. Mean target artery stenosis before the procedure was 83% and mean target stenosis after stenting was 28%. There was a 2.6% periprocedural complication rate (2 deaths, 2 strokes without death) in the cohort who met FDA-approved indications). This was lower than the 4% periprocedural primary event safety benchmark set for the interim analysis in the study, and the trial was stopped early. There was a 23.9% periprocedural complication rate for those patients who did not meet the FDA-approved indications for use (2 deaths, 9 strokes without death all occurring in the territory of the stented artery). Mean Wingspan case experience for interventionalists in the WEAVE trial was 37 stents. Those with more than 50 Wingspan cases prior to the study had 0% periprocedural stroke and death index rate, while interventionalists with less than 50 Wingspan cases before trial had a 4.8% index event rate in trial patients. The authors compared this data to the median number of Wingspan stents delivered by interventionalists in the SAMMPRIS trial before beginning enrollment (10 stents) demonstrating the WEAVE trial had more experienced interventionalists than those involved in SAMMPRIS. The WOVEN study (Alexander, et al 2021) conducted a one year follow up chart review and imaging analysis of 129 patients from the original cohort. The goal was to provide a more homogenous patient group for analysis and evaluate 1-year stroke and death rates in stented patients, which was 8.5%. The authors concluded that with experienced interventionalists, and proper patient selection following the on-label usage guidelines, the use of the Wingspan stent for intracranial atherosclerotic disease demonstrated a low periprocedural complication rate and excellent safety profile.

Given the results of the mandated post-market study, the FDA issued a safety communication in April 2019 reiterating that the use of Wingspan in patients who do not meet the FDA-approved indications for use criteria have a significantly increased risk of stroke or death and also called out the revised indications for its use: patients between 22 and 80 years of age and who have had two or more strokes despite aggressive medical management; whose most recent stroke occurred more than seven days prior to planned treatment with Wingspan; who have 70-99% stenosis due to atherosclerosis of the intracranial artery related to the recurrent strokes; and who have made good recovery from the previous stroke and have a modified Rankin Scale score of three or less prior to Wingspan treatment.

A 2020 Cochrane Systematic Review by Wang et al. aimed to compare the safety and efficacy of endovascular therapy with medical management versus medical management alone for the treatment of symptomatic intracranial atherosclerotic stenosis. Primary outcomes were death of any cause or non-fatal stroke within three months of randomization. The literature search yielded three RCTs, representing 632 patients. Modalities for endovascular therapy included angioplasty alone, balloon- mounted stent use, and angioplasty followed by a placement of a self-expanding stent. Medical management consisted of controlling risk factors (hypertension, hyperlipidemia and diabetes) as well as antiplatelet therapy. Endovascular therapy was associated with worse outcomes in the 30-day death and stroke rate (risk ratio (RR) 3.07, 95% Confidence Interval (CI) 1.80 to 5.24), and one-year death or stroke rate (RR 1.69, 95%CI, 1.21-2.36).

Blinding is not possible in these studies due to the intervention. The studies were terminated early, and there were high rates of loss to follow-up. The authors concluded that for individuals with symptomatic severe intracranial atherosclerotic stenosis, endovascular therapy does not prevent recurrent strokes and has an increased risk of harm.

Luo et al. (2023) completed a Cochrane review that evaluated endovascular therapy plus conventional medical treatment versus medical treatment alone for symptomatic intracranial artery stenosis. The review included four (4) randomized control trials (RCTs) involving a total of 989 patients as well as two (2) identified ongoing RCTs. All trials had a high risk of performance bias, and the certainty of included evidence ranged from low to moderate. The review also incorporated various subgroup analyses. Overall, endovascular therapy plus conventional medical treatment was found to increase the risk of the primary outcome of short-term stroke and death within three (3) months of randomization in patients with recent symptomatic intracranial artery stenosis. Endovascular therapy plus conventional medical treatment was also found to increase the risk of short-term ipsilateral stroke (RR, 3.26; 95% CI, 1.94 to 5.48; moderate certainty), short-term ischemic stroke (RR, 2.24; 95% CI, 1.30 to 3.87; moderate certainty), and long-term death or stroke (RR,1.49; 95% CI, 1.12 to 1.99; moderate certainty). Long-term results that were reported appeared to be due to the early risks of endovascular therapy.

Vertebral Artery

Stayman et al. (2011) conducted a systematic review of the literature to determine the risk of endovascular treatment of extracranial vertebral artery stenosis (ECVAS). A total of 27 articles were identified, with a total of 980 of the 993 patients treated with stents. The technical success rate was very high, with 973 of the 980 (99.3%) stenting cases demonstrating less than 20 percent residual stenosis at the conclusion of the procedure. The use of drug-eluting stents was reported in 305 (31%) patients. A total of 11 vertebrobasilar strokes were reported during the first 30 days after the procedure, yielding a 1.2 percent procedural risk of stroke, whereas an additional eight (0.9%) vertebrobasilar TIAs were reported. A small number of deaths were reported during the 30 days after the procedure, but none was directly related to posterior ischemia provoked by vertebral artery stenting. During a follow-up period spanning an average of 21 months, 13 of 980 (1.3%) patients had a vertebrobasilar territory infarction, and 64 of 980 (6.5%) had recurrent vertebrobasilar TIA symptoms. Of 993 patients, 498 (50%) were reported to have undergone follow-up angiography. Most studies did not have a set protocol for follow-up angiography, and such procedures were largely performed on an as-needed basis for patients exhibiting recurrent symptoms. The authors concluded the following:

> Heterogeneity in patient selection, clinical/angiographic follow-up, and outcome measures comprises a limitation in analysis of the data. Nonetheless, even a conservative appraisal of cumulative outcomes leads to a favorable conclusion regarding the safety and feasibility of stent placement for vertebral artery origin stenosis. The question remains as to how long-term outcomes (i.e., vertebrobasilar stroke, recurrent vertebrobasilar TIA) differ between patients undergoing stenting and those receiving optimal medical management.

In a systematic review by Antoniou and colleagues (2011) of PTA and stenting in patients with proximal vertebral artery stenosis, the authors concluded that there was limited comparative evidence on the safety and efficacy of medical, surgical, and endovascular treatment of proximal vertebral artery disease. PTA and stenting have evolved as a safe, minimally invasive therapeutic method, associated with low peri-procedural neurologic adverse events and death. There seems to be a significant restenosis rate associated with angioplasty and primary stenting, which has, however, an asymptomatic course and leads to a lower reintervention rate. Further randomized trials comparing stenting with medical therapy are required, and the role of novel therapeutic modalities with the use of drug-eluting stents in the long-term efficacy of the endovascular treatment must be separately evaluated.

Markus et al. (2019) noted that symptomatic vertebral artery stenosis is associated with a high risk of recurrent stroke, with higher risks for intracranial than for extracranial stenosis. Vertebral artery stenosis can be treated with stenting with good technical results; however, whether it results in improved clinical outcome is uncertain. These researchers compared vertebral stenting with medical treatment for symptomatic vertebral stenosis. They performed a pre-planned pooled individual patient data analysis of three completed RCTs comparing stenting with medical treatment in patients with symptomatic vertebral stenosis. The primary outcome was any fatal or non-fatal stroke. Analyses were carried out for

vertebral stenosis at any location and separately for extra-cranial and intra-cranial stenoses. Data from the intention-to-treat (ITT) analysis were used for all studies. These investigators estimated HRs with 95% CIs using Cox proportional-hazards regression models stratified by trial. Data were from 354 subjects from three trials, including 179 patients from VIST (148 with extra-cranial stenosis and 31 with intra-cranial stenosis), 115 patients from VAST (96 with extra-cranial stenosis and 19 with intra-cranial stenosis), and 60 patients with intracranial stenosis from SAMMPRIS (no patients had extra-cranial stenosis). Across all trials, 168 participants (46 with intracranial stenosis and 122 with extra-cranial stenosis) were randomly assigned to medical treatment and 186 to stenting (64 with intracranial stenosis and 122 with extracranial stenosis). In the stenting group, the frequency of peri-procedural stroke or death was higher for intracranial stenosis than for extracranial stenosis (10 (16 %) of 64 patients versus 1(1 %) of 121 patients; $p < 0.0001$). During 1,036 person-years of follow-up, the HR for any stroke in the stenting group compared with the medical treatment group was 0.81 (95 % CI: 0.45 to 1.44; $p = 0.47$). For extracranial stenosis alone, the HR was 0.63 (95 % CI: 0.27 to 1.46) and for intracranial stenosis alone it was 1.06 (0.46 to 2.42; p interaction =0.395). The authors concluded that stenting for vertebral stenosis had a much higher risk for intracranial as compared with extracranial stenosis. This pooled analysis did not show evidence of a benefit for stroke prevention for either treatment. There was no evidence of benefit of stenting for intracranial stenosis. Stenting for extracranial stenosis might be beneficial; however, larger trials are needed to determine the treatment effect in this subgroup.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
0075T (**E/I**)	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel
0076T (**E/I**)	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, each additional vessel (List separately in addition to code for primary procedure)
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed

Code	Description
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selective vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery) (List separately in addition to code for primary procedure)
37215	Transcatheter placement of intravascular stents(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection
37216	Transcatheter placement of intravascular stents(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection
37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation
61630 **(E/I)**	Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous
61635 **(E/I)**	Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed

HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

Code	Description
G45.0-G45.2 G45.8-G45.9	Transient cerebral ischemic attacks and related syndromes (code range)
I63.011-I63.019	Cerebral infarction due to thrombosis of precerebral artery (code range)
I63.111-I63.119	Cerebral infarction due to embolism of precerebral artery (code range)
I63.211-I63.219	Cerebral infarction due to unspecified occlusion or stenosis of precerebral arteries (code range)
I63.031-I63.039	Cerebral infarction due to thrombosis of carotid artery (code range)
I63.131-I63.139	Cerebral infarction due to embolism of carotid artery (code range)
I63.231-I63.239	Cerebral infarction due to unspecified occlusion or stenosis of carotid arteries (code range)
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery
I65.01-I65.09	Occlusion and stenosis of bilateral vertebral arteries (code range)
I65.21-165.29	Occlusion and stenosis of carotid artery (code range)
I65.8	Occlusion and stenosis of other precerebral arteries
I65.9	Occlusion and stenosis of unspecified precerebral artery

Code	Description
I66.01-I66.9	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction (code range)

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*Key Article

KEY WORDS

Angioplasty, Carotid angioplasty, Carotid stenosis, Carotid stents, CEA, CAS, Intracranial Circulation, Neurolink System, Percutaneous Transluminal Angioplasty (PTA), Wingspan Stent

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD# 20.7) for Percutaneous Transluminal Angioplasty of the Carotid Artery concurrent with stenting. Please refer to the following NCD website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=201] accessed 11/15/24.