Medical Coverage Policy

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Angioplasty (Extracranial, Intracranial) and Intracranial Aneurysm Repair

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Overview

This Coverage Policy addresses endovascular treatment of intracranial aneurysm and atherosclerosis (intracranial, extracranial), using angioplasty, with or without stent placement. Angioplasty is a minimally invasive procedure performed to restore blood flow through a blocked or narrowed artery. It is an alternative to carotid endarterectomy. The coverage criteria in this Medical Coverage Policy are primarily based on recommendations from published practice parameters, recommendations and professional society/organization consensus guidelines.

Coverage Policy

Angioplasty (Extracranial, Intracranial)

Extracranial carotid artery angioplasty with stent placement, transfemoral or transcarotid approach (TCAR), as treatment for carotid artery stenosis is considered medically necessary in a high risk individual who meets the following criteria:

- symptomatic within the previous six months (i.e., stroke or transient ischemic attack [TIA]), has 50-99% stenosis of the common or internal carotid artery, and is considered high risk for carotid endarterectomy because of the presence of ANY of the following comorbidities or anatomic features:

  - knowledge of two or more proximal or major diseased coronary arteries with $\geq$ 70% stenosis that have not or cannot be revascularized
  - currently on a list for major organ transplantation (i.e., heart, lung, liver, kidney) or is being evaluated for such
  - left ventricular ejection fraction $<$ 30%
  - New York Heart Association (NYHA) Functional Class III or higher congestive heart failure
  - uncontrolled diabetes defined as fasting glucose $>$ 400 mg/dl and ketones $>$ 2+
  - restenosis after previous carotid artery endarterectomy (CEA) or stenting
  - patient is status/post-radiation treatment to the neck
  - patient is status/post-radical neck surgery
  - surgically inaccessible lesions (e.g., lesions above the level of C2 or below the clavicle, lesions obstructed by tumors in the neck)
  - spinal immobility (i.e., inability to flex neck beyond neutral or kyphotic deformity)
  - contralateral laryngeal nerve paralysis
  - age ≥ 80 years
  - severe chronic obstructive pulmonary disease (e.g., FEV less than 50% predicted)
  - coronary artery bypass within six weeks
  - tracheostomy
  - recent myocardial infarction (≤ 30 days)
  - recent coronary artery bypass grafting or valve repair

- high or low placed carotid lesions
- dialysis-dependent renal failure
- unstable angina defined as rest angina with electrocardiogram (ECG) changes
- contralateral internal carotid artery occlusion

Extracranial carotid artery angioplasty with stent placement performed by a transfemoral approach as treatment for carotid artery stenosis is considered medically necessary in a standard risk individual who meets the following criteria:

- asymptomatic, has 60-99% stenosis of the common or internal carotid artery, and ANY of the following imaging characteristics or other findings suggestive of increased stroke risk while on medical therapy:

  - stenosis progression
  - silent infarction on computerized tomography (CT)
  - large plaque area
  - plaque echolucency
  - intra-plaque hemorrhage on magnetic resonance imaging (MRI)
  - impaired cerebral vascular reserve
  - spontaneous embolization on transcranial Doppler
  - history of contralateral TIA

Extracranial carotid artery angioplasty with stent placement is considered not medically necessary for ANY other indication, including the following:

- carotid stenosis with angiographically visible intraluminal thrombus
- total vessel occlusion
- the stenosis cannot be safely reached or accessed by endovascular approach
- acute arterial dissection
- asymptomatic chronic dissection

Extracranial vertebral artery angioplasty with stent placement is considered medically necessary when BOTH the following criteria are met:

- recurrent vertebrobasilar territory symptoms refractory to maximum medical management
- 50-99% extracranial vertebral artery stenosis

Extracranial vertebral artery angioplasty with stent placement is considered experimental, investigational or unproven for treatment of ANY other indication, including asymptomatic vertebral artery stenosis.

Intracranial angioplasty, with stent placement, for treatment of atherosclerosis of intracranial arteries is considered experimental, investigational or unproven.

<u>Intracranial Aneurysm Repair</u>

Either of the following is considered medically necessary for repair of an intracranial aneurysm:

- surgical clipping
- endovascular treatment using either embolization coiling or balloon–assisted coiling

Intracranial stent placement (e.g., stent assisted coil, endoluminal flow diversion) using a stent approved by the U.S. Food and Drug Administration for the intended use, is considered medically necessary for treatment of a wide-necked intracranial aneurysm (e.g., neck diameter of > 4 mm or a dome-to-neck ratio of < 2) arising from a parent artery measuring at least 2 mm but no greater than 4.5 mm in diameter when the aneurysm is not amenable to surgical or standard endovascular treatment (e.g., clipping, coil embolization).

Endovascular repair of an intracranial aneurysm using an intrasaccular flow-disruption device (e.g., Woven EndoBridge [WEB] Aneurysm Embolization System [MicroVention, Inc.]) is considered experimental, investigational or unproven.

General Background

Atherosclerosis is the buildup of plaque inside arteries. When plaque buildup occurs in the extracranial or intracranial arteries, the vessel becomes blocked or severely narrowed and may lead to stroke and associated neurologic impairment. Risk factors associated with extracranial and intracranial atherosclerosis are generally the same as those for atherosclerotic disease that occurs in other areas of the body.

Stroke is the fifth leading cause of death and leading cause of disability in the United States; on average the incidence is 800,000 cases/year with a majority resulting from acute ischemic stroke (AIS) from cerebrovascular occlusion (Eskey, et al., 2018). Intravenous thrombolytic therapy with recombinant tissue plasminogen activator (tPA) is a well-established treatment of stroke and associated with improved clinical outcomes when administered within 3-4.5 hours of the onset of symptoms.

Carotid endarterectomy is an established treatment for symptomatic carotid artery stenosis. Symptomatic is defined as focal neurologic symptoms caused by ischemic stroke in the carotid artery territory or TIAs, and ipsilateral to significant carotid atherosclerotic pathology. Endovascular treatment may be performed as a viable alternative for some patients.

Angioplasty (Extracranial, Intracranial)

Carotid and cerebral angiography are considered the gold standard for imaging vasculature in the head and neck region and can identify arterial dissections, arteriovenous malformations or fistulas, intracranial occlusive disease, and traumatic vascular injuries. Angiography is the radiographic visualization of blood vessels following injection of a radiopaque substance. Other techniques such as duplex ultrasonography, computed tomography (CT) angiography and magnetic resonance (MR) imaging angiography may also be used to determine the degree of stenosis.

Carotid Artery: The common carotid arteries are each located on the side of the neck and supply blood to the brain, neck and face. Each common artery branch has two divisions: the internal carotid and external carotid. Treatment for stenosis occurring in the carotid artery depends on the degree of blockage and the presence of symptoms. Asymptomatic patients (no history of ischemic stroke or TIA) with stenosis are treated medically with antiplatelet therapy (e.g., aspirin) to decrease the likelihood of a blood clot and decrease the risk of stroke. Patients with severe symptomatic stenosis are referred for surgery. Carotid artery endarterectomy (CEA) is considered the treatment of choice for significant blockage or stenosis that occurs in the carotid arteries and is symptomatic. CEA has been shown to reduce risk of stroke in both asymptomatic and symptomatic patients in several randomized controlled trials (RCTs) (Brothers, et al., 2015). However, CEA has been associated with an increased risk of morbidity and mortality resulting in

the presence of significant comorbidities and anatomic factors, resulting in both neurological and non-neurological complications (Brott, et al., 2013).

For individuals who meet criteria for revascularization, carotid artery angioplasty and stenting (CAS) may be considered an alternative (Burton and Lindsay, 2005) to CEA. In contrast to CEA, angioplasty of the carotid artery is not associated with potential for cranial nerve injury and can be performed under local anesthesia. This procedure is a minimally invasive endovascular procedure performed to restore blood flow through a narrowed artery, reduce the chance of embolization, and prevent stenosis and stroke. CAS can be performed percutaneously or through a small incision in the neck. Percutaneous CAS obtains vascular access through the groin (transfemoral), axillary artery (transaxillary), brachial artery (transbrachial), radial artery (transradial), or direct puncture of the carotid (transcervical) (UpToDate, 2023). Stent implantation involves the permanent placement of a small mesh tube within the narrowed artery to compress the obstructive material and maintain patency of the artery, therefore restoring blood flow. The balloon is then deflated and the catheter is removed. In some circumstances, an embolic protection device may be inserted to accompany stent placement. The embolic protection device typically consists of a small wire mesh or basket that is used to capture any embolic debris that may dislodge from the lesion in order to prevent the debris from reaching the brain or other intracranial areas (Ricotta, et al., 2011). Such devices are purported to further decrease the neurologic event risk from carotid angioplasty and similar procedures. Selection of device depends on the lesion characteristics and anatomic considerations (Ricotta, et al., 2011). Transcarotid artery revascularization (TCAR) is a specific technique that accesses the carotid through a short incision at the base of the neck over the proximal ipsilateral common carotid artery. The TCAR procedure is performed through a short carotid sheath in conjunction with flow reversal for embolic protection using a proprietary device (UpToDate, 2023).

Similar to CEA, CAS is associated with risks. Risk stratification for CAS is similarly divided into two categories: anatomic (e.g., lesion location, lesion type) and physiologic characteristics (e.g., comorbid conditions). CAS has been recommended for patients who have high perioperative coronary risk or anatomic risk for CEA (Murad, et al., 2011; Gurm, et al., 2008a). For normal risk patients, studies suggest CEA has resulted in lower perioperative and longer term stroke and death rates when compared with carotid artery stenting (Brothers, et al., 2015). A meta-analysis published by Murad and colleagues (2011) evaluated efficacy and safety of CEA versus CAS in subjects with carotid artery disease. Thirteen RCTs were included in the review, 7,484 subjects in total, and 80% were symptomatic. Compared with CEA, CAS was associated with an increased risk of any stroke, decreased risk of perioperative myocardial infarction (MI), and nonsignificant increase in mortality. When the analysis was limited to the most recent RCTs published, which were described by the authors as having better methodology and 56% of the total cohort (two RCTS), results demonstrated CAS was associated with significant increased risk of any stroke and mortality, and a nonsignificant decrease for risk of MI. The available clinical data on the TCAR procedure consisted of safety and efficacy studies, institutional reports, and real-world outcomes reported in the TCAR Surveillance Project (TSP). The updated Society for Vascular Surgery guidelines on the management of extracranial cerebrovascular disease note that TCAR procedure is at least equivalent to CEA, with some potential improvements, and compared with TF-CAS, the overall data demonstrate better outcomes. TCAR may be preferable to CEA and TF-CAS for high-risk patients (anatomic and physiologic) (AbuRahma, 2022).

High Risk Indicators: Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors who would be poor candidates for CEA in the opinion of a surgeon (CMS, 2005). Comorbid conditions and/or anatomic features that should be considered prior to selection of endovascular management can be found in each of the manufacturers' U.S. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data for their CAS system. These are consistent with the inclusion and exclusion criteria for subjects in the CAS trials and studies

(e.g., ARCHER, CABERNET, SAPPHIRE trials). For example, in order for patients to qualify as a high-risk or nonsurgical candidate in any of the three ARCHER trials, two or more of the criteria listed in a-e OR one or more of the criteria listed in f-q had to be met:

a) knowledge of two or more proximal or major diseased coronary arteries with $\geq$ 70% stenosis that have not or cannot be revascularized
b) unstable angina defined as rest angina with electrocardiogram (ECG) changes
c) MI within the previous 30 days and current need for carotid artery revascularization
d) concurrent requirement for aortocoronary bypass or cardiac valve surgery within 30 days
e) contralateral occlusion of the internal carotid artery
f) currently on a list for major organ transplantation (i.e., heart, lung, liver, kidney) or is being evaluated for such
g) ejection fraction $<$ 30% or New York Heart Association (NYHA) Functional Class III or higher
h) $FEV_1 <$ 30% (predicted)
i) dialysis-dependent renal failure
j) uncontrolled diabetes defined as fasting glucose $>$ 400 mg/dl and ketones $>$ 2+
k) restenosis after previous CEA
l) patient is status/post-radiation treatment to the neck
m) patient is status/post-radical neck surgery
n) surgically inaccessible lesions (e.g., lesions above the level of C2 or below the clavicle, lesions obstructed by tumors in the neck)
o) spinal immobility (i.e., inability to flex neck beyond neutral or kyphotic deformity)
p) presence of tracheostomy stoma
q) contralateral laryngeal nerve paralysis

In addition, published guidelines (Brott, et al., 2013), textbooks and various other sources indicate that for the management of individuals with extracranial and vertebral artery disease, although no adequate studies have validated high risk criteria, generally accepted criteria for high risk includes at least one of the following (based on SAPPHIRE 2004, SAPPHIRE 2008, and CREST 2010 trials):

- clinically significant cardiac disease (congestive heart failure, abnormal stress test, or need for open heart surgery)
- severe pulmonary disease
- contralateral carotid occlusion
- contralateral laryngeal nerve palsy
- previous radical neck surgery or radiation therapy to the neck
- recurrent stenosis after endarterectomy
- age ≥ 80 years
- chronic obstructive pulmonary disease
- prior CEA or CAS
- prior coronary artery bypass surgery

In 2018, Naylor and colleagues reported within the European Vascular Surgery Clinical Practice Guidelines that data is conflicting, and there is no general consensus regarding how 'high risk" is defined. These authors recommend management decisions based on an individual patient basis with consideration of comorbidities as well as anatomical features and the experience of the CAS surgeon (Naylor, et al., 2018).

Risks associated with angioplasty include restenosis (although uncommon) after implantation of the stent, non-neurologic complications during the procedure (e.g., hemodynamic instability), and complications resulting from embolic debris that become dislodged from the site of the lesion

either during or after the procedure which may lead to stroke or death. Stroke following CAS may be the result of embolization at the time of the procedure, delayed embolization, or hemorrhagic stroke related to hyperperfusion (Gurm, et al., 2008a). In general however, the overall postoperative neurologic complication rates for angioplasty and stenting of the extracranial carotids for the treatment of stenosis range from 0% to 10%.

Absolute contraindications to CAS include carotid stenosis with an angiographically visible intraluminal thrombus, complete vessel occlusion, endovascular inaccessible stenosis, or other significant contraindications for angiography.

Vertebral Artery: The vertebral arteries are located on each side of the neck, rise from the subclavian artery, branches into four segments (three are extracranial and one is intracranial) as it rises superiorly, and then joins to form the basilar artery at the skull. The basilar artery carries blood to the brain. Atherosclerosis of the vertebral or basilar arteries accounts for 20-25% of strokes (Naylor, et al., 2018).

Non-invasive imaging using contrast enhanced magnetic resonance angiography or computed tomography is recommended for diagnosing vertebral artery disease due to the risk for angiography-related stroke (Naylor, et al., 2018). The risk of stroke remains high in symptomatic patients despite best medical management; in asymptomatic patients risk is much lower. Padalia and colleagues (2018) reported that for symptomatic patients according to the WASID (Warfarin Aspirin Symptomatic Intracranial Disease) trial, one year risk of ischemic stroke in the territory of a 50% intracranial stenosis was about 11-12% on high dose aspirin and warfarin. The rate increased to 23% when the degree of stenosis was 70% (Padalia, et al., 2018).

Symptomatic blockage that occurs within the intracranial arteries is standardly treated with medical therapy. According to the 2012 Society of Neuro Interventional Surgery (Hussain, et al., 2012), medical management of symptomatic intracranial atherosclerotic disease includes aspirin and clopidogrel for three months with aggressive risk factor modification (i.e., hypertension, hyperlipidemia, diabetes and smoking cessation) as first line therapy. 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).

Recommendations and clinical practice guidelines from professional societies for intracranial angioplasty and stenting vary. Brott et al. (2013) published guidelines on the management of patients with extracranial carotid and vertebral artery disease and reported that randomized controlled trials are lacking for vertebral artery stenting, and there is insufficient evidence to support endovascular management is superior to best medical management for treatment of vertebral artery stenosis. In 2012, Hussain and associates published a standard of practice for endovascular treatment of intracranial atherosclerosis. Within this document, the authors report endovascular angioplasty with or without stenting is a possible therapeutic option for selected individuals with symptomatic intracranial arterial disease, defined as subjects with symptomatic 70-99% intracranial stenosis when aggressive maximal medical therapy has failed (Hussain, et al., 2012).

The American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Peripheral Vascular Disease and Council on Clinical Cardiology updated the 2013 guidelines for early management of patients with acute ischemic stroke (AIS) (Powers, et al., 2019). Within these guidelines, the authors acknowledge the following:

- For patients with acute ischemic stroke (AIS) and extracranial carotid or vertebral arterial dissection, treatment with either antiplatelet or anticoagulant therapy for 3-6 months is reasonable (Benefit outweighs risk IIa, Moderate quality evidence B-NR)
- Regarding patients with AIS and extracranial carotid or extracranial vertebral arterial dissection who have definite recurrent cerebral ischemic events despite medical therapy, the value of endovascular stenting is not well established (Moderate IIb, Limited Data C-LD)
- Emergent angioplasty and/or stenting of the extracranial carotid or vertebral arteries in unselected patients is not well established (Class IIb, Level of Evidence C).

Within these guidelines:

- Class IIa evidence is defined as: Benefit > Risk, reasonable.
- Class IIb evidence is defined as: Benefit ≥ Risk, Additional studies with broad objectives are needed, additional registry data would be helpful; Procedure /Treatment may be considered.
- Level of evidence "B-NR" is defined as: moderate quality evidence from non-randomized studies.
- Level of evidence "C-LD" is defined as: Limited data. Randomized or nonrandomized observational or registry studies with limitations of design or execution; meta-analyses of such studies; physiologic or mechanistic studies in human subjects.

A scientific statement from the American Heart Association (Eskey, et al., 2018) supports intracranial stenting with the Wingspan or Pharos stent system for individuals with 70-99% stenosis when there is progressing symptoms, recurrent TIA or stroke despite medical management with dual antiplatelet therapy, systolic BP of < 140, and high intensity statin therapy. These criteria are in accordance with the FDA Humanitarian Device Exemption (HDE) approval. Within this guideline, the authors note in detail the SAMMPRIS (Chimowitz, et al., 2011) and VISSIT (Zaidat, et al., 2015) trials; both trials were halted early because the 30-day endpoint of stroke, death or intracranial hemorrhage occurred in more patients who underwent stenting than medical management. In addition, at one year there was an increased risk of stroke or TIA in the stent group.

U.S. Food and Drug Administration (FDA)

The FDA has listed numerous stents and stent systems that have received Premarket Approval (PMA) for treatment of carotid stenosis and embolic protection devices from various manufacturers. The first carotid stenting system was approved in 2004 (i.e., ACCULINK™ Carotid Stent System and the RX ACCULINK™ Carotid Stent System [Guidant Corporation, Santa Clara, CA] used in conjunction with carotid embolic protection systems [ACCUNET™ and RX ACCUNET™ Embolic Protection Systems, Guidant Corporation, Santa Clara, CA]); however, several stenting systems have been approved since then. The FDA-approved stents and distal embolic protection devices differ in the deployment methods once they reach the targeted lesion. The FDA-approved stents and distal embolic protection devices were initially approved based on either RCTs (i.e., Precise and AngioGuard), or the devices were approved based on uncontrolled trials, single-arm trials or registries, and comparison to historical controls. Additional stents and embolic protection devices have since been approved, and various PMA supplements have been approved since the initial approval on most devices. In 2015 the FDA approved transcarotid artery revascularization (TCAR) for high-risk patients with carotid artery stenosis (P140026). While TCAR's long-term durability still remains unknown (Malas, et al., 2019; Kashyap et al., 2020, 2022; Zhang, et al. 2022), in 2022 the FDA granted an expanded indication to TCAR, approving its use among standard-risk patients (Columbo, et al., 2023) (P140026/S016).

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 the following:

- contraindication to anticoagulant and/or antiplatelet therapy
- severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system, or stent system
- known hypersensitivity to nickel-titanium
- uncorrected bleeding disorders
- lesions in the ostium of the common carotid artery

Literature Review
Early studies were conflicting and did not show a benefit of CAS compared with CEA for reduction of stroke or death in the treatment of atherosclerosis of the carotid arteries. However, there is a growing body of evidence to support CAS is not inferior to CEA. A number of randomized clinical trials, nonrandomized trials, systematic reviews and meta-analyses support safety and efficacy of carotid artery angioplasty and stenting for select individuals requiring revascularization (Murad, et al., 2011; Yavin, et al., 2011; Meier, et al., 2010; Eckstein, et al., 2008; Eisenhauer and White, 2008; Gurm, et al., 2008a; Gurm, et al., 2008b; Iyer, et al., 2008; Gray, et al, 2007; Katzen, et al., 2007; White, et al., 2006; Burton and Lindsay, 2005; Groschel, et al., 2005; Zahn, et al., 2005). The preponderance of the evidence supports the conclusion that CAS with embolic protection is not inferior to CEA in either symptomatic or asymptomatic patients at increased risk for surgical complications of CEA (White, et al., 2008). Individuals with surgical high risk features (anatomic and comorbid) for CEA have been proven to have outcomes similar to CEA; this was reported in a randomized controlled trial (SAPPHIRE). The SAPPHIRE study is an accepted study by the FDA as evidence supporting CAS device approval (Yadav, 2004). Three year outcomes data from the SAPPHIRE study have confirmed the long-term safety and efficacy in this high risk subset of patients. The author reported that 73.8% of patients in the stenting group and 69.7% in the endarterectomy group were free of major adverse events at three years (the pre-specified major end point, defined as death, myocardial infarction, or stroke within 30 days or death or ipsilateral stroke between 31 days and 1,080 days). A total of 80.0% of patients in the stenting group and 75.8% in the endarterectomy group were alive at three years. A total of 92.0% of patients in the stenting group and 93.3% in the endarterectomy group were free of stroke at three years (defined as stroke within 30 days or ipsilateral stroke between 31 days and 1,080 days) (Gurm, et al., 2008b).

The medical literature does not lend firm support to treatment of asymptomatic candidates. For individuals with asymptomatic disease, the American Heart Association/American Stroke Association (AHA/ASA) has noted that advances in optimal medical therapy have resulted in uncertainty about the need for, and benefit of, either treatment modality in the asymptomatic subgroup with carotid artery stenosis. The recommendations for selection of asymptomatic patients for carotid revascularization indicate decisions should be guided by an assessment of comorbid conditions and life expectancy, as well as other individual factors and a thorough discussion regarding risks and benefits of the procedure. The authors concluded that more data is needed to compare long-term outcomes following carotid artery endarterectomy and angioplasty in asymptomatic individuals with carotid artery stenosis (Goldstein, et al., 2011).

The updated Society for Vascular Surgery Guidelines for Management of Extracranial Carotid Disease (Ricotta, et al., 2011), the AHA/ASA guidance regarding asymptomatic disease (Goldstein, et al., 2011), and the National Institute for Health and Clinical Excellence (NICE, 2011a) agree the current evidence for safety of carotid artery stent placement in asymptomatic carotid stenosis shows well-documented risk, particularly for stroke.

Arhuidese et al., 2021, published a study on patients undergoing transfemoral carotid stenting for dissection. The retrospective analyses looked at patients who underwent TF-CAS for dissection between January 2006 and December 2019. The objective was to evaluate the outcomes of transfemoral carotid stenting (TF-CAS) for the treatment of carotid dissection from a contemporary large representative cohort of patients. The median age of the patients was 53 years (interquartile range 42-66 years). Patients with trauma or fibromuscular dysplasia were excluded. There were 608 patients who underwent transfemoral carotid stenting for carotid dissection. The outcomes of interest were new ipsilateral periprocedural stroke, myocardial infarction (MI), 30-day mortality as well as the composites of 30-day stroke/death and 30-day stroke/death/MI and length of stay. The patients were followed for 337 days. The majority of these procedures were performed in patients who were asymptomatic 416 (68.4%). Embolic protection devices (EPD) were used in 255 (41.9%) patients. The incidence of new periprocedural ipsilateral stroke was 23.2%. This outcome was 32.9% for asymptomatic patients and 2.1% for symptomatic patients (P < .001). The risk adjusted analyses showed no significant association between EPD use and new ipsilateral stroke (adjusted odds ratio, 0.78; 95% confidence interval, 0.47-1.30; P= 0.34) as this outcome remained high in patients with (20%) and without (25.5%) EPD use (P = 0.11). Periprocedural MI was 0.5% and 30-day mortality was 4.4%. The composite of 30-day stroke/death was 25.5% while 30-day stroke/death/MI was 26%. The increase in the composite outcomes were largely driven by the elevated periprocedural stroke. There were no significant predictors of ipsilateral periprocedural stroke identified. The median length of hospital stay was 4 days (interquartile range, 2-8 days). The study was limited by retrospective design. The authors concluded that TFCAS for carotid dissection is associated with prohibitive risk of peri procedural stroke in these patients. The use of EPDs does not mitigate this high risk. The underpinnings of the disparate incidence of stroke between asymptomatic and symptomatic patients deserve further granular evaluation. None the less, the prevalent practice of carotid stenting of asymptomatic carotid dissections should be avoided.

In 2020, early results of the post-approval study of TCAR were published. The ROADSTER 2 study (Reverse Flow used during carotid artery stenting procedure) followed the initial 30-day safety and efficacy study of TCAR (the ROADSTER study), which included 141 subjects considered high risk for CEA at 18 sites between November 2012 and July 2014. This study demonstrated acute device and technical success rates of 99% (140 of 141 subjects) and an all-stroke rate of 1.4% (2 of 141); stroke and death was 2.8% (4 of 141); and stroke, death and myocardial infarction (MI) was 3.5% (5 of 141). One subject (0.7%) experienced postoperative hoarseness from potential tenth (Xth) cranial nerve injury (CNI), which completely resolved at the 6-month follow-up visit (Kwolek, 2015 NCT01685567).

The ROADSTER 2 study of 632 adult subjects with significant carotid artery disease evaluated the safety and efficacy of TCAR performed by a broad group of physicians with variable TCAR experience. It was a prospective, observational, single arm, multicenter, post-approval registry for subjects undergoing TCAR, which included individuals considered at high risk for complications from CEA with symptomatic stenosis ≥ 50% or asymptomatic stenosis ≥ 80%. Subjects included a wide age range (≤64 years of age = 16.%, 65-69 years of age = 20.3%, 70-74 years of age = 21.5%, 75-79 years of age = 20.6% and ≥80 years of age = 21.2%). Included subjects had the presence of a high clinical and/or a high anatomic risk. Subjects were excluded if any of the following were present: presence of an alternative source of cerebral embolus, intracranial hemorrhage in the past 12 months, evolving stroke, severe dementia, major cardiovascular surgery within 30 days, MI in the past 72 hours, an intraluminal defect consistent with carotid thrombus or carotid occlusion. Specific exclusions for TCAR consisted of inflow disease or previous intervention in the proximal ipsiliateral carotid/brachiocephalic artery, severe disease in the common carotid artery, entry cite <5 centimeters to bifurcation, isolated hemisphere or open neck stoma. The primary end point was procedural success, which encompassed technical success plus

the absence of stroke, MI, or death within the 30-day postoperative period. Secondary end points included technical success and individual/composite rates of stroke, death, and MI. All trial participants underwent independent neurological assessments before the procedure, within 24 hours, and at 30 days after TCAR. An independent clinical events committee adjudicated all major adverse events. Between 2015 and 2019, 692 individuals (intent-to-treat population) were enrolled at 43 sites. Sixty cases had major protocol violations, leaving 632 subjects adhering to the FDA approved protocol (per-protocol population). The majority (81.2%) of operators were TCAR naïve before study initiation. Trial subjects underwent TCAR for neurological symptoms in 26% of cases, and all subjects had high risk factors for CEA (anatomic-related 44%; physiological 32%; both 24%). Technical success occurred in 99.7% of all cases. The primary end point of procedural success rate in the intent-to-treat population was 96.5% (per-protocol 97.9%). The early postoperative outcomes in the intent-to-treat population included stroke in 13 subjects (1.9%), death in 3 cases (0.4%), and MI in six individuals (0.9%). The composite 30-day stroke/death rate was 2.3%, and stroke/death/MI rate was 3.2%. In the per-protocol population, there were strokes in 4 subjects (0.6%), death in one case (0.2%), and MI in six individuals (0.9%) leading to a composite 30-day stroke/death rate of 0.8% and stroke/death/MI rate of 1.7%. The authors acknowledge study limitations (short term follow-up, variations in technique could have affected outcomes and single arm design). The authors concluded that TCAR results in excellent early outcomes with high technical success combined with low rates of post-procedure stroke and death. It was noted that these results were achieved by a majority of operators new to this technology at the start of the trial. Adherence to the study protocol and peri-procedural antiplatelet therapy optimized these outcomes. Longer-term follow-up data are needed to confirm these early outcomes. Until comparative data is available, TCAR should be used judiciously with tracking of patient outcomes. (Kashyap, 2020; NCT02536378).

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 1 year. They close by stating, further comparative studies with CEA are warranted.

Intracranial Aneurysm Repair

Clipping, Coiling, Stenting, Endoluminal Flow Diversion: Aneurysms occur when there is a weakened area within the arterial wall and the artery becomes distended, often resulting from atherosclerosis, trauma, infection, or from other medical conditions. They may occur anywhere anatomically, but most commonly occur in the aorta or brain (i.e., cerebral). Cerebral aneurysms are associated with morbidity and mortality resulting from subarachnoid hemorrhage following rupture. Treatment is indicated for ruptured and nonruptured cerebral aneurysms and may include either clipping, balloon–assisted coiling, stent-assisted coiling, or flow diversion (Eskey, et al., 2018). Clipping involves placing an implantable clip over the neck of the aneurysm, isolating it from circulation. Coiling involves endovascular placement of embolization coils into the aneurysm sac to exclude it from the circulation; however, the coil may protrude into the parent artery. More recently, stent-assisted coiling and the use of flow-diverting stents have been investigated as an

alternative for patients with cerebral aneurysms whose anatomy is not amenable to simple coiling, or for treatment of a wide-neck aneurysm. Wide-neck aneurysms are defined as having a neck of 4 mm or a dome-to-neck ratio of < 2 (FDA). Stent-assisted coiling or endoluminal flow diversion using flow diverting stents is considered an alternative treatment only in select cases and in accordance with FDA indications (Eskey, et al., 2018).

U.S. Food and Drug Administration:
Two intracranial stents have received approval from the FDA through the humanitarian device exemption (HDE) program for treatment of intracranial aneurysms. The Neuroform™ Microdelivery Stent System (Stryker, Kalamazoo, MI) received approval in 2002 for use with embolic coils for treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping (FDA, H020002). A second device, the Enterprise™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular Inc.,Miami Lakes, FL) received approval in 2007 and is intended for use with embolic coils for treatment of wide-neck, intracranial, saccular or fusiform aneurysms (FDA, H060001).

Neuroform Atlas Stent System (Stryker, Fremont, CA) intracranial coil-assist stent received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA, P180031) in 2019 for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked (neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm. A supplement was submitted and approved in 2020 to include treatment of posterior circulation intracranial aneurysms.

A flow diversion device, the Pipeline® Embolization Device (Micro Therapeutics, Irvine, CA), received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA, P100018) in 2011 for endovascular treatment of large or giant wide-necked intracranial aneurysms in the intracranial artery. It is a braided multi-alloy mesh cylinder designed for placement in the neck of an intracranial aneurysm. Additional flow diversion devices that have received FDA PMA approval for treatment of wide-necked intracranial aneurysms include Surpass Streamline Flow Diverter (Stryker Neurovascular, Freemont, CA), Flow Re-Direction Endoluminal Device (FRED) System (MicroVention, Inc, Aliso Viejo, CA) and an expanded approval in 2019 for the Pipeline Flex device. The FDA recalled the Pipeline Flex Embolization Device on September 20, 2021 due to a risk of the delivery system's wire and tubes fracturing and breaking off when the system is being used to place, retrieve or move the stent inside the patient. Information available at clinicaltrials.gov indicate another device, the SILK Vista Baby Flow Device (Balt Extrusion, Montmorency France) is currently being investigated although an FDA approval was not found on the FDA site.

According to the PMA labeling indications, the Pipeline® Embolization Device is indicated for the endovascular treatment of adults (age 22 and above) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments (FDA, PMA P100018A). In the clinical trials for the PMA, inclusion criteria were individuals with a single target intracranial aneurysm located on the petrous, cavernous, or paraophthalmic region of the internal carotid artery (n=108); a neck of the target aneurysm of ≥ 4 mm or no discernible neck, and a maximum fundus diameter ≥ 10 mm. The parent artery diameter was defined as 2.5 to 5.0 mm distal and proximal to the target aneurysm. Subjects were not enrolled if they had a stenosis of the extracranial carotid artery or of the IA parent artery of > 50%, or if they had a subarachnoid hemorrhage within the prior 60 days, or intracerebral hemorrhage or major surgery in the preceding 42 days. The expanded approval for the Pipeline Flex device indicates the device is intended for patients with small or medium, wide-necked brain aneurysms in the territory from the petrous to the terminus of the internal carotid artery (ICA).

According to the FDA labeling, the Surpass Streamline Flow Diverter (Stryker Neurovascular, Freemont, CA) device is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm (FDA, PMA P170024).

FDA labeling information for the Flow Re-Direction Endoluminal Device (FRED®) System indicates the intended use of this device is for the internal carotid artery from the petrous segment to the terminus, for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm (FDA, PMA 180027).

Literature Review: Evidence in the peer-reviewed scientific literature and professional society recommendations tend to support clinical safety and efficacy for the use of flow diversion devices as treatment of an intracranial aneurysm, as an alternative to coil embolization, consistent with FDA indications when there is a wide-neck bifurcation aneurysm (4 mm or more) or when the sack-to-neck ratio is less than 2:1 (Jankowitz, et al., 2022; Eskey, et al., 2018; Beckse, et al., 2017; Kallmes, et al., 2017; Kallmes, et al., 2015; Thompson, et al., 2015). Endoluminal flow diversion is considered a reasonable option for patients with intracranial aneurysms that, due to their morphology, complexity, or location, are not amenable to treatment with other endovascular techniques or standard surgery, or for patients who are not appropriate candidates for open surgery due to comorbidity.

Hayes published a review for the use of the Pipeline Embolization Device (PED) as an endovascular treatment for adult patients with intracranial aneurysms not amenable to standard therapies and who do not have acute subarachnoid hemorrhage or other contraindications to treatment, and noted that there is a large, low-quality body of evidence that PED offers benefit in the selected patient population, with generally acceptable rates of occlusion and neurologic morbidity and mortality. Although ample data provide estimates of occlusion and overall neurologic morbidity and mortality rates associated with flow diversion devices, comparative data are insufficient to draw conclusions regarding whether these outcomes are higher, lower, or the same as standard interventions. Hayes noted a concern for patients whose aneurysm characteristics are amenable to treatment by standard therapies (Hayes, 2020).

Intrasaccular Flow Disruption: Intrasaccular flow diversion devices are currently under investigation for treatment of a bifurcating intracranial aneurysm. A bifurcating aneurysm is defined as a weakness located at a junction between two diverging vessels. This device is used to block the flow of blood into the aneurysm, to reduce the chance of it rupturing, or to stop further bleeding from an aneurysm that has already ruptured. Antiplatelet premedication is not required for WEB aneurysm treatment. During the procedure, a catheter is inserted into the femoral artery and then advanced into the cerebral circulation under X-ray guidance. A second, smaller catheter is then placed inside the first and is inserted into the aneurysm. A basket-like device made of fine wire mesh is then pushed through the second catheter and placed into the aneurysm sac. The mesh device covers the aneurysm neck and obstructs blood flow into the aneurysm sac, creating blood stasis and promoting endothelial growth across the neck of the aneurysm. The appropriate device size is selected according to the aneurysm width and height.

U.S. Food and Drug Administration:
The Woven Endobridge (WEB) Aneurysm Embolization System (MicroVention, Inc.) was granted FDA approval (PMA P170032) in 2018. The device is intended for use at the middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) terminus, anterior communicating artery (AComm)

complex, or basilar artery apex for the endovascular treatment of adult patients with saccular, wide neck, bifurcating intracranial aneurysms with dome diameter from 3 mm to 10 mm, and either neck size 4 mm or greater, or the dome-to-neck ratio is greater than 1 and less than 2. According to the FDA, one-year follow-up data from the WEB Intrasaccular Therapy Study (WEB-IT) was used to support the approval and a PMA five year post approval study is required by the FDA. The WEB-IT study (Arthur, et al., 2019) is a prospective, multi-center non-randomized pivotal study that was conducted under IDE G130286 and was initiated prior to device approval. The five year results of the WEB-IT study (Fiorella 2023) are now available and documented under the literature review section. The FDA's post market surveillance of long-term safety reporting will conclude in December 2023.

Literature review:
Fiorella and colleagues published the five year results of the WEB-IT study in 2023. The US Woven EndoBridge Intra-saccular Therapy (WEB-IT) study was a pivotal, prospective, single arm, investigational device exemption study to evaluate the safety and effectiveness of the WEB device for the treatment of wide neck bifurcation aneurysms (WNBAs) in 150 patients. Eighty three patients completed the five year imaging follow up and 123 patients completed the five year clinical follow up. Enrolled patients were diagnosed with aneurysms having the following characteristics: Ruptured or unruptured aneurysms that were saccular in shape, located at the basilar apex, MCA bifurcation, internal carotid artery terminus, or anterior communicating artery complex. The aneurysms of the enrolled patients had to have a dome-to- neck ratio ≥ 1; neck size ≥ 4 mm or dome-to- neck ratio < 2; also needed was a diameter appropriate for treatment with the WEB device according to the device instructions for use. Patients with ruptured aneurysms were required to be neurologically stable with a Hunt–Hess score of I or II. Key exclusion criteria included vascular tortuosity or morphology that could preclude safe access and support during treatment with the WEB and a modified Rankin Scale score of ≥2 at baseline or before rupture. There was no comparator. The WEB-IT study's primary effectiveness endpoint was the proportion of subjects with complete aneurysm occlusion without retreatment, recurrent subarachnoid hemorrhage, or significant parent artery stenosis (defined as >50% stenosis) at one year post treatment. The study's primary safety endpoint was the proportion of subjects with primary safety events, which included death from any non-accidental cause or any major stroke (defined as an ischemic or hemorrhagic stroke resulting in an increase of ≥4 points on the National Institutes of Health Stroke Scale and persisting for 7 days after the procedure) within the first 30 days after treatment, or a major ipsilateral stroke or neurologic death from day 31 to one year after treatment. During the five year follow up, no ruptured (0/9) or unruptured aneurysm (0/141) rebled or bled. No new device or procedure related adverse events or serious adverse events were reported after one year. At five years, using the last observation carried forward, complete occlusion was observed in 58.1% and adequate occlusion in 87.2% of patients. For patients with both one year and five year occlusion statuses available, 76.8% (63/82) of aneurysms remained stable or improved with no retreatment. After one year, 18 aneurysms were retreated, 11 of which were adequately occluded at one year, and 15 of which were retreated in the absence of any deterioration in occlusion grade. The most notable observations from the five year US WEB-IT data set were: (1) no patient experienced bleeding from their treated aneurysm throughout the entire five year period, (2) the angiographic occlusion results observed at one year were stable or improved in the majority of patients at five years or last observed follow-up, (3) the high procedural and post-procedural safety rates observed at one year persisted through to five years with no additional device related adverse events, and (4) 15.5% of patients were retreated during the study, the majority of whom had no deterioration in occlusion status . While most retreatments were accomplished safely, two resulted in subarachnoid hemorrhage, one of which was fatal. The most significant limitation of the present study was the lack of five year follow-up imaging for a substantial proportion of the cohort; 58.6% of patients with one year angiography underwent follow-up imaging at five years. The authors attributed the attrition to the COVID pandemic which interrupted normally scheduled imaging follow-up over a protracted period.

Clinical follow-up was maintained up to five years in the majority of patients (83%, 123/148). The authors concluded the five year follow-up data demonstrated the WEB device is safe and effective when used in the treatment of WNBAs. No patients treated in the study had a rebleed of their ruptured index aneurysm or a hemorrhage of their unruptured index aneurysm over the course of the study. Aneurysm occlusion rates achieved at the one year follow-up were durable, with the majority of aneurysms remaining stable at five years and with rates of progressive occlusion exceeding rates of recurrence over time in the rest.

Chen et al., 2022, published a systematic literature review with pooled analysis to summarize the long-term outcomes of intrasaccular flow disruption (IFD) treated brain aneurysms. The review was comprised of 1,217 subjects with 1,249 aneurysms across 22 studies. Studies with greater than or equal to five patients that reported on outcomes for IFD devices (e.g. Woven Endobridge-WEB) were included. Case reports and case series with less than five patients, or studies that reported only outcomes of flow-diverting stents or other aneurysm embolization techniques were excluded. There were no comparators in the reviewed studies. Primary outcomes related to angiographic outcomes and were classified as complete occlusion, residual neck and residual aneurysm. Secondary outcomes encompassed need for retreatment, permanent neurological deficit and mortality. Mean radiographic follow-up was 15.7 months. The mean aneurysm diameter and neck width were 6.9 and 4.5 mm, respectively, and 27.6% of aneurysms were ruptured. The complete occlusion rates at 12 months and final follow-up (pooled mean duration 15.7 months) were 50.1% and 58.2%, respectively. Adjunctive devices were used in 6.4% of cases. The rates of hemorrhage, symptomatic infarction, permanent neurological deficit, and mortality were 1.2%, 2.8%, 1.0%, and 2.6%, respectively. Symptomatic and asymptomatic procedure-related complications occurred in 12% of IFD aneurysm interventions, which compared favorably with a complication rate of up to 21% with stent assisted coil embolization (SAC). IFD is associated with a symptomatic ischemic stroke rate of 2.8% (95% CI 1.6%–4.3%), which appears to be lower than the rates associated with SAC and flow diversion. The absence of an IFD device within the parent artery could reduce the risk of intraluminal thromboembolic phenomena. The 1.2% (95% CI 0.2%–2.8%) risk of hemorrhage is also slightly lower for aneurysm patients treated with IFD than the 3%–7% hemorrhage risk after flow diversion or SAC, which may be attributable to the reduced need for antiplatelet therapy in IFD. There were many limitations acknowledged by the authors which included: the inability to separate ruptured versus unruptured aneurysm cases likely worsened the overall pooled outcomes; the inability to directly compare IFD with either flow diversion or SAC; selection and reporting biases due to the inclusion of predominantly single arm studies; long term outcomes reported in only a subset of studies lead to lack of accuracy in representing the entire cohort; potential overestimation of complete occlusion rates due to lack of dedicated imaging core and self-adjudicated outcomes; and inherent differences in sensitivities and specificities between CTA or MRA versus DSA allowed for variability in angiographic outcomes among patients and studies. The authors concluded IFD to be a safe treatment option for appropriately selected brain aneurysms. They stated the long-term efficacy of this therapy leaves room for improvement, since complete occlusion is achieved in only half of IFD-treated aneurysms at one year and becomes modestly more likely beyond this time point. The authors stated the need for technological advancements, additional long-term follow-up data, increased operator experience, and direct comparisons with alternative endovascular approaches to clarify the role of IFD in aneurysm management.

In 2019, Arthur and colleagues published the one year outcomes of the WEB-IT study, a prospective, multicenter, single-arm, interventional study conducted at 21 United States and six international centers. The study enrolled 150 adults with a wide-necked bifurcating aneurysm of the anterior and posterior intracranial circulation. Clinical follow-up occurred at 30 days, six months and one year, and is scheduled to occur every year for five years total. The one year primary endpoint is the proportion of patients with complete aneurysm occlusion without re-treatment, recurrent subarachnoid hemorrhage, or significant parent artery stenosis (defined as >

50% stenosis). The one year primary safety endpoint is the proportion of patients with primary safety events (i.e., death from any non-accidental cause or any major stroke, defined as an ischemic or hemorrhagic stroke resulting in an increase of ≥ 4 points on the National Institutes of Health Stroke Scale and persisting for seven days after the procedure) within the first 30 days after treatment, or a major ipsilateral stroke or neurologic death from day 31 to one year subsequent to treatment. Required characteristics of the aneurysm noted by the authors included the following: ruptured or unruptured, saccular in shape, located at the basilar apex (BA), middle cerebral artery (MCA) bifurcation, internal carotid artery terminus, or anterior communicating artery complex, dome-to-neck ratio ≥ 1, wide-neck intracranial aneurysm with neck size ≥ 4 mm or dome-to-neck ratio < 2, and diameter appropriate for treatment with the WEB device according to the device instructions for use. Exclusion criteria included vascular tortuosity or morphology that could preclude safe access and support during treatment with WEB and a modified Rankin Scale score of ≥ 2 at baseline or before rupture. The authors reported one primary safety event occurred; the event occurred on postoperative day 22 and was a delayed ipsilateral parenchymal hemorrhage. Angiograph results at 12 month follow up demonstrated 53.8% of subjects (77/143) had complete occlusion of the aneurysm and adequate occlusion of the aneurysm occurred in 84.6% of subjects (121/143). During the 12 months following treatment, 5.6% of subjects underwent or had planned target aneurysm retreatment (one with coils, four with stent assisted coiling, and three with flow diversion). When coupled with an additional six subjects considered failures within the first six months, the retreatment rate was 9.8% (14/143 subjects). The authors concluded that the WEB device provides an option for patients with wide-neck bifurcation aneurysms that when compared to other reported outcomes, is safer and more effective than currently available therapies.

While comparative trials are limited, clinicaltrials.gov documents a randomized trial evaluating the intrasaccular woven EndoBridge device (RISE Trial) for treatment of intracranial aneurysm. The trial is currently recruiting subjects with a goal of 250 participants. The study model description is listed as a comparison of the use of a standard best conventional treatment option (surgical or endovascular) versus the WEB embolization device (Clinicaltrials.gov, NCT03936647). The estimated completion of the study will occur in 2024.

There is a growing body of evidence in the peer-reviewed scientific literature evaluating WEB treatment for bifurcating intrasaccular aneurysms as an alternative to coiling. A majority of evidence is in the form of prospective case series (Goertz, et al., 2020; Pierot, et al., 2020; Pierot, et al., 2018; Fiorella, et al., 2017, 2023; van Rooji, et al., 2017; Papagiannaki, et al., 2014), retrospective case series (Kabbasch, et al., 2019; Sauvigny, et al., 2019; Maurer, et al., 2019; Lawson, et al., 2018; Mine, et al., 2018; Popielski, et al., 2018; Liebig, et al., 2015) and systematic reviews (Zhang, et al., 2020; Lv, et al., 2018; Tau, et al., 2018; Armoiry, et al., 2016). Outcomes are generally short-term and there is lack of high-quality evidence evaluating the long-term effectiveness and safety of the Woven Endobridge (WEB) device for use in the endovascular treatment of an intracranial bifurcating aneurysm. Although preliminary studies lend support to satisfactory results in the short term, randomized controlled trials and long-term clinical outcomes (e.g., 3-5 years post procedure) are lacking and further study is needed.

A number of systematic reviews have been published, many of which involve an overlapping of subjects/trials. In 2020, Zhang and colleagues conducted a systematic review and meta-analysis evaluating the effectiveness, safety and risk factors of the Woven EndoBridge (WEB) device in the treatment of wide-neck intracranial aneurysms. A total of 36 studies involving 1,759 patients with 1,749 aneurysms were included with a mean follow-up of 9.34 months. Eligible studies included those with five or more patients undergoing WEB for wide-neck intracranial aneurysms, reported angiographic or clinical outcomes and risk factors, and were published after December 1, 2012. The authors concluded that WEB has a satisfactory safety profile and shows promising efficacy in treating wide-neck intracranial aneurysms, adequate occlusion rates were nearly 80%, the most

common complication was thromboembolism (9%), and morbidity and mortality were 6% and 7%, respectively. However, the risk factors for the long-term angiographic results and complications after WEB treatment in wide-neck aneurysms should be further studied by well-designed clinical trials (Zhang, et al., 2020).

Tau and associates (2018) published a systematic review with meta-analysis for the Woven EndoBridge (WEB) for endovascular therapy of intracranial aneurysms. In total (initial review and update), 12 uncontrolled case-series were included reporting outcomes for 940 patients, studies were published between January 2010 through September 2015 (initial report), and October 2015 through December 2017 (update). The median clinical follow-up was seven months (range 3-27.9 months), adequate occlusion rate was 81%, 9% of subjects required additional treatment, 14% had periprocedural complications, and mortality was 5% at seven months follow-up. The authors concluded that although WEB showed high rates of adequate aneurysm occlusion at mid-term, procedure-related complications and mortality rates were not negligible, and that additional studies are needed to compare the WEB device with other established treatment options.

Lv et al. (2018) conducted a systematic review of the published literature to evaluate the complications, complete occlusion rate, and morbidity and mortality of embolization results for WNBAs using the WEB device. A total of 19 studies, including 935 patients, were identified. The technical success rate was 97%, adequate occlusion rate was 81%, morbidity during follow-up was 3%, and mortality was 2%. Mid-term occlusion rates were slightly lower when compared to single-stent coiling.

At present, investigators continue to evaluate the safety and efficacy of intrasaccular flow diversion as a treatment alternative to coiling for treatment of an intracranial bifurcating aneurysm. Although preliminary studies lend support to satisfactory results in the short term, and in one 5 year follow-up, patient selection criteria is not firmly established and comparative, controlled trials with long-term clinical outcomes are lacking in the peer reviewed literature base; further trials are necessary to safety and efficacy.

Professional Society Recommendations

Society for Vascular Surgery: The Society for Vascular Surgery published clinical practice guidelines for the management of extracranial cerebrovascular disease in 2022 (AbuRahma, et al.). Within these guidelines, the authors stated the following:

- For low surgical risk patients with asymptomatic carotid bifurcation atherosclerosis and stenosis of >70% (documented by validated duplex ultrasound or CTA/angiography), we recommend CEA with best medical therapy instead of maximal medical therapy alone for the long-term prevention of stroke and death. Level of recommendation: grade 1 (strong); quality of evidence: B (moderate)
- CEA is recommended over maximal medical therapy for low risk patients; Level of recommendation: Grade 1 (strong); Quality of evidence B (moderate).
- We recommend CEA over TF-CAS in low- and standard-risk patients with >50% symptomatic carotid artery stenosis. Level of recommendation: grade 1 (strong); quality of evidence: A (high).
- Screening for asymptomatic carotid artery stenosis in the general population is not recommended; Level of recommendation: Grade 1 (strong); Quality of evidence B (moderate).
- For patients with symptomatic carotid stenosis of 50% to 99%, who require both CEA and CABG, we suggest CEA before, or concomitant with, CABG to potentially reduce the risk of stroke and stroke/death. The sequencing of the intervention depends on the clinical presentation and institutional experience. Level of recommendation: grade 2 (weak); quality of evidence: C (low).

The Society for Vascular Surgery (2022) further states, "to date the vast majority of TCAR procedures have been performed in patients at high anatomic or medical risk for CEA and the data at present are inadequate to a recommendation on the role of TCAR for low risk surgical patients with symptomatic carotid stenosis. Carotid dissection is not addressed in the clinical practice guidelines published in 2022.

American Association of Neurological Surgeons (AANS): The AANS provides general information regarding treatment of cerebral aneurysm using stent-assisted coiling, flow diversion stents and intrasaccular flow disruption. The AANS suggests stent-assisted coiling is performed to prevent herniation of the coiled mass into the parent artery which can lead to stroke. The stent is permanently placed across the aneurysm neck; anti-platelet medication is required. Flow diversion is generally performed for the treatment of aneurysms that are challenging and less amenable to traditional endovascular coiling, such as complex aneurysms, including large and giant aneurysms, wide-neck aneurysms, fusiform aneurysms and recanalized aneurysms after previous coiling. Stent-assisted coiling and balloon-assisted coiling are alternative endovascular options for such aneurysms; however, some studies reported their limited efficacy due to high recanalization rates and flow disruption. For treatment using intrasaccular flow disruption, a device such as the WEB device is used for management of wide-necked aneurysms at the bifurcation of an artery. The WEB device is placed within an aneurysm in contrast to the flow diversion devices which are placed in the parent artery. One of the biggest advantages is the reduced need for antiplatelet medications, especially for the ruptured aneurysms, which is particularly helpful in patients with subarachnoid hemorrhage; however, the clinical experience with its use is currently limited.

American Heart Association: The American Heart Association published a scientific statement regarding indications for the performance of intracranial endovascular neurointerventional procedures (Eskey, et al., 2018). Within this document, the AHA notes the document is not a clinical practice guideline The treatments are changing rapidly, and as such, recommendations and levels of evidence are not included. The AHA makes the following suggestions regarding treatment of individuals with stroke or transient ischemic attack (TIA) resulting from stenosis of a major intracranial artery:

- For 50-69% stenosis, treatment with medical therapy
- For 70-99% stenosis, optimal medical therapy (aspirin, clopidogrel, systolic <140, statin therapy) and risk factor modification
- For 70-99% stenosis, intracranial stenting with the Wingspan or Pharos stent system should not be initial therapy, even in individuals on antithrombotic therapy at the time of stroke or TIA
- For severe stenosis (70-99%) and progressing symptoms, recurrent TIA or stroke, despite dual antiplatelet therapy, systolic <140, and high intensity statin therapy, angioplasty with or without Wingspan stent may be warranted
- The utility of angioplasty alone or placement of other than Wingspan of Pharos stent is unknown and investigational.

The American Heart Association/American Stroke Association published guidelines (Thompson, et al., 2015) for management of patients with unruptured intracranial aneurysms. The guideline is endorsed by the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and the Society of Noninterventional Surgery. Within these guidelines, the authors report that endoluminal flow diversion represents a new treatment and should be considered in carefully select cases for treatment of unruptured intracranial aneurysms (Class IIb, Level of Evidence B). Strict adherence to U.S. FDA indications is recommended. Class IIb Level B recommendation is defined as "usefulness / efficacy is less well established, greater conflicting evidence from a single randomized trial or nonrandomized studies."

American Stroke Association (ASA)/American College of Cardiology Foundation (ACCF)/American Association of Neuroscience Nurses (AANN)/American Association of Neurological Surgeons (AANS)/ American College of Radiology (ACR), American Society of Neuroradiology (ASNR), Congress of Neurological Surgeons (CNS), Society of Atherosclerosis Imaging and Prevention (SAIP), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), Society of NeuroInterventional Surgery (SNIS), Society for Vascular Medicine (SVM), and Society for Vascular Surgery (SVS) (2011): Brott et al. (2013) published joint consensus guidelines regarding the management of extracranial carotid and vertebral artery disease. Regarding the selection of patients for carotid revascularization, the authors made the following statements for carotid angioplasty and stenting (CAS):

- 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% (documented by noninvasive imaging) or > 50% (documented by catheter angiography) and the anticipated rate of periprocedural stroke or mortality is < 6% (level of evidence B [defined as data from a single randomized trial or non-randomized studies]).(Class I, level of evidence B recommendation [procedure is useful/effective, evidence from single RCT or nonrandomized studies])
- CAS is indicated for asymptomatic patients with 70-99% stenosis (Class IIb, level of evidence B recommendation [recommendation in favor of procedure being useful/effective, some conflicting evidence from single RCT or nonrandomized trials])

Regarding extracranial vertebral artery stenosis the authors concluded there is insufficient evidence to demonstrate that endovascular management is superior to medical therapy.

American College of Cardiology: In 2007, the American College of Cardiology (ACC) issued a joint expert consensus document on CAS (American College of Cardiology Foundation, et al., 2007). The document states, "Carotid artery stenting is a reasonable alternative to CEA, particularly in patients at high risk for CEA. Although there are no randomized studies comparing CAS with and without embolic protection devices, the use of embolic protection devices appears to be important in reducing the risk of stroke during CAS. Careful neurological assessment is required before and after CAS. At the present time, there is insufficient evidence to support CAS in high-risk patients with asymptomatic stenosis less than 80% or in any patient without high-risk features. Operators should previously have achieved a high level of proficiency in catheter-based intervention, complete dedicated training in CAS, and be credentialed at their hospital."

The document outlines the high-risk criteria for CEA into anatomical criteria and medical comorbidities. Anatomical criteria includes: lesion at C-2 or higher, lesion below clavicle, prior radical neck surgery or radiation, prior ipsilateral CEA, contralateral laryngeal nerve palsy, and tracheostoma. Medical comorbidities include: age ≥ 80 years, Class III/IV congestive heart failure, Class III/IV angina pectoris, left main/≥ two vessel coronary disease, urgent (< 30 days) heart surgery, left ventricle ejection fraction ≤ 30%, recent (< 30 days) MI, severe chronic lung disease, and severe renal disease. There has been no update to this consensus document since 2007.

The Society of Cardiac Angiography and Interventions (SCAI), the Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS): Carotid stenting is a technically complex procedure. Minor embolic events can lead to major complications. The Society of Cardiac Angiography and Interventions (SCAI), the Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS) issued a clinical competence statement on carotid stenting addressing the training and credentialing for carotid stenting. This multispecialty consensus recommendation states that physicians who perform carotid stenting with embolic protection must meet or exceed minimum qualifications deemed necessary to offer

safe and effective therapy. The qualifications must include proficiency in the cognitive, technical, and clinical skills necessary to care for patients with carotid artery disease (Rosenfield, et al., 2005).

Coding Information

Notes:

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Extracranial Angioplasty and Stenting

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
37215	Transcatheter placement of intravascular stent(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 stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; without distal embolic protection
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
0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel
0076T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel (List separately in addition to code for primary procedure)

Intracranial Aneurysm Repair

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
61700	Surgery of simple intracranial aneurysm, intracranial approach; carotid circulation
61702	Surgery of simple intracranial aneurysm, intracranial approach; vertebrobasilar circulation
61703	Surgery of intracranial aneurysm, cervical approach by application of occluding clamp to cervical carotid artery (Selverstone-Crutchfield type)
61705	Surgery of aneurysm, vascular malformation or carotid-cavernous fistula; by intracranial and cervical occlusion of carotid artery
61708	Surgery of aneurysm, vascular malformation or carotid-cavernous fistula; by intracranial electrothrombosis
61710	Surgery of aneurysm, vascular malformation or carotid-cavernous fistula; by intra-arterial embolization, injection procedure, or balloon catheter

Intracranial Angioplasty and Stenting

Experimental, Investigational or Unproven when used to report treatment of atherosclerosis of intracranial arteries:

CPT®* Codes	Description
61630	Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous
61635	Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed

Intracranial Stent Placement

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)

Experimental, Investigational, Unproven when used to report intrasaccular flow diversion:

CPT®* Codes	Description
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	●Updated to new template and formatting standards. ●Clarification of intent to coverage statement regarding TCAR for high risk and standard risk individuals	11/15/2023