Angioplasty (Extracranial, Intracranial) and Endoluminal Flow Diverting Stents

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.

Carotid angioplasty and stenting is usually safely performed as an ambulatory/outpatient procedure (i.e., less than twenty four hour stay). When clinically appropriate, however, some individuals undergoing carotid artery angioplasty and stenting may require an inpatient hospital stay greater than twenty four hours.

Coverage Policy
**Angioplasty (Extracranial, Intracranial)**

Extracranial carotid artery angioplasty with stent placement as treatment for carotid artery stenosis is considered medically necessary when EITHER of the following criteria is met:

- The individual is or has been symptomatic within the previous 6 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 ≥ 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 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 6 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

- The individual is 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
Inpatient Admission
When the above medical necessity criteria has been met for extracranial carotid artery angioplasty and stenting, an inpatient admission is considered medically necessary when EITHER of the following criteria is met:

- The individual is considered to be high risk for peri or post-procedural complications resulting from one of the following significant comorbidities:
  - Poorly controlled diabetes mellitus
  - Severe pulmonary disease
  - End stage renal disease
  - New York Heart Association (NYHA) Functional Class III or higher Congestive Heart Failure
  - Severe carotid tortuosity
  - Contralateral carotid stenosis > 50%
  - Age ≥ 80 years
  - Multiple significant co-morbidities
  - Carotid artery pseudoaneurysm
  - Presence of moderate or severe aortic stenosis
  - Severe plaque calcification, circumferential carotid plaque
  - Heavily calcified aortic arch
  - Near occlusion of the carotid artery (i.e., string sign)
  - Ulcerated plaque
  - ≥7 age-related white matter changes on magnetic resonance imaging
  - Carotid arteriovenous (AV) fistula formation
  - Oral anticoagulant therapy (i.e., warfarin, direct oral anticoagulants [DOACs])

- Occurrence of ANY of the following intra or post-procedural complications:
  - Hemodynamic instability (e.g., tachycardia, hypotension, inadequate perfusion)
  - Presence of neurological deficit (e.g., difficulty swallowing, facial drooping, stroke)
  - Bleeding or hematoma at the operative site
  - Myocardial compromise (e.g., ischemia, infarct)
  - Inability to deploy a cerebral protection device
  - Intravascular procedural complications such as acute vessel closure, stent malposition, or vessel dissection
  - Carotid artery stent fracture
  - Inability to use a closure device
  - Cerebral hyperperfusion syndrome

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

- recurrent vertebobasilar 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.

Endoluminal Flow Diverting Stents

Endoluminal flow diversion using an intracranial flow diverting stent is considered medically necessary for treatment of an intracranial aneurysm when the aneurysm is not amenable to surgical treatment or
standard endovascular treatment (e.g., clipping, coil embolization) and EITHER of the following criteria are met:

- Pipeline® Embolization Device and all of the following criteria are met:
  - The individual is age ≥ 22 years
  - A large or giant wide-necked intracranial aneurysm (i.e., a neck diameter of 4 mm or more) or no discernible neck and a maximum fundus diameter > 10 mm.
  - A parent artery diameter is 2.5 to 5.0 mm distal and proximal to the target aneurysm.
  - Aneurysm located in the internal carotid artery from the petrous to the superior hypophysseal segments.

- Surpass Streamline™ Flow Diverter and all of the following criteria are met:
  - The individual is age ≥ 18 years
  - A large or giant saccular wide-neck (i.e., neck width >= 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysm
  - A parent vessel diameter of ≥ 2.5 mm and ≤ 5.3 mm
  - Aneurysm is located in the internal carotid artery from the petrous segment to the terminus.

### 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 to 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) (Brother, 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, et al., 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. 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. 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).

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 (Brother, 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 their review; 7484 subjects in total were included, 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. 

High Risk Indicators: Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors and 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 ≥ 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) FEV1 < 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), textbook 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 and 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 (Society for Neurointerventional Surgery; Hussain, 2012).

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

- Emergent intracranial angioplasty and/or stenting is not well established and should only be used in a clinical trial setting (Class IIb, Level of Evidence C)
- 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). Use of these techniques may be considered in the presence of acute ischemic stroke resulting from cervical atherosclerosis or dissection (Class IIb, Level of Evidence C).

Within these guidelines 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 consider. Level of evidence "C" is defined a: Very limited populations evaluated [Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use], Only consensus opinion of experts, case studies or standard of care.

The European Society for Vascular Surgery supports extracranial angioplasty and stenting for patients with recurrent vertebrobasilar symptoms (despite best medical management) and who have 50-99% extracranial vertebral artery stenosis (Naylor, et al, 2018). The evidence is insufficient to support safety and efficacy of intracranial angioplasty and stenting.

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 managing 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.

Contraindications for each CAS system and distal embolic protection device is 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 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 (Yavin, et al., 2011; Murad, et al., 2011; Meier, 2010; Gurm, et al., 2008a, Iyer, et al., 2008; Eckstein, et al., 2008 [SPACE trial]; Eisenhauer, 2008; Gurm, et al., 2008b; Gray, et al, 2007; Katzen, et al., 2007; White, et al., 2006; Zahn, et al., 2005; Burton, et al., 2005; Groschel et al., 2005; FDA, 2004). 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 (Yadov, et al., 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 1080 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 1080 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 are needed to compare long-term outcomes following carotid artery endarterectomy and angioplasty in asymptomatic individuals with carotid artery stenosis (Goldstein, 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, 2011) agree the current evidence for safety of carotid artery stent placement in asymptomatic carotid stenosis shows well-documented risk, particularly for stroke.

**Endoluminal Flow Diverting Stents**

The use of flow-diverting stents are employed as an alternative treatment for patients with cerebral aneurysms whose anatomy is not amenable to simple coiling or for treatment of wide-neck aneurysms. 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 occurs 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 wide-neck aneurysms. Wide-neck aneurysms are defined as having a neck of 4mm or a dome-to-neck ratio of <2 (FDA). 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:** One device, the Pipeline® Embolization Device (Micro Therapeutics, Irvine, CA) is a flow diversion device that 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.

**FDA Indications:** According to the PMA labeling indications the 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 individual’s with a single target intracranial aneurysm located on the petrous, cavernous, or parapapillary region of the internal carotid artery (n=108); a neck of the target aneurysm of ≥ 4mm or no discernible neck and a maximum fundus diameter ≥ 10mm. 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.

An additional flow diversion device that has received FDA PMA approval for treatment of wide-necked intracranial aneurysms is Surpass Streamline Flow Diverter (Stryker Neurovascular, Freemont, CA). According to the FDA labeling this 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).

**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 aneurysms (4 mm or more) or when the sack-to-neck ratio is less than 2:1. (Beckse, et al., 2013; Kallmes, et al., 2015, Thompson, et al., 2015 (AHA /ASA Guidelines); Kallmes, et al., 2017; Eskey, et al., 2018 (AHA Guidelines).

**Professional Society Recommendations**

**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”.

European Society for Vascular Surgery: Guidelines for the management of atherosclerotic carotid and vertebral artery disease (Naylor, et al., 2018) provide evidence based recommendations for treatment of extracranial atherosclerosis. Recommendations are defined as follows:

Class I- evidence and/or general agreement a given treatment or procedure is beneficial, useful, and effective
Class II: conflicting evidence and/or divergence of opinion about the usefulness/efficacy of the given treatment or procedure
Class IIa: weight of evidence /opinion is in favor of usefulness/efficacy
Class IIb: usefulness/efficacy is less well established by evidence/opinion
Class III: evidence or general agreement that the given treatment of procedure is no useful/effective, and in some cases may be harmful

Levels of evidence are defined as follows:
Level A: data derived from multiple randomized clinical trials or meta-analyses
Level B: data derived from a single randomized clinical trial or large non-randomised studies
Level C: consensus of opinion of the experts and/or small studies, retrospective studies, registries

Regarding management of vertebral artery stenosis the guideline states:
• Asymptomatic vertebral artery atherosclerosis should not be treated by open or endovascular interventions (Class III, Level C)
• Patients with recurrent vertebrobasilar territory symptoms despite best medical therapy, and who have a 50-99% extracranial vertebral artery stenosis may be considered for vascularization (Class IIb, Level B)

Regarding carotid artery stenosis the guideline states:
• It is recommended most patients who have suffered carotid territory symptoms within the preceding 6 months and who are aged >70 years and who have 50-99% stenosis should be treated by carotid endarterectomy rather than stenting (Class I, Level A)
• When revascularization is indicated in patients who have suffered carotid territory symptoms within the preceding 6 months and who are aged <70 years, carotid stenting may be considered an alternative to endarterectomy provided the documented procedural death/stroke rate is <6% (Class IIb, Level A)
• Carotid endarterectomy or carotid artery stenting are not recommended in symptomatic patients with a chronic internal carotid near-occlusion, unless associated with recurrent ipsilateral symptoms (despite optimal medical therapy) and following multidisciplinary team review (Class III, Level C)
• Carotid artery endarterectomy or stenting may be considered in recently symptomatic patients with <50% stenosis if they suffer recurrent symptoms despite best medical therapy and following multidisciplinary team review (Class IIb, Level C)
• In recently symptomatic patients with 50-99% stenosis and anatomical and/or medical comorbidities that are considered by the multidisciplinary team to make then ‘higher risk for carotid endarterectomy’,
carotid stenting should be considered as an alternative to endarterectomy provided the documented procedural death/stroke rate is < 6% (Class IIa, Level B).

- In average or high surgical risk patients with asymptomatic stenosis 60-99% and in the presence of one or more imaging characteristics that may be associated with an increased risk of ipsilateral stroke, CAS may be an alternative when the perioperative stroke/death rates are < 3% and the patient’s life expectancy is greater than 5 years. Imaging characteristics of high stroke risk may include stenosis progression, silent infarction on CT, large plaque area, plaque echolucency, intra-plaque hemorrhage on magnetic resonance imaging, impaired cerebral vascular reserve, spontaneous embolization on transcranial Doppler, or history of contralateral TIA (Class IIb, Level B)

- Prophylactic carotid artery endarterectomy and carotid stenting are not recommended in patients with asymptomatic carotid stenosis prior to major non-cardiac, non-vascular surgical procedures (Class III, Level B)

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 nonrandomized 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 (Bates, 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.

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
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).

The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative American Academy of Neurology: The AAN Choosing Wisely recommendation (2013) does not recommend carotid endarterectomy for asymptomatic carotid stenosis unless the complication rate is low (< 3%). According to the AAN statement "Based on studies reporting an upfront surgical complication rate ranging from 2.3% (ACAS) to 3.1% (ACST) among patients undergoing carotid endarterectomy (CEA) for asymptomatic stenoses of >60%, and an absolute risk reduction for stroke or death of roughly 5-6% in the surgical group at 5 years, several specialty societies (Goldstein et al., 2011; Brott et al., 2013; Chaturvedi et al., 2005; Ricotta et al., 2013) have recommended that surgery for asymptomatic patients should be reserved for those with a perioperative complication risk of <3% and a life expectancy of greater than 3–5 years. The cited 3% threshold for complication rates may be high because more recent studies have reported lower stroke rates with improvements in both surgical (Brott, 2010) and medical (Marquardt) management. However, there are no recent randomized trials comparing these treatments. Given this, the more recent AHA guidelines (Brott, 2013) state that it is “reasonable” to perform CEA for asymptomatic patients with >70% stenosis if the surgical complication rate is “low.” Reported complication rates vary widely by location (Kresowik), and are dependent on how complications are tracked (self-report vs. neurologist’s evaluation vs. administrative data (Wolff T). Despite calls for rigorous monitoring 15 years ago (Goldstein), most patients will likely need to rely on the surgeon’s self-reported rates.”

Centers for Medicare & Medicaid Services (CMS)
- National Coverage Determination (NCD): National Coverage Determination 20.1 for Vertebral Artery Surgery, is a longstanding NCD and is broader in scope than this Coverage Policy. NCD Percutaneous Transluminal Angioplasty (PTA) (20.7) effective 1/1/2013 is similar in scope.
- Local Coverage Determination(s) (LCDs): no LCDs found.

Use Outside of the US


Choosing Wisely Canada
Vascular Surgery recommendations from Choosing Wisely Canada state: Don’t perform carotid endarterectomies or stenting in most asymptomatic high risk patients with limited life expectancy. The purpose of carotid artery surgery and stenting is to prevent stroke and, when combined with appropriate medical therapy, is a successful strategy in selected, mainly symptomatic, patients. Medical therapy alone is an effective alternative in many asymptomatic patients and safer in those who are elderly or at high risk for surgery and stenting and don’t have the life expectancy to benefit from such a prophylactic procedure.

Coding/Billing Information

Note: 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
Extracranial Angioplasty and Stenting

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

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>37215</td>
<td>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</td>
</tr>
<tr>
<td>37216</td>
<td>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</td>
</tr>
<tr>
<td>37217</td>
<td>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</td>
</tr>
<tr>
<td>37218</td>
<td>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</td>
</tr>
<tr>
<td>0075T</td>
<td>Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel</td>
</tr>
<tr>
<td>0076T</td>
<td>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)</td>
</tr>
</tbody>
</table>

Intracranial Angioplasty and Stenting

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

<table>
<thead>
<tr>
<th>CPT® Codes</th>
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<tbody>
<tr>
<td>61630</td>
<td>Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous</td>
</tr>
<tr>
<td>61635</td>
<td>Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed</td>
</tr>
</tbody>
</table>

Endoluminal Flow Diverting Stent

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

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>61624</td>
<td>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)</td>
</tr>
</tbody>
</table>


References


