7.01.148	Endovascular Therapies for Extracranial Vertebral Artery Disease		
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Policy Statement

I. Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered **investigational** for the management of extracranial vertebral artery diseases.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The extracranial vertebral artery is considered to be segments V1 to V3 of the vertebral artery from its origin at the subclavian artery until it crosses the dura mater.

Coding

The following are CPT category III codes for the stenting procedure:

- **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)

CPT also instructs that when the ipsilateral extracranial vertebral arteriogram (including imaging and selective catheterization) confirms the need for stenting, then 0075T and 0076T include all ipsilateral extracranial vertebral catheterization, all diagnostic imaging for ipsilateral extracranial vertebral artery stenting, and all related radiologic supervision and interpretation. If stenting is not indicated, then the appropriate codes for selective catheterization and imaging should be reported in lieu of 0075T and 0076T (e.g., 36226, 36228).

Description

Vertebral artery diseases, including atherosclerotic stenosis, dissections, and aneurysms, can lead to ischemia of the posterior cerebral circulation. Conventional management of extra-cranial vertebral artery diseases may include medical therapy (e.g., antiplatelet or anti-coagulant medications), medications to reduce atherosclerotic disease risk (e.g., statins), and/or surgical revascularization. Endovascular therapies have been investigated as an alternative to conventional management.

Related Policies

- Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
- Extracranial Carotid Artery Stenting

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Currently, no endovascular therapies have been approved by the U.S. Food and Drug Administration (FDA) specifically for treatment of extracranial vertebral artery disease.

Various stents, approved for use in the carotid or coronary circulation, have been used for extracranial vertebral artery disease. These stents may be self- or balloon-expandable.

Two devices have been approved by the FDA through the humanitarian device exemption process for *intracranial* atherosclerotic disease. This form of FDA approval is available for devices used to treat conditions with an incidence of 4000 or less per year; the FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows:

1. Neurolink System® (Guidant). "The Neurolink system is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with ≥50% stenosis and that are accessible to the stent system."
2. Wingspan™ Stent System (Boston Scientific). "The Wingspan Stent System with Gateway PTA [percutaneous transluminal angioplasty] Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system."

Rationale

Background

Vertebrobasilar Circulation Ischemia

Ischemia of the vertebrobasilar or posterior circulation accounts for about 20% of all strokes. Posterior circulation strokes may arise from occlusion of the innominate and subclavian arteries, the extracranial vertebral arteries, or the intracranial vertebral, basilar, or posterior cerebral arteries. Compared with carotid artery disease, relatively little is known about the true prevalence of specific causes of posterior circulation strokes, particularly the prevalence of vertebral artery disease. In a report from a stroke registry, Gulli et al (2013) estimated that, in 9% of cases, posterior circulation strokes are due to stenosis of the proximal vertebral artery.[1] Patients who experience strokes or transient ischemic attacks of the vertebrobasilar circulation face a 25% to 35% risk of stroke within the subsequent 5 years. In particular, the presence of vertebral artery stenosis increases the 90-day risk of recurrent stroke by about 4-fold.

Relevant Clinical Anatomy and Pathophysiology

Large artery disease of the posterior circulation may be due to atherosclerosis (stenosis), embolism, dissection, or aneurysms. In about a third of cases, posterior circulation strokes are due to stenosis of the extracranial vertebral arteries or the intracranial vertebral, basilar, and posterior cerebral arteries. The proximal portion of the vertebral artery in the neck is the most common location of atherosclerotic stenosis in the posterior circulation. Dissection of the extracranial or intracranial vertebral arteries may also cause posterior circulation ischemia. By contrast, posterior cerebral artery ischemic events are more likely to be secondary to embolism from more proximal vessels.

The vertebral artery is divided into 4 segments, V1 though V4, of which segments V1, V2, and V3 are extracranial. V1 originates at the subclavian artery and extends to the C5 or C6 vertebrae; V2 crosses

the bony canal of the transverse foramina from C2 to C5; V3 starts as the artery exits the transverse foramina at C2 and ends as the vessel crosses the dura mater and becomes an intracranial vessel. The most proximal segment (V1) is the most common location for atherosclerotic occlusive disease to occur, while arterial dissections are most likely to involve the extracranial vertebral artery just before the vessel crosses the dura mater. Compared with the carotid circulation, the vertebral artery system is more likely to be associated with anatomic variants, including a unilateral artery.

Atherosclerotic disease of the vertebral artery is associated with conventional risk factors for cerebrovascular disease. However, risk factors and the underlying pathophysiology of vertebral artery dissection and aneurysms differ. Extracranial vertebral artery aneurysms and dissections are most often secondary to trauma, particularly those with excessive rotation, distraction, or flexion/extension, or iatrogenic injury, such as during cervical spine surgeries. Spontaneous vertebral artery dissections are rare, and in many cases are associated with connective tissue disorders, including Ehlers-Danlos syndrome type IV, Marfan syndrome, autosomal dominant polycystic kidney disease, and osteogenesis imperfecta type I.[2]

Management of Extracranial Vertebral Artery Disease

The optimal management of occlusive extracranial vertebral artery disease is not well-defined. Medical treatment with antiplatelet or anticoagulant medications is a mainstay of therapy to reduce stroke risk. Medical therapy also typically involves risk reduction for classical cardio-vascular risk factors. However, no randomized trials have compared specific antiplatelet or anticoagulant regimens.

Surgical revascularization may be used for vertebral artery atherosclerotic disease, but open surgical repair is considered technically challenging due to poor access to the vessel origin. Surgical repair may involve vertebral endarterectomy, bypass grafting, or transposition of the vertebral artery, usually to the common or internal carotid artery. Moderately-sized, single-center case series of surgical vertebral artery repair from 2012 and 2013 have reported overall survival rates of 91% and 77% at 3 and 6 years postoperatively, respectively, and arterial patency rates of 80% after 1 year of follow-up.[3,4] Surgical revascularization may be used when symptomatic vertebral artery stenosis is not responsive to medical therapy, particularly when bilateral vertebral artery stenosis is present or when unilateral stenosis is present in the presence of an occluded or hypoplastic contralateral vertebral artery. Surgical revascularization may also be considered in patients with concomitant symptomatic carotid and vertebral disease who do not have relief from vertebrobasilar ischemia after carotid revascularization.

The management of extracranial vertebral artery aneurysms or dissections is controversial due to uncertainty about the risk of thromboembolic events associated with aneurysms and dissections. Antiplatelet therapy is typically used; surgical repair, which may include vertebral bypass, external carotid autograft, and vertebral artery transposition to the internal carotid artery, or endovascular treatment with stent placement or coil embolization, may also be used.

Given the technical difficulties related to surgically accessing the extracranial vertebral artery, endovascular therapies have been investigated for extracranial vertebral artery disease. Endovascular therapy may consist of percutaneous transluminal angioplasty, with or without stent implantation.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the

magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Angioplasty With or Without Stenting for Extracranial Vertebral Artery Stenosis

Clinical Context and Therapy Purpose

The purpose of percutaneous transluminal angioplasty (PTA) with or without stent implantation in individuals who have extracranial vertebral artery stenosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals with extracranial vertebral artery stenosis.

Interventions

The therapy being considered is PTA with or without stent implantation.

Comparators

The following practice is currently being used to treat extracranial vertebral artery stenosis: medical management with antiplatelet or anticoagulant medications. Medical management also typically involves risk reduction for classical cardiovascular risk factors. The optimal management of occlusive extracranial vertebral artery disease is not well-defined.

Outcomes

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Several systematic reviews of published studies were published prior to the Vertebral Artery Ischaemia Stenting Trial (VIST)[5,] and the Vertebral Artery Stenting Trial (VAST),[6,] which are described in the Randomized Controlled Trials section. A meta-analysis of the Stenting and Aggressive Medical Management of Preventing Recurrent stroke in Intracranial Stenosis (SAMMPRIS) trial, VAST, and VIST showed no advantage for stenting/angioplasty for stroke prevention compared with medical therapy alone.[7,]

Lattanzi et al (2018) conducted a systematic review and meta-analysis of 4 RCTs, including VAST and VIST, of endovascular treatment compared to medical treatment in patients with symptomatic vertebral artery stenosis.[8,] Consistent with previous systematic reviews, the researchers found no overall effect of endovascular treatment on any primary or secondary outcome, including any stroke, any vertebrobasilar territory stroke, ischemic stroke, transient ischemic attack (TIA), myocardial infarction, vascular death, and the composite vascular outcome either within or after 30 days.[8,]
Xu et al (2022) published a Cochrane review of 3 RCTs that assessed the safety and efficacy of PTA (with or without stenting) combined with medical treatment, compared to medical treatment alone, in individuals with episodes of cerebral ischemia due to vertebral artery stenosis.[9,] Two of the 3 RCTs were VIST and VAST, and the third RCT included patients only with *intracranial* vertebral artery stenosis. Thus, results of the systematic review are not discussed in detail in this evidence review. Consistent with previous systematic reviews, the researchers did not find significant differences in either short- or long-term risks of death, stroke, or TIA between patients who received endovascular treatment plus medical treatment and those who just received medical treatment.

Randomized Controlled Trials

The VIST trial is the largest RCT published to date comparing stenting with medical therapy in patients who had symptomatic vertebral artery disease.[5,10,] Enrollment was originally planned for 1302 patients, but was stopped after 182 participants entered due to slow recruitment and the end of funding. Patients with symptomatic extracranial or intracranial vertebral artery stenosis and vertebrobasilar TIA or stroke in the previous 3 months were randomized to vertebral artery stenting plus best medical therapy or best medical therapy alone. Of the 91 patients randomized to stenting, 33% did not undergo the procedure. The primary endpoint of fatal or nonfatal stroke occurred in 5 patients in the stent group and 12 in the medical management group (hazard ratio, 0.40; 95% confidence interval [CI], 0.14 to 1.13; p=.08 by intention-to-treat analysis). Although this trial found no benefit of stenting, it was underpowered and lacked the precision to exclude a benefit from stenting.
The VAST trial was a multicenter, phase 2 trial that included 115 patients who had TIA or minor stroke attributed to vertebral artery stenosis.[6,] Randomization to stenting plus medical therapy or medical therapy alone was stratified by center and level of stenosis; 83.5% of patients had extracranial lesions and the rest had intracranial lesions. Stent selection was by surgeon preference. The primary outcome was the composite of vascular death, stroke, or myocardial infarction within 30 days.

Patients were followed yearly by telephone. The median follow-up was 3.0 years (range, 1.3 to 4.1). Endovascular therapy plus best medical therapy was not superior to best medical therapy alone in this trial. The primary outcome occurred in 3 (5%) of 57 patients (95% CI, 0% to 11%) in the stenting group and 1 (2%) of 58 patients (95% CI, 0% to 5%) in the medical treatment group. During follow-up, the composite primary outcome occurred in 11 (19%) patients in the stenting group and in 10 (17%) patients in the medical therapy group. The periprocedural risk of a major vascular event in the stenting group was 5%.

Noncomparative Studies

A large number of noncomparative studies, most often enrolling few patients, have described outcomes for patients treated with endovascular therapies for extracranial vertebral artery disease. Some cohort studies reporting prospectively collected complication and restenosis rates are shown in Table 1.

Table 1. Cohort Studies of Endovascular Treatment of Extracranial Vertebral Artery Stenosis

Study	Study Design	Population	FU	Main Results	ISR Rate
Kikuchi et al (2014)[11],	Retrospective review of prospectively collected data	404 patients from a registry treated with endovascular therapy	30 d	Postprocedural morbidity: 2.0% Postprocedural mortality: 0.3%	NR
Sun et al (2015)[12],	Retrospective review of prospectively collected data	188 patients with posterior circulation TIA or stroke and mRS score ≤2	16.5 mo[a]	Technical success rate: 100% 34 patients had recurrent TIA after 30 d No cases of stroke or death occurred	21.2%
Mohammadian et al (2013)[13],	Prospective interventional study	206 patients with clinical signs of vertebral occlusion (239 treated lesions, 202 extracranial)	13.15 mo[a]	Technical success rate: 100%. 89.2% were balloon-expandable bare-metal stents Periprocedural complication rate: 7.2% Complications during FU: overall 6.3%	15.9%
Hatano et al (2011)[14],	Retrospective review of prospectively collected data	117 patients (108 symptomatic, 9 asymptomatic)	48 mo[a]	Technical success rate: 99% During FU, 5 patients had posterior circulation ischemia, 1 had cerebellar infarction with ISR, 2 had posterior circulation strokes without ISR	9.6% at 6 mo

FU: follow-up; ISR: in-stent restenosis; mRS: modified Rankin Scale; NR: not reported; TIA: transient ischemic attack.
[a] Mean value.

Section Summary: Angioplasty With or Without Stenting for Extracranial Vertebral Artery Stenosis

The evidence on the overall efficacy of endovascular therapies for extracranial vertebral artery stenosis includes a phase 3 and a phase 2 RCT (VIST and VAST) that compared endovascular therapy with best medical therapy alone for vertebral artery stenosis. These trials found no advantage of endovascular intervention over best medical therapy alone, with a periprocedural adverse event rate of 5% for the invasive procedures in the VAST trial. Evidence from noncomparative studies has indicated that vertebral artery stenting can be performed with high rates of technical success and low periprocedural morbidity and mortality, and that vessel patency can be achieved in a high percentage of cases. However, long-term follow-up has demonstrated high rates of in-stent stenosis.

Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, or Arteriovenous Fistula(e)

Clinical Context and Therapy Purpose

The purpose of PTA with stent implantation in individuals who have extracranial vertebral artery aneurysms, dissections, or arteriovenous (AV) fistula(e) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations
The relevant population of interest is individuals with extracranial vertebral artery aneurysms, dissections, or AV fistula(e).

Interventions
The therapy being considered is PTA with stent implantation.

Comparators
The following practice is currently being used to treat extracranial vertebral artery aneurysms, dissections, or AV fistula(e): continued clinical observation, medical management, and surgical treatment. The management of extracranial vertebral artery aneurysms or dissections is controversial due to uncertainty about the risk of thromboembolic events associated with aneurysms and dissections. Antiplatelet therapy is typically used; surgical repair, which may include vertebral bypass, external carotid autograft, and vertebral artery transposition to the internal carotid artery, or endovascular treatment with stent placement or coil embolization, may also be used.

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

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

Review of Evidence
Systematic Reviews
Pham et al (2011) conducted a systematic review of studies evaluating endovascular stenting for extracranial carotid and vertebral artery dissections. Eight studies of extracranial vertebral artery stenting with 10 patients (12 vessels) were included.[15,] Of the 10 patients included, 70% had associated pseudoaneurysms and 20% had bilateral lesions. Most dissections (60%) were traumatic in etiology, while 20% were spontaneous and 20% were iatrogenic. The indications for stenting were failure of medical management in 40% (defined as a new ischemic event, progression of initial symptoms, or demonstration of an enlarging pseudoaneurysm despite adequate anticoagulation or antiplatelet treatment), contraindication to anticoagulation in 20%, and/or severity of dissection hemodynamics in 60%. No stent-related complications or mortalities were reported in any study. One dissection-related death was reported, although stenting was considered technically successful.

Case Series and Reports
Badve et al (2014) retrospectively compared the clinical characteristics of patients who had vertebrobasilar dissections with and without aneurysmal dissection treated at a single institution from 2002 to 2010.[16,] Thirty patients were identified, 7 with aneurysmal dissections (1 of which was extracranial) and 23 with nonaneurysmal dissections (10 of which were extracranial, and 12 of which were combined intracranial/extracranial). Patients were treated with antiplatelet agents (aspirin or clopidogrel; n=8), anticoagulation with warfarin (n=13), or neurointerventional procedures (n=6). One patient in the nonaneurysmal dissection group treated with aspirin died. Kondo et al (2021) retrospectively reviewed patients who had an acute ischemic stroke and received urgent

endovascular reperfusion therapy between 2017 and 2019.[17,] Three patients with strokes caused by vertebral artery dissection were identified. Dissections at the V3, V4, and extensions of V3 to V4 segments were seen in 1 patient each. Endovascular reperfusion thrombectomy without stenting, stenting alone, and a combination of thrombectomy and stenting were performed in the 3 patients, respectively. In all 3 patients, effective recanalization and functional independence based on modified Rankin scores (scores 0 to 2 at 90 days after onset) were achieved.

The use of endovascular therapy for extracranial vertebral artery aneurysms and AV fistulae is similarly limited to small case series and reports. In an early report, Horowitz et al (1996) described a left-sided vertebral artery pseudoaneurysm with dissection between the vessel media and adventitia at the C7 vertebra that was treated with a balloon-expandable stent.[18,] Follow-up angiography 3 months postprocedure showed no filling of the pseudoaneurysm and normal patency of the parent artery. Felber et al (2004) reported on outcomes from endovascular treatment with stent grafts of 11 patients who had aneurysms or AV fistulae of craniocervical arteries, 2 of whom were treated for extracranial vertebral artery disorders with coronary stents (1 aneurysm, 1 traumatic AV fistula).[19,] The procedure was technically successful in both subjects, without complications. At follow-up (5 years and 14 months postprocedure in the aneurysm and fistula patients, respectively), the target vessel was patent without stenosis. Herrera et al (2008) reported on outcomes for a single-center series of 18 traumatic vertebral artery injuries, including 16 AV fistulae (7 of which had an associated pseudoaneurysm) and 2 isolated pseudoaneurysms, treated with endovascular therapy.[20], Endovascular therapy consisted of balloon occlusion of the parent vessel and AV fistula in 12 (66.6%) patients, coil embolization in 2 (11.1%) patients, and detachable balloon and coil embolization, balloon occlusion, and stent delivery with coil and *n*-butyl cyanoacrylate embolization of an AV fistulae each in 1 (5.5% each) patient. Angiography immediately after endovascular treatment demonstrated complete occlusion in 16 (88.9%) patients and partial occlusion in 2 (11.1%) patients. Seventeen (94.5%) patients had complete resolution of symptoms.

Other case reports have described successful use of endovascular treatment with stenting for iatrogenic vertebral artery pseudoaneurysms,[21,] iatrogenic vertebral artery AV fistula,[22,] extracranial vertebral artery aneurysm with an unknown cause,[23,] and extracranial vertebral artery aneurysm with a cervical vertebral AV fistula.[24,]

Section Summary: Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, or Arteriovenous Fistula(e)

The evidence on use of endovascular therapies for the treatment of extracranial vertebral artery dissections, aneurysms, or AV fistula(e) consists of small case series and case reports. These reports and series have indicated that endovascular therapy for extracranial vertebral artery disorders other than stenosis is feasible and might be associated with favorable outcomes. However, given the lack of evidence comparing endovascular therapies with alternatives, the evidence is insufficient to draw conclusions about the efficacy of endovascular therapy for treating extracranial vertebral artery dissections, aneurysms, or AV fistula(e) versus existing alternative therapies.

Supplemental Information

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

Practice Guidelines and Position Statements

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

American Heart Association and American Stroke Association

The American Heart Association and American Stroke Association (2014) issued joint guidelines on prevention of stroke in patients with stroke and transient ischemic attack with recommendations about treatment of extracranial vertebrobasilar disease.[25,] These guidelines were updated in 2021 and the most recent recommendations and evidence statements about treatment of extracranial vertebrobasilar disease are listed in Table 2.[26,]

Table 2. Guidelines on Stroke Prevention in Patients With Stroke and Transient Ischemic Attack

Recommendation	COR	LOE
"In patients with recently symptomatic extracranial vertebral artery stenosis, intensive medical therapy (antiplatelet therapy, lipid lowering, BP control) is recommended to reduce stroke risk"	I	A
"In patients with ischemic stroke or TIA and extracranial vertebral artery stenosis who are having symptoms despite optimal medical treatment, the usefulness of stenting is not well established"	IIb	B-R
"In patients with ischemic stroke or TIA and extracranial vertebral artery stenosis who are having symptoms despite optimal medical treatment, the usefulness of open surgical procedures, including vertebral endarterectomy and vertebral artery transposition, is not well established"	IIb	C-EO

BP: blood pressure; COR: class of recommendation; LOE: level of evidence; TIA: transient ischemic attack.
Level of Evidence: A: high-quality evidence from more than 1 RCT; B-R: moderate quality of evidence from 1 or more randomized controlled trials; C-EO: consensus of expert opinion based on clinical experience.

American Stroke Association et al

In 2011, a multisociety task force issued guidelines on the management of extracranial vertebral and carotid artery disease, which made the following statement about catheter-based revascularization of extracranial vertebral artery disease: "Although angioplasty and stenting of the vertebral vessels are technically feasible, as for high-risk patients with carotid disease, there is insufficient evidence from randomized trials to demonstrate that endovascular management is superior to best medical management."[27,] No specific recommendations were made about endovascular therapies.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has a national coverage determination addressing the use of percutaneous transluminal angioplasty in the treatment of atherosclerotic obstructive lesions of the lower or the upper extremities (not including the head or neck vessels), of a single coronary artery, of renal arteries, and of arteriovenous dialysis fistulas and grafts.[28,] It also addresses the use of percutaneous transluminal angioplasty concurrent with carotid stent placement in U.S. Food and Drug Administration investigational device exemption clinical trials, in U.S. Food and Drug Administration-approved postapproval studies, and in patients at high risk for carotid endarterectomy.

The national coverage determination states that all other indications for percutaneous transluminal angioplasty, with or without stenting, to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel

Type	Code	Description
	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)
	36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
	36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery) (List separately in addition to code for primary procedure)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
05/29/2015	BCBSA Medical Policy adoption
07/01/2016	Policy revision without position change
07/01/2017	Policy revision without position change
09/01/2018	Policy revision without position change
07/01/2019	Policy revision without position change
07/01/2020	Annual review. No change to policy statement. Literature review updated.
07/01/2021	Annual review. No change to policy statement. Literature review updated.
07/01/2022	Annual review. No change to policy statement. Literature review updated.
07/01/2023	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will

be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Endovascular Therapies for Extracranial Vertebral Artery Disease 7.01.148 **Policy Statement:** Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered **investigational** for the management of extracranial vertebral artery diseases.	**Endovascular Therapies for Extracranial Vertebral Artery Disease 7.01.148** **Policy Statement:** I. Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered **investigational** for the management of extracranial vertebral artery diseases.