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Endovascular Therapies for Extracranial Vertebral Artery Disease

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Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

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

Policy Guidelines

None.

Description

Vertebral artery diseases, including atherosclerotic stenosis, dissections, and aneurysms, can lead to ischemia of the posterior cerebral circulation. Conventional management of extracranial vertebral artery diseases may include medical therapy (e.g., antiplatelet or anticoagulant 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.

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 four segments, V1 through 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 cardiovascular 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.

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 $\geq 50\%$ 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 $\geq 50\%$ stenosis that are accessible to the system."

Rationale

This medical policy was created in January 2020 and has been updated periodically with searches of the PubMed database. The most recent literature update was performed through March 16, 2023.

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

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 policy.

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 (OS), symptoms, morbid events, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

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 medical policy. 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 transient ischemic attack or stroke in the previous three 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, 0.14 to 1.13; $p=0.08$ 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 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, 1.3-4.1 years). 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% confidence interval, 0% to 11%) in the stenting group and 1 (2%) of 58 patients (95% confidence interval, 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 registry treated with endovascular therapy	30 d	<ul style="list-style-type: none"> • Post-procedural morbidity: 2.0% • Post-procedural mortality: 0.3% 	Not reported
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	<ul style="list-style-type: none"> • 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)	13.5 mo ^a	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Technical success rate: 99% • During FU, 5 patients had posterior 	9.6% at 6 mo

				circulation ischemia, 1 had cerebellar infarction with ISR, 2 had posterior circulation strokes without ISR	
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d: day(s); FU: follow-up; ISR: in-stent restenosis; mo: month; mRS: modified Rankin Scale; 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, and Arteriovenous Fistula(e)

Clinical Context and Therapy Purpose

The purpose of PTA with stent implantation in individuals who have extracranial vertebral artery aneurysms, dissections, and 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 policy.

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, and 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 OS, symptoms, morbid events, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

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 (one of which was extracranial) and 23 with nonaneurysmal dissections (10 of which were extracranial, 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 three 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 a 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, and AV Fistula(e)

The evidence on use of endovascular therapies for the treatment of extracranial vertebral artery dissections, aneurysms, and 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, and AV fistula(e) versus existing alternative therapies.

Summary of Evidence

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty (PTA) with or without stent implantation, the evidence includes randomized controlled trials (RCTs) and noncomparative studies. Relevant outcomes are overall survival (OS), symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs, the Vertebral Artery Ischaemia Stenting Trial (VIST) and the Vertebral Artery Stenting Trial (VAST), found no advantage for endovascular intervention compared with best medical therapy alone. Evidence from noncomparative studies has shown 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have extracranial vertebral artery aneurysm(s), dissection(s), or arteriovenous (AV) fistula(e) who receive PTA with stent implantation, the evidence includes small case series and reports. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. The available evidence has indicated that endovascular therapy for extracranial vertebral artery disorders other than stenosis is feasible and may be associated with favorable outcomes. However, given the lack of data comparing endovascular therapies to alternatives, the evidence is insufficient to permit conclusions about the efficacy of endovascular therapy for extracranial vertebral artery aneurysms, dissections, or AV fistulae. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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
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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.

Medicare National Coverage

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 AV dialysis fistulas and grafts. (28) It also addresses the use of percutaneous transluminal angioplasty concurrent with carotid stent placement in 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 policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0075T, 0076T, 36226, 36228
HCPCS Codes	C2623

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision	
Date	Description of Change
12/31/2025	Document became inactive.
09/15/2024	Reviewed. No changes.
01/01/2024	Document updated with literature review. Coverage unchanged. Added references 9, 17 and 26; other(s) removed.
08/15/2022	Reviewed. No changes.
09/01/2021	Document updated with literature review. Coverage unchanged. The following references were added: 7 and 9.
08/15/2020	Reviewed. No changes.
01/15/2020	New medical document. Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered experimental, investigational and/or unproven for the management of extracranial vertebral artery diseases. NOTE: 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.

