



# Louisiana

## Endovascular Therapies for Extracranial Vertebral Artery Disease

Policy # 00466

Original Effective Date: 06/17/2015

Current Effective Date: 07/11/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers endovascular therapy, including percutaneous transluminal angioplasty (PTA) with or without stenting, for the management of extracranial vertebral artery disease to be **investigational**.\*

### Background/Overview

#### **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. 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 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

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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.

### **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. 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.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

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Currently, no endovascular therapies have been approved by the U.S. 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 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; FDA only requires data showing “probable safety and effectiveness.” Devices with their labeled indications are as follows:

1. NeuroLink System<sup>®†</sup> (Guidant, Santa Clara, CA). “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<sup>™†</sup> Stent System (Boston Scientific, Fremont, CA). “The Wingspan Stent System with Gateway PTA 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.”

### Centers for Medicare and Medicaid Services (CMS)

Centers for Medicare and Medicaid Services has a national coverage determination (NCD) that addresses the use of PTA 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. It also addresses the use of PTA concurrent with carotid stent placement in FDA investigational device exemption clinical trials, in FDA-approved postapproval studies, and in patients at high risk for carotid endarterectomy.

The NCD states that all other indications for PTA, with or without stenting, to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

### **Rationale/Source**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 one or more intended clinical use of the technology in the intended population and compare

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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.

Appropriate comparators for studies evaluating vertebral artery stenting for vertebral artery stenosis include surgical repair and/or medical management.

### **ANGIOPLASTY AND STENTING FOR EXTRACRANIAL VERTEBRAL ARTERY STENOSIS**

The evidence base for the efficacy of endovascular interventions for vertebral artery stenosis consists of a large number of case series, most of which are small and retrospective. A small number of controlled trials have been published, which is the emphasis for this review.

#### **Systematic Reviews**

Several systematic reviews of published studies were identified. These systematic reviews were published prior to the Vertebral Artery Ischaemia Stenting Trial and the Vertebral Artery Stenting Trial (VAST), which are described in the Randomized Controlled Trials section. Meta-analysis of SAMMPRIS, VAST, and the Vertebral Artery Ischaemia Stenting Trial showed no advantage of for stenting/angioplasty compared with medical therapy alone.

#### **Randomized Controlled Trials**

The Vertebral Artery Ischaemia Stenting Trial is the largest RCT published to date comparing stenting with medical therapy in patients who had symptomatic vertebral artery disease. 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 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 end point 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.

VAST was a multicenter phase 2 trial that included 115 patients who had transient ischemic attack or minor stroke attributed to vertebral artery stenosis. 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

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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 enroll 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)	Retrospective review of prospectively collected data	404 patients from registry treated with endovascular therapy	30 d	<ul style="list-style-type: none"> <li>Postprocedural morbidity: 2.0%</li> <li>Postprocedural mortality: 0.3%</li> </ul>	Not reported
Sun et al (2015)	Retrospective review of prospectively collected data	188 patients with posterior circulation TIA or stroke and mRS score $\leq 2$	16.5 mo <sup>a</sup>	<ul style="list-style-type: none"> <li>Technical success rate: 100%</li> <li>34 patients had recurrent TIA after 30 d</li> <li>No cases of stroke or death occurred</li> </ul>	21.2%
Mohammadian et al (2013)	Prospective interventional study	206 patients with clinical signs of vertebral occlusion (239 treated lesions, 202 extracranial)	13.15 mo <sup>a</sup>	<ul style="list-style-type: none"> <li>Technical success rate: 100%.</li> <li>89.2% were balloon-expandable bare-metal stents</li> <li>Periprocedural complication rate: 7.2%</li> <li>Complications during FU: overall 6.3%</li> </ul>	15.9%
Hatano et al (2011)	Retrospective review of prospectively collected data	117 patients (108 symptomatic, 9 asymptomatic)	48 mo <sup>a</sup>	<ul style="list-style-type: none"> <li>Technical success rate: 99%</li> <li>During FU, 5 patients had posterior circulation ischemia, 1 had cerebellar infarction with ISR, 2 had posterior circulation strokes without ISR</li> </ul>	9.6% at 6 mo

FU: follow-up; ISR: in-stent restenosis; mRS: modified Rankin Scale; TIA: transient ischemic attack.

<sup>a</sup> 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 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.

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### **ANGIOPLASTY WITH STENTING FOR EXTRACRANIAL VERTEBRAL ARTERY ANEURYSMS, DISSECTIONS, AND ARTERIOVENOUS FISTULA(E)**

A smaller body of literature has addressed the use of endovascular procedures for extracranial vertebral artery aneurysms, dissections, and arteriovenous (AV) fistula(e). These lesions most commonly occur after trauma or iatrogenic injury. Because aneurysms, dissections, and AV fistulae may coexist in the same vessel, studies reporting outcomes for endovascular treatment of these conditions are discussed together. The available literature consists entirely of case reports, case series, and a systematic review of case series.

#### **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. 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**

Since the publication of the 2011 Pham systematic review, additional case series on the use of endovascular therapies for extracranial vertebral artery dissections have been published.

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. 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.

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. 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). The procedure was technically successful in both

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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. 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, iatrogenic vertebral artery AV fistula, extracranial vertebral artery aneurysm with an unknown cause, and extracranial vertebral artery aneurysm with a cervical vertebral AV fistula.

### **Section Summary: Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, and Arteriovenous 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) vs existing alternative therapies.

### **SUMMARY OF EVIDENCE**

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty with or without stent implantation, the evidence includes RCTs and noncomparative studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs, the Vertebral Artery Ischaemia Stenting Trial and the Vertebral Artery Stenting Trial, 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 the effects of the technology on health outcomes.

For individuals who have extracranial vertebral artery aneurysm(s), dissection(s), or arteriovenous fistula(e) who receive percutaneous transluminal angioplasty with stent implantation, the evidence includes small case series and reports. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. The available evidence has indicated that endovascular therapy for

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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 arteriovenous fistulae. The evidence is insufficient to determine the effects of the technology on health outcomes.

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### Policy History

Original Effective Date: 06/17/2015

Current Effective Date: 07/11/2018

- 06/04/2015 Medical Policy Committee review
- 06/17/2015 Medical Policy Implementation Committee approval. New policy.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 06/02/2016 Medical Policy Committee review
- 06/20/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 07/06/2017 Medical Policy Committee review
- 07/19/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 07/05/2018 Medical Policy Committee review
- 07/11/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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# Louisiana

## Endovascular Therapies for Extracranial Vertebral Artery Disease

Policy # 00466  
Original Effective Date: 06/17/2015  
Current Effective Date: 07/11/2018

Next Scheduled Review Date: 07/2019

### **Coding**

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)<sup>†</sup>, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0075T, 0076T, 36226, 36228
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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