



Louisiana

Endovascular Therapies for Extracranial Vertebral Artery Disease

Policy # 00466

Original Effective Date: 06/17/2015

Current Effective Date: 08/10/2020

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.

Note: Extracranial Carotid Angioplasty Stenting is addressed separately in medical policy 00155.

Note: Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) is addressed separately in medical policy 00198.

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**.*

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.

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

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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.

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

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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)

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

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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 the 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/Source

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 (eg, antiplatelet or anticoagulant medications), medications to reduce atherosclerotic disease risk (eg, statins), and/or surgical revascularization. Endovascular therapies have been investigated as an alternative to conventional management.

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty with or without stent implantation, the evidence includes randomized controlled trials and noncomparative studies. The relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Two randomized controlled trials, 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

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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. The relevant outcomes are overall survival, 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 arteriovenous fistulae. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

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, which made the following recommendations about treatment of extracranial vertebrobasilar disease (see Table 1).

Table 1. Guidelines on Stroke Prevention in Patients with Stroke and Transient Ischemic Attack

Recommendation		

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BP: blood pressure; COR: class of recommendation; LOE: level of evidence.

American Stroke Association et al

In 2011, a multi society task force issued guidelines on the management of extracranial vertebral and carotid artery disease, which made the following statements 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." No specific recommendations were made about endovascular therapies.

European Society for Vascular Surgery

The European Society for Vascular Surgery (2018) made the following recommendation: "Patients with recurrent vertebrobasilar territory symptoms (despite best medical therapy) and who have a 50 to 99% extracranial vertebral artery stenosis may be considered for revascularisation." The recommendation was based on Level B evidence (data derived from a single randomized controlled trial or large non-randomized studies) and considered Class IIb (i.e., the usefulness/efficacy is less well established).

U.S. Preventive Services Task Force Recommendations

Not applicable.

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 arteriovenous dialysis fistulas and grafts. 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 Food and Drug Administration-approved post approval 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.

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Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in April 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

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guideline on the management of patients with extracranial carotid and vertebral artery disease. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. *Circulation*. Jul 26 2011;124(4):e54-130. PMID 21282504

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- 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

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07/11/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/13/2019 Coding update

07/03/2019 Medical Policy Committee review

07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/02/2020 Medical Policy Committee review

07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2021

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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
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. Food and Drug Administration (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
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