

## Corporate Medical Policy

### Endovascular Therapies for Extracranial Vertebral Artery Disease

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#### Description of Procedure or Service

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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, including 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.

#### Overview of 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. Reports from one stroke registry estimate 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. In 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-V4, of which segments V1-V3 are extracranial. V1 originates at the subclavian artery and extends to the 5th or 6th cervical vertebrae; V2 crosses the bony canal of the transverse foramina from C2-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

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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 therapy 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 report rates of overall survival of 90.7% and 77.3% at 3 and 6 years postoperatively, and arterial patency rates of 80% after 1 year of follow-up. Surgical revascularization may be used in cases of symptomatic vertebral artery stenosis that 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 of 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/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 surgical access of the extracranial vertebral artery, endovascular therapies have been investigated for extracranial vertebral artery disease. Endovascular therapy may consist of percutaneous transluminal angioplasty (PTA), with or without stent implantation.

## Regulatory Status

There are currently no endovascular therapies approved by the U.S. Food and Drug Administration (FDA) specifically for the treatment of extracranial vertebral artery disease. A variety of stents approved for use in the carotid or coronary circulation have been used for extracranial vertebral artery disease, which may be self- or balloon-expandable.

Two devices have received approval for *intracranial* atherosclerotic disease from FDA through the Humanitarian Device Exemption process. 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® (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.”

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2. Wingspan™ 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.”

## Related Policies

Carotid Artery Angioplasty and Stenting

Endovascular Procedures for Intracranial Arterial Disease

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered investigational for the management of extracranial vertebral artery disease. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Endovascular Therapies for Extracranial Vertebral Artery Disease are covered

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Not applicable.

## When Endovascular Therapies for Extracranial Vertebral Artery Disease are not covered

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

## Policy Guidelines

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

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty with or without stent implantation, the evidence includes a phase 2 randomized controlled trials (RCTs) and noncomparative studies. 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 indicates 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.

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For individuals who have extracranial vertebral artery aneurysm(s), dissection(s), and arteriovenous (AV) fistula(e) who receive percutaneous transluminal angioplasty with stent implantation, the evidence includes small case series and case reports. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. The available evidence indicates 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, and AV fistulae. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbnc.com](http://www.bcbnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 0075T, 0076T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.148, 2/12/2015

Specialty Matched Consultant Advisory Panel 5/25/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.148, 5/19/2016

Specialty Matched Consultant Advisory Panel 5/31/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.148, 5/8/2017

Specialty Matched Consultant Advisory Panel 5/23/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.148, 5/4/2018

## Policy Implementation/Update Information

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5/26/15 New policy. Endovascular therapy for extracranial vertebral artery disease is considered investigational. (sk)

7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. Reference added. Policy Guidelines updated. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

7/28/17 Reference added. (sk)

6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)

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8/24/18 Reference added. Policy Guidelines updated. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.