MEDICAL POLICY – 7.01.148
Endovascular Therapies for Extracranial Vertebral Artery Disease

BCBSA Ref. Policy: 7.01.148
Effective Date: July 1, 2017
Last Revised: June 22, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

The vertebral arteries travel along the spine, up the back of the neck, and enter the brain. When one of these arteries is narrowed, blocked, or there is a bulge before it enters the brain, it’s known as extracranial vertebral artery disease. (Extracranial means outside the skull.) Treatment usually involves medication or surgery. Other treatments that are done inside the blood vessels are being studied. They are known as endovascular therapies. An example of an endovascular therapy is placing a tiny tube inside a blocked artery to allow blood to flow through it. Endovascular therapy for extracranial vertebral artery disease is investigational. These treatments are still being studied to see if they are as effective as standard treatments.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered investigational for the management of extracranial vertebral artery disease.

Note: 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.

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0075T</td>
<td>Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel</td>
</tr>
<tr>
<td>0076T</td>
<td>Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

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**Related Information**

N/A

**Evidence Review**
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, including 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.

Background

Vertebrobasilar Circulation Ischemia

Ischemia of the vertebrobasilar or posterior circulation accounts for about 20% of all strokes. Posterior circulation strokes may arise from occlusion of the innominate and subclavian arteries, the extracranial vertebral arteries, or the intracranial vertebral, basilar, or posterior cerebral arteries. Compared with carotid artery disease, relatively little is known about the true prevalence of specific causes of posterior circulation strokes, particularly the prevalence of vertebral artery disease. Reports from 1 stroke registry have 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 next 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 matter and becomes an intracranial vessel (V4). 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 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.

**Summary of Evidence**

**Angioplasty With or Without Stenting**

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 trial (RCT). Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. The phase 2 RCT, the Vertebral Artery Stenting Trial (VAST), found no advantage for endovascular intervention compared to best medical therapy alone, with a periprocedural adverse event rate of 5% for the invasive procedures. A larger phase 3 trial comparing endovascular therapy to medical therapy for vertebral artery stenosis is ongoing, although the lack of benefit of endovascular therapy demonstrated in VAST raises questions about the need for a phase 3 trial. 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.

**Angioplasty with Stenting**

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 determine whether endovascular therapy for extracranial vertebral artery aneurysms, dissections, and AV fistulae improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02328781</td>
<td>Prospective Multi-center Single-arm Target Value Clinical Trial for Evaluating Clinical Use Safety and Efficacy of the Firehorus Vertebral Artery Rapamycin-target-eluting Stent System</td>
<td>150</td>
<td>Dec 2016 (ongoing)</td>
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<tr>
<td>ISRCTN95212240</td>
<td>Vertebral artery Ischaemia Stenting Trial (VIST)</td>
<td>540</td>
<td>Nov 2017</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02197559</td>
<td>A Prospective Cohort Study of Bare-Metal Stents and Drug-Eluting Stents in the Treatment of Patients With Vertebral Artery Ostium Stenosis</td>
<td>168</td>
<td>Jun 2016 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Practice Guidelines and Position Statements

American Heart Association and American Stroke Association

In 2014, the American Heart Association and American Stroke Association issued guidelines for prevention of stroke in patients with stroke and TIA, which make the following recommendations about treatment of extracranial vertebrobasilar disease\textsuperscript{24}.
Table 2. Guidelines on Stroke Prevention in Patients With Stroke and Transient Ischemic Attack

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Routine preventive therapy with emphasis on anti-thrombotic therapy, lipid lowering, BP control, and lifestyle optimization is recommended for all patients with recently symptomatic extracranial vertebral artery stenosis”</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>“Endovascular stenting of patients with extracranial vertebral stenosis may be considered when patients are having symptoms despite optimal medical treatment.”</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>“Open surgical procedures, including vertebral endarterectomy and vertebral artery transposition, may be considered when patients are having symptoms despite optimal medical treatment.”</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

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

American Stroke Association et al

In 2011, a multisociety task force issued guidelines on the management of extracranial vertebral and carotid artery disease and 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 are made regarding endovascular therapies.

European Society of Cardiology

In 2011, the European Society of Cardiology issued guidelines on the management of peripheral artery disease, including extracranial vertebral artery disease, and made the following recommendations about revascularization for vertebral artery stenosis:

Table 3. Guidelines on Management of Peripheral Artery Disease

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“In patients with symptomatic extracranial VA stenosis, endovascular treatment may</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>
**Recommendation**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>be considered for lesions ≥50% in the case of recurrent ischaemic events despite optimal medical management.&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;Revascularization of an asymptomatic VA stenosis is not indicated, irrespective of the degree of severity.&quot;</td>
<td>III</td>
<td>C</td>
</tr>
</tbody>
</table>

COR: class of recommendation; LOE: level of evidence; VA: vertebral artery.

**Medicare National Coverage**

Centers for Medicare and Medicaid Services has a national coverage determination (NCD) that addresses the use of percutaneous transluminal angioplasty (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 Food and Drug Administration (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.

**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 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® (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 ≥50% stenosis and that are accessible to the stent system.”
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 ≥50% stenosis that are accessible to the system.”

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/14/15</td>
<td>New Policy. Policy created with literature review through January 6, 2015. Endovascular</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>05/27/15</td>
<td>therapy for extracranial vertebral artery disease considered investigational.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Minor update. Notation added to Policy Guidelines section: CPT codes 0075T and 0076T should only be utilized if the procedure is related to vertebral arteries.</td>
</tr>
</tbody>
</table>

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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