This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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

Summary of Evidence

Comparative evidence is lacking to determine whether endovascular therapy, including percutaneous transluminal angioplasty (PTA) with or without stent implantation, for extracranial vertebral artery disease improves outcomes compared with alternatives. For endovascular treatment of extracranial vertebral artery stenosis, there is one very small randomized controlled trial comparing endovascular therapy with medical therapy. Evidence from a large number of small- to moderate-sized noncomparative studies from single institutions indicates that vertebral artery stenting can be performed with high rates of technical success and low periprocedural morbidity and mortality. However, long-term follow-up demonstrates high rates of in-stent stenosis. Given the lack of data comparing endovascular therapy to either medical or surgical management, the evidence is insufficient to determine whether vertebral artery stenting or angioplasty improves the net health outcome.

The evidence related to the use of endovascular therapies for the treatment of extracranial vertebral artery dissections, aneurysms, and arteriovenous (AV) fistulae consists of small case series and case reports. The available cases reports and case series indicate 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 evidence comparing endovascular therapies with alternatives, the evidence is insufficient to determine whether endovascular therapy for extracranial vertebral artery dissections, aneurysms, and AV fistulae improves the net health outcome.

Given the limitations in the evidence base, endovascular therapies are considered investigational for the treatment of extracranial vertebral artery disease.
Policy
Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered investigational for the management of extracranial vertebral artery disease.

Policy Guidelines
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.

Background
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 five years. In particular, the presence of vertebral artery stenosis increases the 90-day risk of recurrent stroke by about four fold.\(^1\)

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 four segments, V1-V4, of which segments V1-V3 are extracranial. V1 originates at the subclavian artery and extends to the 5\(^{th}\) or 6\(^{th}\) 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 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 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 regiments.

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 three and six years postoperatively, and arterial patency rates of 80% after one year of follow-up.\textsuperscript{3,4} 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 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.

Currently 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\textsuperscript{®} (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\textsuperscript{™} 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 Protocols

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Extracranial Carotid Angioplasty/Stenting

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


