Protocol

Endovascular Therapies for Extracranial Vertebral Artery Disease

(701148)

Medical Benefit		**Effective Date**: 07/01/15	**Next Review Date**: 05/18
Preauthorization	No	**Review Dates**: 05/15, 05/16, 05/17	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With extracranial vertebral artery stenosis	Interventions of interest are: • Percutaneous transluminal angioplasty with or without stent implantation	Comparators of interest are: • Medical management	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With extracranial vertebral artery aneurysm(s)	Interventions of interest are: • Percutaneous transluminal angioplasty with stent implantation	Comparators of interest are: • Observation • Surgical treatment	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With extracranial vertebral artery dissection(s)	Interventions of interest are: • Percutaneous transluminal angioplasty with stent implantation	Comparators of interest are: • Observation • Surgical treatment	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With extracranial vertebral artery arteriovenous fistula(e)	Interventions of interest are: • Percutaneous transluminal angioplasty with stent implantation	Comparators of interest are: • Observation • Surgical treatment	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related mortality • Treatment-related morbidity

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

Summary of Evidence

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty with or without stent implantation, the evidence includes a phase two randomized controlled trial (RCT). Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. The phase two 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 three 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 three 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.

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.

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 have 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 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 though 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.[2]

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 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 have reported overall survival rates of 90.7% and 77.3% at three and six years postoperatively, and arterial patency rates of 80% after one year of follow-up.[3, 4] 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/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, with or without stent implantation.

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."

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.

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28. National Government Services, Inc. (Primary Geographic Jurisdiction - Illinois, New York - Entire State, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont, Wisconsin, Minnesota) Local Coverage Determination (LCD): Category III CPT® Codes (L33392), Revision Effective Date for services performed on or after 01/01/2017.