BlueCross BlueShield of Alabama

Name of Policy:
Endovascular Therapies for Extracranial Vertebral Artery Disease

Policy #: 579
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

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% cases, posterior circulation strokes are due to stenosis of the proximal vertebral artery. Patients who experience strokes or transient ischemic attacks (TIAs) of the vertebrobasilar circulation face a 25-35% 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.

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 4 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.

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 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, 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.

Policy:

Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational for the management of extracranial vertebral artery disease**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best

medical judgment in providing the c are they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was updated through March 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Appropriate comparators for studies evaluating vertebral artery stenting for vertebral artery stenosis include surgical repair and/or medical management.

Angioplasty and Stenting for Extracranial Vertebral Artery Stenosis

The evidence base for the efficacy of endovascular interventions for vertebral artery stenosis consists of a large number of case series, most of which are small and retrospective. A small number of controlled trials have been published. The emphasis for this review will be on controlled trials.

Systematic Reviews

Several systematic reviews of published studies were identified. These systematic reviews were published prior to the Vertebral Artery Stenting Trial (VAST) and the Vertebral Artery Ischaemia Stenting Trial (VIST), which are described in the Randomized Controlled Trials subsection. Meta-analysis of SAMMPRIS,VAST, and VIST showed no advantage of for stenting/angioplasty compared with medical therapy alone.

Randomized Controlled Trials

VIST is the largest RCT published to date comparing stenting with medical therapy in patients who had symptomatic vertebral artery disease. Enrollment was originally planned for 1302

patients, but was stopped after 182 participants due to slow recruitment and the end of funding. Patients with symptomatic extracranial or intracranial vertebral artery stenosis and vertebrobasilar transient ischemic attack or stroke in the previous 3 months were randomized to vertebral artery stenting plus best medical therapy or best medical therapy alone. Of the 91 patients randomized to stenting, 33% did not undergo the procedure. The primary end point of fatal or nonfatal stroke occurred in 5 patients in the stent group and 12 in the medical management group (hazard ratio, 0.40; 95% confidence interval [CI], 0.14 to 1.13; p=0.08 by intention-to-treat analysis). Although this study found no benefit of stenting, it was underpowered and lacked the precision to exclude a benefit from stenting.

VAST was a multicenter Phase 2 study included 115 patients who had a transient ischemic attack (TIA) or minor stroke attributed to vertebral artery stenosis. Randomization to stenting plus medical therapy or medical therapy was stratified by center and by the level of stenosis; 83.5% of patients had extracranial lesions and the rest had intracranial lesions. Stent selection was by surgeon preference. All patients were followed yearly by telephone. The median follow-up was 3.0 years (range, 1.3 to 4.1). The primary outcome was the composite of vascular death, stroke, or myocardial infarction (MI) within 30 days. Secondary outcomes were stroke in the territory of the symptomatic artery, the composite outcome measure during follow-up, and the degree of restenosis. Endovascular therapy plus best medical therapy was not superior to best medical therapy alone in this trial. The primary outcome occurred in 3 (5%) of 57 patients (95% confidence interval [CI], 0% to 11%) in the stenting group and 1 (2%) of 58 patients (95% CI, 0% to 5%) in the medical treatment group. During follow-up, the composite primary outcome occurred in 11 (19%) patients in the stenting group and in 10 (17%) patients in the medical therapy group. The periprocedural risk of a major vascular event in the stenting group was 5%.

Non-comparative Studies

A large number of non-comparative studies, most often with small numbers of patients, have described outcomes for patients treated with endovascular therapies for extracranial vertebral artery disease. Some of the cohort studies that report on prospectively collected complication and restenosis rates are shown in Table 1.

Section Summary: Angioplasty With or Without Stenting for Extracranial Vertebral Artery Stenosis

The evidence on the overall efficacy of endovascular therapies for extracranial vertebral artery stenosis includes a Phase 3 and Phase 2 RCTs that compared endovascular therapy to best medical therapy alone for vertebral artery stenosis. These trials found no advantage of endovascular intervention over best medical therapy alone, with a periprocedural adverse event rate of 5% for the invasive procedures in the VAST trial. Evidence from noncomparative studies has indicated 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.

Table 1: Cohort Studies of Endovascular Treatment of Extracranial Vertebral Artery Stenosis

Study	Study Type	Population/ Intervention	FU Period	Main Results	In-Stent Restenosis Rate
Kikuchi et al (2014)	Retrospective review of prospectively collected data	404 subjects from a registry treated with endovascular therapy	30 d	• Postprocedural morbidity: 2.0% • Postprocedural mortality: 0.3%	Not reported
Sun et al (2014)	Retrospective review of prospectively collected data	188 patients with posterior circulation TIA or stroke and mRS score ≤2	16.5 mo[a]	• Technical success rate: 100% • 34 patients had recurrent TIA after 30 d. • No cases of stroke or death occurred	21.2%
Mohammadian et al (2013)	Prospective interventional study	206 subjects with clinical signs/symptoms of vertebral occlusion (239 treated lesions; 202 of extracranial)	13.15 mo[a]	• Technical success rate: 100% • 89.2% were balloon-expandable bare-metal stents; • Periprocedural complication rate: 7.2% • Complications during FU: overall 6.3%	15.9%
Hatano et al (2011)	Retrospective review of prospectively collected data	117 patients (108 symptomatic, 9 asymptomatic)	48 mo[a]	• Technical success rate: 99% • During FU: 5 patients developed posterior circulation ischemia, 1 patient had cerebellar infarction with ISR, 2 patients had posterior circulation strokes without ISR	9.6% at 6 mo

FU: follow-up; ISR: in-stent restenosis; mRS: TIA: transient ischemic attack. [a] Mean value.

Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, and Arteriovenous Fistula(E)

A smaller body of literature has addressed the use of endovascular procedures for extracranial vertebral artery aneurysms, dissections, and arteriovenous (AV) fistula(e). These lesions most commonly occur after trauma or iatrogenic injury. Because aneurysms, dissections, and AV fistulae may coexist in the same vessel, studies reporting outcomes for endovascular treatment of these conditions are discussed together. The available literature consists entirely of case reports, case series, and a systematic review of case.

Systematic Reviews

In 2011, Pham et al conducted a systematic review of studies evaluating endovascular stenting for extracranial carotid and vertebral artery dissections. Eight studies of extracranial vertebral artery stenting with 10 patients (12 vessels) were included. Of the 10 patients included, 70% had associated pseudoaneurysms and 20% had bilateral lesions. Most dissections (60%) were traumatic in etiology, while 20% were spontaneous and 20% were iatrogenic. The indications for stenting were failure of medical management in 40% (defined as a new ischemic event, progression of initial symptoms, or demonstration of an enlarging pseudoaneurysm despite adequate anticoagulation or antiplatelet treatment), contraindication to anticoagulation in 20%, and/or severity of dissection hemodynamics in 60%. No stent-related complications or mortalities were reported in any study. One dissection-related death was reported, although stenting was considered technically successful.

Case Series and Case Reports

Since the publication of the 2011 Pham systematic review, additional case series related to the use of endovascular therapies for extracranial vertebral artery dissections have been published.

In 2014, Badve et al retrospectively compared the clinical characteristics of patients with vertebrobasilar dissections with and without aneurysmal dissection treated at a single institution from 2002 to 2010. Thirty patients were identified, 7 with aneurysmal dissections (1 of which was 1 extracranial) and 23 with nonaneurysmal dissections (10 of which were extracranial, 12 of which were combined intracranial/extracranial). Patients were treated with antiplatelet agents (aspirin or clopidogrel; n=8), anticoagulation with warfarin (n=13), or neurointerventional procedures (n=6). One patient in the nonaneurysmal dissection group treated with aspirin died.

The use of endovascular therapy for extracranial vertebral artery aneurysms and AV fistulae is similarly limited to small case series and reports. In an early report, Horowitz et al (1996) described a left-sided vertebral artery pseudoaneurysm with dissection between the vessel media and adventitia at the C7 vertebra that was treated with a balloon-expandable stent. Follow-up angiography 3 months postprocedure showed no filling of the pseudoaneurysm and normal patency of the parent artery. In 2004, Felber et al reported outcomes from endovascular treatment with stent grafts of 11 patients with aneurysms or AV fistulae of craniocervical arteries, 2 of whom were treated for extracranial vertebral artery disorders with coronary stents (1 aneurysm, 1 traumatic AV fistula). The procedure was technically successful in both subjects, without complications. At follow-up (5 years and 14 months postprocedure in the aneurysm and fistula patients, respectively), the target vessel was patent without stenosis. In 2008, Herrera et al reported outcomes for a single-center series of 18 traumatic vertebral artery injuries, including 16 AV fistulae (7 of which had an associated pseudoaneurysm) and 2 isolated pseudoaneurysms, treated with endovascular therapy. Endovascular therapy consisted of balloon occlusion of the parent vessel and AV fistula in 12 (66.6%) patients, coil embolization in 2 (11.1%) patients, and detachable balloon and coil embolization, balloon occlusion, and stent delivery with coil and n-butyl cyanoacrylate embolization of a AV fistulae each in 1 (5.5% each) patient. Angiography immediately after endovascular treatment demonstrated complete occlusion in 16 (88.9%) patients and partial occlusion in 2 (11.1%) patients. Seventeen (94.5%) patients had complete resolution of symptoms.

Other case reports have described successful use of endovascular treatment with stenting for iatrogenic vertebral artery pseudoaneurysms, iatrogenic vertebral artery AV fistula, extracranial vertebral artery aneurysm with an unknown cause, and extracranial vertebral artery aneurysm with a cervical vertebral AV fistula.

Section Summary: Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, and Arteriovenous Fistula(e)

The evidence on use of endovascular therapies for the treatment of extracranial vertebral artery dissections, aneurysms, and AV fistula(e) consists of small case series and case reports. The available reports and series have 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 evidence comparing endovascular therapies to alternatives, the evidence is insufficient to determine whether endovascular therapy for extracranial vertebral artery dissections, aneurysms, and AV fistula(e) improves the net health outcome better than existing alternative therapies.

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 2 randomized controlled trial (RCT). Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs, the Vertebral Artery Ischaemia Stenting Trial (VIST) and the Vertebral Artery Stenting Trial (VAST), found no advantage for endovascular intervention compared to 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 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 (AV) fistula(e) who receive percutaneous transluminal angioplasty with stent implantation, the evidence includes small case series and reports. 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 determine whether endovascular therapy for extracranial vertebral artery aneurysms, dissections, or AV fistulae improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Heart Association and American Stroke Association

In 2014, the American Heart Association (AHA) and American Stroke Association (ASA) issued guidelines for prevention of stroke in patients with stroke and transient ischemia attack (TIA),

which make the following recommendations about treatment of extracranial vertebrobasilar disease:

- Class I Recommendations:
  - Routine preventive therapy with emphasis on antithrombotic therapy, lipid lowering, BP [blood pressure] control, and lifestyle optimization is recommended for all patients with recently symptomatic extracranial vertebral artery stenosis (Level of Evidence: C).

- Class IIb recommendations:
  - Endovascular stenting of patients with extracranial vertebral stenosis may be considered when patients are having symptoms despite optimal medical treatment (Level of Evidence: C).
  - Open surgical procedures, including vertebral endarterectomy and vertebral artery transposition, may be considered when patients are having symptoms despite optimal medical treatment (Level of Evidence: C).

American Stroke Association et al

In 2011, a multi-society task force issued guidelines on the management of extracranial vertebral and carotid artery disease with 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Key Words:

Endovascular, extracranial, vertebral artery, percutaneous transluminal angioplasty, PTA, extracranial stenting, extracranial angioplasty, angioplasty, vertebral artery stenosis, vertebral artery aneurysm, vertebral artery dissection, vertebral artery arteriovenous fistulae, Neurolink System®, Wingspan™ Stent System

Approved by Governing Bodies:

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."

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel
0076T	each additional vessel (List separately in addition to code for primary procedure)

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Policy History:

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Medical Policy Panel, May 2016
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Medical Policy Panel, May 2017
Medical Policy Group, May 2017 **(4)** Updates to Description and Key Points. No change to policy statement.
Medical Policy Panel, May 2018
Medical Policy Group, May 2018 **(4)**: Updates to Key Points and References. No change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.