

MEDICAL POLICY

POLICY TITLE	ENDOVASCULAR THERAPIES FOR EXTRACRANIAL VERTEBRAL ARTERY DISEASE
POLICY NUMBER	MP 1.149

CLINICAL BENEFIT	<input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	11/1/2024

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I. POLICY

Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered **not medically necessary** 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.

The American Heart Association/American Stroke Association states the following in their 2021 Guideline for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack (TIA):

- Extracranial vertebral artery stenosis is thought to account for 10% of posterior circulation strokes. Revascularization procedures are not performed often for vertebral artery stenosis. Small trials (VAST, VIST) did not show a clear benefit for vertebral artery stenting, and a recent combined analysis also did not demonstrate clear benefit for vertebral artery stenting compared with medical therapy.

The VIST and VAST trials included individuals with TIA or non-disabling ischemic stroke of the posterior circulation as well as stenosis of the vertebral artery of 50% or greater and presumed to be of atherosclerotic origin and accessible for endovascular treatment. Exclusion criteria included a potential cause of TIA or minor stroke other than stenosis in a vertebral artery (e.g. atrial fibrillation), vertebral artery stenosis caused by arterial dissection, and previous surgical or endovascular treatment of the stenosis.

Cross-reference:

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MP 2.032 Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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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 (e.g., 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.

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 a stroke registry, Gulli et al (2013) 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 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. By contrast, posterior cerebral artery ischemic events are more likely to be secondary to embolism from more proximal vessels.

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The vertebral artery is divided into four segments, V1 through 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.

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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.

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). “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). “The Wingspan Stent System with Gateway PTA (percutaneous transluminal angioplasty) 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.”

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty with or without stent implantation, the evidence includes randomized controlled trials 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 (VIST) and the Vertebral Artery Stenting Trial (VAST), found no advantage for endovascular intervention compared with 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. There is limited evidence

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concerning the net benefit of angioplasty and stenting for vertebral arteries, and large well designed trial results are not available at this time.

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. There is limited evidence concerning the net benefit of angioplasty and stenting for vertebral arteries, and large well designed trial results are not available at this time.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined

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by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not Medically Necessary; therefore, not covered for endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, for the management of extracranial vertebral artery disease

Procedure Codes							
37246	37247	0075T	0076T	C7532			

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.149	07/17/2019 Consensus review. No change to policy statements. References updated.
	06/19/2020 Consensus review. No change to policy statement. Rationale and references updated.
	05/12/2021 Minor review. Change statement from INV to not medically necessary. Updated Background, rationale, and references. No changes to coding.
	07/07/2022 Consensus review. Updated FEP, background, and references. Added CPT codes 37246 and 37247 to NMN coding table.

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	11/29/2022 Administrative update. Added procedure code C7532 Effective 1/1/23.
	05/24/2023 Consensus review. Updated cross references, rationale, and references. No changes to coding.
	05/15/2024 Consensus review. Updated policy guidelines and references. No changes to coding.

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