BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.148 Endovascular Therapies for Extracranial Vertebral Artery Disease

Effective Policy Date: October 1, 2023

Original Policy Date: June 2015

Related Policies:

2.01.54 - Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)
7.01.68 - Extracranial Carotid Artery Stenting

Endovascular Therapies for Extracranial Vertebral Artery Disease

Description

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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 (eg, 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.

OBJECTIVE

The objective of this evidence review is to determine whether percutaneous transluminal angioplasty with or without stent implantation improves the net health outcome in individuals who have extracranial vertebral artery stenosis, aneurysm(s), dissection(s), or arteriovenous fistula(e).

POLICY STATEMENT

Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered **investigational** for the management of extracranial vertebral artery diseases.

POLICY GUIDELINES

The extracranial vertebral artery is considered to be segments V1 to V3 of the vertebral artery from its origin at the subclavian artery until it crosses the dura mater.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 the 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; the 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."

RATIONALE

Summary of Evidence

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty (PTA) with or without stent implantation, the evidence includes randomized controlled trials (RCTs) and noncomparative studies. 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 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have extracranial vertebral artery aneurysm(s), dissection(s), or arteriovenous fistula(e) who receive PTA 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 permit conclusions about the efficacy of endovascular therapy for extracranial vertebral artery aneurysms, dissections, or arteriovenous fistulae. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association and American Stroke Association

The American Heart Association and American Stroke Association (2014) issued joint guidelines on prevention of stroke in patients with stroke and transient ischemic attack with recommendations about treatment of extracranial vertebrobasilar disease.[25,] These guidelines were updated in 2021 and the most recent recommendations and evidence statements about treatment of extracranial vertebrobasilar disease are listed in Table 1.[26,]

Table 1. Guidelines on Stroke Prevention in Patients With Stroke and Transient Ischemic Attack

Recommendation	COR	LOE
"In patients with recently symptomatic extracranial vertebral artery stenosis, intensive medical therapy (antiplatelet therapy, lipid lowering, BP control) is recommended to reduce stroke risk"	I	A
"In patients with ischemic stroke or TIA and extracranial vertebral artery stenosis who are having symptoms despite optimal medical treatment, the usefulness of stenting is not well established"	IIb	B-R
"In patients with ischemic stroke or TIA and extracranial vertebral artery stenosis who are having symptoms despite optimal medical treatment, the usefulness of open surgical procedures, including vertebral endarterectomy and vertebral artery transposition, is not well established"	IIb	C-EO

BP: blood pressure; COR: class of recommendation; LOE: level of evidence; TIA: transient ischemic attack.
Level of Evidence: A: high-quality evidence from more than 1 RCT; B-R: moderate quality of evidence from 1 or more randomized controlled trials; C-EO: consensus of expert opinion based on clinical experience.

American Stroke Association et al

In 2011, a multisociety task force issued guidelines on the management of extracranial vertebral and carotid artery disease, which made the following statement 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."[27,] No specific recommendations were made about endovascular therapies.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has a national coverage determination addressing the use of percutaneous transluminal angioplasty 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 arteriovenous dialysis fistulas and grafts.[28,] It also addresses the use of percutaneous transluminal angioplasty concurrent with carotid stent placement in U.S. Food and Drug Administration investigational device exemption clinical trials, in U.S. Food and Drug Administration-approved postapproval studies, and in patients at high risk for carotid endarterectomy.

The national coverage determination states that all other indications for percutaneous transluminal angioplasty, with or without stenting, to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

REFERENCES

1. Gulli G, Marquardt L, Rothwell PM, et al. Stroke risk after posterior circulation stroke/transient ischemic attack and its relationship to site of vertebrobasilar stenosis: pooled data analysis from prospective studies. Stroke. Mar 2013; 44(3): 598-604. PMID 23386676
2. Morasch MD, Phade SV, Naughton P, et al. Primary extracranial vertebral artery aneurysms. Ann Vasc Surg. May 2013; 27(4): 418-23. PMID 23540677
3. Coleman DM, Obi A, Criado E, et al. Contemporary outcomes after distal vertebral reconstruction. J Vasc Surg. Jul 2013; 58(1): 152-7. PMID 23478503
4. Ramirez CA, Febrer G, Gaudric J, et al. Open repair of vertebral artery: a 7-year single-center report. Ann Vasc Surg. Jan 2012; 26(1): 79-85. PMID 22176877
5. Markus HS, Larsson SC, Kuker W, et al. Stenting for symptomatic vertebral artery stenosis: The Vertebral Artery Ischaemia Stenting Trial. Neurology. Sep 19 2017; 89(12): 1229-1236. PMID 28835400
6. Compter A, van der Worp HB, Schonewille WJ, et al. Stenting versus medical treatment in patients with symptomatic vertebral artery stenosis: a randomised open-label phase 2 trial. Lancet Neurol. Jun 2015; 14(6): 606-14. PMID 25908089
7. Markus HS, Harshfield EL, Compter A, et al. Stenting for symptomatic vertebral artery stenosis: a preplanned pooled individual patient data analysis. Lancet Neurol. Jul 2019; 18(7): 666-673. PMID 31130429
8. Lattanzi S, Brigo F, Di Napoli M, et al. Endovascular treatment of symptomatic vertebral artery stenosis: A systematic review and meta-analysis. J Neurol Sci. Aug 15 2018; 391: 48-53. PMID 30103970
9. Xu R, Zhang X, Liu S, et al. Percutaneous transluminal angioplasty and stenting for vertebral artery stenosis. Cochrane Database Syst Rev. May 17 2022; 5(5): CD013692. PMID 35579383
10. Markus HS, Larsson SC, Dennis J, et al. Vertebral artery stenting to prevent recurrent stroke in symptomatic vertebral artery stenosis: the VIST RCT. Health Technol Assess. Aug 2019; 23(41): 1-30. PMID 31422789
11. Kikuchi T, Ishii A, Nakahara I, et al. Japanese Registry of Neuroendovascular Therapy: extracranial steno-occlusive diseases except for internal carotid artery stenosis. Neurol Med Chir (Tokyo). 2014; 54(1): 40-5. PMID 24257542
12. Sun X, Ma N, Wang B, et al. The long term results of vertebral artery ostium stenting in a single center. J Neurointerv Surg. Dec 2015; 7(12): 888-91. PMID 25332411
13. Mohammadian R, Sharifipour E, Mansourizadeh R, et al. Angioplasty and stenting of symptomatic vertebral artery stenosis. Clinical and angiographic follow-up of 206 cases from Northwest Iran. Neuroradiol J. Aug 2013; 26(4): 454-63. PMID 24007733
14. Hatano T, Tsukahara T, Miyakoshi A, et al. Stent placement for atherosclerotic stenosis of the vertebral artery ostium: angiographic and clinical outcomes in 117 consecutive patients. Neurosurgery. Jan 2011; 68(1): 108-16; discussion 116. PMID 21099720
15. Pham MH, Rahme RJ, Arnaout O, et al. Endovascular stenting of extracranial carotid and vertebral artery dissections: a systematic review of the literature. Neurosurgery. Apr 2011; 68(4): 856-66; discussion 866. PMID 21242839
16. Badve MS, Henderson RD, O'Sullivan JD, et al. Vertebrobasilar dissections: case series comparing patients with and without dissecting aneurysms. J Clin Neurosci. Nov 2014; 21(11): 2028-30. PMID 24913932
17. Kondo R, Ishihara S, Uemiya N, et al. Endovascular Treatment for Acute Ischaemic Stroke Caused by Vertebral Artery Dissection: A Report of Three Cases and Literature Review. NMC Case Rep J. 2021; 8(1): 817-825. PMID 35079554
18. Horowitz MB, Miller G, Meyer Y, et al. Use of intravascular stents in the treatment of internal carotid and extracranial vertebral artery pseudoaneurysms. AJNR Am J Neuroradiol. Apr 1996; 17(4): 693-6. PMID 8730189
19. Felber S, Henkes H, Weber W, et al. Treatment of extracranial and intracranial aneurysms and arteriovenous fistulae using stent grafts. Neurosurgery. Sep 2004; 55(3): 631-8; discussion 638-9. PMID 15335430
20. Herrera DA, Vargas SA, Dublin AB. Endovascular treatment of traumatic injuries of the vertebral artery. AJNR Am J Neuroradiol. Sep 2008; 29(8): 1585-9. PMID 18499790
21. Ambekar S, Sharma M, Smith D, et al. Successful treatment of iatrogenic vertebral pseudoaneurysm using pipeline embolization device. Case Rep Vasc Med. 2014; 2014: 341748. PMID 25276469
22. Jang HJ, Oh SY, Shim YS, et al. Endovascular treatment of symptomatic high-flow vertebral arteriovenous fistula as a complication after c1 screw insertion. J Korean Neurosurg Soc. Oct 2014; 56(4): 348-52. PMID 25371787
23. Shang EK, Fairman RM, Foley PJ, et al. Endovascular treatment of a symptomatic extracranial vertebral artery aneurysm. J Vasc Surg. Nov 2013; 58(5): 1391-3. PMID 23561429
24. Takahashi S, Katayama K, Tatsugawa T, et al. A successful hybrid repair for vertebral arteriovenous fistula with extracranial vertebral artery aneurysm. Ann Vasc Surg. Jan 2015; 29(1): 126.e5-8. PMID 25304908
25. Kernan WN, Ovbiagele B, Black HR, et al. Guidelines for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. Jul 2014; 45(7): 2160-236. PMID 24788967
26. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association. Stroke. Jul 2021; 52(7): e364-e467. PMID 34024117
27. Brott TG, Halperin JL, Abbara S, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of

Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. Circulation. Jul 26 2011; 124(4): e54-130. PMID 21282504
28. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7). 2013; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201. Accessed March 16, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2015	New policy	Endovascular therapy for extracranial vertebral artery disease considered investigational.
September 2016	Replace policy	Policy updated with literature review through March 28, 2016; reference 5 added and some references removed. Policy statement unchanged.
September 2018	Replace policy	Policy updated with literature review through March 5, 2018; reference 6 added; some references removed. Policy statement unchanged.
September 2019	Replace policy	Policy updated with literature review through March 6, 2019; References added. Policy statement unchanged.
September 2020	Replace policy	Policy updated with literature review through March 23, 2020; references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through March 29, 2021; no references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through April 1, 2022; reference added, guideline updated. Policy statements unchanged.
September 2023	Replace policy	Policy updated with literature review through March 16, 2023; reference added. Policy statements unchanged.